FEDERAL TRADE COMMISSION DECISIONS

FINDINGS, OPINIONS, AND ORDERS

JANUARY 1, 2013, TO JUNE 30, 2013

IN THE MATTER OF

POM WONDERFUL LLC, ROLL GLOBAL LLC, STEWART A. RESNICK, LYNDA RAE RESNICK

AND

MATTHEW TUPPER

OPINION OF THE COMMISSION AND FINAL ORDER

Docket No. D-9344; File No. 082 3122
Complaint, September 24, 2010 – Decision, January 10, 2013

The complaint alleged that respondent POM Wonderful LLC ("POM"), its sister company Roll Global LLC, and principals Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper (collectively "Respondents") falsely advertised that POM-branded pomegranate juice could treat prostate cancer and erectile dysfunction or reduce the risk of heart disease. The complaint alleged that Respondents lacked a reasonable basis for making these representations. Following an administrative hearing, the Administrative Law Judge issued an Initial Decision, 153 F.T.C. ___, ruling that 19 of the challenged advertisements were false or deceptive. On appeal, the Commission upheld the Initial Decision, finding that Respondents made false or deceptive claims in 36 of the challenged advertisements and promotional materials. The Commission issued an Order barring Respondents from making any claim that a food, drug, or dietary supplement is effective in the diagnosis, treatment, or prevention of any disease, including heart disease, prostate cancer, and erectile dysfunction, without supporting evidence from two clinical trials. The Order also prohibits misrepresentations regarding any test, study, or research, and requires Respondents to provide competent and reliable scientific evidence to support any health claims regarding any food, drug, or dietary supplement.

Participants

For the *Commission: Tawana Davis, Devin Domond, Janet Evans, Heather Hippsley, Theodore Hoppock, Mary Johnson, Michael Ostheimer, Elizabeth Nach, Serena Viswanathan, Elise Whang, Andrew Wone.*

For the *Respondents: Michael C. Small, Akin Gump Strauss Hauer & Feld LLP; Bruce A. Friedman, Bingham McCutchen LLP; John Graubert* and *Skye Perryman, Covington & Burling; Bertram Fields, Greenberg Glusker;* and *Kristina W. Diaz, Brooke Hammond, Alicia D. Mew, Paul A. Rose, Johnny Traboulsi,* and *Adam P. Zaffios, Roll Law Group P.C.*

OPINION OF THE COMMISSION

By OHLHAUSEN, Commissioner, for a unanimous Commission.

I. Introduction

Respondents POM Wonderful LLC ("POM Wonderful" or "POM"), Roll Global LLC ("Roll Global"), Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper (collectively, "Respondents") appeal from Administrative Law Judge ("ALJ")[1] D. Michael Chappell's Initial Decision and Order holding them liable for violating Sections 5(a) and 12 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. §§ 45 and 52, by making false or misleading claims in multiple media fora to promote their pomegranate juice products, specifically POM Wonderful Juice, POMx Pills, and POMx Liquid (collectively,

[1] For purposes of this opinion, we use the following abbreviations in referencing the record:
ALJ: Administrative Law Judge D. Michael Chappell
Tr.: Transcript of trial testimony before the ALJ
Dep.: Transcript of deposition
ID: Initial Decision
IDF: Initial Decision Findings of Fact
CCA: Complaint Counsel's Appeal Brief
RA: Respondents' Appeal Brief
RAns: Respondents' Answering Brief
RR: Respondents' Reply Brief
CX: Complaint Counsel Exhibit
PX: Respondent Exhibit

"Challenged POM Products"). Complaint Counsel cross-appeal the ALJ's finding that some of the challenged advertisements did not make the representations alleged in the Complaint, his holding concerning the level of scientific support needed to make the alleged claims, and the injunctive relief outlined in the ALJ's Order. We conclude that the Respondents have violated Section 5(a) and Section 12 of the FTC Act, based on both the findings of the ALJ and on additional challenged advertisements, and we issue a Final Order which differs in some respects from the Order attached to the Initial Decision.

Respondents have marketed the Challenged POM Products using a variety of means since they began selling and marketing POM Wonderful Juice in 2002. Between 2002 and 2010, sales for all Challenged POM Products totaled close to $250 million.

On September 24, 2010, the Commission issued an administrative complaint alleging that Respondents engaged in deceptive acts and practices and disseminated false advertising in violation of Sections 5(a) and 12 of the FTC Act in promoting the Challenged POM Products. The Complaint alleged that Respondents disseminated advertising and promotional materials representing that consumption of certain doses of Challenged POM Products treats, prevents or reduces the risk of heart disease, prostate cancer, or erectile dysfunction ("ED"), without having a reasonable basis to substantiate these claims. The Complaint also alleged that Respondents disseminated advertising and promotional materials representing that clinical studies, research, and/or trials prove that consumption of the Challenged POM Products in certain doses treats, prevents or reduces the risk of heart disease, prostate cancer, or ED, when in fact clinical studies, research, or trials do not so prove.

At trial, Complaint Counsel challenged a total of 43 items, including print advertisements, newsletters, separate "web captures" of Respondents' websites, Internet banner advertisements, press releases, and media interviews. Respondents denied that such materials make the claims alleged and argued that the claims that were made in their advertising and promotional materials were substantiated adequately by scientific research. Some of POM's ads and marketing materials stated that

the Challenged POM Products were supported by over $30 million in medical research.

In his Initial Decision, the ALJ found that 19 of the 43 challenged advertisements and promotional materials contained implied claims that the Challenged POM Products treat, prevent or reduce the risk of heart disease, prostate cancer, or ED, and that in 14 of these ads, there were implied claims that the effects on disease were clinically proven; that those claims were false or misleading; and that the claims were material to consumers' purchasing decisions. ID at 5-6. In his opinion, the ALJ determined that in the case of a safe food that is not advertised as a substitute for medical treatment, competent and reliable scientific evidence includes clinical studies though not necessarily double-blind, randomized, placebo-controlled clinical trials. *Id.* at 328. The ALJ attached to the Initial Decision an order that would, if issued by the Commission, prohibit the Respondents from making representations that any food, drug, or dietary supplement, including but not limited to the Challenged POM Products, is effective in diagnosing, curing, treating, mitigating, or preventing any disease unless such representations are not misleading and are based on competent and reliable scientific evidence. *Id.* at 332. The order would also prohibit Respondents from misrepresenting the results of any test, study or research in connection with the advertisement or sale of any food, drug, or dietary supplement, including but not limited to the Challenged POM Products. *Id.* In addition, the order would prohibit Respondents from making any representation about the health benefits, performance, or efficacy of any food, drug, or dietary supplement, including but not limited to the Challenged POM Products, unless the representation is non-misleading and based on Respondents' reliance on competent and reliable scientific evidence. *Id*. The order would define "competent and reliable scientific evidence" as "tests, analyses, research, or studies, 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.* at 331.

Respondents' principal claims on appeal are that the ALJ erred in (1) finding that any of the challenged advertising and promotional materials contain implied efficacy or establishment claims (*i.e.*, those asserting that the efficacy claims are established

scientifically) that the Challenged POM Products treat, prevent or reduce the risk of heart disease, prostate cancer, or ED; (2) holding that substantiation for such claims required clinical studies; and (3) finding the foregoing claims to be material. Respondents also allege that the relief ordered is impermissibly broad and runs afoul of the First and Fifth Amendments.

Complaint Counsel's principal claims on cross-appeal are (1) the ALJ should have found that all of the challenged advertisements and promotional materials (including four media interviews) made efficacy claims; (2) all but four of these materials also included establishment claims; (3) the ALJ incorrectly applied a substantiation standard requiring only clinical studies, rather than the higher standard of well-designed, well-conducted, double-blind, randomized controlled clinical trials (referred to in this opinion as "RCTs"); and (4) in his order, the ALJ should have required pre-approval by the Food and Drug Administration ("FDA") of any future disease claims made by Respondents with respect to the Challenged POM Products.

Based on our consideration of the entire record in this case and the arguments of counsel, we deny Respondents' appeal and grant in part, and deny in part, Complaint Counsel's cross-appeal. We find Respondents liable on the basis of a larger number of advertisements containing false and misleading claims than the ALJ found. The basis of Respondents' liability under the FTC Act is their lack of sufficiently reliable evidence — namely, RCTs (as described more fully below in this opinion) — to substantiate the claims that we found. Complaint Counsel's experts testified that two RCTs are necessary to substantiate the heart disease claims at issue, while the prostate cancer and ED claims can be substantiated with at least one RCT. *See* CX1291 at 15 (Sacks Expert Report) (for heart disease "most scientists and researchers . . . believe that at least two-well designed studies . . . showing strong results are needed to constitute reliable evidence"); CX1287 at 6 (Eastham Expert Report) (stating "qualified experts in the field of urology, including the prevention and treatment of prostate cancer, . . . would require that Respondents' claims be supported by at least one well-conducted, randomized, double-blind, placebo-controlled clinical trial with an appropriate endpoint"); and CX1289 at 4 (Melman Expert Report) ("[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"). The Commission need not, and does not, reach the question of the number of RCTs needed to substantiate the claims made because, as discussed below, Respondents failed to proffer even one RCT that supports the challenged claims that we found they made.[2] The Final Order we issue today differs from that proposed by the ALJ and contains fencing-in relief by providing that any disease-related establishment or efficacy claims made about the Challenged POM Products or in connection with Respondents' sale of any food, drug, or dietary supplement must be supported by at least two RCTs.[3] However, we do not reach the question of liability based on the four challenged media interviews, and today's Final Order does not include a provision requiring FDA pre-approval of any future claims made by Respondents.

II. Factual Background and Proceedings Below

Respondent POM Wonderful is a limited liability company wholly owned by the Stewart and Lynda Resnick Revocable Trust dated December 27, 1988. IDF 1, 3. In 2002, POM Wonderful launched the first of the Challenged POM Products, POM Wonderful Juice, and currently sells all of the Challenged POM Products. IDF 5, 6. Respondent Roll Global is a separate corporation wholly owned by the same trust; Roll Global owns a number of companies, including POM Wonderful LLC, FIJI Water, Suterra, Paramount Farms, Paramount Citrus, Teleflora, Neptune Shipping, Paramount Farming, and Justin Winery. IDF 7, 9, 11. Roll International Corporation reorganized at the end of 2010 and is currently known as Roll Global. IDF 8. Roll Global uses an in-house advertising agency for POM and its other affiliated companies. IDF 14.

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[2] The Commission applies the same rationale throughout this opinion when it refers to a requirement of "RCTs" for Respondents' liability under the FTC Act.

[3] As explained more fully in Section X.B, Commissioner Ohlhausen supports an order provision requiring at least one RCT, viewed in light of the relevant scientific evidence, for disease-related efficacy and establishment claims made about the Challenged POM Products or in connection with the sale of any food, drug, or dietary supplement by the Respondents.

The individual Respondents in this case include Stewart Resnick, Lynda Resnick, and Matthew Tupper. Stewart Resnick is the Chairman and CEO of POM Wonderful, and Chairman and President of Roll Global. IDF 19-21.[4] His responsibilities include setting the marketing, advertising, and medical research budgets for POM Wonderful. IDF 23. Although he leaves most of the marketing decisions about POM Wonderful to his wife, Lynda Resnick, he considers himself responsible for whether advertising should or should not be published and has been involved at a high level with POM's advertising and marketing campaigns. IDF 25-26. Lynda Resnick is Vice Chairman of Roll Global and sole owner of POM Wonderful along with Stewart Resnick. IDF 15, 28. Mrs. Resnick was still the chief marketing executive at POM as of 2011, working with POM's marketing department and internal advertising agency to implement creative concepts for POM's campaigns. IDF 31, 33. Mrs. Resnick has the "final say" with respect to POM's marketing and advertising content and concepts. IDF 34. Matthew Tupper joined POM in 2003 as Chief Operating Officer and became President of POM Wonderful in 2005 before retiring from POM at the end of 2011. IDF 37-38, 40. Mr. Tupper was responsible for the day-to-day affairs of POM, including managing the operations of the marketing team. IDF 44. The head of POM's Marketing Department reported to Mr. Tupper, and one of Mr. Tupper's responsibilities was to serve as a liaison between the marketing staff and the researchers who performed the medical studies sponsored by POM. IDF 50, 52.

The Challenged POM Products are POM Juice, POMx Liquid, and POMx Pills. POM Juice is a 100% juice product produced by pressing whole pomegranates, filtering and/or enzyme-treating the juice, concentrating the juice, reconstituting it with water, pasteurizing it, and bottling it. IDF 58-60. A single serving of POM Juice is eight ounces, and it is sold in grocery stores for a price of approximately $3 for an eight-ounce bottle. IDF 64-65, 97. POM Juice contains a variety of polyphenols (including ellagitannins and gallotannins, anthocyanins, and ellagic acid). IDF 62-63. POMx Liquid "is the product of the pressed whole

[4] Another Respondent, Mark Dreher, Ph.D., agreed to an administrative consent order to resolve the claims against him. *See* http://www.ftc.gov/os/caselist/0823122/100927pomagree.pdf.

fruit after most of the juice is extracted and the polyphenols are concentrated by filtering and concentrating using juice processing." IDF 67 (quoting CX0096, *in camera*, at 0014). A single serving is one teaspoon daily. IDF 69. POMx Pills are made through a process by which POMx Liquid is extracted. IDF 70. POMx Pills do not contain anthocyanins, nor do they contain the calories or sugar found in POM Juice. IDF 73, 75. A single serving is one pill daily. IDF 76. POMx Pills and POMx Liquid are available for sale via the Respondents' website or through a telephone call center; POMx Pills are also available through some retail outlets. IDF 68, 72. If purchased from the POM website, the cost of a bottle containing 30 POMx Pills or a five ounce bottle of POMx Liquid (containing extract) was $29.95, excluding shipping. IDF 101-102.

POM Wonderful has engaged in a number of advertising campaigns to promote the Challenged POM Products, including print advertisements in magazines, freestanding inserts in newspapers, billboards, posters in bus shelters, posters in health clubs and doctors' offices, advertising on prescription drug bags, Internet websites, online banner advertisements, medical outreach, radio and television ads, and press releases. IDF 171. POM Wonderful considers health-conscious, educated, affluent consumers to be its target audience. IDF 172, 176, 178, 181.

The POM Juice print advertisements at issue were disseminated in a wide variety of publications, including but not limited to the *Chicago Tribune*, *Prevention*, *Details*, *Rolling Stone*, *Health*, *InStyle*, *Town and Country*, *Men's Health*, and *Men's Fitness*. IDF 169. The POMx Pills print advertisements challenged by Complaint Counsel were disseminated in publications including but not limited to *Fortune*, *The New York Times*, *Discover*, *Men's Health*, *Popular Science*, *Time*, and *Playboy*. IDF 170. Some of POM's challenged advertisements are creative in nature, depicting the POM Wonderful Juice bottle in a number of unusual ways (for example, as an intravenous bag; covered by medical equipment such as a blood pressure cuff or EKG sensors; anthropomorphized lying on a therapist's couch or in a bikini top; and as a superhero) and accompanied by headlines such as "[a]maze your cardiologist" and "[l]ucky I have super HEALTH POWERS." *See* CX0033; CX0034; CX0103; CX0109; CX0192; CX0274; CX0372. Many of the challenged

advertisements include statements touting the Challenged POM Products' effects on heart disease, prostate cancer, and/or ED, sometimes by quoting from or citing to various scientific studies.

At trial, Complaint Counsel challenged 43 promotional materials that Respondents disseminated. The Complaint alleges that POM's materials claim that drinking POM Juice, taking POMx Pills, or taking POMx Liquid daily (1) prevents or reduces the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart (Compl. ¶ 12.A); (2) treats heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart (Compl. ¶ 12.B); (3) prevents or reduces the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time ("PSADT") (Compl. ¶ 14.A); (4) treats prostate cancer, including by prolonging PSADT (Compl. ¶ 14.B); (5) prevents or reduces the risk of ED (Compl. ¶ 16.A); and (6) treats ED (Compl. ¶ 16.B). In sum, the Complaint alleges that Respondents made six different claims regarding the efficacy of the Challenged POM Products.

The Complaint also alleges that Respondents have represented that "clinical studies, research, and/or trials prove that" drinking POM Juice or taking POMx Pills or Liquid treats heart disease, prostate cancer, and erectile dysfunction or prevents or reduces the risk of each of these diseases. Compl. ¶¶ 12, 14, 16. Thus, in addition to the claim that the Challenged POM Products treat, prevent or reduce the risk of disease, the Complaint alleges that some of the ads convey that there is clinical proof of the efficacy of the Challenged POM Products, *i.e.*, that they make "establishment" claims.

Following an administrative trial that began on May 24, 2011, and concluded on November 4, 2011, the ALJ filed a 335-page Initial Decision, with 1,431 findings of fact and a 108-page appendix on May 17, 2012. The ALJ found that 19 of the 43 challenged advertisements and promotional materials contained implied claims that the Challenged POM Products treat, prevent or reduce the risk of heart disease, prostate cancer, or ED, and that 14 of these ads also contained implied claims that these effects on disease were clinically proven. ID at 211-34. The ALJ also found that the claims at issue are material to consumers. *Id.* at

290-96. The ALJ further determined that the appropriate level of substantiation for such claims is competent and reliable scientific evidence, which for claims that a food or food-derived product treats, prevents or reduces the risk of disease must include adequate clinical studies, though not necessarily RCTs. *Id*. at 234-50. The ALJ determined that Respondents did not have such evidence to substantiate their claims, rendering them false or misleading under Sections 5(a) and 12 of the FTC Act. *Id.* at 250-290. According to the ALJ's cease and desist order against the corporate and individual Respondents pursuant to Section 5(b) of the FTC Act, Respondents would be prohibited from engaging in deceptive advertising practices with respect to any food, drug, or dietary supplement that may be advertised by Respondents in the future. *Id.* at 309-25. The ALJ did not require that Respondents seek FDA pre-approval for any future disease claims with respect to the Challenged Products. *See id*. at 314-23.

III. Legal Standard

The Commission reviews the record *de novo* by considering "such parts of the record as are cited or as may be necessary to resolve the issues presented and . . . exercis[ing] all the powers which [the Commission] could have exercised if it had made the initial decision." 16 C.F.R. § 3.54. In this case, the Commission adopts the ALJ's findings of fact to the extent those findings are not inconsistent with this opinion.

An advertisement is deceptive if it contains a representation or omission of fact that is likely to mislead a consumer acting reasonably under the circumstances, and that representation or omission is material to a consumer's purchasing decision.[5] *FTC Policy Statement on Deception*, 103 F.T.C. 174, 175 (1984) (appended to *Cliffdale Assocs., Inc.*, 103 F.T.C. 110 (1984)) ("*Deception Statement*"); *see also, e.g.*, *In re Novartis Corp.*, 127 F.T.C. 580, 679 (1999), *aff'd*, 223 F.3d 783 (D.C. Cir. 2000); *In*

[5] The Complaint alleges that Respondents violated both Sections 5 and 12 of the FTC Act. Section 5 prohibits "deceptive" acts or practices in or affecting commerce, 15 U.S.C. § 45(a), while Section 12 specifically addresses the dissemination of any "false advertisement," *i.e.*, one that is "misleading in a material respect," 15 U.S.C. § 55(a)(1), for food, drugs, devices, services, or cosmetics. The deception standard is the same under both provisions. *Deception Statement*, 103 F.T.C. at 182.

re Stouffer Foods Corp., 118 F.T.C. 746, 798 (1994); *In re Kraft, Inc.*, 114 F.T.C. 40, 120 (1991), *aff'd*, 970 F.2d 311 (7th Cir. 1992). In addition, the Commission long has held that making objective claims without a reasonable basis constitutes a deceptive practice in violation of Section 5. *FTC Policy Statement Regarding Advertising Substantiation*, 104 F.T.C. 839 (1984) (appended to *Thompson Med. Co.*, 104 F.T.C. 648 (1984)) ("*Substantiation Statement*"); *see, e.g.*, *In re Auto. Breakthrough Scis., Inc.*, 126 F.T.C. 229, 293 & 293 n.20 (1998); *In re Jay Norris, Inc.*, 91 F.T.C. 751, 854 (1978), *aff'd as modified*, 598 F.2d 1244 (2d Cir. 1979). Consequently, the determination of whether Respondents disseminated false advertisements in violation of the FTC Act requires a three-part inquiry: (1) whether Respondents disseminated advertisements conveying the claims alleged in the Complaint; (2) whether those claims were false or misleading; and (3) whether those claims are material to prospective consumers. *Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992); *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1095 (9th Cir. 1994); *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 297 (D. Mass. 2008), *aff'd*, 684 F.3d 1 (1st Cir. 2010).

IV. Respondents Disseminated Advertising or Promotional Material Making Disease Treatment, Prevention and Risk Reduction Claims

The Commission's approach to ad interpretation is well established, and the general framework is not disputed on appeal. The Commission "will deem an advertisement to convey a claim if consumers, acting reasonably under the circumstances, would interpret the advertisement to contain that message." *In re Thompson Med. Co.*, 104 F.T.C. 648, 788 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986); *Deception Statement*, 103 F.T.C. at 176. A reasonable interpretation is one that would be shared by at least a significant minority of reasonable consumers. *Kraft, Inc.*, 114 F.T.C. at 122; *In re Telebrands Corp*., 140 F.T.C. 278, 291 (2005) ("[a]n ad is misleading if at least a significant minority of reasonable consumers are likely to take away the misleading claim"), *aff'd*, 457 F.3d 354 (4th Cir. 2006); *Deception Statement*, 103 F.T.C. at 177 n.20 (citing *In re Kirchner*, 63 F.T.C. 1282 (1963) (explaining a reasonable interpretation is one that would be shared by more than an insignificant and unrepresentative segment of the class of persons to whom the represented is

addressed)). Where an ad conveys more than one meaning, only one of which is misleading, a seller is liable for the misleading interpretation even if non-misleading interpretations are possible. *See, e.g.*, *In re Bristol-Myers Co.*, 102 F.T.C. 21, 320 (1983), *aff'd*, 738 F.2d 554 (2d Cir. 1984); *Nat'l Comm'n on Egg Nutrition v. FTC*, 570 F.2d 157, 161 n.4 (7th Cir. 1977). The primary evidence of the representations that an advertisement conveys to reasonable consumers is the advertisement itself. *Deception Statement*, 103 F.T.C. at 176; *see also Novartis Corp.*, 127 F.T.C. at 680; *Stouffer Foods Corp.*, 118 F.T.C. at 798; *Kraft, Inc.*, 114 F.T.C. at 121. In determining what claims may reasonably be attributed to an advertisement, the Commission examines the entire advertisement and assesses the overall "net impression" it conveys. *Deception Statement*, 103 F.T.C. at 178; *see also Novartis Corp.*, 127 F.T.C. at 679; *Kraft, Inc.*, 114 F.T.C. at 122; *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 958 (N.D. Ill. 2006) ("the Court looks to the overall, net impression made by the advertisement to determine whether the net impression is such that the ads would be likely to mislead reasonable consumers"), *aff'd*, 512 F.3d 858 (7th Cir. 2008).

The Complaint alleges that Respondents' advertisements claim that consuming the Challenged POM Products daily treats, prevents or reduces the risk of heart disease, prostate cancer, or ED. These claims that the Challenged POM Products are effective without expressly or impliedly representing a particular level of support are "efficacy claims." The Complaint also alleges that Respondents have represented that "clinical studies, research, and/or trials prove that" drinking POM Juice or taking POMx Pills or Liquid treats the diseases or prevents or reduces the risk of each of the diseases. A claim that there is a certain type or level of support is considered an "establishment claim." *Thompson Med. Co.*, 791 F.2d at 194; *see also Bristol-Myers Co.*, 102 F.T.C. at 321 (noting that a claim of clinical proof can be express or implied). While "[t]here is no conceptual or practical reason to single out such claims . . . for special treatment . . . the express or implied claim that an advertiser possesses a particular level of substantiation" is an additional representation, which we also evaluate to ensure that it is not misleading. *Thompson Med. Co.*, 104 F.T.C. at 821-22 n.59.

It is well established that the Commission has the common sense and expertise to determine "what claims, including implied ones, are conveyed in a challenged advertisement, so long as those claims are reasonably clear." *Kraft, Inc.*, 970 F.2d at 319; *accord FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 391-92 (1965); *FTC v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1189-90 n.12 (N.D. Ga. 2008) (holding that facial analysis is a sufficient basis to find an alleged claim was made if it is "clear and conspicuous" or "apparent" on the face of the ad), *aff'd*, 356 Fed. Appx. 358, (11th Cir. 2009) (unpublished opinion); *Daniel Chapter One*, 2009 WL 5160000 at *14-15 (F.T.C. 2009), *aff'd*, 405 Fed. Appx. 505 (D.C. Cir. 2010) (unpublished opinion), *available at* 2011-1 Trade Cas. (CCH) ¶77,443 (D.C. Cir. 2010).

Claims may be either express or implied. The Commission reviews implied claims as if they are on a continuum: at one end claims are virtually synonymous with express claims; at the other end are claims that use language that few consumers would interpret as making a particular representation. *Novartis Corp.*, 127 F.T.C. at 680. To determine whether a particular implied claim has been made, the Commission starts with a facial analysis of the advertisement. A facial analysis of an ad considers "an evaluation of such factors as the entire document, the juxtaposition of various phrases in the document, the nature of the claim, and the nature of the transaction." *Deception Statement*, 103 F.T.C. at 176. "If, after examining the interaction of all the different elements in the ad, the Commission can conclude with confidence that an advertisement can reasonably be read to contain a particular claim, a facial analysis is sufficient basis to conclude that the advertisement conveys the claim." *Stouffer Foods Corp.*, 118 F.T.C. at 798; *accord Novartis Corp.*, 127 F.T.C. at 680; *Kraft, Inc.*, 114 F.T.C. at 121. Nonetheless, "the Commission may not inject novel meanings into ads . . . ; ads must be judged by the impression they make on reasonable members of the public." *Bristol-Myers Co.*, 102 F.T.C. at 320.

Extrinsic evidence is unnecessary to establish the impression that consumers would take away from an ad if the claims are reasonably clear from the face of the advertisement. *Kraft Inc.*, 970 F.2d at 319 (holding that "the Commission may rely on its own reasoned analysis to determine what claims, including implied ones, are conveyed in a challenged ad, so long as those

claims are reasonably clear from the face of the advertisement."); *accord Nat'l Urological Grp.*, 645 F. Supp. 2d at 1189-90 n.12 (holding that facial analysis is a sufficient basis to find an alleged claim was made if claims are "clear and conspicuous" or "apparent" on the face of the advertisement); *FTC v. QT, Inc.*, 448 F. Supp. 2d at 958 (quoting *FTC v. Febre*, No. 94 C 3625, 1996 WL 396117, at *4 (N.D. Ill. July 3, 1996), *aff'd*, 128 F.3d 530 (7th Cir. 1997)); *Kraft, Inc.*, 970 F.2d at 320) ("'There is no authority for defendants' contention that implied claims cannot be found to be deceptive absent extrinsic evidence. The courts and the FTC have consistently recognized that implied claims fall along a continuum from those which are so conspicuous as to be virtually synonymous with express claims to those which are barely discernible. It is only at the latter end of the continuum that extrinsic evidence is necessary.' Where implied claims are conspicuous and 'reasonably clear from the face of the advertisements,' extrinsic evidence is not required.") (citations omitted); *Stouffer Foods Corp.*, 118 F.T.C. at 798 ("If after examining the interaction of all the different elements in the ad, the Commission can conclude with confidence that an ad can reasonably be read to contain a particular claim, a facial analysis is sufficient basis to conclude that the ad conveys the claim."); *see also Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 652-53 (1985) ("When the possibility of deception is as self-evident as it is in this case, we need not require the State to 'conduct a survey of the . . . public before it [may] determine that the [advertisement] had a tendency to mislead.'") (quoting FTC v. Colgate-Palmolive Co., 380 U.S. at 391-92).

Yet, if extrinsic evidence has been introduced, that evidence "must be considered by the Commission in reaching its conclusion" about the meaning of the advertisement. *Bristol-Myers Co.*, 102 F.T.C. at 319; *see also Thompson Med. Co.*, 104 F.T.C. at 794 (finding that the Commission was "obliged to consider" extrinsic evidence offered by the parties). In this case, extrinsic evidence includes expert testimony by Dr. Ronald Butters and Dr. David Stewart, a survey of consumer responses to billboard headlines, and evidence regarding the intent of Respondents to convey particular messages in their advertising.

We find that in the context of POM Wonderful's challenged advertisements, reasonable consumers would read claims to

"prevent" or "reduce the risk of" heart disease, prostate cancer, or ED as conveying the claim that consuming the Challenged POM Products substantially reduces the likelihood that the consumer will contract the disease or condition, not that the products would absolutely prevent the onset of these conditions. Because the development of heart disease, cancer, or ED may be influenced by many factors, in the context of the particular advertisements challenged in this matter, most reasonable consumers would not interpret the language, imagery, and other elements of the advertisements to convey claims that consuming the Challenged POM Products would eliminate all possibility that the consumer might develop these diseases at some later time. This interpretation of the implied claims in Respondents' advertisements does not affect our conclusion that Respondents disseminated advertisements or promotional materials that contained the claims alleged in the Complaint, which was phrased in the disjunctive (prevent or reduce risk) rather than the conjunctive (prevent and reduce risk).[6]

A. Facial Analysis

In the Initial Decision, Judge Chappell found claims alleged by Complaint Counsel were conveyed in 19 advertisements or promotional materials. He found that 11 of these ads conveyed efficacy claims that the Challenged POM Products treat, prevent or reduce the risk of heart disease. IDF 580, 583. He found that eight ads conveyed efficacy claims that the Challenged POM Products treat, prevent or reduce the risk of prostate cancer, IDF 581, and four ads conveyed efficacy claims that the Challenged POM Products treat, prevent or reduce the risk of ED. IDF 582.[7] In 15 of the 19 advertisements, the ALJ found that the advertisements contained establishment claims that clinical studies supported the heart disease, prostate cancer, and ED efficacy claims. IDF 580, 581, 582. In our review of the ads, the

[6] To the extent this interpretation affects the substantiation that the Respondents must possess to support their claims, we incorporate this interpretation in our analysis. *See* discussion *infra* Section V.A.

[7] The ALJ found some of the ads to make claims relating to more than one disease.

Commission finds that 36[8] ads convey the claims alleged by Complaint Counsel.[9] The attached Claims Appendix provides an analysis of each of the challenged ads in this case. We evaluate treatment claims separately from claims that the Challenged POM Products prevent or reduce the risk of disease (which, as explained above, are viewed as equivalent in the context of this matter). We also explain in the Claims Appendix the basis for our findings that Respondents made establishment claims. The Claims Appendix describes the facial analysis of each ad.

Although we find that more ads contain claims alleged by Complaint Counsel than the ALJ did, we agree with Judge Chappell's approach to the facial analysis regarding the juxtaposition of elements in the ads to find that Respondents represented that the Challenged POM Products treat heart disease and that the Challenged POM Products prevent or reduce the risk of heart disease. As Judge Chappell explained,

> Respondents made these claims indirectly and obliquely, typically presenting, through words and images, a logical syllogism that: free radicals cause or contribute to heart disease; the POM Products contain antioxidants that neutralize free radicals; and, therefore, the POM Products are effective for heart disease. IDF 294-295, 301-303, 348, 374, 394-396, 398, 407, 414, 444, 452-453, 460-462.

ID at 225. We also adopt the ALJ's reasoning regarding the basis for finding establishment claims in the ads that contain heart disease claims and incorporate his findings.

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[8] The Commission finds three of the 39 exhibits we reviewed on appeal contain none of the disease claims alleged in the Complaint and seven of those 39 exhibits contain only some of the asserted claims. As explained below, *see* discussion *infra*, the Commission did not reach the question of whether the four media interviews conveyed the challenged claims.

[9] For most of the challenged advertisements, Commissioner Ohlhausen agrees with the majority of the Commission about the claims conveyed. As explained in her Concurring Statement, for some advertisements, however, Commissioner Ohlhausen either did not find certain claims were made or believes extrinsic evidence is necessary to determine whether consumers would take away such claims.

> Against this background, many of the advertisements further state or represent that the POM Products have been shown in one or more clinical, medical, or scientific studies [sic], to reduce plaque, lower blood pressure, and/or improve blood flow to the heart, in a context where it is readily inferable that the referenced study results involve heart disease risk factors and, therefore, constitute clinical support for the effectiveness claim. IDF 295, 301, 303, 349, 373, 376, 379, 395-397, 400, 407, 414, 420.

ID at 225-26.

We similarly adopt and incorporate the ALJ's approach to the facial analysis of Respondents' ads regarding the presence of prostate cancer claims.

> These advertisements typically communicate the claim by juxtaposing statements and representations that prostate cancer is a leading cause of death in men; antioxidants, such as those provided by the POM Products, may help prevent cancer; that PSA is an indicator of prostate cancer; that PSA doubling time is an indicator of prostate cancer progression; and that the POM Products have been shown in clinical testing to slow PSA doubling time. IDF 310-318, 332, 334-336, 352-353, 371, 381, 389-392, 398, 400-405, 409, 429.

ID at 228. The ALJ further explained that he found the establishment claims because the ads "connect both POM-provided antioxidants, and the study results, to effectiveness for prostate cancer." *Id.*

We likewise adopt and incorporate the ALJ's reasoning for the facial analysis for the ads containing ED claims.

> Respondents disseminated print advertisements that stated and represented, for example, that (1) the superior antioxidants in the POM Products protect against free radicals, which can damage the body; (2) powerful antioxidants enhance the actions of nitric oxide in vascular endothelial cells, showing potential for management of "ED"; and (3) a preliminary study on "erectile function"

> showed that men who consumed POM Juice reported "a 50% greater likelihood of improved erections," as compared to a placebo. IDF 323-324. . . . Presenting a study on "erectile function" showing "improved erections" is reasonably read to imply effectiveness for erectile dysfunction, particularly when juxtaposed to an express reference to management of "ED." IDF 323-325.

ID at 229-230.

Respondents argue that this chain of reasoning to determine whether a significant minority of reasonable consumers would interpret the ads as containing the alleged claims is improper because the approach requires leaps in logic or the addition of missing elements in a chain of deduction. Respondents further argue that a facial analysis cannot provide those missing elements, but instead such analysis is strictly constrained by what actually appears in ad. We disagree. When conducting a facial analysis of an advertisement, the advertisement must be viewed as a whole "without emphasizing isolated words or phrases apart from their context[.]" *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1496 (1st Cir. 1989) (quoting *Am. Home Prods. Corp. v. FTC*, 695 F.2d 681, 687 (3d Cir. 1982)); *FTC v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir. 1963) (explaining "[t]he entire mosaic should be viewed rather than each tile separately"). Respondents' ads drew a logical connection between the antioxidant claims and the specific disease treatment or prevention claims through the associated explanatory text, the specific findings of the study results, and references to diseases or medical conditions. Ultimately, we assess the net impression of each ad, and we find that for many of Respondents' ads, the net impression is more than any individual element of the ad.

The ALJ did not individually analyze those exhibits for which he did not find the claims alleged by Complaint Counsel. Instead, he summarized generally a variety of factors explaining why he did not find such claims, including that the "advertisements . . . do not mention heart disease, prostate cancer, or erectile dysfunction; use vague, non-specific, substantially qualified, and/or otherwise non-definitive language; use language and/or images that, in the context of the advertisement, are inconsistent with the alleged claim; and/or do not draw a connection for the reader, such as

through associated explanatory text, between health benefits, or study results, and effectiveness for heart disease, prostate cancer, or erectile dysfunction." ID at 222.

Based on a facial analysis of the ads, as well as a consideration of the relevant extrinsic evidence, we find that Respondents conveyed the efficacy claims alleged in the Complaint in more ads than the ALJ did. [10]

For example, we overrule the ALJ's with regard to Figure 7 ("Cheat Death" print ad) because we find that this ad conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily prevents heart disease. We make this finding based on the net impression of the advertisement, including the statements that drinking eight ounces of POM Juice a day "can help prevent . . . heart disease," and "[t]he sooner you drink it, the longer you will enjoy it," as well as imagery of the POM Juice bottle with a noose around the neck of the bottle.

We also overrule some of the ALJ's findings with regard to Figure 11 ("Decompress" print ad) because we find that this ad conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease. The ad containing medical imagery depicts the POM Juice bottle wrapped in a blood pressure cuff. Moreover, express language in the ad establishes a link between POM Juice, which "helps guard . . . against free radicals [that] . . . contribute to disease," and the $20 million of "scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health." The ad also states that POM Juice will help "[k]eep your ticker ticking." In combination, these elements communicate the message that POM Juice prevents or reduces the risk of heart disease, and that those efficacy claims are scientifically established.

In addition, we reverse the findings of the ALJ with regard to Figure 22 ("Drink to Prostate Health" print ad). Based on the

[10] *See* Summary Table of Commission Findings Regarding POM Exhibits, appended to this opinion.

overall net impression, we find that this ad conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily treats prostate cancer and that this claim is scientifically established. Factors contributing to this net impression include the language "Drink to prostate health" and express language equating POM Juice to "good medicine." Furthermore, the ad describes "[a] recently published preliminary medical study [that] followed 46 men previously treated for prostate cancer" which found that "[a]fter drinking 8 ounces of POM Wonderful 100% Pomegranate Juice daily for at least two years, these men experienced significantly longer PSA doubling times."

Regarding the establishment claims, we agree with the ALJ that "[t]he majority of the Challenged Advertisements that have been found herein to have made the claims alleged in the Complaint [also] represented that clinical studies supported the claimed effectiveness of the POM Products." ID at 225. Not "every reference to a test [or study] necessarily gives rise to an establishment claim. The key, of course, is the overall impression created by the ad." *Bristol-Myers Co.*, 102 F.T.C. at 321 n.7. An establishment claim may be made by such words and phrases as "established" or "medically proven," but an establishment claim may also be made "through the use of visual aids (such as scientific texts or white-coated technicians) which clearly suggest that the claim is based upon a foundation of scientific evidence." *Id.* at 321 (citing *Am. Home Prods.*, 98 F.T.C. 136, 375 (1981), *aff'd*, 695 F.2d 681 (3d Cir. 1982)).

For four ads, Figures 4-7, the ALJ found that the ads conveyed heart disease efficacy claims but not establishment claims. *See* IDF 583. As recognized by Judge Chappell, Complaint Counsel did not allege establishment claims for two of the ads, Figures 5 and 7. For Figures 4 and 6, the ALJ explained that he did not find establishment claims when the ads "either do not reference any clinical testing or refer to clinical testing in such a way and in such context, that it cannot be concluded with confidence that a significant minority of reasonable consumers would take away the message that the efficacy claim is 'clinically proven.'" ID at 227. The ALJ found that these ads represented that the Challenged POM Products treat, prevent or reduce the risk of heart disease, but he explained that "the only reference to any scientific support

is in very small print, at an asterisk at the bottom of the page, which states 'Aviram, M. Clinical Nutrition, 2004. Based on a clinical pilot study.'" He concluded that "this small print, single reference to a study, particularly in the context of a qualified assertion that POM Juice 'can' reduce plaque, is insufficient to conclude with confidence" that reasonable consumers would interpret the ads "to be claiming that POM Juice is clinically proven to be effective for heart disease." *Id.* at 227-28 (citing IDF 446-447, 466-467).

The Commission disagrees.[11] We find that specificity of the representation in the text of the ad that drinking "eight ounces a day can reduce plaque by up to 30%!" – which is in the same size font as the rest of the ad text – would lead at least a significant minority of reasonable consumers to interpret the ad to convey that there is clinical proof of the heart disease claims. The specific percentage reduction of plaque in someone's arteries cannot be ascertained by any means other than by scientific measurement, and the statement therefore implies that the claim of plaque reduction is scientifically established. The claim of scientific proof is bolstered by the asterisk that directs the reader to the quoted citation for the "clinical pilot study," which the Commission acknowledges is in small print.

Respondents argue that none of their ads make establishment claims asserting "clinical proof" because any references to studies in the ads are only accurate descriptions of specific study findings rather than broad establishment claims. Respondents claim that it is improper to treat reports of particular study results about PSADT or reduced plaque in arteries as claimed clinical proof of treatment or prevention of prostate cancer or heart disease. We disagree. As we explain in the Claims Appendix, these ads drew a logical connection between the study results and effectiveness for the particular diseases. Reasonable consumers are unlikely to differentiate the precise medical differences after reading a headline proclaiming "Prostate Cancer Affects 1 Out of Every 6 Men," *see* Figure 17; a statement that "Prostate cancer is the most commonly diagnosed cancer in men in the United States," *see*

[11] Commissioner Ohlhausen would uphold the ALJ's findings for CX0031 and CX0034 (Figures 4 and 6). *See* Commissioner Ohlhausen's Concurring Statement.

Figures 21 and 27; or the headline "Amaze your cardiologist." *See* Figure 6.

Respondents also argue that the ads cannot reasonably be interpreted as making establishment claims asserting "clinical proof" because the ads simply report study results in a qualified manner with words such as "preliminary," "promising," "encouraging," or "hopeful." It is well established that if the disclosure of information is necessary to prevent a representation from being deceptive, the disclosure must be clear. *See, e.g.*, *Pantron I Corp*., 33 F.3d at 1088; *Thompson Med. Co*., 104 F.T.C. at 789 n.9, 842-43. Respondents' use of one or two adjectives does not alter the net impression that clinical studies prove their claims. This is especially true when the chosen adjectives – promising, encouraging, or hopeful – provide a positive spin on the studies rather than a substantive disclaimer.[12] As the ALJ explained, in the context of the particular ads, "the foregoing language fails to materially alter the overall net impression that such advertisements were claiming clinical proof." *See, e.g.*, IDF 300-301, 312, 333, 342, 349-350, 354; *see also* IDF 519 (noting that Dr. Stewart had opined that "the typical consumer would likely have little understanding of what 'initial' or 'pilot' means, particularly in the context of [a study] being referred to as having been published in a major journal").[13]

[12] Our analysis here is consistent with the Commission's experience in other situations where it has found the use of qualifiers to be inadequate to sufficiently modify an otherwise false or misleading claim to render it non-deceptive. *See, e.g.*, Guides Concerning Use of Endorsements and Testimonials in Advertising, 16 C.F.R. § 255.2 (ads with endorsements will likely be interpreted as conveying that the endorser's experience is representative of what consumers will generally achieve, even when they include disclaimers such as "Results not typical" and "These testimonials are based on the experiences of a few people and you are not likely to have similar results"); FTC Staff Report, *Effects of Bristol Windows Advertisement with an "Up To" Savings Claim on Consumer Take-Away and Beliefs* (May 2012), *available at* http://www.ftc.gov/opa/2012/06/uptoclaims.shtm (when marketers use the phrase "up to" in their ads, such as making a claim that consumers will save "up to 47%" in energy costs by purchasing replacement windows, the qualifier does not affect consumers' overall takeaway that the percentage savings depicted is typical of what they can expect to achieve).

[13] In Commissioner Ohlhausen's view, the use of qualified terms such as "preliminary studies," or "initial studies" in the main text of an ad is significantly different than including a disclosure like "results not typical" in small print at the bottom of an ad. In her opinion, for some of the exhibits, the

Moreover, we note that in many instances, ads describing study results using such qualifying language include other elements that also contribute to the net impression that the claims at issue are clinically proven, such as the use of medical imagery (including the caduceus, a well-recognized symbol of the medical profession), or statements relating to the overall amount of money spent on "medical" research, ranging from $20 million to over $30 million, depending on the relevant time period. When an ad represents that tens of millions of dollars have been spent on medical research, it tends to reinforce the impression that the research supporting product claims is established and not merely preliminary.

Whether an ad conveys the implied claims alleged by Complaint Counsel is a question of fact. *See, e.g.*, *Removatron Int'l*, 884 F.2d at 1496, *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1189. As we explain here, and in more detail in the Claims Appendix, based on our weighing of all of the evidence, the Commission finds that the net impression conveyed to at least a significant minority of reasonable consumers was that there is clinical proof for the disease treatment, prevention or risk reduction claims at issue. In this case, extrinsic evidence is not required because the establishment claims are in fact apparent from the overall, common-sense, net impression of the words and images of the advertisements themselves.

B. Extrinsic Evidence

Even though only a facial analysis is necessary to determine whether Respondents had indeed made the claims alleged by Complaint Counsel, both Complaint Counsel and Respondents provided extrinsic evidence in support of their arguments regarding claim interpretation. Specifically, Respondents offered the expert report and testimony of Dr. Ronald R. Butters, who was qualified as an expert in linguistics, as to the meaning of Respondents' advertisements. IDF 262, 264. In rebuttal, Complaint Counsel offered the expert report and testimony of

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qualifying language regarding studies warrants extrinsic evidence before finding implied establishment claims. *See* Commissioner Ohlhausen's Concurring Statement.

rebuttal witness Dr. David Stewart, who is accepted as an expert in advertising, marketing, consumer behavior, and survey methodology, to review Dr. Butters' report and counter his conclusions. IDF 287-89. Complaint Counsel also relied on the Bovitz Survey, a 2009 study of billboard headlines commissioned by Respondents to compare the impact of two advertising campaigns related to a number of the advertisements challenged by Complaint Counsel. ID at 222. Except where noted here and in the accompanying Claims Appendix, we agree with the ALJ's conclusions with respect to the extrinsic evidence provided in this case.

Extrinsic evidence can include results from methodologically sound surveys about the ads in question, the common usage of language, accepted principles from market research concerning consumers' response in general to ads, and the opinions of expert witnesses on how an advertisement might reasonably be interpreted. *See Kraft Inc.*, 114 F.T.C. at 121 (explaining extrinsic evidence includes "reliable results from methodologically sound consumer surveys"); *Thompson Med. Co.*, 104 F.T.C. at 790.

1. Dr. Butters' Expert Report and Dr. Stewart's Analysis

Dr. Butters examined the challenged ads and offered his opinion that none of them conveyed that scientific research proves that the use of the Challenged POM Products successfully treats, prevents or reduces the risk of heart disease, prostate cancer, or ED. IDF 264, 480-83; PX0158 (Butters Expert Report at 0003). He concluded that, at most, the ads would convey that pomegranate juice is a health beverage and that preliminary research suggests there may be health benefits. IDF 486; PX0158 (Butters Expert Report at 0003, 0043.) Additionally, Dr. Butters opined that what people might infer with respect to a food product may differ from what they might infer with respect to a drug regarding treatment claims. IDF 491-92; Butters, Tr. 2817-18. During trial, Dr. Butters testified and proffered his opinion on the interpretation of many of the challenged ads. *See* IDF 496-511. Dr. Stewart provided a useful analysis of Dr. Butters' expert report, but Dr. Stewart did not conduct his own facial analysis of the challenged ads, and because he could not opine on what the ads meant, his analysis has inherent limitations. IDF 513. He

explained that Dr. Butters' linguistic approach to ad interpretation fails to take into account the characteristics of the viewer and how consumers use information. Stewart, Tr. 3170-73.

We agree with the ALJ's conclusion that, notwithstanding Dr. Butters' opinion to the contrary, the use of qualified language such as "may" or "can" with respect to the effects of the Challenged POM Products on disease does not modify the messages being conveyed.[14] In fact, we agree that such qualifiers may create the inference of a stronger claim by garnering reader trust and that their meaning can depend on context. ID at 233; IDF 527, 589. We also agree with the ALJ's conclusion that notwithstanding Dr. Butters' opinion to the contrary, the use of humor, parody, and hyperbole in an advertisement does not block communication of a serious message. ID at 233; IDF 487-89. Indeed, it may be the humor that grabs the reader's eye but the serious message that holds the reader's interest. The Commission agrees with the ALJ's conclusion based on Dr. Stewart's testimony that qualifying language with respect to cited studies (such as "preliminary," "promising," "encouraging," or "hopeful") "fails to materially alter the overall net impression that such advertisements were claiming clinical proof." ID at 232; IDF 519. In sum, we find Dr. Butters' linguistic analysis of the advertisements in question to be of limited value in our overall assessment of the net impression of the ads at issue.

2. Bovitz Survey

In 2009, POM engaged the Bovitz Research Group to design a consumer survey to evaluate the relative effectiveness of the then-running "Super Hero" advertising campaign compared to POM's earlier "Dressed Bottle" campaign. The survey exposed survey respondents to POM's billboard advertising, which included taglines related to antioxidants but contained no additional text. Four of the billboard advertisements share headlines and imagery that appear in certain challenged ads in this case. IDF 544, 546, 547, 550, 552. We note at the outset that Complaint Counsel offered the Bovitz Survey as supporting extrinsic evidence only in

[14] Commissioner Ohlhausen believes that the qualifying language in some of the exhibits requires extrinsic evidence before finding implied claims. *See* Commissioner Ohlhausen's Concurring Statement.

the context of the testimony of its rebuttal witness, Dr. Stewart. Stewart, Tr. 3205-21; 3241-42.

In determining whether a consumer survey is methodologically sound, we consider whether the survey "draws valid samples from the appropriate population, asks appropriate questions in ways that minimize bias, and analyzes the results correctly." *Thompson Med. Co.*, 104 F.T.C. at 790. The Commission does not require methodological perfection before it will rely on a copy test or other type of consumer survey, but looks to whether such evidence is reasonably reliable and probative. *See Stouffer Foods Corp.*, 118 F.T.C. at 807; *Bristol-Myers Co.*, 85 F.T.C. at 743-44, 744 n.14. Flaws in the methodology may affect the weight that is given to the results of the survey. *See Stouffer Foods Corp.*, 118 F.T.C. at 807-08.

We agree with the ALJ's conclusion that the Bovitz study is not particularly persuasive. The ALJ concluded that the Bovitz Survey's conclusions on consumers' interpretations of billboard messages are entitled to little weight for assessing whether the print advertisements at issue in this case conveyed the alleged claims. ID at 223. The ALJ reasoned that even when the billboard headlines appeared in the challenged print ads, the billboard images did not include the additional text contained in the print ads, such as references to scientific studies, that might modify the message. *Id.*

3. Respondents' Intent

Finally, the ALJ rejected Complaint Counsel's argument that Respondents' intent to make disease claims in their advertisements should be considered in this matter as extrinsic evidence that the claims were made. *See* ID at 216 ("This Initial Decision need not, and does not, determine whether or not Respondents intended to make the disease claims alleged in the Complaint because the evidence is sufficient to conclude that Respondents disseminated advertisements containing the alleged claims, without regard to Respondents' alleged intent."). It is true that a showing of intent to make a particular claim is not required to find liability for violating Section 5. *See, e.g.*, *Chrysler Corp. v. FTC*, 561 F.2d 357, 363, 363 n.5 (D.C. Cir. 1977); *Novartis Corp.*, 127 F.T.C. at 683; *Kraft, Inc.*, 114 F.T.C. at 121. But it is

also well established that a showing that an advertiser intended to make particular claims can help demonstrate that the alleged claim was in fact conveyed to consumers. *See Telebrands Corp.*, 140 F.T.C. at 304 (concluding that "ample evidence that respondents intended to convey the challenged claims" provided further support for the conclusion that advertisements made the alleged claims); *Novartis Corp.*, 127 F.T.C. at 683 ("evidence of intent to make a claim may support a finding that the claims were indeed made"); *Thompson Med. Co.*, 104 F.T.C. at 791.

Here, we only consider whether Respondents intended to make the disease claims challenged by Complaint Counsel in their advertisements; whether Respondents intended to make claims about general health benefits in their advertisements is not relevant to our analysis.

We find that the record includes evidence of Respondents' intent to make claims in their advertisements about the Challenged POM Products' effects on heart disease, prostate cancer, and ED. For example, Mr. Resnick testified that POM communicates to consumers the company's "belief that pomegranate juice is beneficial in treating some causes of impotence, for the purpose of promoting sales of its product." IDF 1316 (citing CX1372 at 45 (S. Resnick, Tropicana Dep.)). Separate creative briefs for POMx Pills, dated September 1 and 5, 2006, respectively, stated that their "main creative focus is prostate cancer," and that other versions of the creative brief "should definitely focus on the other benefits of POM – antioxidant, anti-aging, heart health, etc." IDF 1327, 1328. Although we rely principally on a facial analysis of the challenged ads in determining their net impression, evidence of Respondents' intent to convey claims about disease treatment and prevention supports our reading of Respondents' ads.

V. Respondents' Disease Claims Are False or Deceptive

Having determined that a significant number of the advertisements at issue on their face convey the claims challenged by Complaint Counsel, we turn next to whether such claims are false or likely to mislead consumers. There are two analytical routes by which Complaint Counsel can prove that Respondents' ads are deceptive or misleading, and both arise in this case.

The first is to demonstrate that the claims in the ads are false. *See Thompson Med. Co.*, 104 F.T.C. at 818-19. In this case, the claims that Complaint Counsel alleges are false are Respondents' establishment claims. These claims may be deemed false where Respondents represent expressly or implicitly that there is clinical proof that the Challenged POM Products treat, prevent or reduce the risk of heart disease, prostate cancer, or ED but Respondents lacked such proof at the time the representations were made. If Respondents do not have such clinical proof, Respondents' establishment claims are false. *See*, *e.g.*, *Removatron Int'l Corp.*, 111 F.T.C. 206, 297-99 (1988) ("If an advertisement represents that a particular claim has been scientifically established, the advertiser must possess a level of proof sufficient to satisfy the relevant scientific community of the claim's truth."), *aff'd*, 884 F.2d 1489 (1st Cir. 1989); *Sterling Drug*, 102 F.T.C. 395, 762 (1983) ("when an advertiser represents in its ads that there is a particular level of support for a claim, the absence of that support makes the claim false").

The second approach is through the "reasonable basis" theory, which Complaint Counsel asserts with regard to the efficacy claims in Respondents' ads. This theory rests on the principle that an objective claim about a product's performance or efficacy carries with it an express or implied representation that the advertiser had a reasonable basis of support for the claim. *Thompson Med. Co.*, 104 F.T.C. at 813 n.37. "Consumers find these representations of support to be important in evaluating the reliability of the product claims. Therefore, injury is likely if the advertiser lacks support for the claims." *Id.* For that reason, "[t]he reasonable basis doctrine requires that firms have substantiation before disseminating a claim." *Substantiation Statement*, 104 F.T.C. at 840. To determine what constitutes a reasonable basis, the Commission considers the "*Pfizer* factors," which are factors relevant to the benefits and costs of developing substantiation for the claim. *See In re Pfizer Inc.*, 81 F.T.C. 23 (1972); *Substantiation Statement*, 104 F.T.C. at 840 (the "determination of what constitutes a reasonable basis depends . . . on a number of relevant factors relevant to the benefits and costs of substantiating a particular claim …[including,] the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the

claim, and the amount of substantiation experts in the field believe is reasonable").

In the Initial Decision, the ALJ recognized that both the falsity of the establishment claims and the lack of a reasonable basis for Respondents' efficacy claims involved questions of the level of substantiation that Respondents needed to possess. He further recognized that the experts who testified in this case explained that they would find the establishment and efficacy claims to be properly supported with the same level of evidence. *See* ID at 243. Thus, the ALJ consolidated his analysis of the establishment and efficacy claims and appears to have applied the *Pfizer* factors to both types of claims when he evaluated the expert testimony. *See id.* at 243-44. To the extent that the ALJ's approach may be interpreted as applying the *Pfizer* factors to determine the level of substantiation necessary to support the establishment claims, we do not adopt the analysis. *Removatron Int'l Corp.*, 111 F.T.C. at 297 ("[I]f the ad . . . implies a particular level of substantiation to reasonable consumers, application of the *Pfizer* factors is not required."); *Thompson Med. Co.*, 104 F.T.C. at 821-22 n.59; *Bristol-Myers*, 102 F.T.C. at 321, 331.

The ALJ also failed to differentiate the opinions and testimony of the expert witnesses regarding the particular claims that they were addressing. The ALJ correctly recognized that the level of evidence "required to support a claim depends on the claim being made." IDF 688 (citing Stampfer, Tr. 830-31; Miller, Tr. 2195, 2210). *See also* PX0206 at 11 (Miller Expert Report) ("whether clinical science is necessary to substantiate a particular claim would vary according to the strengths of the basic science and the particular claim"). Yet, the ALJ appears to have relied on expert testimony about the level of substantiation necessary for broad, generalized health and nutritional benefits when he determined the level of substantiation needed to address the specific disease treatment, prevention and risk reduction claims at issue in this case. Our review of the record leads us to conclude that, to the extent the ALJ did so, his conclusions are not properly supported.

Throughout this case, Respondents have argued that their scientific studies of the Challenged POM Products support claims about broad health benefits, which may contribute to a reduced

risk of disease.[15] Thus, within the category of claims related to disease risk reduction, Respondents would include general dietary recommendations and qualified claims regarding any health benefits of food, which they contend are equivalent to the representations made in their ads.

The starting point for Respondents' experts was the position that Respondents put forward on ad interpretation, namely that the challenged ads convey only that the Challenged POM Products generally promote good health. As a result, Respondents' experts provided opinions regarding the level of science needed to substantiate claims about general health benefits, testifying that lower levels of substantiation — for instance, the totality of the evidence, including basic science and pilot studies — are sufficient. *See* PX0025 at 5 (Ornish Expert Report) ("Taken as a whole, the scientific evidence from basic science studies, animal research, and clinical trials in humans indicates that pomegranate juice in its various forms . . . is likely to be beneficial in maintaining cardiovascular health and is likely to help reduce the risk of cardiovascular disease."); PX0192 at 9, 11 (Heber Expert Report) ("It is not appropriate to require the use of double-blind placebo-controlled studies for evaluating the health benefits of foods that have been consumed for their health benefits for thousands of years" and "the body of research on pomegranate juice and extract, revealing how they act in the body, provides support for potential health benefits for heart disease, and prostate cancer."); PX0149 at 6-7 (Burnett Expert Report) ("[T]he basic scientific and clinical evidence is sufficient to support the use of pomegranate juice as a potential benefit for vascular blood flow and the vascular health of the penis. . . . It is also my opinion that further such studies as double blinded, placebo-based tests are not required before permitting this information to be given to the public."); PX0189 at 3 (Goldstein Expert Report) ("[P]hysicians

[15] *See, e.g.*, RAns at 5 ("[T]he gist of these ads – their 'net effect' – is to convey the idea that POM's Products are natural foods high in health-enhancing antioxidants, much like other healthy foods, such as broccoli and blueberries, which may improve one's odds of staying in good health but are not medicine to prevent or treat disease."); RA at 26 ("What, then, do the statements in POM's advertisements mean? The plain reading of these messages is that the high antioxidant content of POM juice is likely a good thing, because it can help promote healthy functioning of various natural processes in the body.").

who treat patients concerned with erectile health would not hold pomegranate juice to the standards of safety and efficacy traditionally required by the FDA for approval of a pharmaceutical (including performance of large, double-blind, placebo-controlled pivotal clinical trials) before recommending pomegranate juice to their patients. The available body of scientific literature – including in vitro, in vivo, and preliminary clinical trials – strongly suggests that consuming pomegranate juice promotes erectile health.").

Yet, on cross-examination these experts revealed that even they distinguish the type of evidence that would be necessary to substantiate disease treatment, prevention or risk reduction claims, which are precisely the type of the representations we conclude are made in Respondents' ads. *See, e.g.*, IDF 684 ("Dr. Burnett testified that the standard of substantiation is different for a product that is directly associated as a treatment for erectile dysfunction and for a product that claims to have helpful benefits for or improves one's erectile function."); PX0192 at 40-41 (Heber Expert Report) ("To the extent [Complaint Counsel's expert] Dr. Stampfer claims that pomegranate juice and extract have not been proven absolutely effective to treat, prevent, or reduce the risk of heart disease and prostate cancer, I agree. But . . . [i]n my expert opinion, there is credible scientific evidence that pomegranate juice and pomegranate extracts have significant health benefits for human cardiovascular systems . . . [and] the following effects on prostate biology relevant to reducing the risk of prostate cancer . . ."). Likewise, as the ALJ recognized, claims regarding general health benefits for heart, prostate, or erectile function are not the equivalent of claims to treat, prevent or reduce the risk of heart disease, prostate cancer, and erectile dysfunction. *See* ID at 282, 288, 289.[16]

Similarly, Complaint Counsel's experts, who testified that RCTs would be necessary to support Respondents' disease

[16] This key distinction between general health benefit claims and disease treatment, prevention or risk reduction claims is the basis for Commissioner Ohlhausen's Concurring Statement regarding what claims were made in a number of Respondents' advertisements. *See* Commissioner Ohlhausen's Concurring Statement Regarding Exhibit Claims.

treatment and prevention claims, have explained that less rigorous evidence may be sufficient to support some claims regarding health or nutritional benefits of food. *See* IDF 637 (Dr. Stampfer has made public health recommendations regarding diet that were not supported by RCTs), 644-45 (Dr. Sacks testified that RCTs are not necessary to test the benefit of food categories that are included in a diet already tested in an RCT for the same benefit).

In fact, the testimony of experts called by both Complaint Counsel and Respondents was consistent on this issue. They acknowledged the differences in the level of substantiation that would be necessary for general nutritional and health benefit claims compared to the level of substantiation necessary for the specific disease treatment and prevention claims at issue in this case. *See* IDF 631 (citing Stampfer, Tr. 830-31) (explaining if the claim does not imply a causal link, then evidence short of RCTs may support that claim), 649 (explaining even if a product is safe and might create a benefit, like a fruit juice, Dr. Eastham would still require an RCT to justify claims that Respondents are charged with making) (citing Eastham, Tr. 1325-31), 684 ("Dr. Burnett testified that the standard of substantiation is different for a product that is directly associated as a treatment for erectile dysfunction and for a product that claims to have helpful benefits for or improves one's erectile function."); Heber, Tr. 2145-47 (explaining that his prior testimony was that the totality of evidence showed that the Challenged POM Products likely reduced the risk in a "probabilistic sense" rather than "actual"; he did not previously testify that the Challenged POM Products treat prostate cancer, but rather they "help to treat" prostate cancer because he would not opine that the Challenged POM Products should substitute for conventional treatment); PX0206 at 11 (Miller Expert Report) ("an unqualified claim that the product has been shown to slow the progression of PSA doubling times should actually be supported by clinical evidence" whereas a "qualified claim that POM products may be effective … is reasonable" if additional conditions are met, including there is "no suggestion" that pomegranate alone can "absolutely prevent the disease").

Although there is substantial expert testimony regarding the level of support required for generalized nutritional and health benefit claims, such evidence does not address the issue before us. We need not determine the level of substantiation required to

support all health claims, and we therefore decline to make such a finding. We consider only the claims that, as found by the Commission, Respondents made in this case — that the Challenged POM Products treat, prevent or reduce the risk of heart disease, prostate cancer, and ED, and that such claims are scientifically established. The expert evidence was clear that RCTs are necessary for adequate substantiation of these representations.

Accordingly, we reject the ALJ's conclusion that "RCTs are not required to convey information about a food or nutrient supplement where . . . the safety of the product is known; the product creates no material risk of harm; and the product is not being advocated as an alternative to following medical advice." *See* ID at 243. Other than to endorse the Commission's prior statements that health claims in food advertising be supported by "competent and reliable scientific evidence,"[17] we do not reach the issue regarding the level of substantiation for other unspecified health claims involving food products. We simply reject the ALJ's findings and conclusions regarding any health benefits not specifically challenged in the Complaint.

Just as we limit our findings to the specific disease treatment and prevention claims that are before us, we also reject the ALJ's determination that the level of substantiation needed to support representations that a product treats, prevents or reduces the risk of disease varies according to whether the advertiser offers the product as a replacement for traditional medical care. *See* ID at 243. Again, we address only the level of substantiation needed to support the claims that are at issue in this case and do not address hypothetical claims.

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[17] "'[C]ompetent and reliable scientific evidence' has been more specifically defined in Commission orders addressing health claims for food products to mean: tests, analysis, 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." *FTC Enforcement Policy Statement on Food Advertising*, (1994), *available at* http://www.ftc.gov/bcp/policystmt/ad-food.shtm (citing *Gracewood Fruit Co*., 116 F.T.C. 1262, 1272 (1993); *Pompeian, Inc.*, 115 F.T.C. 933, 942 (1992)) ("*Food Advertising Statement*").

A. Claims That Are False

We turn next with more specificity to Respondents' claims that are alleged to be false. According to the Complaint, and as we found above, Respondents have represented that "clinical studies, research, and/or trials prove" that the Challenged POM Products treat, prevent or reduce the risk of heart disease, prostate cancer, and ED. Compl. ¶¶ 12, 14, 16. When "ads contain express or implied statements regarding the amount of support the advertiser has for the product claim . . . , the advertiser must possess the amount and type of substantiation the ad actually communicates to consumers."[18] *Substantiation Statement*, 104 F.T.C. at 839. Moreover, "[i]f an advertisement represents that a particular claim has been scientifically established, the advertiser must possess a level of proof sufficient to satisfy the relevant scientific community of the claim's truth." *See Thompson Med. Co.*, 104 F.T.C. at 821-22 n.59; *Removatron Int'l Corp.*, 111 F.T.C. at 297.

Because Complaint Counsel bears the burden of showing that these claims are false, *Thompson Med. Co.*, 104 F.T.C. at 818-19, Complaint Counsel must demonstrate that Respondents did not have the amount and type of substantiation they claimed to have had. *See Sterling Drug*, 102 F.T.C. at 762; *Thompson Med. Co.*, 791 F.2d at 194. To meet this burden, Complaint Counsel must establish the standards that clinical studies, research, or trials must meet to pass muster in the view of the relevant scientific and medical communities as support for the claims Respondents were making, and then show that the studies Respondents possessed did not meet those standards. If Respondents do not possess the level of clinical studies, research, or trials demanded by those scientific and medical communities, then Respondents' claims of clinical proof are false. *See*, *e.g.*, *Sterling Drug*, 102 F.T.C. at 762

[18] As noted above, for these establishment claims, unlike efficacy claims, we need not perform an evaluation of the various factors set out in *Pfizer* to establish the appropriate level of substantiation because the ads themselves make express or implied substantiation claims. We simply hold Respondents to the level of substantiation that the ads claim. "We treat such claims like any other representations contained in the ad. We verify that it is reasonable to interpret the ad as making them, that the claims were material, and that they are false. If so, they are deceptive under Section 5(a) of the FTC Act." *Thompson Med. Co.*, 104 F.T.C. at 821-22 n.59.

("[W]hen an advertiser represents in its ads that there is a particular level of support for a claim, the absence of that support makes the claim false.").

Based on our review of the entire record, we conclude that a higher level of substantiation is necessary to support Respondents' establishment claims than what the ALJ found. The ALJ found that experts in the relevant fields would require "competent and reliable evidence [that] must include clinical studies although not necessarily RCTs" to support Respondents' claims. *See* ID at 253. We disagree. The Commission finds that experts in the relevant fields would require RCTs (*i.e.*, properly randomized and controlled human clinical trials described in more detail below) to establish a causal relationship between a food and the treatment, prevention, or reduction of risk of the serious diseases at issue in this case.

To determine the standards that the relevant scientific and medical communities would demand, we review the testimony of expert witnesses qualified in the fields of heart disease, prostate cancer, and ED. The Commission finds that the preponderance of the credible expert testimony establishes that the level of substantiation experts in the field would consider necessary to support Respondents' establishment claims – that clinical studies, research, or trials prove that the Challenged POM Products treat and prevent or reduce the risk of heart disease, prostate cancer, or ED – is RCTs. *Cf. Thompson Med. Co.*, 104 F.T.C. at 821 (finding the standard generally adhered to by the medical scientific community for testing the efficacy of a drug is well-controlled clinical tests (or RCTs)). Here, Respondents' advertisements on their face convey the net impression that clinical studies or trials show that a causal relation has been established between consumption of the Challenged POM Products and its efficacy to treat, prevent or reduce the risk of the serious diseases in question. The record testimony in this case indicates that experts in the fields of heart disease, prostate cancer, and ED would find that causation has been shown only if RCTs have been conducted and the appropriate data demonstrates that each study's hypothesis has been fully supported. *See* CX1293 at 8, 9 (Stampfer Expert Report) (observational studies "typically cannot confirm causality" and "best evidence of a causal relationship between a nutrient or drug . . . and a disease

outcome in humans is a randomized, double blind, placebo-controlled, clinical trial"); IDF 639 (stating Dr. Sacks testified that most scientists in the fields of nutrition, epidemiology and the prevention of disease believe RCTs "are needed to constitute reliable evidence that an intervention causes a result"); IDF 687 (explaining Dr. Goldstein testified that "RCTs are considered the criterion standard for determining causality"); *accord* Federal Judicial Center, *Reference Manual on Scientific Evidence* 218 (3d ed. 2011) ("[r]andomized controlled experiments are ideally suited for demonstrating causation"). That is, we find that RCTs are required to substantiate Respondents' disease claims because it is necessary to isolate the effect of consuming the Challenged POM Products on the incidence of the disease, and the expert testimony revealed that only RCTs can isolate that effect.

As discussed previously, our conclusion differs from that of the ALJ in that the ALJ relied on expert testimony describing the level of substantiation that would support general claims of "health benefits" associated with the consumption of the Challenged POM Products, rather than focusing on the expert testimony about the level of substantiation needed to support the specific disease treatment and prevention claims that are conveyed by Respondents' ads. *See* ID at 222. The ALJ recognized that "claims of efficacy can be made only when a causal relationship with human disease is established by competent and reliable scientific evidence." *Id.* at 247. Yet, the ALJ nonetheless relied on expert testimony addressing health benefit claims that do not assert a causal relationship to conclude that clinical evidence that is less than RCTs would support Respondents' claims. *See id.* at 247 (relying on IDF 631 (explaining public health recommendations that are not based on causation could be supported by evidence other than RCTs)). We find that the ALJ's conclusion that clinical evidence that is less than RCTs would substantiate Respondents' disease treatment, prevention, and risk reduction claims is not supported by the record.

Based on the expert testimony, we also find that the RCTs necessary to substantiate the serious disease claims made by Respondents share several essential attributes. First, to show the efficacy of the Challenged POM Products to treat, prevent or reduce the risk of disease, experts in the field would require the

studies or trials to show causation, which would require the trial to be well-controlled. *See, e.g.*, CX1293 at 8-10 (Stampfer Expert Report); CX1291 at 11 (Sacks Expert Report); *cf.* Burnett, Tr. 2260-62 (discussing well-controlled studies to be validated by FDA). "A controlled study is one that includes a group of patients receiving the purported treatment . . . and a control group . . . . A control group provides a standard by which results observed in the treatment group can be evaluated. A control group allows investigators to distinguish between real effects from the intervention, and other changes, including those due to the mere act of being treated ('placebo effect'), the passage of time, change in seasons, other environmental changes, and equipment changes." IDF 611 (citations omitted).

Second, subjects should be randomly assigned to the test and control groups. Randomization "increases the likelihood that the treatment and control groups are similar in relevant characteristics, so that any difference in the outcome between the two groups can be attributed to the treatment . . . [and] also prevents the investigator from . . . introduc[ing] bias into the study." IDF 612.

Third, for clinical studies or trials to prove that the Challenged POM Products treat, prevent or reduce the risk of heart disease, prostate cancer, or ED, the studies need to examine variables that are known to be predictive of or measure the incidence of the disease. That is, the studies or trials need to examine disease endpoints or validated surrogate markers that "have been shown to be so closely linked to a direct endpoint that a change in the surrogate marker is confidently predictive of a change in the disease." IDF 621. Validated measures or assessment tools are those that have been established as reliable through rigorous assessments. IDF 621. Study results affecting variables that are not confidently predictive of a change in the incidence of disease do not prove that the Challenged POM Products treat, prevent or reduce the risk of the particular diseases.

Fourth, the testimony indicates that the scientific and medical communities would require that results of the trial be statistically significant to demonstrate that clinical studies prove that the tested product treats or prevents disease. IDF 616 (citing CX1291 at 12-13 (Sacks Expert Report); Burnett, Tr. 2269) ("If the results

of the treatment group are *statistically significant* from those of the control group at the end of the trial, it can be concluded that the tested product is effective.") (emphasis added), 618 (citing CX1291 at 12 (Sacks Expert Report); Eastham, Tr. 1273; Ornish, Tr. 2368; Melman, Tr. 1102-03) (explaining statistical significance means that differences are not due to chance or other causes). Moreover, the population from which the groups draw must be appropriate for the purposes of the study. *See* CX1287 at 12, 15 (Eastham Expert Report) (explaining that in a prostate cancer prevention trial the appropriate population would involve healthy men having no sign of prostate cancer, whereas in a prostate cancer treatment trial, the appropriate sample population would depend on the stage of the disease targeted by the study).

Fifth, the clinical trials should be double-blinded when feasible. Blinding refers to steps taken to ensure that neither the study participants nor the researchers conducting the outcome measurements are aware of whether a patient is in the active group or the control group. IDF 614. Double blinding, which is the blinding of both the subjects and investigators, is optimal to prevent bias arising from actions of the subjects or investigators. IDF 615. The expert testimony revealed in some instances that it may not be possible to conduct blinded clinical trials of food products. In that regard, the experts in the field might demand different well-controlled human clinical trials of foods than they would expect in other areas. The expert testimony in this case indicated that, for clinical tests involving food, participants in the study may be able to determine the products that they are consuming.[19] *See* IDF 641; Sacks, Tr. 1435-36 (describing controlled study testing low sodium diet in which subjects were able to taste the saltiness of the diet); Ornish, Tr. 2328-29, 2356; Goldstein, Tr. 2600-01. In such cases, there may be some flexibility in the double-blind requirement when determining

[19] This testimony is consistent with the FDA's "Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims – Final," *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm, which states: "When the substance is a food, it may not be possible to provide a placebo and therefore subjects in such a study may not be blinded. Although the study may not be blinded in this case, a control group is still needed to draw conclusions from the study."

whether a well-controlled human clinical trial satisfies the standard that experts in the field would consider support for particular claims for food. Although we note that Respondents submitted several studies with pomegranate juice that were described as double blind RCTs,[20] and we recognize that double-blinding would lend more credence to a clinical trial, we acknowledge that blinding of subjects may not always be feasible for the reasons stated above. We note, however, that clinical trials involving products such as the POMx pills should not face these types of blinding challenges.

Respondents argue that they should not be required to meet "an impossibly high and legally untenable standard of dispositive proof through the clinical studies" that their products treat, prevent or reduce the risk of disease in order to provide substantiation for their claims. RA at 30. We reject Respondents' argument. Respondents' ads convey a net impression that scientific and medical evidence support their representations. We are simply holding Respondents to their claims by requiring the standard by which the scientific and medical communities would accept their claims of efficacy. We do not impose a standard requiring "dispositive" proof; rather we require the scientific standard for proof, which demands statistically significant results on a metric that is recognized as a valid marker for the particular disease in a controlled human clinical study. According to the expert testimony, statistical significance with a p-value that is less than or equal to 0.05 is the recognized standard to show that a study's hypothesis has been proven. IDF 618. This is the level of "proof" that Respondents' must possess.

Respondents further argue that statistically significant proof requires studies that are too large and costly. The response to this argument is twofold. First the need for RCTs is driven by the claims Respondents have chosen to make (*i.e.*, establishment claims about a causal link between the Challenged POM Products and the treatment or prevention of serious diseases). Second, the requisite size of a clinical trial – the number of subjects required for an appropriately designed study – is guided by several factors, including the need to produce both clinically and statistically

[20] *See, e.g.*, IDF 808-818 (Ornish MP study), 849-859 (Ornish CIMT study), 872-883 (Davidson CIMT study), 941-943 (Heber/Hill Diabetes study).

significant results. *See, e.g.*, CX1287 at 15 (Eastham Expert Report) (explaining that clinical and statistical significance for a prostate cancer treatment trial may require a sample population that involves hundreds to thousands of men). A large number of participants is not always necessary, however. RCTs differ widely in size, depending, in part, on what the study is trying to show. If, despite a relatively small size, a well-conducted RCT produces significant results, then the study would constitute evidence of efficacy that would provide the substantiation that experts would accept. The main limitation of smaller studies is that it may prove difficult to detect real differences between the active and control substances, because sampling variance is inversely related to sample size. *Cf.* CX1338, *in camera* (Padma-Nathan, Dep. at 108-09) (larger number of participants may have helped Forest/Padma-Nathan study achieve overall statistical significance). Smaller studies may require a large difference in outcomes between the two arms of a clinical trial to produce statistically significant results. Thus, designers of clinical studies have a natural incentive to make them as large as possible.

Similarly, Respondents argue that it is improper to impose the testing standards for drugs on food products. We do not impose such standards in this case. Although the Commission does not enforce federal drug approval requirements, we note at the outset that our sister federal agency, the Food and Drug Administration, promulgates and enforces regulations regarding investigational new drug approvals, and that those regulations require multiple phases of clinical trials that collectively represent different – and considerably greater – substantiation than the RCTs required here.[21] We note too, that FDA regulations separately require FDA approval of health claims made on behalf of food products, and that approval of such claims requires the submission of well-designed scientific evidence.[22] Respondents' representations

[21] *See, e.g.*, 21 CFR §§ 312.21-23 (regarding three phases of clinical trials for investigational new drug applications for products not previously tested, where both Phase 2 and Phase 3 trials comprise clinical studies of effectiveness).

[22] *See, e.g.*, 21 CFR § 101.14(c) (validity requirement for food health claims); *see also* FDA, Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims, *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm.

claim clinical proof of efficacy for treating, preventing, or reducing the risk of serious diseases (two of which are potentially fatal). Nonetheless, the Commission's determination that experts in the field would require RCTs to support Respondents' health claims does not require the FDA standard of proof for drugs.

1. Evidence Regarding Substantiation for Heart Disease Claims

We find that the greater weight of credible expert testimony establishes that experts in the field of heart disease would require RCTs to support Respondents' claims that clinical studies establish that the Challenged POM Products treat, prevent or reduce the risk of heart disease. Complaint Counsel's expert, Dr. Frank Sacks, testified that to show that clinical studies, research, or trials prove that a product treats, prevents or reduces the risk of heart disease, it is necessary to rely on appropriately analyzed results of "well-designed, well-conducted, randomized, double-blinded, controlled human clinical studies (RCTs)." CX1291 at 10-11 (Sacks Expert Report). Dr. Sacks also opined that the findings of the studies must be statistically significant; the results must demonstrate significant changes in valid surrogate markers of cardiovascular health that are recognized by the FDA or experts in the field, such as blood pressure, LDL cholesterol, C-reactive protein, HDL cholesterol, and triglycerides. IDF 711, 712, 761-63, 765-66. Similarly, Dr. Meir Stampfer, another expert witness for Complaint Counsel, testified that scientists in the fields of clinical trial epidemiology and the prevention of cardiovascular disease would believe that randomized, double-blind, placebo-controlled studies are needed to show that products such as POM Juice, POMx Pills, and POMx Liquid can prevent, reduce the likelihood of, or treat cardiovascular disease because a well-controlled clinical trial is necessary to establish a causal inference. Stampfer, Tr. 717-18.

Respondents' experts, Dr. David Heber and Dr. Dean Ornish, testified that the preponderance of scientific evidence from basic scientific studies, animal research, and human clinical trials reveals that pomegranates are likely to be beneficial in maintaining cardiovascular health and are likely to help reduce the risk of cardiovascular disease. IDF 954, 959. Yet, as we previously observed, Respondents' experts generally do not

address the specific heart disease claims alleged in the Complaint. For example, Dr. Ornish only addressed whether RCTs would be necessary "to test and substantiate health claims of something like pomegranate juice." Ornish, Tr. 2329. He did not specifically address whether *in vitro* and animal studies could provide support for claims that a product treats, prevents or reduces the risk of heart disease. Similarly, Dr. Heber testified about "the juice's ability to promote health" when he explained that experts would look at the totality of science rather than requiring RCTs as the only acceptable evidence. Heber, Tr. 1948-49; *see also* PX0192 at 9, 40 (Heber Expert Report) (explaining "[i]t is not appropriate to require the use of double-blind placebo-controlled studies for evaluating the *health benefits* of foods . . ." and "there is credible scientific evidence that pomegranate juice and pomegranate extracts have *significant health benefits* for human cardiovascular systems, including: 1) decreases in arterial plaque; 2) lowering of blood pressure; and 3) improvement of cardiac blood flow") (emphasis added).

Based on our evaluation of this evidence, we conclude that the expert testimony establishes that to support claims that clinical studies prove that the Challenged POM Products treat, prevent or reduce the risk of heart disease, experts in the field of heart disease would require RCTs.

Respondents have sponsored several *in vitro* and *in vivo* animal studies to examine the effect of the Challenged POM Products on cardiovascular health. The ALJ considered 13 *in vitro* and *in vivo* studies and made findings regarding the results of the studies, as well as the expert witnesses' assessments of the studies. *See* IDF 732-55. We adopt the ALJ's findings on this basic science and the preclinical studies regarding cardiovascular health. As Judge Chappell observed, experts for both Complaint Counsel and Respondents acknowledge that some of Respondents' *in vitro* studies have shown pomegranate juice's favorable effects on particular mechanisms involved in cardiovascular disease, *see* IDF 745, 746, but experts for both sides also acknowledged that *in vitro* and animal studies do not provide reliable scientific evidence of what effects a treatment will have inside the human body. IDF 752, 753. Thus, while the basic research possessed by Respondents is part of the totality of evidence that must be examined, we conclude, similar to the ALJ,

that experts in the field would agree that Respondents' *in vitro* and animal studies need to be replicated in humans to show an effect on preventing or treating a disease and therefore do not provide adequate substantiation for Respondents' heart disease claims alleged in the Complaint. IDF 755.

The Complaint alleges that Respondents claim that clinical studies, research, or trials prove that the Challenged POM Products treat, prevent or reduce the risk of heart disease by (1) lowering blood pressure; (2) decreasing arterial plaque; and/or (3) improving blood flow to the heart. The Initial Decision methodically examines in detail Respondents' ten published clinical studies and several unpublished clinical studies on humans regarding the effect of the Challenged POM Products on cardiovascular health. *See* IDF 756-947; ID at 256-69. For each study, the ALJ describes the methodology, including any shortcomings in design, as well as the results. The ALJ also describes the expert testimony regarding each study. After evaluating each study in detail, Judge Chappell concludes that these studies "do[] not provide competent and reliable scientific evidence to support claims that the Challenged POM Products treat, prevent, or reduce the risk of heart disease." IDF 786 (Aviram ACE/BP Study), 804 (Aviram CIMT/BP Study), 848 (Ornish MP Study), 868 (Ornish CIMT Study), 900 (Davidson CIMT Study), 914 (Davidson BART/FMD Study), 938 (Denver and San Diego Overweight Studies), 947 (Diabetes Studies).

For Respondents' claims that the Challenged POM Products lower blood pressure, the ALJ describes and evaluates the Aviram ACE/BP Study, *see* IDF 774-86, and the Aviram CIMT/BP Study, *see* IDF 787-804, and examines the results of five other studies that measured blood pressure as part of the protocol. The ALJ concludes that the expert testimony regarding the Aviram ACE/BP Study and Aviram CIMT/BP Study is conflicting, but "[t]he greater weight of the persuasive expert testimony on the studies sponsored by Respondents measuring blood pressure demonstrates that the scientific evidence relied upon by Respondents is not adequate to substantiate a claim that the Challenged POM Products treat, prevent, or reduce the risk of heart disease through reducing blood pressure, or that clinical studies show the same." ID at 259.

With respect to claims that the Challenged POM Products reduce arterial plaque, the ALJ describes and evaluates the Aviram CIMT/BP Study, *see* IDF 787-804, the Davidson CIMT Study, *see* IDF 869-900, and the Ornish CIMT Study, *see* IDF 849-68. Again, the ALJ concludes that "[t]he greater weight of the persuasive expert testimony on the studies sponsored by Respondents measuring CIMT demonstrates that the scientific evidence relied upon by Respondents is not adequate to substantiate a claim that the Challenged POM Products treat, prevent, or reduce the risk of heart disease through reducing arterial plaque, or that clinical studies show the same." ID at 265.

For Respondents' claims that the Challenged POM Products improve blood flow, the ALJ describes and evaluates the Ornish MP Study, *see* IDF 805-48. Here, the ALJ concludes that "[t]he greater weight of the persuasive expert testimony on the Ornish MP Study demonstrates that the scientific evidence relied upon by Respondents is not adequate to substantiate a claim that the Challenged POM Products treat, prevent, or reduce the risk of heart disease through improving blood flow, or that clinical studies show the same." ID at 269.

The ALJ also describes and evaluates additional clinical studies regarding heart disease. The ALJ considers the Denver Overweight Study, *see* IDF 915-23, 934-36; the San Diego Overweight Study, *see* IDF 924-33; the Rock Diabetes Study, *see* IDF 939-40, 944; and the Heber/Hill Diabetes Studies, *see* IDF 941-47. Again, the ALJ concludes that the studies do not provide scientific evidence to substantiate a claim that the Challenged POM Products treat, prevent or reduce the risk of heart disease.

We rely on the ALJ's detailed findings regarding each of the studies. Indeed, Respondents do little on appeal to contest the ALJ's findings regarding the particular clinical studies regarding cardiovascular health and heart disease. Instead, Respondents urge us only to overlook particular shortcomings of some of the studies in order to conclude that Respondents possess adequate substantiation for their claims. *See* RR at 7-10. We do not find Respondents' arguments persuasive and we agree with the ALJ's conclusions that each study fails to provide substantiation for Respondents' claim that clinical evidence proves that the

Challenged POM Products treat, prevent or reduce the risk of heart disease.

In particular, Respondents encourage us to focus on the improved measurements of blood pressure and arterial plaque in the Aviram ACE/BP and Aviram CIMT/BP studies rather than focus on the small size of the studies. RR at 7-8. Yet, the criticism of the studies is not limited to their size. In the Aviram ACE/BP study, ten elderly, hypertensive patients drank 50 ml of pomegranate concentrate daily for two weeks. IDF 774. The study was unblinded and had no control group. Instead, each patient's "before" measures were compared to the "after" measures. IDF 776. Expert testimony criticized the study because the sample size was too small to provide reliable evidence that the observed effects would be generally applicable to a larger population; the two-week period was too short to provide evidence that the improvements would last; one of the measured endpoints (angiotensin converting enzyme (ACE) activity) is not a validated surrogate marker of cardiovascular disease; and the lack of a control group meant that it is not possible to conclude that consumption of the pomegranate concentrate was the cause of reported improvements in blood pressure levels. IDF 780-81.

Similarly, in the Aviram CIMT/BP study, a group of ten patients with severe carotid artery stenosis drank up to 50 ml of concentrated pomegranate juice daily for one year, and five continued doing so for three years. A second group of nine patients did not consume pomegranate juice and acted as a control group. IDF 790. Respondents emphasize that the study found that members of the group that drank pomegranate juice consumption experienced, after one year, a reduction in carotid intima-media thickness (CIMT) by up to 30% and statistically significant reductions in systolic blood pressure. IDF 791, 794. Expert testimony regarding the study explained, however, that "a qualified scientist would not be able to conclude with any credibility that the Aviram CIMT/BP Study's reported improvements in the treatment group were caused by their consumption of pomegranate juice and not some other factor because of the lack of a randomized, placebo-controlled group; the fact that the patients in the active and control groups received different treatment; the small sample size, and the lack of any

between-group statistical analysis." IDF 798. Even one of Respondents' experts conceded the study was "not at all conclusive, the study suggests a benefit." IDF 802 (quoting Dr. Ornish). We find that the limitations of the Aviram ACE/BP and Aviram CIMT/BP studies go beyond the small sample size. As discussed above, there are several ways in which these two studies do not satisfy the criteria for well-controlled, well-designed clinical studies that are necessary to demonstrate that a product treats, prevents or reduces the risk of heart disease.

Regarding the specifics of the Davidson CIMT Study, Respondents argue that the Study should be recognized for the positive results for patients at the 12-month mark despite the lack of positive results for the patient group at 18 months. RR at 9. Respondents argue that "[a]lthough these results were not replicated at 18 months for the entire patient group, . . . the most likely explanation for the drop-off was the fact that patients may have stopped following the protocol of drinking POM Juice." *Id.* We reject Respondents' arguments. First, "[a]dherence to study product consumption was assessed at each visit by reviewing daily consumption diaries maintained by the subjects." IDF 876. Second, while the Study reported the 12-month results, those results were not the basis for any conclusions. *See* IDF 878 (explaining, for instance, "anterior and posterior wall CIMT values and progression rates did not differ significantly between treatment groups at any time"). Moreover, peer reviewers of the study considering the study for publication concluded "it was a negative study." IDF 880, 881-82, 883. We do not find that the 12-month results of the Davidson CIMT Study provide evidence on which experts in the field of heart disease would rely to establish that there is clinical proof that the Challenged POM Products treat, prevent or reduce the risk of heart disease.

Respondents also argue that the Ornish MP Study provides substantiation for the heart disease claims because the Ornish MP study found that POM Juice caused a statistically significant 35% improvement in blood flow to the heart. Respondents emphasize the testimony of Dr. Ornish that blood flow to the heart is the "bottom line" when it comes to heart disease, and Respondents also point out that the "[s]cientists and clinicians routinely consider biomarkers for heart disease other than the two officially recognized by the FDA." RR at 8. Respondents' argument

acknowledges that the Ornish MP Study does not provide evidence that experts in the field of heart disease would accept as support for claims that the Challenged POM Products treat, prevent or reduce the risk of heart disease because the study does not consider surrogate markers that are accepted as correlated to heart disease. IDF 825. As a result, Respondents' argument recognizes the failure of the Ornish MP Study to provide evidence of the issue that is before us. In addition, the Ornish MP Study suffered from significant problems, including that data on all patients was not reported; subjects in the placebo group did not receive a placebo treatment; a group of patients were unblinded before their test dates; the control group differed from the active group at the outset of the study; and the study was ended after three months even though it was designed to last for twelve months. *See* IDF 819-824, 835-837, 843-845. Dr. Ornish admitted many of the problems were not "optimal." IDF 819. As with the other studies, we conclude that the Ornish MP study does not provide clinical proof of the Challenged POM Products' efficacy for heart disease.

2. Evidence Regarding Substantiation for Prostate Cancer Claims

We find that the expert testimony establishes that experts in the field of prostate cancer would require RCTs to support Respondents' claims that clinical studies establish that the Challenged POM Products treat, prevent or reduce the risk of prostate cancer. Complaint Counsel's experts, Dr. James Eastham and Dr. Meir Stampfer, state that to support claims that the Challenged POM Products prevent prostate cancer, or that they have been clinically proven to do so, experts in the field of prostate cancer would require at least one well-designed, randomized, double-blind, placebo-controlled clinical trial involving an appropriate sample population and endpoint. IDF 626, 648. Drs. Eastham and Stampfer also stated that at least one well-designed, randomized, double-blind, placebo-controlled clinical trial would be necessary to support claims that the Challenged POM Products treat prostate cancer, or that they have been clinically proven to do so. IDF 626, 648. Dr. Eastham explained that the appropriate sample population for a cancer prevention trial would involve healthy men, aged 50 to 65, who have no sign of prostate cancer, and that the study must be

conducted over a long enough period to see an effect over time. IDF 1092-93. He also testified that "[t]he primary endpoint in a prostate cancer prevention trial for measuring whether a product has been effective is the prevalence or incidence of prostate cancer between the treatment and placebo groups at the conclusion of the study." IDF 1089.

Respondents' expert stated that *in vitro* and animal studies provide evidence that the Challenged POM Products promote prostate health. Dr. Jean deKernion testified that the Challenged POM Products are beneficial to prostate health. IDF 1124. For instance, Dr. deKernion testified that RCTs are not necessary to substantiate "health benefit" claims for prostate health, but he did not address the level of science needed for prostate cancer treatment or prevention claims. *See* IDF 965; *see also* IDF 1126 (explaining deKernion testified there is a high probability that the Challenged POM Products provide a special benefit to men with detectable PSA after radical prostatectomy). Dr. David Heber similarly provided an opinion that *in vitro* studies, animal studies, and clinical evidence provide a strong scientific rationale for claims that pomegranate juice promotes prostate "health." *See* PX0192 at 0027 (Heber Expert Report). Respondents' experts did not specifically address the claims alleged in the Complaint, which we found Respondents to have made. Therefore, we find that experts in the field of prostate cancer would require RCTs to support Respondents' claims that clinical studies establish that the Challenged POM Products treat, prevent or reduce the risk of prostate cancer.

Respondents had conducted four *in vitro* studies and four animal studies relating to prostate cancer by 2009. IDF 1010. As we have previously described, such studies are used to identify potential biologic mechanisms and generate hypotheses for studies in humans, IDF 594-97, and Respondents' *in vitro* and animal studies showed possible mechanism of action of pomegranates in the prostate. *See* IDF 991-1017. But, as experts for both Complaint Counsel and Respondents testified, the results from *in vitro* and animal studies cannot always be extrapolated to what the results would be in humans, so this evidence alone does not provide clinical evidence that shows that the Challenged POM Products treat, prevent or reduce the risk of prostate cancer. IDF

1019 (describing opinions of Dr. Stampfer and Dr. Eastham), 1022 (describing opinion of Dr. deKernion), 1024.

Respondents also possessed two human clinical trials at the time of the hearing before Judge Chappell. In the Initial Decision, the ALJ makes detailed findings regarding the Pantuck Study, IDF 1026-1069, 1086-1094, 1105-1127, and the Carducci Study. IDF 1064-1085, 1096-1099, 1105-1127. We do not repeat the ALJ's detailed findings regarding the human clinical studies. Based on his findings regarding each study, Judge Chappell concluded "[t]here is insufficient competent and reliable scientific evidence to support the conclusion that the Challenged POM Products treat, prevent, or reduce the risk of prostate cancer or that clinical studies, research and/or trials establish these effects." IDF at 1143.

We reach the same conclusions. We note that neither study included a placebo-control group, *see* IDF 1037, 1068-69, so that even though the studies found statistically significant results, one cannot be sure that the effects observed in each study are attributable to consuming the Challenged POM Products. IDF 1083 ("Dr. Carducci . . . testified that without a placebo, he cannot be sure that the effect on [the observed outcome] in the Carducci Study is attributable to POMx."), 1087-88 (Dr. Stampfer and Dr. Eastham testified that without a placebo control group in the Pantuck Study, it is not possible to know whether the outcome would have been observed in the patient group without receiving the Challenged POM Products), 1096 (without a placebo control group in the Carducci Study, it is not possible to conclude POMx caused the change in outcome), 1114, 1118 (Dr. deKernion testified that a control arm is not necessary for a "Phase II study that is exploratory in nature," but "without a placebo, one cannot be certain that the effect on [outcome] seen in the Carducci Study is attributable to POMx.").

Additionally, both the Pantuck Study and the Carducci Study examined men who had been diagnosed with prostate cancer and had been treated with a radical prostatectomy or other radical treatment. Both studies used prostate specific antigen (PSA) doubling time as the primary endpoint for measuring results. The presence of detectable PSA after radical prostatectomy usually indicates cancer is present. IDF 1041. There is conflicting expert

testimony regarding whether use of PSA doubling time is an appropriate measure. *See* IDF 1059 (Dr. Pantuck stated "[i]t remains controversial whether modulation of PSA levels represents an equally valid clinical endpoint"); 1060-1063 (explaining an RCT examining another product found that PSA levels changed for both the placebo and active groups, which "suggests caution is required when using changes in PSA [doubling time] as an outcome in uncontrolled trials"); 1101-1104 (describing opinions of Drs. Eastham and Stampfer); 1105-1113 (describing assessments by Drs. deKernion and Heber). Yet, experts for both Complaint Counsel and Respondents testified that PSA doubling time is not an accepted surrogate endpoint by experts in the field of prostate cancer. IDF 1100 (describing opinions of Drs. Eastham and Stampfer), 1111 (describing opinion of Dr. deKernion).

Moreover, both the Pantuck Study and the Carducci Study examined men who had been diagnosed with prostate cancer. Thus, the studies do not examine whether the Challenged POM Products prevent or reduce the risk of prostate cancer. IDF 1084 ("According to Dr. Carducci, the Carducci Study was never designed to prove, and did not prove, that POMx prevents or reduces the risk of prostate cancer."), 1091 (Pantuck Study was designed as a treatment study conducted in men with prostate cancer and does not provide any evidence that POM Juice is a prostate cancer preventative), 1099 (Carducci Study cannot provide support for prevention claims because it evaluated effect of POMx in men who already had prostate cancer).

Given these limitations of the Pantuck and Carducci Studies, like the ALJ we find that experts in the field of prostate cancer would not consider these studies to be clinical proof that the Challenged POM Products treat, prevent or reduce the risk of prostate cancer.

3. Evidence Regarding Substantiation for Erectile Dysfunction (ED) Claims

We find that the expert testimony establishes that experts in the field of ED would require RCTs to support claims that clinical evidence proves a product treats, prevents or reduces the risk of

ED. Complaint Counsel's expert, Dr. Melman,[23] opined that in order to make a claim that the Challenged POM Products have been clinically proven to treat, prevent or reduce the risk of ED, at least one well-designed human RCT involving several investigatory sites is required. IDF 654. Dr. Melman also opined that a well-designed human RCT must use a validated tool for measuring treatment outcomes and that the clinical trial must have a sample population that is large enough to produce statistically significant and clinically significant results. IDF 655.

Respondents' expert, Dr. Arthur Burnett, testified that a safe food product, which is not used as a substitute for proper medical treatment, does not require RCTs to substantiate erectile health

[23] We disagree with the ALJ's assessment that Dr. Melman's opinions are "attenuated," *see* ID at 284; we do not find Dr. Melman's opinions to lack credibility. We first note that Judge Chappell's assessment is not based on his observation of Dr. Melman's courtroom demeanor, but rather on his assessment of the breadth of Dr. Melman's knowledge about ED studies. *See id.* We disagree with the ALJ's assessment in light of the fact that Dr. Melman was part of an international consortium that defined the requirements of clinical trials in the field of ED, his prior role as an editor of *Sexuality and Disability*, and his role as an editorial reviewer for prominent medical and urological journals. Melman, Tr. 1113-1114; CX1289 at 2. The ALJ discounted Dr. Melman's testimony because Dr. Melman was unfamiliar with the Global Assessment Questionnaire (GAQ) used in Respondents' study. We do not find that Dr. Melman's unfamiliarity with the tool reduces the value of Dr. Melman's opinion because, as the ALJ and each expert recognized, the GAQ is not a validated measure for assessing erectile function. IDF 1196 (citing Melman, Burnett, Goldstein); Melman, Tr. 1100-1102 (explaining unvalidated tools have not been shown to be reliable, validated tools are commonly used and unvalidated tools would not be used alone). Moreover, Dr. Melman researched the GAQ to provide his opinion in this case. The ALJ also discounted Dr. Melman's opinion because Dr. Melman supposedly made claims about a gene transfer therapy for ED that was based on only an animal study and one preclinical study of eleven men. *See* ID at 284. Yet, the record shows that these alleged statements are not in conflict with his testimony in this case because Dr. Melman's actions were consistent with traditional scientific protocol. Dr. Melman made a presentation about the animal and preclinical study only to a scientific audience and publication. He did not state that such evidence supported marketing claims to the public. Moreover, he is continuing to test the product before it is marketed. Dr. Melman's publicly reported statements were made only in the context of an unsolicited interview with the popular press when he was approached after the scientific presentation. Melman, Tr. 1149-1157. We find Dr. Melman's testimony to be credible.

claims. *See* IDF 683, 684. He testified that a combination of basic science and clinical evidence can support a conclusion that a product improves erectile health and function. *See* IDF 242. Similarly, Respondents' expert, Dr. Goldstein, opined that RCT studies are not required to substantiate claims that pomegranate juice can aid in erectile health and that *in vitro* and animal studies demonstrated a likelihood that pomegranate juice improves erectile health. *See* IDF 686. Yet, Dr. Burnett also testified that "experts in the field of erectile dysfunction would require that a product be scientifically evaluated through rigorous scientific and clinical studies, and believe that animal and *in vitro* studies alone are not sufficient, before concluding that pomegranate juice treats erectile dysfunction in a clinical sense." IDF 1148 (citing Burnett, Tr. 2261-64; 2285-86; 2303). *See also* Burnett, Tr. 2284-85 (explaining that the "erectile dysfunction" testimony of Respondents' nutrition expert, Dr. Heber, addressed the idea that the Challenged POM Products are beneficial to erectile health rather than the clinical condition). Because Respondents' experts testified about the support necessary for general claims regarding erectile function or erectile health rather than claims that a product treats, prevents or reduces the risk of ED, we conclude that, on the basis of the record in this case, experts in the field of ED would require RCTs to substantiate the ED claims alleged in the Complaint.

As the ALJ determined, Respondents did not possess the scientific evidence to substantiate their claims that clinical studies prove that the Challenged POM Products treat, prevent or reduce the risk of ED. *See* ID at 285-89. The ALJ systematically examined Respondents' scientific evidence. The ALJ analyzed Respondents' six preclinical *in vitro* and *in vivo* studies, and that analysis is not appealed. *See* IDF 1260-1302. Similar to the basic science evidence for heart disease and prostate cancer, preclinical studies "are used to identify potential biologic mechanisms and generate hypotheses." IDF 594. These results, however, often are not replicated in humans. *Id.* Here, the basic science describes a possible mechanism by which pomegranate juice may affect human penile erections, but the expert testimony indicated that the studies demonstrated only a "benefit to erectile function," *see, e.g.*, IDF 1299, 1298 ("potential benefit . . . to likely improve one's erection physiology"), 1300, but "cannot alone prove that

POM Juice treats, prevents, or reduces the risk of erectile dysfunction in humans." IDF 1301.

Respondents relied on one human clinical trial regarding ED, the Forest/Padma-Nathan study.[24] That study was an RCT examining 53 men with mild to moderate ED, using the Global Assessment Questionnaire (GAQ) as the primary outcome measure. The GAQ is not a validated instrument for erectile function. In addition, the GAQ results for the Forest/Padma-Nathan study came close to statistical significance but failed to actually reach statistical significance. IDF 1210-25. The study also used the International Index of Erectile Function (IIEF), which is a validated tool; the IIEF results were "nowhere near approaching statistical significance." IDF 1226. Dr. Padma-Nathan testified that the study concluded there was a potential for beneficial effects on ED, but further studies were needed to confirm such a claim. IDF 1229. Moreover, a peer reviewer considering the study for publication stated that it was "a negative study" and the results should be presented that way, and a published review stated that the study had negative results.[25] IDF 1231, 1232. Thus, we conclude that Respondents' human clinical trial does not provide substantiation for the claim that clinical studies prove that the Challenged POM Products treat, prevent or reduce the risk of ED. *See* IDF 1253. In addition, we note that the Forest/Padma-Nathan study examined men with mild to moderate ED; Respondents do not possess any clinical studies examining the effects of consuming the Challenged POM Products on men without ED to substantiate the claims that the Challenged POM Products prevent or reduce the risk of ED.

[24] One cardiovascular study, the Davidson BART/FMD study, also asked a subset of participants to complete an ED questionnaire, but, as the ALJ found, the International Index of Erectile Function (IIEF) results of that study do not support the conclusion that consuming the Challenged POM Products treats, prevents or reduces the risk of ED. *See* IDF 1254-59.

[25] To the extent that the ALJ concluded that the expert testimony regarding the Forest/Padma-Nathan study demonstrates that pomegranate juice provides a positive benefit to erectile health and erectile function, *see* ID at 288, IDF 1250-52, we reject those conclusions because such benefits were not challenged and tried by Complaint Counsel.

Having fully considered and weighed all of the evidence and the expert testimony on Respondents' basic science and clinical trials, the greater weight of the persuasive expert testimony demonstrates that there is insufficient competent and reliable scientific evidence to substantiate a claim that clinical studies, research or trials prove that the Challenged POM Products treat heart disease, prostate cancer, or ED. Similarly, we find that the greater weight of the persuasive expert testimony demonstrates that there is insufficient competent and reliable scientific evidence to substantiate a claim that clinical studies, research or trials prove that the Challenged POM Products prevent or reduce the risk of heart disease, prostate cancer, or ED. Consequently, such claims are false.

Our conclusion is consistent with the ALJ's finding that Respondents' substantiation was inadequate to meet even the lower substantiation standard that he found was necessary to support Respondents' claims. It naturally follows that Respondents' substantiation for the establishment claims is inadequate to satisfy the higher standard we find is demanded by the record.

B. Claims Lacking A Reasonable Basis

We now turn to whether Respondents had a reasonable basis for the product claims at issue in this case. The theory underlying the analysis is that claims about a product's attributes, performance, or efficacy carry with them the express or implied representation that the advertiser had a reasonable basis of support for the claim. *See, e.g.*, *Daniel Chapter One*, 2009 WL 5160000 at *16; *Thompson Med. Co.*, 104 F.T.C. at 813 n.37; *Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d at 298. "Consumers find these representations of support to be important in evaluating the reliability of the product claims. Therefore, injury is likely if the advertiser lacks support for the claims." *Thompson Med. Co.*, 104 F.T.C. at 813 n. 37.

For each of the ads for which there is an establishment claim that clinical studies or trials prove that the Challenged POM Products treat, prevent or reduce the risk of disease, Respondents also make a corresponding efficacy claim. In addition, for two ads, Figures 5 and 7, we find that Respondents make efficacy

claims without also representing that there is clinical proof of the Challenged POM Products' efficacy to treat, prevent or reduce the risk of disease. *See* discussion *infra* Claims Appendix.

We must first determine the level of substantiation the advertiser is required to have before we can determine whether Respondents had a reasonable basis to make their claims. Then, we determine whether Respondents possessed that level of substantiation. *See*, *e.g.*, *Pantron I Corp.*, 33 F.3d at 1096; *Removatron Int'l Corp.*, 884 F.2d at 1498. Respondents "have the burden of establishing what substantiation they relied on for their product claims. [Complaint Counsel] has the burden of proving that [Respondents'] purported substantiation is inadequate." *QT, Inc.*, 448 F. Supp. 2d at 959. If Respondents cannot meet that substantiation burden, then the ads will be found deceptive.

Starting with *Pfizer Inc.*, 81 F.T.C. 23, our reasonable basis cases have identified several factors that we will weigh in determining the appropriate level of substantiation the advertiser is required to have for objective advertising claims: (1) the type of claim; (2) the type of product; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a false claim; and (6) the amount of substantiation experts in the field would agree is reasonable. *See Substantiation Statement*, 104 F.T.C. at 840; *Removatron Int'l Corp.*, 111 F.T.C. at 306-07; *Thompson Med. Co.*, 104 F.T.C. at 821; *Daniel Chapter One*, 2009 WL 2584873 at *84 (FTC Aug. 5, 2009) (Initial Decision). As we explained in *Pfizer*, the analysis to determine the level of substantiation necessary to support the claims in an ad is not a simple tallying of the number of factors that demand higher or lower levels of substantiation; the analysis is a flexible application that considers the interplay of the *Pfizer* factors. *See Pfizer*, 81 F.T.C. at 64 ("The question of what constitutes a reasonable basis is essentially a factual issue which will be affected by the interplay of overlapping considerations such as (1) the type and specificity of the claim made . . . ; (2) the type of product . . .").

Applying those factors in this case leads us to conclude that Respondents' efficacy claims that POM products treat, prevent or reduce the risk of heart disease, prostate cancer, and ED must be substantiated with RCTs.

The first factor that we consider is the type of claim. Respondents made claims regarding serious diseases. The Commission has previously stated in general terms that the substantiation standard for health claims, including structure/function claims, for food products is "competent and reliable scientific evidence."[26] For such claims, competent and reliable scientific evidence means 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.[27]

Such a standard is consistent with prior cases that have determined that "claims whose truth or falsity would be difficult or impossible for consumers to evaluate by themselves" require a high level of substantiation. *See Removatron Int'l Corp.*, 111 F.T.C. at 306 n.20 (citing *Thompson Med. Co.*, 104 F.T.C. at 822) (discussion of this *Pfizer* factor explained that consumers' limited ability to evaluate claims that hair removal device's results were permanent "militates in favor of a one-clinical [test] requirement").

But our consideration of the type of claim goes beyond merely identifying Respondents' claims broadly as health claims. Here, the evidence in the record shows that many of Respondents' claims went beyond structure/function claims to represent that the Challenged POM Products treat, prevent or reduce the risk of serious diseases. As previously discussed, Respondents' specific disease claims require proof of causation. As the Commission has found in other cases (*see, e.g.*, *Thompson Med. Co.*, 104 F.T.C. at 321), and as demonstrated by the weight of expert testimony in

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[26] *Food Advertising Statement*. Health claims in food labeling are those that "characterize the relationship of a substance in a food to a disease or health-related condition" and "structure/function" claims are those that represent the "effect on the structure or function of the body for maintenance of good health and nutrition." *Id.* at n.2.

[27] *Id.* (citing *Gracewood Fruit Co.*, 116 F.T.C. 1262, 1272 (1993); *Pompeian, Inc.*, 115 F.T.C. 933, 942 (1992)).

this case, proof of causation requires RCTs. *See* discussion *supra*, Section V.A.[28]

The second *Pfizer* factor we consider is the type of product. In this case, the products are foods and dietary supplements derived from a fruit that is known to be safe. Therefore, Respondents argue, and the ALJ concurred, that the level of substantiation for a food product should be set at a lower level than for other products such as drugs. However, as previously discussed, the particular claims made by Respondents assert a causal relationship between the Challenged POM Products and the treatment, prevention or reduction of risk of disease. *See, e.g.*, CX1291 at 10-11 (Sacks Expert Report) (explaining controlled studies are necessary to show a product, "including a conventional food or dietary supplement" treats, prevents, or reduces the risk of heart disease). The relative safety of the product does not alter the requirement that the scientific evidence establish causality.

In other cases we have considered the third and fourth *Pfizer* factors in tandem. The third factor is the benefit of a truthful claim. The fourth factor is the ease of developing substantiation for the claim. Our concern in analyzing these factors is to ensure that the level of substantiation we require is not likely to prevent consumers from receiving potentially valuable information about product characteristics. *Thompson Med. Co.*, 104 F.T.C. at 823.

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[28] See also *Food Advertising Statement* (explaining the level of substantiation required for claims about a diet-disease relationship: "The NLEA directed FDA to apply [a] 'significant scientific agreement' standard in determining whether there was adequate substantiation to permit health claims for ten specific diet-disease relationships. . . . In evaluating health claims, the Commission looks to a number of factors to determine the specific level of scientific support necessary to substantiate the claim. Central to this analysis is an assessment of the amount of substantiation that experts in the field would consider to be adequate. The Commission regards the 'significant scientific agreement' standard, as set forth in the NLEA and FDA's regulations, to be the principal guide to what experts in the field of diet-disease relationships would consider reasonable substantiation for an unqualified health claim. Thus, it is 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.").

In the discussion of these factors and based on the rationale for their consideration, the ALJ found that in a nutritional context, RCTs can be prohibitively expensive and may not be feasible. ID at 247-48. Thus, in order to prevent limiting information about product characteristics that might provide benefits to consumers, he concluded that where the product is safe and where the advertisement does not suggest that the product be used as a substitute for conventional medical care or treatment, it is appropriate to favor disclosure. *Id*. at 248. But the ALJ's failure to distinguish Respondents' particular disease treatment and prevention claims from those asserting some general health benefits led him to an incorrect conclusion. A determination that RCTs are necessary to support Respondents' specific claims that the Challenged POM Products treat, prevent or reduce the risk of particular diseases will not erect a barrier that will prevent the disclosure to the public of useful nutritional information. We have not determined the level of substantiation that is required to support all health and nutritional claims.[29] Thus, while our reasoning may be informative about our likely approach to evaluate other health claims, our ruling in this case should address only the substantiation of claims regarding the efficacy of particular foods to treat, prevent or reduce the risk of serious diseases.

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[29] Regarding support for structure/function claims, the Commission has previously indicated its desire for consistency with the Dietary Supplement Health and Education Act of 1994 (DSHEA)**:** "DSHEA … requires that structure/function claims in labeling be substantiated and be truthful and not misleading. This requirement is fully consistent with the FTC's standard that advertising claims be truthful, not misleading and substantiated." Dietary Supplements: An Advertising Guide for Industry (2001), *available at* http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry. The FDA has also signaled its intent to be consistent with the FTC in the application of a standard for such claims: "The FTC has typically applied a substantiation standard of 'competent and reliable scientific evidence' to claims about the benefits and safety of dietary supplements and other health-related products. FDA intends to apply a standard for the substantiation of dietary supplement claims that is consistent with the FTC approach." Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act (2008), *available at* http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/dietarysupplements/ucm073200.htm.

Moreover, we do not interpret these two *Pfizer* factors to give an advertiser license to make particular claims that go beyond the substantiation it possesses and then ask the Commission to excuse the inadequacy of its support by asserting that advertiser did the best it could because the proper substantiation for the actual claim would be too expensive. *See* Eastham, Tr. 1328-29 (explaining cost does not change scientific burden). As we have previously explained, "[w]here the demands of the purse require such compromises [in methodology], the advertiser must generally limit the claims it makes for its data or make appropriate disclosures to insure proper consumer understanding of the survey's results." *Kroger Co.*, 98 F.T.C. 639, 737 (1981).

We also observe that among the studies that Respondents present as support for their claims are several clinical trials that were designed as RCTs. *See, e.g.*, IDF 808-818 (describing Ornish MP study), 849-859 (describing Ornish CIMT study), 872-883 (describing Davidson CIMT study), 941-943 (describing Heber/Hill Diabetes study). Among the limitations of these studies was that the results were not statistically significant. As discussed above, we determined that these well-controlled human clinical trials do not provide substantiation for Respondents' claims. In our evaluation of the evidence, we interpret the failure of these RCTs to provide support for Respondents' claims as evidence that there is insufficient scientific and clinical evidence of the efficacy of the Challenged POM Products; we do not interpret the results of the particular studies as an indication that the appropriate standard here – that Respondents possess RCTs with statistically significant results – is set too high.

The fifth factor that we weigh is the consequences of a false claim. In this regard, the ALJ stated that he found no evidence that Respondents urged individuals to consume the Challenged POM Products in place of medical treatment. Thus, he concluded the injury is limited to consumers paying a premium for an ineffective product and that such economic injury is not a significant factor in determining the required level of substantiation in this case. ID at 248-49. [30] We disagree with the

[30] The ALJ noted that although these costs may not be insignificant at least for the POM Juice, consumers are at a minimum buying what is considered to be a premium fruit juice. ID at 249.

ALJ that the economic injury from unsubstantiated health benefits is immaterial under *Pfizer*. *See Thompson Med. Co.*, 104 F.T.C. at 824 (significant economic harm "result[s] from the repeated purchase of an ineffective product by consumers who are unable to evaluate" the efficacy claims, even where "there is little potential for the product to cause serious injury to consumers' health"); *FTC v. Pantron I Corp.*, 33 F.3d at 1102 ("[A] major purpose of the Federal Trade Commission Act is to prevent consumers from economic injuries."). Consumers pay a higher price for POM products at least in part because of their ostensible health benefits.[31]

The sixth and final factor that we consider is the amount of substantiation experts in the field would agree is reasonable. As the prior detailed discussion indicated, experts in the fields of heart disease, prostate cancer, and ED would expect RCTs to support Respondents' particular disease claims.

Therefore, based upon our review of the six *Pfizer* factors, the Commission concludes that the proper level of substantiation for Respondents' disease efficacy claims is RCTs. "The inability of consumers to evaluate" the treatment and prevention effects of the Challenged POM Products "by themselves in an uncontrolled environment is a persuasive reason for consumers to expect (and us to require) appropriate scientific testing before efficacy claims are made." *Thompson Med. Co.*, 104 F.T.C. at 826. We note that under this analysis we would expect the same attributes in RCTs as we discussed in Section V.A., *supra* (*i.e.*, randomized controls, valid endpoints, and statistically significant results).

Having determined that Respondents are required to have RCTs to support their claims that the Challenged POM Products treat, prevent or reduce the risk of heart disease, prostate cancer, and ED, and based upon our prior review of the substantiation that

[31] As the ALJ noted, a one-year supply of POM Juice cost at least $780 and a one-year supply of POMx cost approximately $315, amounts that the ALJ acknowledged were "not insignificant." ID at 249. There is record evidence that consumers paid a premium for POM Products, at least in part because of the ostensible disease-fighting capability of the Challenged POM Products. *See* CX0221 at 0009 ("POM Juice's 16 oz skus are $4+/bottle, roughly a 30% premium to our pomegranate competitors."); CX0283 at 002 ("Health benefits – this is why they put up with the price").

Respondents possess, we conclude they lack support for each of their claims.[32] We therefore hold that Respondents' advertising is deceptive for failure to have a reasonable basis. Thus, Respondents' advertising violates Sections 5(a) and 12 of the FTC Act. *See Removatron Int'l Corp.*, 884 F.2d at 1498 (finding that where advertisers lack a reasonable basis, their ads are deceptive as a matter of law).

VI. Respondents' False and Misleading Claims are Material

The ALJ found that a preponderance of the evidence demonstrated that the challenged claims that he determined were false and misleading are material to consumers' decisions to purchase the Challenged POM Products. ID at 292. On appeal, Respondents argue that any false or misleading claims are not material and accordingly that such claims cannot form the basis for liability under the FTC Act. Respondents argue that the lack of materiality is demonstrated by the results of the Reibstein Survey and the fact that none of the challenged advertisements had more than a single run such that consumers were not repeatedly exposed to them. RA at 36-37. Respondents further argue that the Commission should discount their creative advertisement briefs because they were written by junior employees and only demonstrated an intent to communicate generalized benefits, and that other surveys relied upon by the ALJ as evidence of materiality were methodologically flawed. RA at 37-39. Although we find that the challenged advertisements contain more false and misleading claims than found by the ALJ (as set forth in Section IV), we agree with the ALJ's ultimate conclusion that such claims are material and accordingly run afoul of Section 5 and Section 12 of the FTC Act.

"A misleading claim or omission in advertising will violate Section 5 or Section 12, however, only if the omitted information

[32] We separately find that Respondents lack support for their claims that (1) the Challenged POM Products treat heart disease, (2) the Challenged POM Products prevent or reduce the risk of heart disease, (3) the Challenged POM Products treat prostate cancer, (4) the Challenged POM Products prevent or reduce the risk of prostate cancer, (5) the Challenged POM Products treat erectile dysfunction, and (6) the Challenged POM Products prevent or reduce the risk of erectile dysfunction.

would be a material factor in the consumer's decision to purchase the product." *Am. Home Prods. Corp.*, 98 F.T.C. at 368. A "material" misrepresentation is defined as one that is likely to affect a consumer's conduct with respect to the product or service. *Deception Statement*, 103 F.T.C. at 182. In determining whether false or misleading claims in an advertisement are "material" to consumers, the Commission may first consider whether a claim is presumptively material, including "express claims, claims significantly involving health or safety, and claims pertaining to the central characteristic of the product." *Novartis Corp.*, 127 F.T.C. at 686 (citing *Deception Statement*, 103 F.T.C. at 182). A respondent may rebut a presumption of materiality by providing evidence that the claim is not material: "Respondent can present evidence that tends to disprove the predicate fact from which the presumption springs (*e.g.*, that the claim did *not* involve a health issue) or evidence directly contradicting the initial presumption of materiality. This is not a high hurdle." *Id.* at 686. If Respondent rebuts the presumption of materiality, then the Commission examines the facts that gave rise to the presumption, any rebuttal evidence, and any other evidence on materiality provided by Complaint Counsel. *Id.* at 686-87. The Commission should also consider an advertiser's intent to make a claim, which, in the case of implied claims like the ones at issue in this case, requires consideration of (though not reliance on) extrinsic evidence. *Id*. at 687-88.

The claims made in the challenged advertisements are health-related claims, which are presumptively material as set forth in *Novartis Corp*. ID at 292; IDF 580-83. Respondents do not refute this. However, the ALJ determined that he need not rely on a presumption of materiality given Respondents' presentation of rebuttal evidence because "the preponderance of the evidence shows that the challenged claims are material." ID at 292. After considering the fact that the claims in the challenged advertisements are health-related, Respondents' own statements and creative briefs, and the three surveys relied upon by Complaint Counsel and Respondents as either evidence of materiality or lack thereof, we agree that the preponderance of the evidence demonstrates that the challenged claims are material.

As set forth above, Respondents do not refute that the claims made in the challenged advertisements are health-related. In fact,

their main argument with respect to what kind of claims are made in the advertisements is that the advertisements make claims about the Challenged POM Products' health benefits rather than disease claims. Respondents' own statements and creative briefs provide further evidence of materiality, as set forth in the ALJ's opinion and detailed findings of fact. ID at 292-95; IDF 113, 128, 131, 145-51, 154, 181, 1316-21, 1323-35, 1340-43. For example, Mrs. Resnick testified that POM juice is "health in a bottle," which is its "unique selling proposition." IDF 112; CX1375 at 41-42 (L. Resnick, Tropicana Dep.). Mr. Resnick similarly stated his belief that a large number of POM Juice consumers purchase the product because they believe "that we've proven that . . . [POM Juice] really does prolong people's lives if they are getting the onset of prostate cancer." IDF 1318 (quoting CX1376 at 218-19 (S. Resnick Ocean Spray Dep.)).

The focus of the ads challenged by Complaint Counsel were POM's disease claims, not the products' taste, price, or other attributes. The products' central characteristic, as depicted in the challenged ads, was their impact on heart disease, prostate cancer or ED. Respondents thought their products impact on health was such a strong selling point that they invested over $35 million to develop supporting evidence that they could use in marketing. ID at 295. As the ALJ explained, under these circumstances, "particularly that POM was aware that among those purchasing the Challenged POM Products were 'people that have heart disease or prostate cancer in their family, or have a fear of having it themselves,' [IDF] 1320, it defies credulity to suggest that Respondents would advertise study results related to these conditions if such advertising did not affect consumer behavior." We agree with the ALJ that it is "no great leap," *Novartis Corp.*, 127 F.T.C. at 687, to find that consumer purchasing decisions would likely be influenced by claims that the Challenged POM Products treat, prevent, or reduce the risk of these diseases.

In support of their contention that the claims were not material, Respondents rely on the Reibstein Survey. The ALJ rejected this argument, citing methodological and other flaws in that survey, including that "it only assessed consumer motivations generally; it did not actually assess whether any of the challenged claims . . . would be important to the survey respondent's decision to purchase the products," and "the survey did not ask any follow-

up questions, including of the 35.2% of POM Juice purchasers who stated that they bought or would repurchase POM Juice because it was 'healthy.'" ID at 295-96; IDF 1354, 1361, 1373, 1375. We agree with the ALJ's assessment of the Reibstein Survey.

Accordingly, the Commission holds that Respondents' misleading claims were material.[33]

VII. First Amendment Analysis

Respondents contend that a finding of liability would violate the First Amendment. They argue that the ALJ ignored Supreme Court case law that defines what it means for commercial speech to be false or misleading. We disagree. As Respondents acknowledge, *see* RA at 19, commercial speech must at least "concern lawful activity and not be misleading" to qualify for constitutional protection. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980); *see also, e.g.*, *In re R.M.J.*, 455 U.S. 191, 200 (1982) ("False, deceptive or misleading advertising remains subject to restraint.").

Respondents first contend that the Commission cannot determine that ads are "actually misleading" unless there is empirical or extrinsic evidence that consumers were deceived. Next, Respondents contend that the FTC cannot judge an advertisement to be "inherently misleading" on its face when the ad states accurate and verifiable facts. Respondents then argue that based on the evidence the Commission may only determine that Respondents' ads are "potentially misleading." If the ads are only potentially misleading, according to Respondents' logic, then precedent establishes that, at most, the FTC could require limited disclaimers that are tailored to satisfy the test in *Central Hudson*, because a disagreement about the meaning of scientific evidence cannot justify a bar of Respondents' health claims. We address Respondents' arguments in turn.

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[33] In light of this conclusion based on the foregoing considerations that Respondents' claims were important to consumers in making purchasing decisions, the Commission need not decide whether the OTX A&U Study or the Zoomerang study, on which Complaint Counsel relies, offer further evidence of materiality.

A. Actually Misleading

Contrary to Respondents' claim, empirical or extrinsic evidence is not necessarily required for the Commission to conclude that Respondents' ads are actually misleading. Respondents mischaracterize the law in arguing that the Commission is limited to finding an advertisement is actually misleading only in instances where extrinsic or empirical evidence exists of actual deception. In terms of First Amendment jurisprudence, the Commission's determination of whether particular ads establish that the ads are "actually misleading" does not require extrinsic or empirical evidence. *See Kraft, Inc.*, 970 F.2d at 319, 325 (in a case where "the Commission found implied claims based solely on its own intuitive reading of the ads (although it did reinforce that conclusion by examining the proffered extrinsic evidence)," explaining "[t]o begin with, the Commission determined that the ads were *actually* misleading, not potentially misleading, thus justifying" the Commission's remedy); *Daniel Chapter One*, 2009 WL 5160000 at *20, n.2 (explaining "implied claims . . . have been specifically adjudicated in the present case to be actually misleading" in a case where Complaint Counsel did not introduce extrinsic evidence).

Just as in *Kraft* and *Daniel Chapter One*, in this case, the Commission's findings based on its own expertise – Respondents disseminated advertising or promotional material that contained implied claims, Respondents lacked substantiation to support those claims, and the claims are material – legally establish that Respondents' advertising is actually misleading. Here, in 34 ads, Respondents represented to consumers that clinical studies proved that the Challenged POM Products treat, prevent or reduce the risk of heart disease, prostate cancer, or ED when, in fact, well-controlled clinical studies did not establish such efficacy for the particular diseases; these claims that clinical research or studies proved the efficacy of the Challenged POM Products were false. Therefore, Respondents' ads were deceptive and actually misleading. In addition, in 36 ads, Respondents represented that the Challenged POM Products treat, prevent or reduce the risk of heart disease, prostate cancer, or ED when Respondents did not possess a reasonable basis to support such claims. Again, Respondents' ads are deceptive as a matter of law. *See FTC v.*

Direct Mktg. Concepts, Inc., 624 F.3d 1, 8 (1st Cir. 2010) ("Where the advertisers lack adequate substantiation evidence, they necessarily lack any reasonable basis for their claims. And where the advertisers so lack a reasonable basis, their ads are deceptive as a matter of law.") (citation omitted).

The proposition that the First Amendment requires extrinsic evidence in every case has been raised and rejected by the Supreme Court and courts of appeals. *See, e.g.*, *Zauderer*, 471 U.S. at 652-53 (stating that no First Amendment concerns are raised when facially apparent claims are found without "conduct[ing] a survey of the . . . public" to determine that an ad is misleading); *Kraft, Inc.*, 970 F.2d at 321 ("Kraft's first amendment challenge is doomed by the Supreme Court's holding in *Zauderer*, which established that no first amendment concerns are raised when facially apparent implied claims are found without resort to extrinsic evidence."); *Daniel Chapter One*, 2009 WL 5160000 at *14-15 ("Respondents repeatedly assert . . . the ALJ was obliged by the Due Process Clause and the First Amendment of the Constitution to consider 'extrinsic' evidence. More specifically, Respondents claim that 'Complaint Counsel should have been required to produce evidence that consumers were actually misled by Respondents' promotional efforts and representations[.]' . . . That is not the law. Federal courts have long held that the Commission has the common sense and expertise to determine 'what claims, including implied ones, are conveyed in a challenged advertisement, so long as those claims are reasonably clear.'") (citation omitted). Indeed, even the case which Respondents cite for their claim that empirical evidence is necessary, *Peel v. Att'y Registration & Disciplinary Comm'n*, 496 U.S. 91 (1990), relied on a facial analysis of the ads – not empirical evidence – to find that the ads were not actually misleading. *Id.* at 105-06 (describing evaluations and explaining "two state courts that have evaluated lawyers' advertisements of their certifications as civil trial specialists by NBTA have concluded that the statements were not misleading or deceptive *on their face*, and that, under our recent decisions, they were protected by the First Amendment") (emphasis added).

Once the Commission has determined that Respondents' ads are actually misleading, no further analysis is necessary because misleading commercial speech is not protected by the First

Amendment. Each of the cases cited by Respondents acknowledges that '[t]he Federal Government [is] free to prevent the dissemination of commercial speech that is false, deceptive, or misleading." *Zauderer*, 471 U.S. at 638. The three-part analysis for determining whether regulation of commercial speech is constitutional under *Central Hudson* – whether the regulation is based on a substantial governmental interest, whether the regulation directly advances the governmental interest asserted, and whether the regulation is not more extensive than necessary to serve that interest – is applicable only if a threshold inquiry determines that the speech in question is not false or misleading. *See Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 566; *Edenfield v. Fane*, 507 U.S. 761, 768 (1993); *Daniel Chapter One*, 2009 WL 5160000 at *19-20. We nonetheless address Respondents' additional First Amendment arguments.

B. Inherently Misleading

Respondents contend that "an advertisement cannot be inherently misleading on its face when it states objectively accurate and verifiable facts," but also admit "[a]n advertisement that states accurate and verifiable facts may, in some instances, be potentially misleading." RA at 20. Indeed, Respondents' admission is the more accurate description of the law. Courts have regularly found "that even literally true statements can have misleading implications" and challenging such deception does not violate the First Amendment. *Kraft Inc.*, 970 F.2d at 322 (citing *Zauderer*, 471 U.S. at 652; *Thompson Med. Co.*, 791 F.2d at 197; *Removatron Int'l Corp.*, 111 F.T.C. at 292-95; *Am. Home Prods. Corp.*, 695 F.2d at 687).

It appears that Respondents' argument is that when addressing advertising that is considered inherently misleading on its face, each element of the ad is to be evaluated in isolation for its accuracy. The cases that Respondents cite – *R.M.J.*, 455 U.S. at 205, *Zauderer*, 471 U.S. at 645; *Peel*, 496 U.S. at 100; *Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation, Bd. of Accountancy*, 512 U.S. 136, 144 (1994) – addressed bans on statements in professional advertising where the regulatory bodies found advertising to be misleading based on simple affirmative representations, such as stating the jurisdictions where the attorney was licensed or certifications that the attorney held. The

Court struck down the regulations because it found that, for example, so long as the attorney was still licensed in the jurisdiction, providing the information to the public was not misleading because consumers could easily confirm the licensing or certification.

Respondents assert that the statements in their ads also are objectively accurate and verifiable facts. Respondents point to statements in their ads that the Challenged POM Products are high in antioxidants and to the citations of their studies to explain that the studies were conducted by world-renowned researchers, the results were published in peer-reviewed journals, and the statements about the disease-specific findings as proof the statements, like those in *R.M.J.*, are objectively are accurate and verifiable. We agree that many of the facts in Respondents' ads are verifiable. However, there are many omissions of material facts in Respondents' ads that consumers cannot verify independently. For example, consumers cannot verify that one of the five studies referenced in the ads, IDF 126, was rejected as an abstract by the American Heart Association and was rejected by the Journal of the American Medical Association because of shortcomings of the research, and was only accepted for publication in the American Journal of Cardiology without peer review. IDF 816-818. Similarly, consumers could not verify that the results of a much larger, well-designed, well-controlled study – the Davidson CIMT Study, which was completed in 2006 and showed, at most, a 5% decrease in arterial plaque in some patients measured at an interim point – were inconsistent with the statement in ads running through 2009 (*e.g.*, CX0029, CX0280, CX0328/CX0331/CX0337, CX0473) that asserted "Pomegranate juice consumption resulted in significant reduction in IMT (thickness of arterial plaque) by up to 30% after one year" based on the unblinded Aviram CIMT/BP study because Respondents delayed publication of the negative results. *See* CX0716 at 0033 (under study protocol, Respondents' approval was needed to present results of the study); S. Resnick, Tr. 1685-96 (explaining that Davidson was denied authorization to submit study results to the American Heart Association meeting in 2007 because of the study's inconsistent findings, but later allowing Davidson to submit the study for publication in 2008); CX1336 at 144, 165-68, 180-81 (Davidson Dep.). We conclude that many of Respondents' representations are qualitatively different from the

verifiable statements in the professional advertising cases that Respondents cite.

C. Potentially Misleading

Finally, Respondents argue that, because their ads are not actually misleading or inherently misleading, a position that this opinion has already rejected, then their ads can only be evaluated as potentially misleading, and potentially misleading commercial speech cannot be prohibited. Respondents assert that the D.C. Circuit's holding in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), leads to the conclusion that Respondents' representations cannot be banned on the basis of a genuine dispute about the level or meaning of scientific evidence. We do not interpret *Pearson v. Shalala* to preclude us from finding that Respondents' claims are misleading because they lack substantiation, even if the Commission's conclusion were evaluated as a finding that Respondents' ads are potentially misleading, rather than actually misleading.

In *Pearson*, manufacturers of dietary supplements sought pre-approval from the FDA for four health claims that the manufacturers wanted to make in labeling for their products. The FDA refused to approve the claims on the grounds that they were not supported by the "significant scientific agreement" standard of evidence under that agency's regulatory scheme. The FDA, consistent with agency practice, refused to consider the manufacturers' argument that the use of disclaimers could prevent these four health claims from being misleading. On appeal from a district court decision upholding the constitutionality of the FDA's determination, the D.C. Circuit reversed. When considering the government's argument that health claims for dietary supplements are potentially misleading to consumers if significant scientific agreement does not support the claims, the D.C. Circuit recognized that the government has a substantial interest in ensuring the accuracy of consumer information in the marketplace and that banning potentially misleading health claims would appear to directly advance that interest. *Id.* at 655-56. The court, however, went on to hold that the government did not meet its burden of proving that there was a reasonable fit between banning these claims and the government's interest in preventing fraud. *Id.* at 657. The D.C. Circuit concluded that potentially

misleading claims could be remedied by "prominent" disclaimers. *Id.* at 658, 659.

In this case, we reviewed Respondents' claims in light of any disclaimers or disclosures that Respondents actually made in their ads. Respondents' disclaimers, disclosures, or qualifications to their claims are much less that what the D.C. Circuit hypothesized would be sufficient to prevent health claims with disputed scientific support from being misleading.[34] If Respondents' had made disclaimers such as those described in *Pearson* (*i.e.*, "the evidence in support of this claim is inconclusive," *id.* at 659), the Commission would have considered the representations in the ads in light of such statements. Without such disclaimers, Respondents' ads are deceptive and misleading.

In addition, the Commission's approach to address misleading advertising, which is a case-by-case adjudication *after* ads have been disseminated, differs from regulatory efforts that prohibit categories of speech or rely on *prior* approval of the language to be used. The latter serve as illustrations of "bars" on commercial speech and are inapplicable to the detailed *ex post* analysis we engage in here, based on a full record about the ads in question. *See Kraft Inc.*, 970 F.2d at 317 (explaining that "a prophylactic regulation applicable to all lawyers, completely prohibiting an entire category of potentially misleading commercial speech" at issue in *Peel*, is sufficiently distinct for constitutional purposes from "an individualized FTC cease and desist order prohibiting a particular set of deceptive ads") (citation omitted); *Daniel Chapter One*, 2009 WL 5160000 at *15 (citing *Kraft, Inc.* to explain that FTC finding that ads are misleading in administrative adjudication does not violate First Amendment). As the ALJ explained in this case, "Respondents' generalized assertion that none of its commercial speech should be 'barred' is without merit. Requiring adequate substantiation for advertising claims does not 'bar' commercial speech, but serves to prevent dissemination of misleading claims." ID at 323 n.32 (internal citation omitted). The FTC's case-by-case adjudication, which examines whether an

[34] Commissioner Ohlhausen's view is that, with regard to some exhibits, the Respondents included sufficient qualifying language to at least raise the need for extrinsic evidence before finding implied misleading claims. *See* Commissioner Ohlhausen's Concurring Statement.

advertiser made limited claims or provided appropriate disclaimers, neither bars nor discourages the free flow of commercial speech that would expand consumer knowledge regarding the goods and services available in the market.

VIII. Fifth Amendment Analysis

In Respondents' Answering Brief, Respondents argue for the first time that a finding that RCTs are required to substantiate Respondents' claims violates constitutional due process principles because the Commission would be retroactively applying a standard that deviates from the Commission's current approach articulated in both FTC policy statements and case law. RAns at 24-28. As set forth above, the Commission finds that the required substantiation for Respondents' disease claims about the Challenged POM Products is RCTs. Given that this substantiation finding is a fact-based determination based on the experts' opinion of what constitutes competent and reliable scientific evidence for the claims at issue, and that basing this factual determination on expert testimony follows clearly established legal precedent, we reject Respondents' claim that such a finding raises due process concerns.

"A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required. This requirement of clarity in regulation is essential to the protections provided by the Due Process Clause of the Fifth Amendment." *FCC v. Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2317 (2012) (citations omitted). A number of the Commission's policy statements provide support for the principle that determining what constitutes sufficient substantiation for particular claims is a fact-based analysis that rests in large part on scientific expert opinion. The *Substantiation Statement* discusses the fact that extrinsic evidence may be useful to determine the proper level of substantiation (including expert testimony or consumer surveys) regarding substantiation of implied efficacy claims: "Extrinsic evidence, such as expert testimony or consumer surveys, is useful to determine what level of substantiation consumers expect to support a particular product claim and the adequacy of evidence an advertiser possesses." *Substantiation Statement*, 104 F.T.C. at 840. The *Food Advertising Statement* provides additional (and more detailed)

support for the Commission's reliance on competent and reliable scientific evidence and expert determination of what constitutes such evidence for particular claims:

Like FDA, the Commission imposes a rigorous substantiation standard for claims relating to the health or safety of a product, including health claims for food products. The Commission's standard that such claims be supported by "competent and reliable scientific evidence" has been more specifically defined in Commission orders addressing health claims for food products to mean:

> tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
> Thus, both the Commission and FDA look to well-designed studies, including clinical research and other forms of reliable and probative scientific evidence, in evaluating health claims for foods. (footnotes omitted).
> . . .
> In evaluating health claims, the Commission looks to a number of factors to determine the specific level of scientific support necessary to substantiate the claim. Central to this analysis is an assessment of the amount of substantiation that experts in the field would consider to be adequate. The Commission regards the "significant scientific agreement" standard, as set forth in the NLEA and FDA's regulations, to be the principal guide to what experts in the field of diet-disease relationships would consider reasonable substantiation for an unqualified health claim.

Food Advertising Statement at § IV.A; *see also id*. at n.79 ("This approach is consistent with the Commission's approach to evaluating the substantiation for claims made for drug products and medical devices regulated by FDA.").

A number of cases and Commission decisions reiterate the principle that the proper level of substantiation is a factual

determination which is rooted in a reliance on expert testimony. *See, e.g.*, *Bristol-Myers Co.*, 102 F.T.C. at 332-38; *QT, Inc.*, 448 F. Supp. 2d at 961-62. Of particular relevance to this case is *Thompson Medical Company*, where the Commission applied the *Pfizer* factors to determine that well-controlled clinical tests (or RCTs) were required as a reasonable basis for efficacy claims regarding a topical analgesic. *Thompson Med. Co.*, 104 F.T.C. at 826. In addition to determining that the type of claim made, as in this matter, was one "whose truth or falsity would be difficult or impossible for consumers to evaluate by themselves," the Commission determined that experts in the field would require well-controlled clinical trials as reasonable substantiation for the efficacy of an analgesic. *Id.* at 822.

In sum, the Commission's determination that RCTs are required to substantiate Respondents' disease claims is founded on the well-established principle that determining the proper level of substantiation is a fact-based and case-specific analysis based on expert testimony as to what constitutes competent and reliable scientific evidence for the claims at issue. Respondents were on notice of this long-standing standard. Therefore, our decision in this case does not raise due process concerns.

IX. Media Interviews

The four media interviews in question on appeal include appearances by Mrs. Resnick on *The Martha Stewart Show* and *The Early Show*, sharing recipes and marketing ideas related in part to POM; a magazine interview with Mrs. Resnick in *Newsweek,* in part promoting the sale of her book about the POM business; and a television interview with Mr. Tupper on FOX Business discussing the current relevance of the pomegranate and pomegranate juice. ID at 208.

The ALJ found that the four media interviews challenged by Complaint Counsel do not constitute advertisements within the meaning of the FTC Act so that the Initial Decision does not evaluate whether any claims made during the interviews are deceptive or misleading. ID at 210. We do not adopt the predicate for the ALJ's ruling – that the media interviews must be advertisements (rather than deceptive commercial speech more broadly) in order to form the basis for liability under Section 5 of

the FTC Act. Instead, given the limited evidence regarding the circumstances surrounding the context of these interviews and the numerous other deceptive claims made by Respondents, the Commission declines to base liability on the four media interviews in question.

In focusing solely on whether or not an advertisement must be paid for in order to fall within the scope of Section 12 as "advertisements," the ALJ did not consider whether statements made during the media interviews violate Section 5 of the FTC Act as deceptive commercial speech.[35] Section 5(a)(2) of the FTC Act states, "[t]he Commission is hereby empowered and directed to prevent persons, partnerships, or corporations . . . from using unfair methods of competition in or affecting commerce and unfair or deceptive act or practices in or affecting commerce." In order to determine as a preliminary matter whether respondents are engaging in commercial speech, we consider a number of factors.

In *In re R.J. Reynolds Tobacco Company*, 111 F.T.C. 539, 547 (1988), the Commission held that respondents' advertisement discussing a "scientific study" that allegedly assessed the hazards of cigarette smoking constituted deceptive commercial speech, reversing the ALJ's ruling granting respondents' motion to dismiss on the grounds that the advertisement did not constitute commercial speech. In considering whether the advertisement constituted commercial speech, the Commission considered (1) the content of the speech, *i.e.*, whether it contained a message promoting the demand for a product or service; (2) whether the speech referred to a specific product or service; (3) whether the

[35] Notwithstanding Respondents' claims to the contrary, deceptive commercial speech is not constitutionally protected. *See Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 566 ("For commercial speech [to be protected by the First Amendment], it at least must concern lawful activity and not be misleading."). Where the Commission finds that claims disseminated through commercial speech lack proper substantiation, such findings establish as a matter of law that such claims are deceptive and thus not protected by the First Amendment. *See Direct Mktg. Concepts, Inc.*, 624 F.3d at 8 ("Where the advertisers lack adequate substantiation evidence, they necessarily lack any reasonable basis for their claims. And where the advertisers so lack a reasonable basis, their ads are deceptive as a matter of law.") (citation omitted).

speech included information about attributes of a product or service, such as type, price, or quality, including information about health effects associated with the use of a product; (4) the means used to publish the speech, including whether it is paid-for advertising; and (5) the speaker's economic or commercial motivation. *Id.* at 544-46. The Commission stated:

> Evidence that may be relevant to deciding whether the Reynolds advertisement is commercial speech includes facts concerning the publication or dissemination of the advertisement, such as whether it was paid-for, where and in which publications it was disseminated, whether it was placed in editorial space (such as an op-ed page) or advertising space in the publication, whether it was prepared as a letter to the editor, whether it was sent to representatives of the media for selection on merit by editorial boards, and to whom it was disseminated outside the media.
>
> Evidence about the promotional nature of the advertisement also may be relevant. Therefore, it might be useful to consider the circumstances surrounding the development of the advertisement, such as whether it was targeted to consumers or legislators; whether it was intended to affect demand for Reynolds' cigarettes or brands or to affect particular legislative or regulatory proposals; whether the advertisement was subjected to copy testing or to review by focus groups and, if so, the nature of the questions used in the copy tests or focus group sessions; and the results of those procedures both in terms of what they showed and what changes, if any, Reynolds made in response to those showings. Evidence relating to the message(s) Reynolds itself intended to convey through the advertisement also may be relevant. In addition, Reynolds' share of the cigarette market may be relevant to deciding whether including a brand name reference is a prerequisite to a determination that the advertisement constitutes commercial speech.

Id. at 550. In other words, the evidence considered by the Commission in *R.J. Reynolds Tobacco Company* focuses in large part on the "means" used to publish the speech, as well as where

and in which publications it was disseminated and where it was placed within such publications. These factors may apply differently when determining whether statements fall within the definition of commercial speech outside of the advertising context. *Compare Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 562-563 ("'commonsense' distinction between speech proposing a commercial transaction, which occurs in an area traditionally subject to government regulation, and other varieties of speech") *with id.* at 546 (discussing case decided by Court on the same day, *Consol. Edison Co. v. Public Serv. Comm'n*, 447, U.S. 530, 544 (1980), holding that "[PSC]'s suppression of bill inserts that discuss controversial issues of public policy directly infringes the freedom of speech protected by the First and Fourteenth Amendments."); *see also Oxycal Labs. v. Jeffers*, 909 F. Supp. 719, 724 (S.D. Cal. 1995) (denying request for injunction pursuant to the Lanham Act after determining that statements in a book about the carcinogenic effects of plaintiffs' vitamins did not constitute commercial speech even though the book also promoted defendants' products: "The Court finds that the main purpose of [defendant's] Book is not to propose a commercial transaction, and [defendant's] writing is not solely related to the economic interests of the speaker and its audience.").

The factual record in this case, however, lacks evidence about several of the commercial speech factors described in *R.J. Reynolds Tobacco Company.* Specifically, in considering the "means" by which such statements were made, we consider that these statements were made in the context of much longer interviews with the media, that the interviewer rather than the interviewee may have a certain amount of control over the content of the speech based on the content of the questions, and that the interviewer may have his or her own agenda that does not focus on advancing the commercial interests of Respondents. Here, the record is devoid of answers to key questions. The record does not reveal, for example, whether and how each of these interviews came to pass or any understanding between the media organizations and Respondents regarding the content of the interviews. Also lacking in the record is evidence about how the media interviews were arranged or procured, and whether Respondents paid for them. These factors are not necessarily all required or dispositive, and may be considered on a sliding scale. However, absent answers to these questions, we cannot make an

informed determination with respect to the media interviews at issue.

Moreover, in light of the number of deceptive claims made in the other challenged exhibits by Respondents, we need not base Respondents' liability in this case on these four media appearances. We follow a precedent of restraint exhibited in other decisions where liability has been found on other grounds. *In re Rubbermaid*, 87 F.T.C. 676, 1976 WL 179998 at *20 (F.T.C. Apr. 13, 1976) ("Because we have found the contracts to be generally violative of Section 5 [as alleged in Count I's charge of illegal price maintenance], there is no need to reach Count II's charge of violations with regard to transactions between certain States, and we decline to do so.").

X. Remedy

A. Cease and Desist Order

The ALJ determined that a cease and desist order is warranted against all Respondents, finding that Respondents' conduct is transferable, serious, and deliberate. ID at 309-13. On appeal, Respondents argue that injunctive relief is not warranted with respect to the Challenged POM products because POM has already stopped running the ads found to contain claims. In addition, Respondents argue that the remedy is not necessary because they began implementing a new review process for POM ads in 2006 and only a handful of ads and web captures of offending claims were made after that implementation. RA at 39-40. At the outset, the Commission rejects Respondents' argument that a cease and desist order is not warranted because some of the advertisements, representing a small subset of the advertisements that the Commission finds to contain false or misleading claims, were issued in or prior to 2006. The Commission also agrees with the ALJ's conclusion that a cease and desist order is appropriate with respect to all Respondents and adopts the ALJ's findings with respect thereto.

In considering whether a cease and desist order is appropriate, the Commission must determine that an order is both sufficiently clear and reasonably related to the unlawful practices at issue. *See Colgate-Palmolive Co.*, 380 U.S. at 392, 394-95.

Specifically, when determining whether an order is reasonably related to the unlawful practices, the Commission should consider "(1) the seriousness and deliberateness of the violation; (2) the ease with which the violative claim may be transferred to other products; and (3) whether the respondent has a history of prior violations." *Stouffer Foods Corp.*, 118 F.T.C. at 811; *see also Telebrands Corp.*, 457 F.3d 354, 358 (4th Cir. 2006); *Kraft, Inc.*, 970 F.2d at 326. "The reasonable relationship analysis operates on a sliding scale — any one factor's importance varies depending on the extent to which the others are found. . . . All three factors need not be present for a reasonable relationship to exist." *Telebrands Corp.*, 457 F.3d at 358-59.

We agree with the ALJ's conclusion that Respondents' actions were serious and deliberate. Respondents claimed the Challenged POM Products treat, prevent or reduce the risk of heart disease, prostate cancer, or ED. Respondents made serious yet unsupported claims about three diseases, some of which can be life-threatening. Respondents also made numerous deceptive representations and were aware that they were making such representations despite the inconsistency between the results of some of their later studies and the results of earlier studies to which Respondents refer in their ads. *See supra* Section V; *see also Standard Oil Co. v. FTC*, 577 F.2d 653, 662 (9th Cir. 1978) ("Among the circumstances which should be considered in evaluating the relation between the order and the unlawful practice are whether the respondents acted in blatant and utter disregard of the law.").

The Commission finds that a greater number of ads than those identified by the ALJ convey the claims alleged by Complaint Counsel. Nevertheless, injunctive relief, such as that ordered by Judge Chappell, is justified even if based only on the smaller number of ads where the ALJ found Respondents conveyed the claims. Thus, whether based on the ALJ's findings or our findings, Complaint Counsel has demonstrated that Respondents disseminated numerous advertisements making the claims alleged in the Complaint. It is unnecessary to find that all of the challenged ads made the alleged claims in order to warrant injunctive relief for deceptive advertising. *Bristol-Myers Co.*, 102 F.T.C. at 321 n.5 ("Although we find a smaller number of violative ads than did the ALJ, there is certainly an adequate

number to support the order . . . ."); *Fedders Corp.* 85 F.T.C. 38, 71-72 (1975) ("The Commission has previously issued orders in cases involving no more than one or a few deceptive advertisements.").

We also agree with the ALJ's conclusion that the kind of claims made by Respondents in this case would be transferable to other products. A violation is transferrable where other products could be sold utilizing similar techniques. *Colgate-Palmolive Co.*, 380 U.S. at 394-95; *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 392, 394-95 (9th Cir. 1982). Here, Respondents could use similar marketing techniques to make disease claims about other food products, including the other food products Respondents currently sell. By way of analogy, in the context of drug products, "misrepresenting that doctors prefer a product, or that tests prove the product's superiority, is a form of deception that could readily be employed for any non-prescription drug product." *Am. Home Prods. Corp.*, 695 F.2d at 708; *see also Daniel Chapter One*, 2009 WL 2584873 at *104 ("In this case, the claims that the Challenged Products prevent, treat, or cure cancer, and the use of testimonials by doctors and consumers to make such claims, could readily be employed for any dietary supplement."). Although, as set forth by the ALJ, Respondents do not have a history of prior violations, ID at 314, the other factors strongly weigh in favor of restraining Respondents' conduct in the future.

B. Fencing-In Provisions

It is well established that the Commission may issue orders containing fencing-in provisions, that is, "provisions that are broader than the conduct that is declared unlawful." *Telebrands Corp.*, 457 F.3d at 357 n.5; *see also*, *e.g.*, *Colgate-Palmolive Co.*, 380 U.S. at 394-95; *FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952). As the Supreme Court recognized in *Ruberoid*, the Commission's orders need not be restricted to the "narrow lane" of a respondent's past actions; the Commission may effectively "close all roads to the prohibited goal, so that its order may not be by-passed with impunity." *Ruberoid Co.*, 343 U.S. at 473.

Consequently, the Order we impose applies to the Challenged POM Products as well as to any other food, drug, or dietary supplement products sold by POM and the other Roll entities. *See*

Order, Definitions, ¶ 4 ("Covered Product" means any food, drug, or dietary supplement, including, but not limited to the POM Products."). Courts have agreed that fencing-in provisions that extend to products beyond those involved in the violations are appropriate. *See, e.g.*, *Colgate-Palmolive Co.*, 380 U.S. at 394-95; *Telebrands Corp.*, 457 F.3d at 361-62; *Kraft, Inc.*, 970 F.2d at 326-27; *Am. Home Prods. Corp.*, 695 F.2d at 704-10. As our prior analysis indicated, and as the ALJ recognized, the kind of claims made by Respondents in this case would easily be transferable to other products. *See* discussion *supra*, Section X.A; ID at 310-12. As the ALJ explained, it is not material that the Challenged POM Products are only a small portion of the products sold by Respondents when the advertising claims made for the Challenged POM Products are readily transferable to the other categories of products covered by the Order, particularly when Respondents have acknowledged that they have sponsored research of the health benefits of other products they sell, such as Wonderful Pistachios and FIJI Water. *See* ID at 311.

In addition, we hold that the Respondents must have at least two RCTs before making any representation regarding a product's effectiveness in the diagnosis, treatment, or prevention of any disease.[36] *See* Order, Part I. Although we did not need to decide

[36] Commissioner Ohlhausen disagrees with the majority's view that two RCTs are warranted in the order as fencing-in relief. She would require only one RCT and would regard that study in view of other available scientific evidence. Requiring a second RCT is not reasonably related to the violations at issue in this case because a second study would not cure any particular statistical or methodological problems. As stated in Section I of this opinion, the Commission did not reach the question of the number of trials that are needed to establish liability. Repetition or replication of poorly designed studies does not make those studies sound. Moreover, although it might provide the Commission with some subjective comfort, requiring two RCTs does so at the expense of limiting consumer access to potentially useful information. The product at issue is an admittedly safe food product – a type of fruit juice. To set an unnecessarily high bar for such a product is in tension with the balanced approach to substantiation set forth in the Commission's own *Pfizer* factors and with our policy commitment to avoid imposing "unduly burdensome restrictions that might chill information useful to consumers in making purchasing decisions." FTC Staff Comment Before the Food and Drug Administration In the Matter of Assessing Consumer Perceptions of Health Claims, Docket No. 2005N-0413 (2006), *available at* http://www.ftc.gov/be/V060005.pdf. To set an especially high bar without an adequate rationale also raises First Amendment concerns. As the court in

how many RCTs are necessary to substantiate Respondents' disease claims in order to establish liability, we specify a two RCT requirement in the Order for two reasons.

First, such a requirement is consistent with Commission precedent, *see Thompson Med. Co.,* 104 F.T.C. at 831-32 ("no lesser standard than two well-controlled clinical tests is appropriate as a general rule for any analgesic product"), and expert testimony in the record before us recognized the need for consistent results in independently-replicated studies. As one expert explained, "[e]ven 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 the uniqueness of the study sample." *See* CX1291 at 14-15 (Sacks Expert Report); Sacks, Tr. 1446-47.

Second, Respondents have a demonstrated propensity to misrepresent to their advantage the strength and outcomes of scientific research, as reflected by our conclusion that they made false and misleading claims about serious diseases, including cancer, in a number of the advertisements before us. Like the ALJ, *see* ID at 312, the Commission finds that Respondents have engaged in a deliberate and consistent course of conduct – no mere isolated incident or mistake – in deceptively touting the Challenged POM Products' purported ability to affect diseases and the scientific studies ostensibly showing such effects. To ensure that Respondents do not bypass our order, we therefore require that they have two substantiating RCTs before they again advertise that one of their products prevents, reduces the risk, or treats any disease.

In imposing a requirement of two RCTs, we reject Complaint Counsel's argument that our Order should prohibit Respondents from making disease-related establishment and efficacy claims about the Challenged POM Products unless such claims are pre-approved by the FDA. According to Complaint Counsel, FDA pre-approval would be reasonably related to the challenged acts

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Pearson noted, "[t]he government insists that . . . the commercial speech doctrine does not embody a preference for disclosure over outright suppression. Our understanding of the doctrine is otherwise." *Pearson*, 164 F.3d at 657 (citing *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977)).

"[b]ecause the level of evidence required to support disease treatment, prevention, and reduction of risk claims found in this matter are similar to FDA's evidentiary standards[.]" CCA at 37-38. We agree with the ALJ's conclusion, *see* ID at 317, that FDA pre-approval is not warranted as part of the remedy in this case.

Complaint Counsel argues that requiring FDA pre-clearance before Respondents may again advertise that their products treat, prevent, or reduce the risk of a disease would offer a number of benefits, including a clear, bright-line standard that would be easy to enforce and, at the same time, provide certainty for Respondents. CCA at 41. The order we issue today sufficiently accomplishes those goals by requiring at least two RCTs.[37]

The requirement for two RCTs in Part I of the Order applies only to claims for disease prevention, risk reduction, and treatment; future representations relating to efficacy or health benefits of covered products that fall short of disease claims are covered by Part III of the Order. That provision requires substantiation consisting of competent and reliable scientific evidence (as defined in that Part), that must be sufficient in quality and quantity when considered in the light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

C. Appropriateness of Applying the Final Order to Matthew Tupper

Respondent Matthew Tupper argues that he should not be held individually liable or subject to any order in this case. We agree with the ALJ's legal conclusions and factual findings holding Matthew Tupper individually liable and determining that he should be subject to a Final Order along with the other Respondents.

Courts and the Commission consistently have held that to find an individual liable for deceptive acts or practices, the individual

[37] In exercising its substantial discretion to fashion relief appropriate to the circumstances of a particular case, the Commission has in several settlements of false advertising claims imposed a FDA pre-approval requirement. Our ruling today does not foreclose that we may again conclude, in an appropriate case, that FDA pre-approval would be an appropriate remedy.

must either have participated directly in or had the authority to control the acts or practices at issue; both participation and control are not required. *See QT*, 512 F.3d at 864 ("[The individual respondent] not only participated in the false promotional activities but also had the authority to control them. Either participation or control suffices."); *FTC v. Freecom Commc'ns, Inc.*, 401 F.3d 1192, 1204 (10th Cir. 2005) ("To justify the imposition of injunctive relief against [an] individual, the FTC is required to show the individual participated directly in the business entity's deceptive acts or practices, *or had the authority to control* such acts or practices."); *FTC v. Publ'g Clearing House, Inc.*, 104 F.3d 1168, 1170 (9th Cir. 1997); *FTC v. Amy Travel Serv. Inc.*, 875 F.2d 564, 573 (7th Cir. 1989); *FTC v. Consumer Alliance, Inc.*, 2003 WL 22287364 at *5 (N.D. Ill. Sept. 30, 2003).

Even though participation and control are not both required, the record shows that Mr. Tupper both participated directly in and had the authority to control the acts or practices at issue.

With respect to his participation in the acts at issue, Mr. Tupper "implement[ed] POM's direction with regard to health benefit advertising and the use of science in connection with the advertising." ID at 305; IDF 51. Mr. Tupper participated in meetings reviewing advertising concepts and content, and reviewed, edited, and in some cases had the final say on advertising concepts and advertising copy. ID at 305; IDF 156, 160, 162, 1410, 1416, 1419-20. Mr. Tupper also participated in reviewing creative briefs, providing specific medical language for use in advertisements, drafting magazine cover wraps found by the ALJ (and here by the Commission) to have made the claims alleged by Complaint Counsel, and reviewing press releases. ID at 305; IDF 306-10, 581, 1417, 1421, 1430-31. Mr. Tupper was heavily involved in the direction of POM's medical research. ID at 305; IDF 53, 119, 142, 144, 1412, 1424-29. Mr. Tupper, in his capacity as an officer of POM, also had the authority to control its challenged practices. ID at 306-07 ("in his capacity as an officer [of POM], Mr. Tupper, together with others, formulated, directed, or controlled the policies, acts, or practices of POM."); IDF 37-38, 42. Mr. Tupper managed the day-to-day affairs of POM, including its marketing team, oversaw and administered its budget, signed checks and contracts on behalf of the company, and had the authority to determine which advertisements should

run. ID at 306; IDF 25, 44, 45, 1406. He also had numerous employees report to him directly and had the authority to hire and fire POM employees, including the head of POM's marketing department. ID at 306-07; IDF 46-50.

In sum, the ordered relief is reasonably related to the deceptive acts and practices of all the Respondents, including Mr. Tupper.

Conclusion

For all the foregoing reasons, we conclude that the Respondents have violated Sections 5(a) and 12 of the FTC Act and we affirm the ALJ's finding as to liability. Consequently, we issue a Final Order to address Respondents' conduct.

APPENDIX A
POM Claims Appendix[1]

Below we examine each of the advertisements and other promotional materials challenged by Complaint Counsel and explain our analysis of the net impression conveyed. We begin with a discussion of recurring elements[2] found in a number of these exhibits and then turn to our review of each challenged ad.

A. Recurring Elements

Medical Imagery, Symbols, and Terminology. Many of the challenged ads include images and symbols strongly associated with medicine, physicians, and equipment, among them the caduceus symbol of the medical profession or the "x" in POMx resembling the R_x abbreviation. These images and symbols contribute to a net impression that certain ads conveyed the disease-related claims challenged by Complaint Counsel. As discussed below, even the use of medical imagery in a humorous manner can buttress this message, such as a POM bottle turned upside down appearing as an intravenous drip bag (Figure 5), a POM bottle connected to electrocardiogram leads (Figure 6), and a POM bottle inside a blood pressure cuff (Figure 11). Medical terminology also contributes to a net impression that the ads conveyed the challenged claims. In several challenged exhibits, the use of the word "disease" as well as references to specific diseases and disease symptoms (*e.g.*, "cancer," "prostate cancer," "erectile dysfunction," "coronary heart disease," "atherosclerosis," "high blood pressure," "hardening of the arteries," and "stroke") conveyed that the Challenged POM Products treat, prevent or reduce the risk of disease.

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[1] For most of the challenged advertisements, Commissioner Ohlhausen agrees with the majority of the Commission about the claims conveyed. However, as explained in her Concurring Statement, for some advertisements, Commissioner Ohlhausen either did not find certain claims were made or believes extrinsic evidence is necessary to determine whether consumers would take away such claims.

[2] The Commission reviewed each ad separately, however, and no individual element should be necessarily construed as sufficient to convey a claim. Instead, each element may contribute to an ad's net impression in combination with other elements as described for each ad in this Claims Appendix.

References to Medical Professionals, Scientific Studies, and Medical Journals. References to physicians by name or to FDA approval or review also contribute to the net impression that the ads conveyed the challenged claims. Moreover, references to medical studies, particular medical journals, or other types of scientific evaluation helped convey the asserted efficacy and establishment claims, as did the use of statements quantifying the amount of money spent on research (*e.g.*, "backed by $25 million in vigilant medical research"). Further, the characterization of the research specifically as "medical" (as opposed to simply Aresearch" or even "nutritional research") contributes to the net impression that the ads conveyed the challenged claims.

Performance Results Requiring Scientific Measurement. Several ads contain references to quantifiable results (*e.g.*, "eight ounces of POM a day can reduce plaque in the arteries by up to 30%!"). Such references tend to communicate that the product's attributes are supported by scientific research because a reduction in the amount of plaque in an individual=s arteries cannot be known through casual observation, *i.e.*, it must be measured by a medical professional.

Use of Humor. Contrary to Respondents' assertion, the use of lighthearted or humorous elements does not detract from the substance of the claims conveyed by the challenged ads. For instance, Figure 6 shows a bottle of POM Wonderful connected to leads for an EKG, along with the title, "Amaze your cardiologist." The ad text further reads, "Ace your EKG . . . . A glass a day can reduce plaque by up to 30%! Trust us, your cardiologist will be amazed." While the depiction of the bottle of pomegranate juice undergoing a medical test is meant to be humorous, the humorous element includes medical imagery that reinforces the claims conveyed by the text. Thus, the ad conveyed the net impression that drinking POM will reduce plaque by up to 30% and produce improvements measurable by an EKG that will be great enough in magnitude to impress a cardiologist. Likewise, Figure 7 depicts a bottle of POM in a noose, along with the headline "Cheat death" and additional text that says "Dying is so dead … POM Wonderful … has more antioxidants than any other drink and can help prevent premature aging, heart disease, stroke, Alzheimer=s,

even cancer . . . ." Again, while the depiction of the bottle in a noose is meant to be humorous, it does not undercut the net impression that drinking POM extends your life to the extent that the drinker will "Cheat death."

Qualifying Language. Many of the ads also include adjectives attached to scientific claims (*e.g.*, "*emerging* science suggests," "*promising* results," "*preliminary* studies, " "*initial* scientific research") (emphasis added). However, the Commission does not find that these adjectives effectively qualify the claims conveyed in the challenged ads, when viewed in the context of each ad in its entirety.[3] For example, Figure 20 states in part: "POM Wonderful 100% pomegranate Juice is supported by $23 million of initial scientific research from leading universities, which has uncovered encouraging results . . . ." While the ad literally states that the research is "initial" and has produced "encouraging results," the references to the fact that the research has taken place at "leading universities" and that it cost $23 million overwhelm these qualifiers. Moreover, in ads specifically discussing the results of scientific studies, simply stating that the studies are "initial" or "hopeful" or "promising" does not neutralize the claims made when the specific results are otherwise described in unequivocally positive terms. For instance, Figures 25 and 28-32 state that "an initial UCLA study on our juice found hopeful results for prostate health, reporting 'statistically significant prolongation of PSA doubling times,' according to Dr. Allen J. Pantuck in *Clinical Cancer Research*, 2006." In these examples, the words "initial" and "hopeful" do not undercut the message that the results of the study were statistically significant and positive for PSA doubling times. The application of these principles regarding qualifiers is consistent with the Commission's experience in other advertising contexts. *See, e.g.*, Guides Concerning Use of Endorsements and Testimonials in Advertising, 16 C.F.R. ' 255.2 (ads with consumer endorsements will likely be interpreted as conveying that the endorser=s experience is representative of what

[3] Commissioner Ohlhausen's view is that, in the context of certain challenged ads, the use of these qualifiers warrant the introduction of extrinsic evidence before the Commission can find that an advertisement conveys establishment claims. *See* Commissioner Ohlhausen's Concurring Statement.

consumers will generally achieve, even when they include disclaimers such as "Results not typical" and "These testimonials are based on the experiences of a few people and you are not likely to have similar results");[4] and FTC Staff Report, *Effects of Bristol Windows Advertisement with an "Up To" Savings Claim on Consumer Take-Away and Beliefs*, (May 2012) *available at* http://www.ftc.gov/opa/2012/06/uptoclaims.shtm (when marketers use the phrase "up to" in their ads, such as making a claim that consumers will save "up to 47%" in energy costs by purchasing replacement windows, the qualifier does not affect consumers' overall takeaway that the percentage savings depicted is typical of what they can expect to achieve).

B. Facial Analysis of Individual Exhibits

Figure 1. CX0013: 2003 press release

The Commission adopts the findings and conclusions of the ALJ with regard to CX0013. *See* ID at ¶¶ 416-420. Accordingly, we conclude that this press release conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily treats, prevents or reduces the risk of heart disease and that these claims have been scientifically established.

Figure 2. CX0016: "Drink and be healthy" print advertisement

The Commission adopts the findings and conclusions of the ALJ with regard to CX0016. *See* ID at ¶¶ 290-296. Accordingly, we conclude that CX0016 conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease and that these claims have been scientifically established.

Figure 3. CX0029: "10 out of 10 People" print advertisement

The Commission adopts the findings and conclusions of the ALJ with regard to CX0029. *See* ID at ¶¶ 297-299, 301-305. Accordingly, we conclude that CX0029 conveyed to at least a significant minority of reasonable consumers that drinking eight

[4] In Commissioner Ohlhausen's view, the use of qualified terms such as "preliminary studies," or "initial studies" in the main text of an ad is significantly different than including a disclosure like "results not typical" in small print at the bottom of an ad.

ounces of POM Juice daily treats, prevents or reduces the risk of heart disease and that these claims have been scientifically established.

Figure 4. CX0031: "Floss Your Arteries" print advertisement
The Commission adopts the conclusions of the ALJ that CX0031 conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily treats, prevents or reduces the risk of heart disease. *See* ID at ¶¶ 440-445. The statement that just drinking eight ounces a day "can reduce plaque by up to 30%" contributes to the treatment, prevention, and risk reduction messages, because an elevated level of plaque in the arteries is associated with the heart disease.

Additionally, the Commission reverses the ALJ's conclusion that the ad did not convey that the efficacy claims are clinically proven. *See* ID at ¶ 448. The Commission concludes that the precise language that "[j]ust eight ounces a day can reduce plaque by up to 30%," within the context of the advertisement's headline and imagery of the POM bottle on a medicine cabinet shelf, conveyed to at least a significant minority of reasonable consumers that the efficacy claims made in this advertisement have been scientifically established. A reduction in the amount of plaque in an individual's arteries cannot be known through casual observation; it must be measured by a medical professional. Thus, the use of language communicating this specific quantified result conveyed that the results were gauged through scientific measurement and that the claim is therefore scientifically established.

Figure 5. CX0033: "Life Support" print advertisement
The Commission adopts the findings and conclusions of the ALJ with regard to CX0033. *See* ID at ¶¶ 449-455. Accordingly, we conclude that this ad conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease.

Figure 6. CX0034: "Amaze Your Cardiologist" print advertisement
The Commission adopts the findings and conclusions of the ALJ that CX0034 conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice

daily, treats, prevents or reduces the risk of heart disease. *See* ID at ¶¶ 456-464.

The statement that the antioxidants in POM fight free radicals that "can cause sticky, artery clogging plaque" helped convey that POM prevents or reduces the risk of heart disease. The statement that a glass a day "can reduce plaque by up to 30%" bolsters this prevention and risk reduction message and also contributes to a claim that POM treats existing heart disease, as an elevated level of plaque in the arteries is associated with heart disease. Further, the ad makes two references to being able to "amaze[]" a cardiologist, a physician specializing in heart disorders such as coronary disease. Most consumers would not have any reason to visit a cardiologist except for diagnosis or treatment of heart disease. Thus, the statement "amaze your cardiologist" along with the remaining text implies that drinking POM will produce significant results for a consumer with reason to visit a cardiologist, *i.e.*, with heart disease.

The Commission reverses the ALJ's finding that this advertisement did not include an establishment claim. *See* ID at ¶¶ 465-468. The Commission concludes that the precise language that a "glass a day can reduce plaque by up to 30%," within the context of the advertisement's headline, medical imagery, and text conveyed to at least a significant minority of reasonable consumers that the efficacy claims made in this advertisement have been scientifically established. A reduction in the amount of plaque in an individual's arteries cannot be known through casual observation; it must be measured by a medical professional. Thus, the use of language communicating this specific quantified result conveyed that the results were gauged through scientific measurement, and that the claim is therefore scientifically established.

Figure 7. CX0036: "Cheat Death" print advertisement

The Commission adopts the findings and conclusions of the ALJ that CX0036 conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily reduces the risk of heart disease. *See* ID at ¶¶ 469-476. We also find that the advertisement conveyed to a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily prevents heart disease. The Commission reverses the ALJ to

the extent that he did not make this finding. ID at ¶ 474. We make this finding based on the net impression of the advertisement, including the statements that drinking eight ounces of POM Juice a day "can help prevent … heart disease," and "[t]he sooner you drink it, the longer you will enjoy it," as well as imagery of the POM Juice bottle with a noose around the neck of the bottle.

Figure 8. CX0044: September 2005 press release

The Commission adopts the findings and conclusions of the ALJ with regard to CX0044. Accordingly, we conclude that this exhibit conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily, treats, prevents or reduces the risk of heart disease, and that these claims have been scientifically established. *See* ID at ¶¶ 421-427.

Figure 9. CX0065: July 2006 press release

The Commission adopts the findings and conclusions of the ALJ that CX0065 conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats prostate cancer, and that this claim has been scientifically established. *See* ID at ¶¶ 428-431. We also conclude that the press release conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily prevents or reduces the risk of heart disease, and that these claims are scientifically established. In this regard, the decision of the ALJ is reversed. *See* ID at ¶¶ 585-586. Several factors contribute to this overriding message regarding the impact of POMx Pills and POM Juice on heart disease and prostate cancer. First, the press release references scientific research specifically indicating that POMx and POM Juice "may protect against cardiovascular … disease[]." Likewise, the press release refers specifically to published research from the American Association for Cancer Research, which claimed that daily consumption of pomegranate juice significantly prolonged PSA doubling time, which is a protein marker for prostate cancer. In addition, the press release quoted comments by a "Professor of Medicine" and "Director, UCLA Center for Human Nutrition" about "the effects" of POMx and POM Juice on prostate cancer.

Figure 10. CX1426 Ex. I: Antioxidant Superpill Brochure

The Commission adopts the findings and conclusions of the ALJ with regard to CX1426 Ex. I. Accordingly, we conclude that this exhibit conveyed to least a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats, prevents or reduces the risk of heart disease and prostate cancer, and that these claims have been scientifically established. *See* ID at ¶¶ 328-342.

The efficacy and establishment claims for treatment of prostate cancer and heart disease are conveyed through language describing scientific studies purportedly showing that drinking POM slows PSA doubling time by 350% and causes a significant decrease in cancer regrowth rate for men with advanced prostate cancer, and that drinking POM caused a 30% decrease in arterial plaque for patients with atherosclerosis and a 17% improvement in blood flow for patients with impaired blood flow to the heart.

The ad also conveyed prevention and risk reduction claims for these two diseases. The ad underscores the importance of taking an antioxidant supplement by identifying the underlying problem of free radicals, which may be linked to "serious health threats like cancer and heart disease. In fact, scientists have already linked free radicals to as many as 60 different types of diseases." The ad also states that: "Science tells us that pomegranate antioxidants neutralize free radicals, helping to prevent the damage that can lead to disease," and that POM "promotes heart and prostate health" and "guards your body against free radicals." These statements contributed to the net impression that the POMx Pill or POM Juice will prevent or reduce the risk of heart disease and prostate cancer in addition to treating these diseases.

Figure 11. CX0103: "Decompress" print advertisement

The Commission adopts the findings and conclusions of the ALJ that the evidence fails to show that CX0103 conveyed to a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily treats heart disease. *See* ID at ¶ 587. However, we find that this exhibit conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease and that these claims have been scientifically established. In this regard, the decision of the ALJ is reversed. The ad

containing medical imagery depicts the POM Juice bottle wrapped in a blood pressure cuff. Moreover, express language in the ad establishes a link between POM Juice, which "helps guard … against free radicals [that] … contribute to disease," and the $20 million of "scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health." The ad also states that POM Juice will help "[k]eep your ticker ticking." In combination, these elements communicate the message that POM Juice prevents or reduces the risk of heart disease, and that those efficacy claims are scientifically established.

Figure 12. CX0109: "Heart Therapy" print advertisement

The Commission finds that CX0109 conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease. This exhibit is analogous to CX0103 (Figure 11 above) in that the text of the advertisement states that drinking eight ounces of POM Juice will "[k]eep your heart healthy," and that scientific evidence "has uncovered encouraging results in . . . cardiovascular health." We also note the bold headline touting "Heart Therapy." In this regard, the decision of the ALJ is reversed. ID at ¶ 587. Additionally, the Commission finds that this advertisement conveyed to at least a significant minority of reasonable consumers that the efficacy claims have been scientifically established. The text stating that POM Juice "is supported by $20 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health" contributes to this net impression. In this regard, the decision of the ALJ is also reversed.

Figures 13-14. CX0120: "One small pill for mankind;" and CX0122: "Science Not Fiction" print advertisements

The Commission adopts the findings and conclusions of the ALJ with regard to CX0120 and CX0122 that the evidence fails to demonstrate that these exhibits conveyed to a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily prevents or reduces the risk of prostate cancer. *See* ID at ¶ 587.

However, the Commission finds that these exhibits conveyed to at least a significant minority of consumers that drinking eight

ounces of POM Juice or taking one POMx Pill daily treats prostate cancer. The text in CX0120 and CX0122 specifically states that a study showed "hopeful results for men with prostate cancer." Further, in CX0120, the advertising copy, indicating that it is a quote from the *New York Times*, states that "[f]indings from a small study suggest that pomegranate juice may one day prove an effective weapon against prostate cancer." While the ads include language that attempts to qualify the claims conveyed, the Commission finds that these attempts to qualify fail to counteract the net impression conveyed through the use of strong descriptive language such as "incredibly powerful," "astonishing levels of antioxidants," and "so extraordinary, it's patent pending." In this regard, the decision of the ALJ is reversed.

Additionally, the Commission finds that the claims made in these exhibits conveyed to at least a significant minority of reasonable consumers that the prostate cancer treatment claims have been scientifically established. Both exhibits state that "an initial UCLA medical study … showed hopeful results for men with prostate cancer." Further, the subtitle in CX0122 states that the product is "backed by $20 million in medical research." In this regard, the decision of the ALJ is also reversed.

Figure 15. CX0128: June 2007 press release

The Commission adopts the findings and conclusions of the ALJ with regard to CX0128. Accordingly, we conclude that this exhibit conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats erectile dysfunction and that this claim has been scientifically established. *See* ID at ¶¶ 432-439.

Figure 16. CX1426 Ex. M: POMx Heart Newsletter

The Commission adopts the findings and conclusions of the ALJ with regard to CX1426 Ex. M. Accordingly, we conclude that this exhibit conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats, prevents or reduces the risk of heart disease, and that these claims have been scientifically established. *See* ID at ¶¶ 346-350.

Figure 17. CX1426 Ex. N: POMx Prostate Newsletter

The Commission adopts the findings and conclusions of the ALJ with regard to CX1426 Ex. N. Accordingly, we conclude that this exhibit conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats, prevents or reduces the risk of prostate cancer, and that these claims have been scientifically established. *See* ID at ¶¶ 351-354. The Commission finds, as the ALJ did, that this newsletter draws a clear link between antioxidants and a reduction in the risk of prostate cancer. After noting that prostate cancer is "the second leading cause of cancer related to death in the United States," the newsletter addresses "risk factors" for prostate cancer, including "diet," and advises a diet that is rich in antioxidants. The newsletter also expressly informs readers of medical research in "top peer-reviewed medical journals that document the pomegranate's antioxidant health benefits such as heart and prostate health."

Figure 18. CX0169/CX1426 Ex. L: "The Power of POM" print advertisement

Based on the overall net impression of CX0169/CX1426 Ex. L, the Commission finds that this exhibit conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking a POMx Pill daily treats, prevents or reduces the risk of heart disease and prostate cancer, and that these claims are scientifically established. This ad includes a discussion of the effects of antioxidants on "free radicals [that] aggressively destroy healthy cells in your body – contributing to premature aging and even disease. The good news is POM Wonderful pomegranate antioxidants neutralize free radicals." The ad also describes $23 million in medical research including a study published in *Clinical Cancer Research*, in which pomegranate juice "delays PSA doubling time in humans." In addition, the ad discusses two studies showing "promising results for heart health," including improvement in "myocardial perfusion in coronary heart patients," and the beneficial effect of pomegranate juice on atherosclerosis. Although the ad attempts to qualify the discussion of the medical research by using the words "promising," "hopeful," and "preliminary," the Commission finds that these adjectives are ineffective, especially where the references to the studies are introduced with a bolded "**Backed by Science**" statement. We also find that the "results"

of the studies are made especially notable by being presented in red text.

In addition, the medical imagery of the prominent caduceus symbol and the use of the subscript "x" in POMx, as well as the reference to $23 million dollars in medical research published in named medical journals all combine to convey to at least a significant minority of reasonable consumers that the claims have been scientifically established. Finally, we note that the text and imagery indicate equivalence between eight ounces of POM Juice and one POMx Pill. Therefore, we reverse the findings of the ALJ with regard to this exhibit.

Figures 19 and 24. CX0180/CX1426 Ex. K: "The antioxidant Superpill;" and CX0279: "Science, Not Fiction" print advertisements

Based on the overall net impression of CX0180/CX1426 Ex. K and CX0279, the Commission finds that these exhibits conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking a POMx Pill daily treats, prevents or reduces the risk of heart disease and prostate cancer, and that these claims are scientifically established. These ads include references to $23 million and $25 million in medical research including a study published in *Clinical Cancer Research* that reports "statistically significant prolongation of PSA doubling times." The ads also describe two studies showing a decrease in "stress-induced ischemia," and "[p]omegranate juice consumption resulted in a significant IMT reduction by up to 30% ," referring to arterial plaque.

In addition, the medical imagery of the caduceus symbol and the use of the subscript "x" in POMx, the references to millions of dollars in medical research published in named medical journals, and the attribution of results to three specific named doctors, all combine to convey to at least a significant minority of reasonable consumers that the claims have been scientifically established. Finally, we note that the text and imagery indicate equivalence between eight ounces of POM Juice and one POMx Pill. Therefore, we reverse the findings of the ALJ with regard to these exhibits.

Figure 20. CX0192: "What Gets Your Heart Pumping" print advertisement

The Commission concludes that the express language of this ad referring to "healthy arteries," the fact that pomegranate juice "helps guard your body against free radicals" that "aggressively destroy healthy cells in your body and contribute to disease," and that "[e]ight ounces a day is enough to keep your heart pumping," created the net impression to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease. In addition, we find the specific reference to "$23 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health," signals that this beneficial effect has been scientifically established. We therefore reverse the findings of the ALJ with regard to this exhibit.

Figures 21 and 27. CX0314: "Drink to Prostate Health;" and CX0372, CX0379, CX0380: Super Health Powers series, magazine wraps

The Commission adopts the findings and conclusions of the ALJ with regard to CX0314, CX0372, CX0379, CX0380. *See* ID at ¶¶ 306-320. Accordingly, we conclude that these exhibits conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily treats, prevents or reduces the risk of prostate cancer, and that these claims have been scientifically established.

Figure 22. CX0260/CX1426 Ex. B: "Drink to Prostate Health" print advertisement

The Commission finds that this exhibit conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily treats prostate cancer and that this claim is scientifically established. Factors contributing to this net impression include the language "Drink to prostate health," and express language equating POM Juice to "good medicine." Furthermore, the ad describes a "recently published preliminary medical study [that] followed 46 men previously treated for prostate cancer" which found that "[a]fter drinking 8 ounces of POM Wonderful 100% Pomegranate Juice daily for at least two years, these men experienced significantly longer PSA doubling

times." Therefore, we reverse the findings of the ALJ with regard to this exhibit.

Figure 23. CX0274/CX1426 Ex. C: "I'm Off to Save Prostates" print advertisement

Based on the overall net impression, the Commission finds that this exhibit conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily prevents or reduces the risk of prostate cancer, and that these claims are scientifically established. The headline "I'm off to save PROSTATES" when read in conjunction with the text that POM Juice "is committed to defending healthy prostates" and will "improve prostate health," implies that POM Juice protects men from prostate cancer. In particular, the word "defend[]" in conjunction with "save" gives the impression that the ad is conveying information about a serious threat to prostates — prostate cancer. The message of "defense" is one of warding off this danger, *i.e.*, preventing or reducing the risk of prostate cancer. In addition, the language that POM Juice is "backed by $25 million in vigilant medical research" communicates that these claims are scientifically established. Therefore, we reverse the findings of the ALJ with regard to this advertisement.

Figures 25 and 28-32. CX0280: "Live Long Enough;" CX0331/CX1426 Ex. J: "Healthy Wealthy;" CX0328: "Your New Health Care Plan;" CX0337: "First Bottle You Should Open;" CX0342/CX0353: "Life Insurance Supplement;" and CX0348/CX0350: "24 Scientific Studies" print advertisements

The Commission concludes that these exhibits conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats, prevents or reduces the risk of heart disease and prostate cancer and that these claims have been scientifically established. These ads begin with the general proposition that "antioxidants are critically important to maintaining good health because they protect you from free radicals, which can damage your body," and that POMx is an "ultra-potent antioxidant extract," that will "help protect you from free radicals." Further, the ads state that research has "revealed promising results for prostate and cardiovascular health." In combination, these statements contribute to the net impression that POM prevents and reduces the risk of prostate cancer and heart disease.

Each of these ads describe a UCLA study on POM juice in *Clinical Cancer Research* that found "statistically significant prolongation of PSA doubling times." Because PSA doubling time is associated with prostate cancer, this statement implies that POM juice treats prostate cancer. In addition, the ads cite a medical study in the *American Journal of Cardiology* that showed a reduction in stress-induced ischemia, which the ad explains means restricted blood flow to the heart. Four of the six ads (CX0280, CX0331, CX0328, and CX0337) also discuss a study that showed consumption of pomegranate juice "resulted in significant reduction in IMT (thickness of arterial plaque) by up to 30% after one year."

Several elements create the net impression that the above claims are scientifically established, including: the express references to $25 million and $32 million in "medical research at the world's leading universities;" the findings of studies regarding POM Juice's impact on PSA doubling times and stress-induced ischemia published in *Clinical Cancer Research* and the *American Journal of Cardiology*, respectively; and the attribution of these test results to several specifically-named doctors. We note that the text and imagery indicate equivalence between eight ounces of POM Juice and one POMx Pill.

Accordingly, we reverse the ALJ's findings with regard to these ads.

Figure 26. CX0475/CX1426 Ex. A: Juice Bottle Hang Tag

The Commission adopts the findings and conclusions of the ALJ with regard to CX0475/CX1426 Ex. A that the evidence fails to establish that the juice bottle hang tag conveyed to a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily treats, prevents or reduces the risk of heart disease, prostate cancer, or ED, or that such claims are clinically established.

Figure 33. CX0351/CX0355: "Only Antioxidant Supplement Rated X" print advertisement

The Commission adopts the ALJ's findings and conclusions that these exhibits conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice or

taking one POMx Pill daily treats, prevents or reduces the risk of, erectile dysfunction, and that these claims are clinically proven. *See* ID at ¶¶ 321-327.

The Commission also concludes that these nearly identical advertisements convey to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats, prevents or reduces the risk of heart disease and prostate cancer, and that these claims have been scientifically established. These ads begin with the general proposition that "antioxidants are critically important to maintaining good health because they protect you from free radicals, which can damage your body," and that POMx is an "ultra-potent antioxidant extract," that will "help protect you from free radicals." Further, the ads state that research has "revealed promising results for . . . prostate and cardiovascular health." In combination, these statements contribute to the net impression that POM prevents and reduces the risk of prostate cancer and heart disease.

Each ad describes a UCLA study on POM juice in *Clinical Cancer Research* that found "statistically significant prolongation of PSA doubling times." Because PSA doubling time is associated with prostate cancer, this statement implies that POM juice treats prostate cancer. In addition, the ads cite a medical study on POM Juice in the *American Journal of Cardiology* showing a reduction in stress-induced ischemia, which the ad explains means restricted blood flow to the heart. We note that the text and imagery indicate equivalence between eight ounces of POM Juice and one POMx Pill.

Several elements create the net impression that the prostate cancer and heart disease claims are scientifically established. Each ad explicitly references $32 million or $34 million in "medical research at the world's leading universities" and then goes on to elaborate on the findings of studies regarding the impact of POM Juice on PSA doubling times, as published in *Clinical Cancer Research*, and POM Juice's impact on stress-induced ischemia, as published in the *American Journal of Cardiology*.

Accordingly, we reverse the ALJ's findings insofar as we find the ads convey efficacy and establishment claims of prostate cancer and heart disease treatment, risk reduction, and prevention.

Figure 34. CX0463: "Heart Therapy" Animated Online Ad

The Commission adopts the findings and conclusions of the ALJ with regard to CX0463 that the evidence fails to establish that this online advertisement conveyed to a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease. *See* ID at ¶ 587.

Figure 35. CX0466/CX1426 Ex. H "Off to Save Prostates" Animated Online Ad

The Commission adopts the findings and conclusions of the ALJ with regard to CX0466/CX1426 Ex. H that the evidence fails to establish that this advertisement conveyed to a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily prevents or reduces the risk of prostate cancer. *See* ID at ¶ 587.

Figures 36 and 37. CX0473: Video Captures of POMWonderful.com Website, including the "Community" Section of the Site; CX0336: Printout of portions of POMWonderful.com "Community" Section of the Site

CX0473 contains video captures of the POMWonderful.com website, including the "Community" section the site, on various dates in 2009 and 2010. CX0336 is a printout of several pages from the "Community" section of the POMWonderful.com website from December 2010. It is unclear whether the ALJ considered the Community section of the POMWonderful.com site separately from the rest of the site. *See* IDF ¶¶ 368-85. Here, we address the site in its entirety.

In the video captures, textual references, graphs, medical imagery, commentary from POM executives and "POM experts" with medical backgrounds, and citations to scientific studies in combination convey the following claims:

Prevention and Risk Reduction Claims. Some examples of the elements that contribute to the message that POM prevents or reduces the risk of heart disease and prostate cancer are:

- One video on the site opens with a voiceover stating that "Pomegranate contains powerful antioxidants needed to prevent cancer and diseases" Videotape: PomWonderful Ads at 00:23-1:03 (Apr.-May 2009). A page on the site titled "Cancer – Emerging Science" states that: "Emerging science has shown that diets rich in fruits and vegetables that contain antioxidants, along with regular exercise, might slow or prevent the development of cancer. [A] great source[] of antioxidants [is] POM Wonderful Pomegranate Juice … ." Videotape: PomWonderful Ad Health Benefits at 03:44 (April-May 2009). The one specific type of cancer highlighted on the website is prostate cancer. For example, the website features a video nearly seven minutes in length titled "Let's Talk About Prostate Cancer with David Heber, MD" Videotape: PomWonderful Ad at 00:14-07:07 (Dec. 2009). A portion of the "Community" portion of the website titled "POM's Health Benefits: Fact or Fiction" quotes Dr. Bradley Gillespie, identified as POM's Vice President of Clinical Development, as stating: "Some of our research areas are beginning to accumulate quite impressive clinical data. For example, I think the human evidence in prostate health is one of the strongest areas, and we continue to fund more research here." CX0336 at 1.

- The site states that the antioxidant activity in POM Juice decreases inflammation, and that along with oxidative stress, inflammation has been implicated in a number of identified diseases, including atherosclerosis, heart failure, hypertension, and cancer. Videotape: PomWonderful Ad at 02:22-02:32 (Oct. 2009).

- In addition, on a page of the website titled "Other protective effects," it states that "Pomegranate juice has a superior ability to prevent LDL cholesterol from being oxidized by free radicals," and that LDL oxidation "may be a precursor to atherosclerosis or arterial plaque." Videotape: PomWonderful Ad at 01:45-02:02 (Oct. 2009).

Treatment Claims. The site describes in detail studies of patients with heart disease, prostate cancer, and erectile dysfunction who

experienced positive effects from drinking POM juice, thereby conveying that POM products treat these three diseases.

Establishment Claims. Through a variety of means the site conveys that all of these disease prevention, risk reduction, and treatment claims are clinically proven, such as citation to clinical studies, reference to specific named physicians – including one identified as a winner of the Nobel Prize in medicine – and statements that POM is backed by tens of millions of dollars in scientific research and "backed by science." We also note the statement from Defendant Tupper that: "When you look at the medical research that has been conducted on POM and compare it to research that's been done on other foods and beverages, what's been done on POM is way, way more extensive. It's almost more akin to research being done on pharmaceutical drugs." CX0336 at 0001.

Figure 38. CX0473: Video Capture of PomegranateTruth.com Website

CX0473 contains a video capture of the PomegranateTruth.com website from April-May 2009.

The Commission adopts the findings and conclusions of the ALJ that the PomegranateTruth.com website conveys to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats, prevents or reduces the risk of heart disease and that these claims have been scientifically proven. *See* ID at ¶¶ 411-414. The Commission also adopts the findings and conclusions of the ALJ that the PomegranateTruth.com website fails to establish that a significant minority of reasonable consumers would interpret the website to claim that drinking eight ounces of POM Juice or taking one POMx Pill daily prevents or reduces the risk of prostate cancer or erectile dysfunction. *See* ID at ¶ 591.

However, the Commission also finds that the PomegranateTruth.com website conveys to a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats prostate cancer and erectile dysfunction and that these claims have been scientifically proven. In this regard, the decision of the ALJ is reversed.

With regard to the prostate cancer treatment claim, the Commission notes the description of the UCLA study of men with prostate cancer who drank POM Juice and experienced an increase in PSA doubling time from 15 to 54 months. The site states, "PSA is a protein marker for prostate cancer, and slower PSA doubling time indicates slower disease progression." This description of the study constitutes both an efficacy and an establishment claim for prostate cancer treatment, although the establishment claim is bolstered through other elements, such as the statement that POM products are "Backed by science" and $25 million in medical research, alongside the prominent depiction of a caduceus.

With regard to the erectile dysfunction treatment claim, the Commission notes the description of a study published in the *International Journal of Impotence Research* regarding 61 subjects with mild to moderate erectile dysfunction who drank POM Juice and were 50% more likely to experience improved erections. This description constitutes both an efficacy and an establishment claim, although the establishment claim is bolstered by the same elements described above.

Figure 39. CX0473: Video Captures of POMPills.com Websites

CX0473 contains video captures of the POMPills.com website from April-May 2009 and January 2010.

The Commission adopts the findings and conclusions of the ALJ that the POMPills.com website conveys to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats, prevents or reduces the risk of heart disease and prostate cancer, and that these claims have been scientifically proven. See ID at ¶¶ 386-410. The Commission also adopts the findings and conclusions of the ALJ that the POMPills.com website conveys to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats erectile dysfunction and that this claim have been scientifically proven.

See also ID at ¶¶ 387, 408. To the extent that the ALJ's decision can be read to state that the ALJ found that the website conveyed claims that POMx prevents and reduces of risk for erectile dysfunction, *see* ID ¶ 387, that finding is reversed.

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Figures Appendix

Tab	Exhibit Number	Date	Description
1	CX0013	01/09/2003	January 2003 POM Juice Press Release
2	CX0016	10/12/2003	"Drink and be healthy." Ad
3	CX0029	11/01/2004	"10 Out of 10 People Don't Want to Die" Ad
4	CX0031	12/01/2004	"Floss your arteries. Daily." Ad
5	CX0033	12/30/2004	"Life support." Ad
6	CX0034	02/01/2005	"Amaze your cardiologist." Ad
7	CX0036	03/10/2005	"Cheat death." Ad
8	CX0044	09/16/2005	September 2005 POM Juice Press Release
9	CX0065	07/10/2006	July 2006 POMx Press Release
10	CX1426 at 0038-42 Ex. I	2007	"Antioxidant Superpill." Brochure
11	CX0103	03/01/2007	"Decompress." Ad
12	CX0109	04/01/2007	"Heart therapy." Ad
13	CX0120	05/28/2007	"One small pill for mankind." Ad
14	CX0122	06/01/2007	"Science, not fiction." Ad
15	CX0128	06/27/2007	June 2007 POM Juice Press Release
16	CX1426 Ex. M	Summer 2007	POMx Heart Newsletter
17	CX1426 Ex. N	Fall 2007	POMx Prostate Newsletter
18	CX0169/ CX1426 Ex. L	01/06/2008	"The power of POM" Ad
19	CX 0180/ CX1426 Ex. K	02/03/2008	"The antioxidant superpill." Ad
20	CX0192	05/01/2008	"What gets your heart pumping?" Ad
21	CX0314	08/25/2008	"Drink to prostate health." Magazine Wrap
22	CX0260/ CX1426 Ex. B	12/01/2008	"Drink to prostate health." Ad
23	CX0274/ CX1426 Ex. C	02/01/2009	"I'm off to save PROSTATES!" Ad
24	CX0279	03/01/2009	"Science, not fiction." Ad
25	CX0280	03/12/2009	"Love Long Enough." Ad
26	CX0475/CX1426 Ex. A	September 2009	"Super Health Powers" Juice Bottle Hang Tag

Tab	Exhibit Number	Date	Description
27	CX0372/ CX0379/ CX0380	09/02/2009	"Lucky I have super Health Powers" Magazine Wrap
28	CX0331/ CX1426 Ex. J	09/27/2009	"Healthy. ~~Wealthy.~~ And Wise." Ad
29	CX0328	11/08/2009	"Your New Health Care Plan." Ad
30	CX0337	01/03/2010	"The First Bottle You Should Open in 2010" Ad
31	CX0342/ CX0353	02/22/2010	"Take Out a Life Insurance Supplement" Ad
32	CX0348/ CX0350	04/01/2010	"24 Scientific Studies" Ad
33	CX0351/ CX0355	06/01/2010	"The Only Antioxidant Supplement Rated X" Ad

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FOR IMMEDIATE RELEASE

Editor's Note: Copies of the medical research, digital photos, interviews and juice samples are available upon request.

CONSUMER DEMAND FOR POM WONDERFUL'S REFRIGERATED ALL-NATURAL POMEGRANATE JUICE GROWS AS THE HEALTH BENEFITS OF POMEGRANATE JUICE BECOME RECOGNIZED.

Scientific support indicates that drinking pomegranate juice provides the body with an active source of antioxidants and shows promise against cardiovascular disease.

LOS ANGELES (January 9 - 2003) - POM Wonderful®, the first company to sell a refrigerated super-premium pomegranate juice, today released information from published medical research regarding the important health benefits associated with its pomegranate juice. It was announced that the antioxidant activity of POM Wonderful pomegranate juice exceeds that of other popular beverages known for their antioxidant properties including red wine, cranberry juice, blueberry juice, orange juice, white wine, red grape juice, white grape juice, apple juice, and grapefruit juice. The antioxidant activity of pomegranate juice is high due to the polyphenols it contains. Polyphenols are powerful, natural antioxidants. Antioxidants may be useful in counteracting premature aging, Alzheimer's, and cancer.

The research shows that the antioxidants found in pomegranate juice may also be more important than previously thought in promoting optimum cardiovascular health. Medical research shows that daily consumption of just 1.5 mmol of polyphenols from pomegranate juice (the equivalent of an 8 fl oz serving of POM Wonderful pomegranate juice) confers heart health benefits by lessening factors that contribute to atherosclerosis (plaque in the arteries).[1] According to the American Heart Association, cardiovascular diseases rank as America's No. 1 killer. In addition, 61.8 million Americans have some form of cardiovascular disease such as diseases of the heart, high blood pressure, and hardening of the arteries.[2]

General Antioxidant Effects

Free radicals are produced as a result of normal metabolic processes, pollution and chemicals in the foods we eat. They attack and damage molecules in the body so that their function is altered. One molecule that is particularly susceptible to attack is LDL (low-density

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lipoprotein) cholesterol. Once attacked and damaged, LDL is said to be oxidized. LDL oxidation is a key factor in the formation of plaque in the arteries, also called atherosclerosis. One of the best ways to defend against the damaging effects of free radicals is to consume foods and beverages that are rich in antioxidants.

Two studies have shown the superior potency of pomegranate antioxidants compared to other popular beverages. In the first study, which used four well-established tests of antioxidant activity, pomegranate juice squeezed from the Wonderful variety of pomegranates had twice the antioxidant activity of both red wine and green tea. Furthermore, pomegranate juice was shown to contain antioxidant compounds not present in either of the other beverages.[3] In a second study, ten beverages known for their antioxidant capacity were tested for their total polyphenol content and their ability to prevent the oxidation of LDL cholesterol (a factor in atherosclerosis). Beverages tested included pomegranate juice (from the Wonderful variety), red wine, apple juice, orange juice, white wine, red grape juice, white grape juice, cranberry juice, blueberry juice, and grapefruit juice. Pomegranate juice surpassed all the other juices in total polyphenol content. It was also the best inhibitor of LDL oxidation.[2]

Effects on Heart Health

The heart is one of the most susceptible of all the organs to premature aging and free radical oxidative stress. Though vulnerable to the effects of oxidative stress, the heart is also receptive to the benefits of antioxidants.[4] New research is showing that antioxidants can play a highly beneficial role in reducing one of the major risk factors in heart disease: atherosclerosis (plaque in the arteries). The progression of atherosclerosis depends on several steps including the oxidation of LDL cholesterol, the uptake of oxidized cholesterol into macrophage cells, clumping of LDL molecules together, and the adhesion of LDL molecules to the inner walls of the blood vessel. In one human study, drinking pomegranate juice containing 1.5 mmol of polyphenols daily for two weeks lowered the susceptibility of LDL cholesterol to oxidation, clumping and adhesion. Furthermore, it increased blood levels of an enzyme, paraoxonase, which protects against oxidation. An additional human study showed that consuming pomegranate juice reduces another enzyme: ACE (angiotensin converting enzyme). Inhibition of ACE lessens the progression of atherosclerosis and it is this enzyme that is targeted by blood pressure medications. Pomegranate juice inhibited ACE by 36% after two weeks of juice consumption. It also caused a 5% decrease in systolic blood pressure, and high blood pressure is a known risk factor for atherosclerosis.[5]

Studies in mice have revealed additional exciting results. When mice predisposed to

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atherosclerosis were given pomegranate juice for 11-14 weeks, the level of LDL oxidation and the uptake of LDL cholesterol into macrophage cells was reduced. Remarkably, the production of atherosclerotic lesions and foam cells (indicators of advanced atherosclerosis) was also reduced by almost half compared to controls.[6] A subsequent study showed that pomegranate juice could actually reduce the size of existing atherosclerotic lesions after two months of pomegranate juice consumption, in effect, reversing atherosclerosis.[7]

About POM Wonderful

POM Wonderful, a subsidiary of Roll International Corporation, cultivates the Wonderful variety of pomegranates in orchards located in the sunny San Joaquin Valley, southwest of Kettleman City, in Central California. The Wonderful variety of pomegranate is renowned for its exquisite sweet flavor, beautiful color, and bountiful juice. In addition to selling fresh pomegranates throughout the United States, **POM** Wonderful has also created a unique, healthy, refreshing super-premium pomegranate juice that is now on sale in the refrigerated produce section of over 900 grocery stores and supermarkets in Southern California, including Von's, Ralph's, Stater Brothers, Bristol Farms, and Gelson's. **POM** Wonderful uses the juice from its fresh pomegranates to make its juice. Pomegranate juice can be enjoyed as a beverage, a drink mixer and in recipes. Each 8 fl oz serving of pomegranate juice contains the juice from approximately two pomegranates. **POM** Wonderful's pomegranate juice is currently available in four flavors, Pure **POM**, **POM** Mango, **POM** Tangerine and **POM** Blueberry and two sizes - 15.2 fl oz and 24 fl oz. The 15.2 fl oz size retails for approximately $3.49, and the 24 fl oz size retails for approximately $5.79. **POM** Wonderful pomegranates and **POM** Wonderful pomegranate juice products promise consistent quality and superb taste. Only fruit and juice that meet the company's strict quality standards appear in store produce sections. **POM** Wonderful prides itself on the quality of its farming operation the sensitivity with which the fruit is hand picked and carried to its sorting and modern juicing facilities, and ultimately delivered to your table. **POM** Wonderful's mission is to educate consumers about the splendor and versatility of this luscious fruit, as well as its refreshing taste and health benefits. To learn more, visit www.pomwonderful.com.

POM Wonderful is a registered trademark of POM Wonderful LLC.

Citations

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Figure 2

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Figure 3

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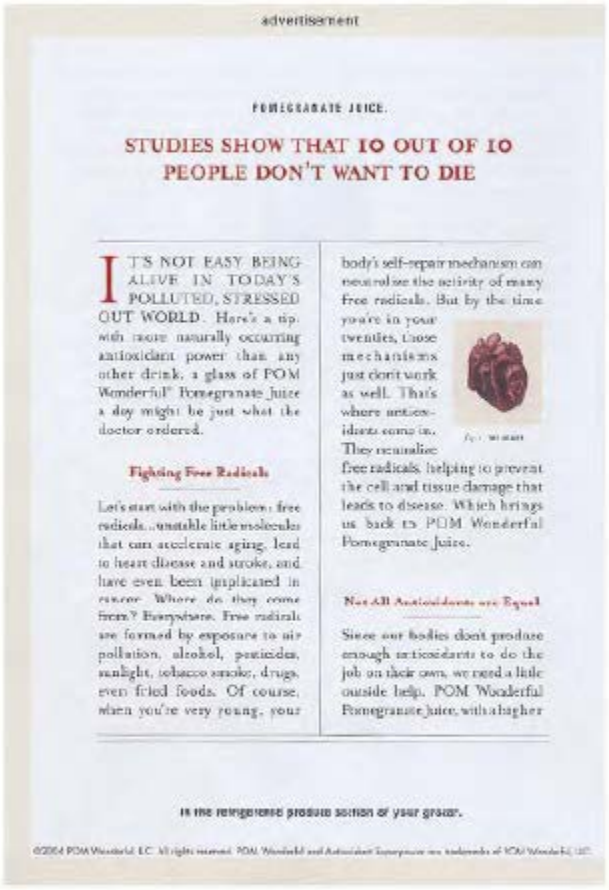
RUN DATE: 11/01/2004



advertisement

POMEGRANATE JUICE.

STUDIES SHOW THAT 10 OUT OF 10 PEOPLE DON'T WANT TO DIE

IT'S NOT EASY BEING ALIVE IN TODAY'S POLLUTED, STRESSED OUT WORLD. Here's a tip with more naturally occurring antioxidant power than any other drink, a glass of POM Wonderful® Pomegranate Juice a day might be just what the doctor ordered.

Fighting Free Radicals

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

Not All Antioxidants are Equal

Since our bodies don't produce enough antioxidants to do the job on their own, we need a little outside help. POM Wonderful Pomegranate Juice, with a higher

In the refrigerated produce section of your grocer.

VMS-0000205

CX0029_0001

APPENDIX B
Figure 3

VMS ID: 04112020I
RUN DATE: 11/01/2004

advertisement

level of antioxidants than any other drink, is a real Antioxidant Superpower!*

Our Research: Heartening

We've been working with a number of top scientists, including a Nobel Laureate, for 6 years now and our seven published, peer-reviewed papers reveal heartening results. Here's the story: Free radicals are the culprits that turn LDL – or "bad" cholesterol – into that sticky stuff that becomes the plaque that clogs your arteries. Our scientific research shows that pomegranate juice is 3 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 Wonderful 100% Pomegranate Juice, consumed daily, reduces plaque in the arteries up to 30%.*

The Heart Stopping Truth

Remember: heart disease is America's number one killer. For women as well as men. 58% of heart attacks are due to atherosclerosis, or too much plaque in the arteries. That same plaque increases your chance of stroke. One fina scary statistic: half of patients who have a severe heart attack have normal cholesterol levels. In other words, we're all at risk.

Just a Glass a Day

To keep your heart healthy: exercise regularly. Eat a healthy diet. And drink 8 ounces of POM Wonderful Pomegranate Juice. Make every day a good day to be alive.

POM

POM Wonderful Pomegranate Juice
is the Antioxidant Superpower! Drink a glass a day!

VMS-0000206

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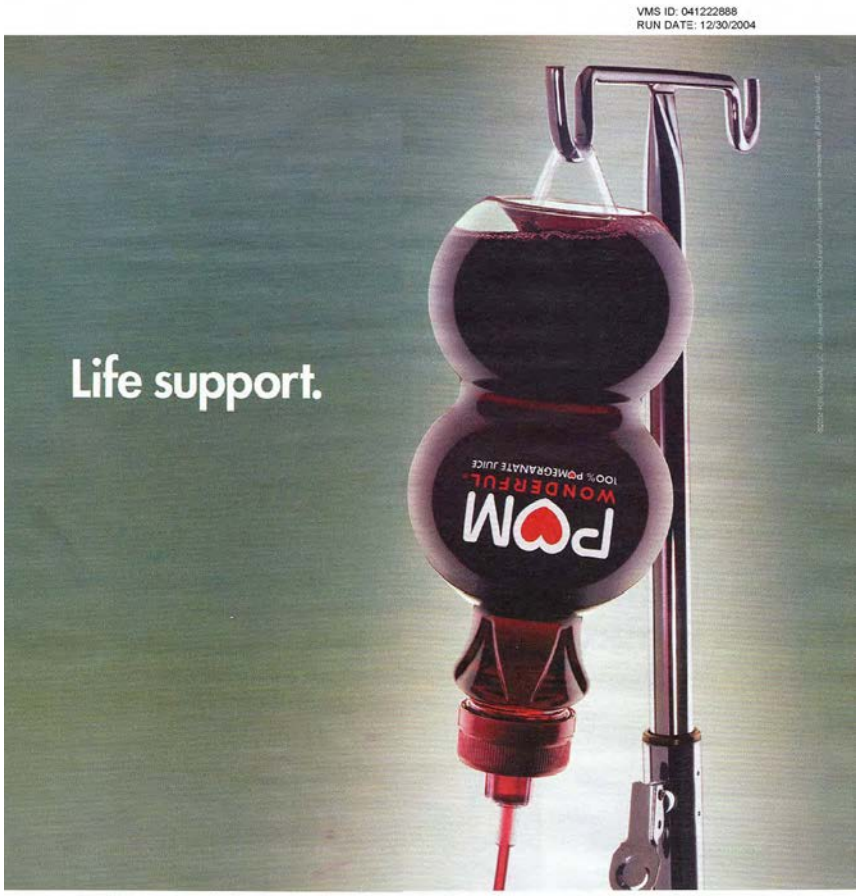
Opinion of the Commission

APPENDIX B
Figure 4

VMS-0000212

CX0031_0001

APPENDIX B
Figure 5



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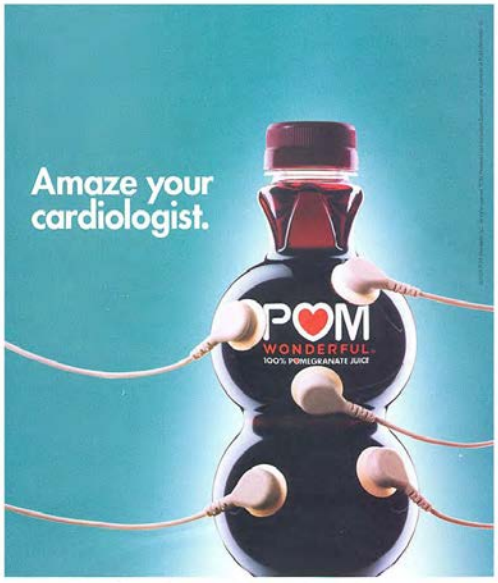
Opinion of the Commission

APPENDIX B
Figure 6

VMS ID: 050220377
RUN DATE: 02/01/2005



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

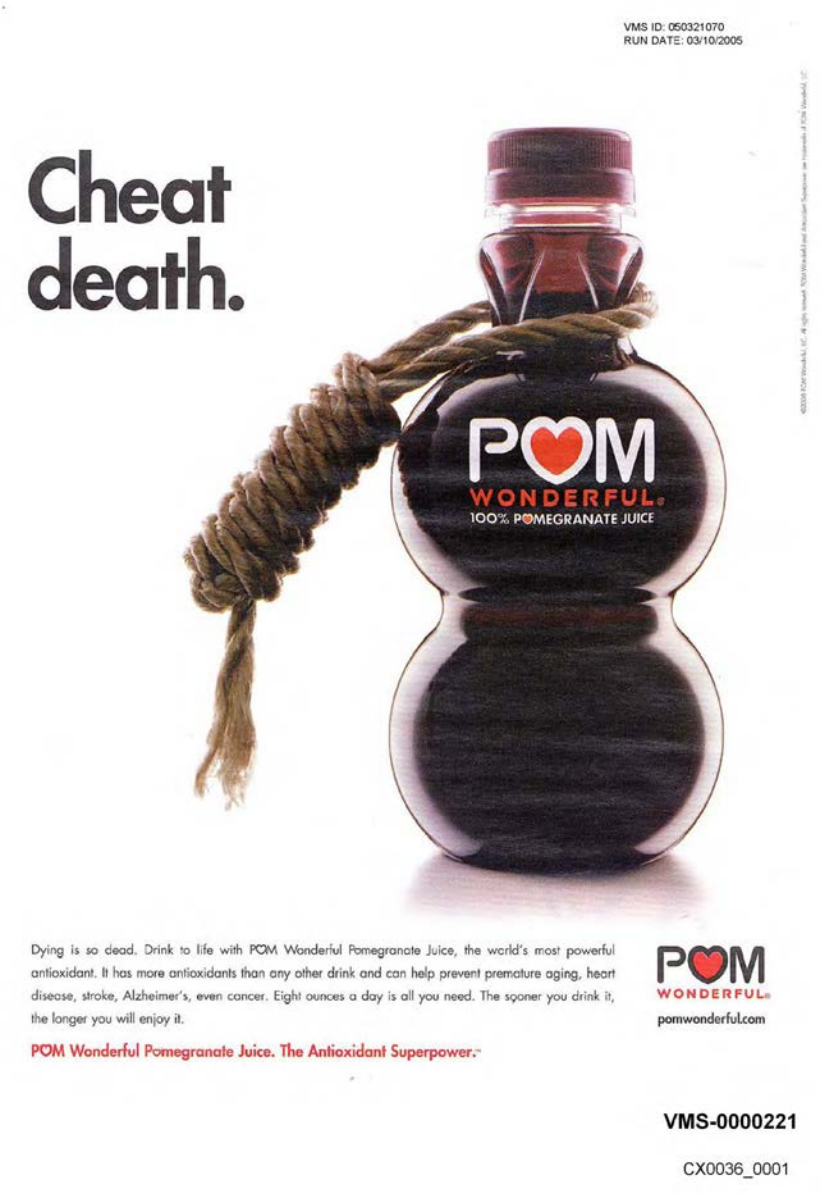
POM Wonderful Pomegranate Juice. The Antioxidant Superpower.*

POM WONDERFUL
pomwonderful.com

VMS-0000219

CX0034_0001

APPENDIX B
Figure 7



Opinion of the Commission

APPENDIX B
Figure 8

Pomegranate Juice May Affect the Progression of Coronary Heart Disease

LOS ANGELES--(BUSINESS WIRE)--Sept. 16, 2005--Men and women with coronary heart disease who drink one glass of pomegranate juice daily may improve blood flow to their heart, according to a new study.

This research is the first randomized, double-blind, placebo-controlled trial showing that pomegranate juice may affect the progression of coronary heart disease, which is the #1 cause of death in the U.S. and in most of the world. Promising results from this research will be published in the September 16th issue of the American Journal of Cardiology, one of the leading peer-reviewed cardiology journals (www.ajconline.org).

Researchers from the non-profit Preventive Medicine Research Institute, University of California, San Francisco, and California Pacific Medical Center studied patients with coronary heart disease who had reduced blood flow to the heart. These 45 patients were randomly assigned into one of two groups: one group who drank a glass of pomegranate juice each day (240 ml/day, which is approximately 8.5 oz/day) or to a placebo group, who drank a beverage of similar caloric content, amount, flavor and color.

After only three months, blood flow to the heart improved approximately 17% in the pomegranate juice group but worsened approximately 18% in the comparison group (i.e., a 35% relative between-group difference). These differences were statistically significant. This benefit was observed without changes in cardiac medications or revascularization in either group. Also, there were no negative

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effects on lipids, blood glucose, hemoglobin A1c, body weight or blood pressure.

Pomegranate juice is rich in polyphenols and other naturally-occurring antioxidants. It demonstrates high capability in scavenging free radicals and inhibiting low-density lipoprotein oxidation in vitro and in vivo. Other studies have shown that pomegranate juice has a number of important health benefits.

"Although the sample in this study was relatively small, the strength of the design and the significant improvements in blood flow to the heart observed after only three months suggest that pomegranate juice may have important clinical benefits in those with coronary heart disease," said senior author, Dean Ornish, M.D., who is founder of the Preventive Medicine Research Institute and clinical professor of medicine at UCSF. "Also, it may help to prevent it."

Pomegranate juice from POM Wonderful was used in this study.

About POM Wonderful

POM Wonderful is the largest producer of California Wonderful pomegranates, and the company exclusively grows and sells this variety. POM Wonderful's pomegranates are grown in Central California, in the sunny San Joaquin Valley. Known for its exquisite sweet flavor, health benefits, large size and plentiful juice, the Wonderful variety is popular with consumers throughout the country. POM Wonderful's pomegranates promise consistent quality. POM Wonderful prides itself on the quality of its farming operation, the sensitivity with which the fruit is hand picked and carried to their sorting and modern juicing facilities, and ultimately delivered to your table. Only fruit that meets the company's strict quality standards appears in store produce sections.

The company also juices its fresh pomegranates to make its delicious, all-natural, POM Wonderful pomegranate juice. POM Wonderful pomegranate juice is available year-round at retail and is found in the refrigerated section of supermarkets and grocery stores nationwide. POM Wonderful pomegranate juice is available in five flavors: POM 100% Pomegranate, POM Cherry, POM Blueberry, POM Tangerine and POM Mango. Each flavor of POM Wonderful pomegranate juice is all-natural, preservative-free and has no added sugar.

POM Wonderful's mission is to educate consumers about the pomegranate's splendor and versatility as well as its refreshing taste and health benefits. To learn more, visit http://www.pomwonderful.com.

POM Wonderful is a registered trademark of POM Wonderful LLC.

Note to Editors: Interviews with Dr. Dean Ornish, Senior Author, are available upon request.

Contacts

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POM Wonderful

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Opinion of the Commission

APPENDIX B
Figure 9

POM WONDERFUL.

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***Note to Editors**: Interviews with medical researchers quoted are available upon request.*

POMx, a Highly Concentrated Form of Healthy Pomegranate Antioxidants, Becomes Available to Consumers for the First Time

LOS ANGELES (July 10 - 2006) – Three years after introducing consumers to the health benefits and delicious taste of the world's first refrigerated, super-premium pomegranate juice, POM Wonderful® announced today that it has developed a concentrated form of pomegranate antioxidants known as POMx. POMx, already being noted by medical researchers as an important natural ingredient, is so concentrated that only a small amount is needed to obtain an optimal level of daily antioxidants. For consumers who are not seeking additional calories and sugars, this is an important product benefit. POMx comes from the same Wonderful variety of pomegranates that are used to make POM Wonderful's healthy pomegranate juices. It also has a similar biochemical profile to pomegranate juice since both contain a diverse range of phytochemicals, of which polyphenols make up a large proportion. POMx is currently an active ingredient in POM Tea (http://pomtea.com), a refreshing, healthy, ready-to-drink iced tea that is available in retail stores nationally.

According to Michael Aviram, DSc, Professor of Biochemistry and Head Lipid Research Laboratory, Technion Faculty of Medicine and Rambam Medical Center, Haifa, Israel, who was at the forefront of the initial research on pomegranates, the research on POMx looks very promising. In 2006, Aviram led a study on POMx which was recently published (*Journal of Agriculture and Food Chemistry*, 2006 54:1928-1935). Commenting on this research, Professor Aviram remarks, "The results showed that POMx is as potent an antioxidant as pomegranate juice and just like pomegranate juice may protect against cardiovascular as well as other diseases."

1 of 4 pgs

The POMx research comes as the benefits derived from the Wonderful variety of pomegranate are, once again, being noted by the worldwide medical community. Recently, the American Association for Cancer Research published research that indicates that a daily pomegranate regimen has a positive effect for men with prostate cancer. Specifically, drinking 8 ounces of POM Wonderful pomegranate juice daily prolonged post-prostate surgery PSA doubling time from 15 to 54 months (*Clinical Cancer Research,* July 1, 2006). PSA is a protein marker for prostate cancer and the faster PSA levels increase in the blood of men after treatment, the greater their potential for dying of prostate cancer.

David Heber, MD, PhD, Professor of Medicine and Director, UCLA Center for Human Nutrition, provided additional commentary on POMx as it relates to prostate cancer. "Basic studies indicate that the effects of POMx and POM Wonderful pomegranate juice on prostate cancer are the same. The most abundant and most active ingredients in pomegranate juice are also found in POMx."

The Wonderful variety of pomegranate is a type of pomegranate rather than a brand. Just as there are different varieties of apples, oranges and grapes, there are several different varieties of pomegranates grown in the United States and in other countries. POM Wonderful's products only use extractions from the Wonderful variety of pomegranate. Of the many published peer-reviewed medical papers that speak to the health benefits of the pomegranate, most were conducted using juice or pomegranate extract from this variety of pomegranate.

About POM Wonderful

POM Wonderful is the largest grower of the Wonderful variety of pomegranate. The company exclusively grows and sells this variety because of its exquisite sweet flavor, health benefits, large size and plentiful juice. POM Wonderful's pomegranates are grown in Central California, in the sunny San Joaquin Valley. Fresh pomegranates are in season from October through January and November is National Pomegranate Month. In addition to selling the fresh fruit, the company also juices its fresh pomegranates to make POM Wonderful pomegranate juice and POMx. To learn more, visit http://www.pomwonderful.com.

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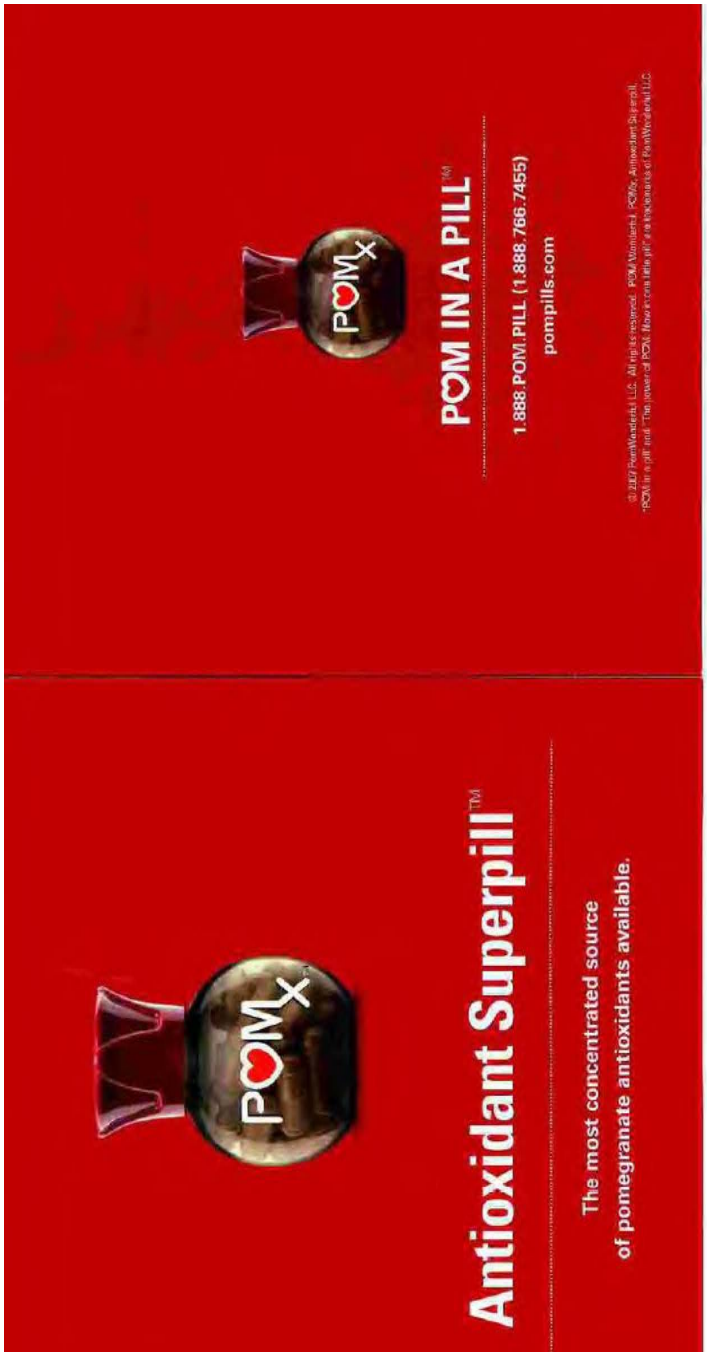
Opinion of the Commission

APPENDIX B
Figure 10



POMx™ is the first and only pomegranate antioxidant supplement reviewed for safety by the FDA.
POMx™ is a highly concentrated, incredibly powerful blend of all-natural polyphenol antioxidants made from the very same pomegranates in POM Wonderful 100% Pomegranate Juice. In fact, our method of harnessing astonishing levels of antioxidants is so extraordinary, it's patent-pending.
The power of POM. Now in one little pill.™
All of the antioxidant power of an 8oz glass of POM Wonderful 100% Pomegranate Juice is now available in the convenience of a single calorie-free pill. Take one daily.
Each bottle contains a one-month supply of 30 pills.
8oz =
POM

Opinion of the Commission

"Findings from a small study suggest that pomegranate juice may one day prove an effective weapon against prostate cancer."
The New York Times (July 4, 2006)
Prostate health.
Prostate cancer is the most commonly diagnosed cancer among men in the United States and the second-leading cause of cancer death in men after lung cancer.[1]
Time pill.
Stable levels of prostate-specific antigens (or PSA levels) are critical for men with prostate cancer. Patients with quick PSA doubling times are more likely to die from their cancer.[2] According to a UCLA study of 46 men age 65 to 70 with advanced prostate cancer, drinking an 8oz glass of POM Wonderful 100% Pomegranate Juice every day slowed their PSA doubling time by nearly 350%.[3]
83% of those who participated in the study showed a significant decrease in their cancer regrowth rate.[3]
One small pill for mankind.
New studies are under way to fu
investigate the possibilities of PO
Wonderful pomegranate antioxi
and their potential ability to slov
rise of PSA levels in patients wit
prostate cancer.
To learn more, visit pompills.com/resear
"The most abundant and most active ingredient in pomegranate juice are also found in POMx. Basic studies indicate that POMx and POM Wonderful Pomegranate Juice may have the same effects on prostate health."
David Heber, MD, PhD, Professor of Medicine and Director, UCLA Center for Human Nutrition
These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.
[1]American Cancer Society [2]vitl/Signer Newsletter, UCLA Healthcare, April 2007 [3]pompills.com/research [4]Data on file
POM WONDERFUL
100% POMEGRANATE JUICE
POMx

Opinion of the Commission

has been proven to promote cardiovascular health, and we believe that POMx may have the same health benefits."

Dr. Michael Aviram, Lipid Research Laboratory, Technion Faculty of Medicine, Haifa, Israel

t health.

groundbreaking preliminary
s, patients who drank POM
rful 100% Pomegranate Juice
enced impressive
vascular results. A pilot study
Rambam Medical Center in
included 19 patients with
sclerosis (clogged arteries).
year, arterial plaque
ased 30% for those patients
onsumed 8oz of POM
rful 100% Pomegranate
daily.[2]

An additional study at the University of California, San Francisco included 45 patients with impaired blood flow to the heart. Patients who consumed 8oz of POM Wonderful 100% Pomegranate Juice daily for three months experienced a 17% improvement in blood flow.[3] Initial studies on POMx share similar promise for heart health, and our research continues.

Fig. 1 THE HEART

The POMx Difference

Ultra-Potent:

- 1000mg of natural pomegranate polyphenol extract in every pill
- More antioxidants than any other pomegranate supplement
- One POMx pill = the antioxidant power of 8oz of POM Wonderful 100% Pomegranate Juice
- Your daily antioxidants in a single pill
- A full spectrum of pomegranate polyphenol antioxidants

Natural:

- Made from pomegranates and nothing else
- No synthetic or other antioxidants added
- No sugar, artificial colors or preservatives
- Calorie-free, vegan, kosho

Science, Not Fiction

- Made from the only pomegranates backed by 1 million in medical researd the POM Wonderful brand
- Promotes heart and prostate health
- Guards your body against free radicals[4]
- Proven to be easily absorb
- Clinically tested on adults[5]

To access the original published studies mentioned, visit pomwills.com/research.

APPENDIX B
Figure 11

VMS ID: 070320792
RUN DATE: 03/01/2007

Amaze your cardiologist. Drink POM Wonderful Pomegranate Juice. It helps guard your body against free radicals, unstable molecules that emerging science suggests aggressively destroy and weaken healthy cells in your body and contribute to disease. POM Wonderful Pomegranate Juice is supported by $20 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. Keep your ticker ticking and drink 8 ounces a day.

POM Wonderful Pomegranate Juice. The Antioxidant Superpower.™

POM WONDERFUL
pomwonderful.com

VMS-0000242

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Opinion of the Commission

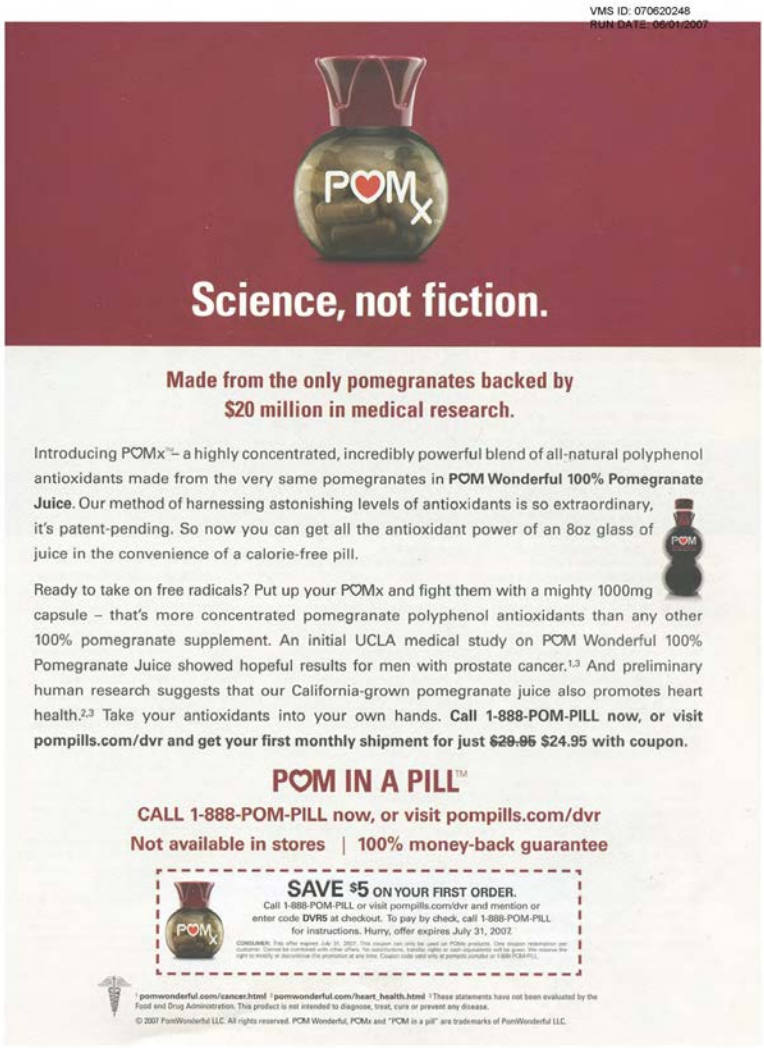
APPENDIX B
Figure 12

APPENDIX B
Figure 13

VMS-0000246

CX0120_0001

APPENDIX B
Figure 14



VMS-0000247

CX0122_0001

APPENDIX B
Figure 15

POM WONDERFUL

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pholmgren@pomwonderful.com

***Note to Editors**: Interviews with medical researcher quoted are available upon request.*

POM Wonderful 100% Pomegranate Juice May Improve Mild to Moderate Cases of Erectile Dysfunction, Study Finds

Research shows 8 ounces a day of POM Wonderful 100% Pomegranate Juice may help the management of erectile dysfunction

LOS ANGELES (June 27 - 2007) – According to a pilot study released in the *International Journal of Impotence Research* (http://www.nature.com/ijir), POM Wonderful 100% Pomegranate Juice was found to have beneficial effects on erectile dysfunction (ED), a disorder that affects 1 in 10 men worldwide and 10 to 30 million men in the United States alone [1, 2] ED can be caused by several factors, including arterial plaque, high blood pressure, heart disease, diabetes, nerve damage, endocrine imbalance or depression. Ultimately, ED is a condition that affects the blood flow to the penis during sexual stimulation.

This randomized, placebo-controlled, double-blind, crossover pilot study examined the efficacy of pomegranate juice versus placebo in improving erections in 61 male subjects. To qualify, participants had to experience mild to moderate ED for at least 3 months; be in a stable, monogamous relationship with a consenting female partner; and be willing to attempt sexual intercourse on at least one occasion per week during each study period.

Mild ED is defined as the mildly decreased ability to get and keep an erection, while moderate ED is the moderately decreased ability to get and keep an erection. The majority of men with ED have moderate ED.

For the first four weeks of the study, the subjects were assigned to drink either 8 oz. of POM Wonderful Pomegranate Juice or 8 oz. of placebo beverage daily with their evening

Opinion of the Commission

meal or shortly after. After a two-week washout period during which the subjects did not consume any study beverage nor utilize any ED treatment, they were assigned to drink 8 oz. of the opposite study beverage every evening for another four weeks. At the end of the each four week period, efficacy was assessed using the International Index of Erectile Function (IIEF) and Global Assessment Questionnaires (GAQ). The IIEF is a validated questionnaire that has been demonstrated to correlate with ED intensity. The GAQ elicits the patient's self-evaluation of the study beverages' effect on erectile activity.

Forty seven percent of the subjects reported that their erections improved with POM Wonderful Pomegranate Juice, while only 32% reported improved erections with the placebo ($p=0.058$). These results compare favorably to a recent 24-week study using a PDE5 inhibitor (such as Cialis), in which roughly 73% of subjects reported a benefit from the PDE5 inhibitor and 26% reported a "placebo effect" (i.e. experiencing improvement while on the placebo).[3]

Although the study did not achieve overall statistical significance, the authors conclude that additional studies with more patients and longer treatment periods may in fact reach statistical significance. The strong directional results of this pilot study are encouraging because almost half of the test subjects experienced a benefit simply by adding pomegranate juice to their daily diet, without the use of ED drugs.

Researchers believe that the results might be due to the potent antioxidant content of pomegranate juice, which can prevent free radical molecules from disrupting proper circulatory function. In several previously published medical studies, pomegranate juice has been shown to enhance blood flow and to slow or reverse arterial plaque growth.[4,5,6] Because an erection requires significant blood flow, these potent pomegranate antioxidants may provide benefit by mitigating arterial plaque and promoting blood vessel dilation.

According to study co-author Harin Padma-Nathan, MD, FACS, FRCS, Clinical Professor of Urology at the Keck School of Medicine, University of Southern California, "These findings are very encouraging as they suggest there is a non-invasive, non-drug way to potentially alleviate this quality of life issue that affects so many men. For men with ED, it is important to

maintain a healthy diet and exercise. Drinking pomegranate juice daily could be an important addition to the diet in the management of this condition."

About POM Wonderful

POM Wonderful is the largest producer of California Wonderful pomegranates and the company exclusively grows and sells this variety. POM Wonderful's pomegranates grow in central California, in the sunny San Joaquin Valley. Fresh pomegranates are in season from October through January and November is National Pomegranate Month.

The company also uses its fresh pomegranates to make its delicious, all-natural, POM Wonderful Pomegranate Juice and POMx, a highly-concentrated blend of all-natural polyphenol antioxidants harnessed from the pomegranate by a patent-pending process. POMx is found exclusively in POM Tea, POMx Pills and POMx Liquid.

POM Wonderful Pomegranate Juice and POM Tea are available year-round at retail and are found in the refrigerated section of supermarkets nationwide. POMx Pills and POMx liquid are available at http://www.pompills.com. To learn more, visit http://www.pomwonderful.com.

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6 Sumner MD, Elliot-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. *American Journal of Cardiology* 2005, 96: 810-814.

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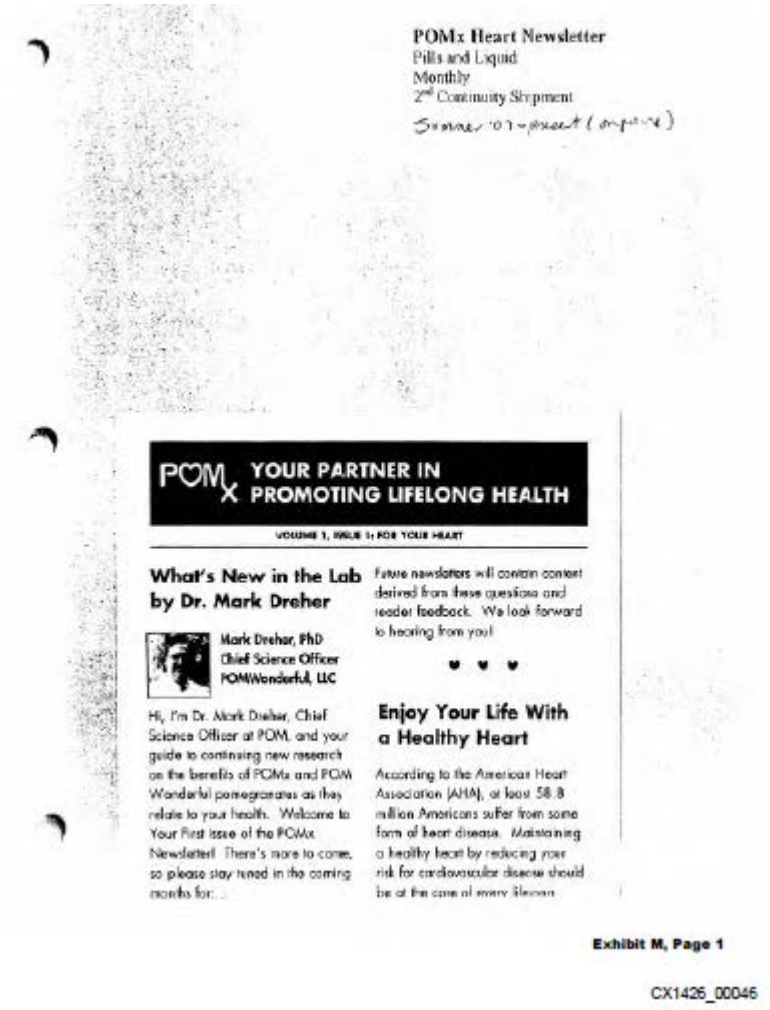
APPENDIX B
Figure 16



POMx Heart Newsletter
Pills and Liquid
Monthly
2nd Continuity Shipment
Summer '01 - present (on-going)

POMx YOUR PARTNER IN PROMOTING LIFELONG HEALTH

VOLUME 1, ISSUE 1: FOR YOUR HEART

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

Mark Dreher, PhD
Chief Science Officer
POMWonderful, LLC

Hi, I'm Dr. Mark Dreher, Chief Science Officer at POM, and your guide to continuing new research on the benefits of POMx and POM Wonderful pomegranates as they relate to your health. Welcome to Your First issue of the POMx Newsletter! There's more to come, so please stay tuned in the coming months for: ...

Future newsletters will contain content derived from these questions and reader feedback. We look forward to hearing from you!

♥ ♥ ♥

Enjoy Your Life With a Healthy Heart

According to the American Heart Association (AHA), at least 58.8 million Americans suffer from some form of heart disease. Maintaining a healthy heart by reducing your risk for cardiovascular disease should be at the core of every lifestyle ...

Exhibit M, Page 1

CX1426_00046

POM YOUR PARTNER IN PROMOTING LIFELONG HEALTH

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

Enjoy Your Life With a Healthy Heart

Did You Know?

Exhibit M, Page 2

CX1426_0004

Opinion of the Commission

The antioxidants in POMx are supported by $20 million in initial scientific research

POMx supplements your diet without adding calories, allowing you to more easily maintain a healthy weight while still getting the necessary antioxidants

Exhibit M, Page 3

CX1426_00048

APPENDIX B
Figure 17

POMx Prostate Newsletter
Pills and Liquid
Monthly
3rd Continuity Shipment
Fall '07 - present (approx.)

POMx YOUR PARTNER IN PROMOTING LIFELONG HEALTH

VOLUME 1, ISSUE 2: PROSTATE HEALTH

Prostate Cancer Affects 1 Out of Every 6 Men

Prostate cancer is the second leading cause of cancer related death in men in the United States according to the National Cancer Institute. Prostate cancer incidence rates rose dramatically in the late1980's with improved detection and diagnosis through widespread use of prostate-specific antigen (PSA) testing.

Prostate cancer is the second leading cause of

fruits and vegetables. Doctors are not sure which of these factors causes the risk to go up but the best advice is to consume daily the equivalent of five or

(continued on back)

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

Mark Dreher, PhD
Chief Science Officer
POMWonderful, LLC

Research studies like the ones discussed in this newsletter and

Exhibit N, Page 1

CX1426_00049

Opinion of the Commission

POM YOUR PARTNER IN PROMOTING LIFELONG HEALTH

Prostate Cancer Affects 1 Out of Every 6 Men

Prostate cancer is the second leading cause of cancer related death in men in the United States according to the National Cancer Institute. Prostate cancer incidence rates rose dramatically in the late 1980's with improved detection and diagnosis through widespread use of prostate-specific antigen (PSA) testing.

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

Since the early 1990's, prostate cancer incidence and deaths have been declining, but the American Cancer Society estimates that there will still be about 219,000 new cases of prostate cancer and 27,000 deaths in the United States in 2007.

According to the American Cancer Society, some of the risk factors for prostate cancer include:

Age – Growing older raises a man's risk of prostate cancer. About two of every three prostate cancers are found in men over the age of 65.

Family History – Men with close family members (father or brother) who have had prostate cancer are more likely to get it themselves, especially if their relatives were young when they got the disease.

Diet – One risk factor that can be changed is diet. The National Cancer Institute's research suggest that obesity and weight gain is linked to increased prostate cancer mortality.

Men who eat a lot of red meat or high-fat dairy products seem to have a greater chance of getting prostate cancer. These men also tend to eat fewer fruits and vegetables. Doctors are not sure which of these factors causes the risk to go up but the best advice is to consume daily the equivalent of five or

(continued on back)

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

Mark Dreher, PhD
Chief Science Officer
POMWonderful, LLC

Research studies like the ones discussed in this newsletter and conducted by UCLA (my alma mater) serve to validate the many reasons I am proud to be affiliated with POM Wonderful and POMx.

POM Wonderful 100% Pomegranate Juice and POMx are backed by a $13 million dollar investment in world-class scientific research. This includes ten clinical studies published in top, peer-reviewed medical journals that document the pomegranate's antioxidant health benefits such as heart and prostate health.

Working at POM Wonderful gives me the unique opportunity to really make a difference in the world. That's what gets me up every morning! I get to work with renowned scientist, including a Nobel laureate, at leading

Studies funded by POM represent the vast majority of medical research ever conducted on pomegranates.

universities around the world. In fact, studies funded by POM represent the vast majority of human medical research ever conducted on pomegranates. No other company that I know of is as dedicated as POM in pursuing the truth and keeping our customers informed.

At POM Wonderful, we aim to be your partner in the promotion of good health that lasts a lifetime. It is our commitment to you, our mission in a summary.

Exhibit N, Page 2

CX1426_00050

Patients with prostate cancer showed a prolongation of PSA doubling time, coupled with corresponding lab effects on reduced prostate cancer as well as reduced oxidated stress.

According to Dr. Dr. Dr. Director of UCLA's Center for Human Nutrition, "The most abundant and most active ingredients in pomegranate juice are also found in POMx. Basic studies in our laboratory as far indicate that POMx and pomegranate juice may have the same effects."

SEND US YOUR QUESTIONS AND COMMENTS

HOW DOES POMWONDERFUL COMPARE WITH OTHER POMEGRANATE SUPPLEMENTS AND COMMERCIALS?

How does POMx compare with other pomegranate supplements for antioxidant potency?

1.888.POMPOMS
WWW.POMPOMS.COM

Exhibit N, Page 3

CX1426_00051

Opinion of the Commission

APPENDIX B
Figure 18

VMS-0000255

CX0169_0001

New York Times Magazine
Issue: January 6th, 2008
In Home: 1/6/08

The power of POM, in one little pill.

POMx

The easy, portable, calorie-free way to get your daily antioxidants.

Antioxidant Superpill® Not all antioxidants are created equal. POMx™ fights free radicals with a mighty, knocking in every pill. That's more concentrated antioxidants than are in other pomegranate antioxidant supplement. There are antioxidants, and then there are POMx antioxidants.

Power of Mind in a Pill. POMx is a highly concentrated, powerful blend of polyphenol antioxidants made from the very same pomegranates as POM Wonderful® 100% Pomegranate Juice. The same pomegranates are grown exclusively in California, where they're harsh-pollution skin.

[illegible] pomegranates. So there are no added sugars, preservatives or any other ingredients – just 100% pomegranate polyphenol antioxidants. So naturally, POMx is absorbed safely into your body. In fact, POMx is the first and only antioxidant supplement reviewed for safety by the FDA.

Backed by Science. POMx is made from the only pomegranate supported by clinical research. Emerging science suggests that free radicals aggressively destroy healthy cells in your body – contributing to premature aging and even disease. The good news is POM Wonderful pomegranate antioxidants neutralize free radicals. An initial UCLA MEDICAL STUDY on POM Wonderful 100% Pomegranate Juice found hopeful results for prostate health. "Pomegranate juice delays PSA doubling time in humans," according to AJ Pantuck, et al, in Clinical Cancer Research, 2006.[1] Two additional preliminary studies on our juice showed promising results for heart health. "Pomegranate juice improves myocardial perfusion in coronary heart patients," per D. Dirinck, et al, in the American Journal of Cardiology, 2005.[2] "Pomegranate extract also reverses suggests anti-atherosclerotic benefits," according to M. Aviram, et al, in Clinical Nutrition, 2004.[3]

One a Day For Life. Ready to take on free radicals? A daily POMx pill is all you need. Invest in your health and order your 30-day supply today. Call now to get your first monthly shipment.

Call 1-888-POM-PILL (766-7455) or visit pompills.com/nb and enter NB30 at checkout.

Try POMx for one month – FREE!

We'll even pay for the shipping. Visit pompills.com/nb or call 1-888-POM-PILL. Use discount code: NB30

POM WONDERFUL

Exhibit L

CX1426_00045

Opinion of the Commission

APPENDIX B
Figure 19

VMS-0000261

CX0180_0001

Exhibit K

CX1426_00044

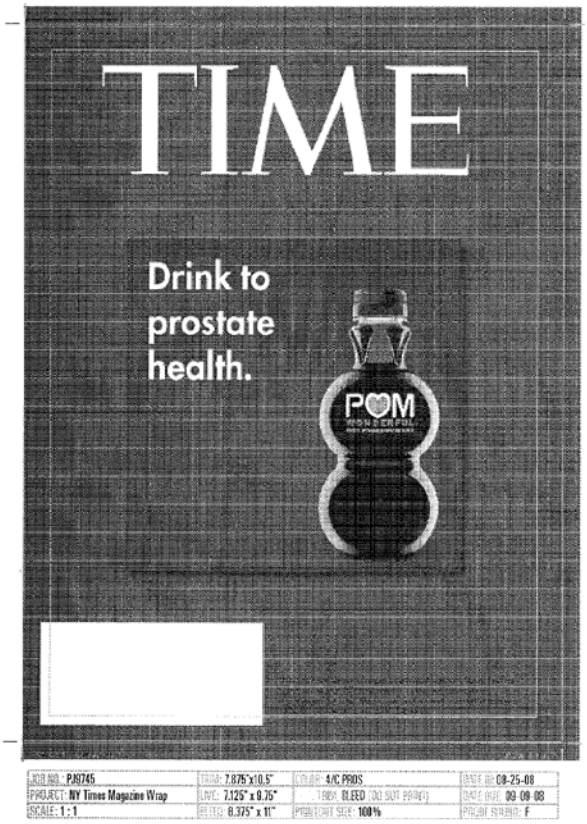
Opinion of the Commission

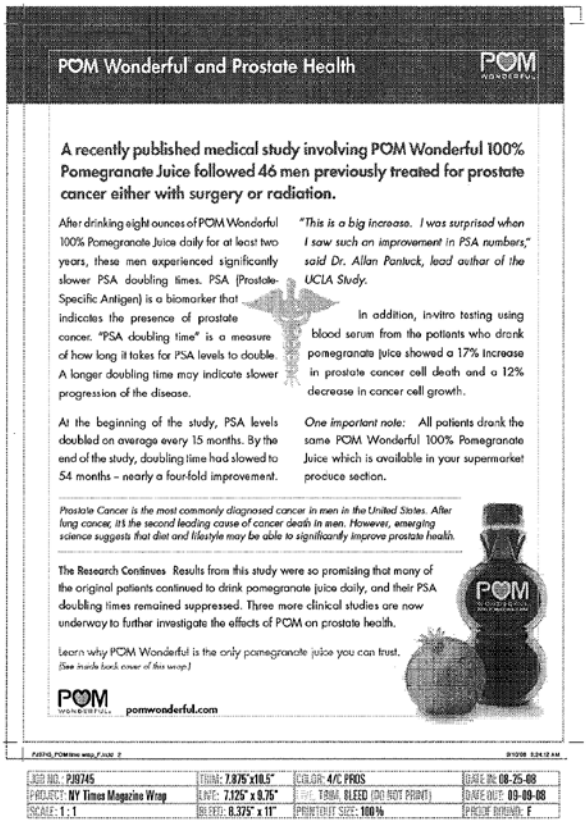
APPENDIX B
Figure 20

VMS-0000266

CX0192_0001

APPENDIX B
Figure 21





POM Wonderful and Prostate Health

POM WONDERFUL

A recently published medical study involving POM Wonderful 100% Pomegranate Juice followed 46 men previously treated for prostate cancer either with surgery or radiation.

After drinking eight ounces of POM Wonderful 100% Pomegranate Juice daily for at least two years, these men experienced significantly slower PSA doubling times. PSA (Prostate-Specific Antigen) is a biomarker that indicates the presence of prostate cancer. "PSA doubling time" is a measure of how long it takes for PSA levels to double. A longer doubling time may indicate slower progression of the disease.

At the beginning of the study, PSA levels doubled on average every 15 months. By the end of the study, doubling time had slowed to 54 months – nearly a four-fold improvement.

"This is a big increase. I was surprised when I saw such an improvement in PSA numbers," said Dr. Allan Pantuck, lead author of the UCLA Study.

In addition, in-vitro testing using blood serum from the patients who drank pomegranate juice showed a 17% increase in prostate cancer cell death and a 12% decrease in cancer cell growth.

One important note: All patients drank the same POM Wonderful 100% Pomegranate Juice which is available in your supermarket produce section.

Prostate Cancer is the most commonly diagnosed cancer in men in the United States. After lung cancer, it's the second leading cause of cancer death in men. However, emerging science suggests that diet and lifestyle may be able to significantly improve prostate health.

The Research Continues Results from this study were so promising that many of the original patients continued to drink pomegranate juice daily, and their PSA doubling times remained suppressed. Three more clinical studies are now underway to further investigate the effects of POM on prostate health.

Learn why POM Wonderful is the only pomegranate juice you can trust.
(See inside back cover of this wrap.)

POM WONDERFUL pomwonderful.com

JOB NO.: PJ9745	TRIM: 7.875"x10.5"	COLOR: 4/C PROS	DATE IN: 08-25-08
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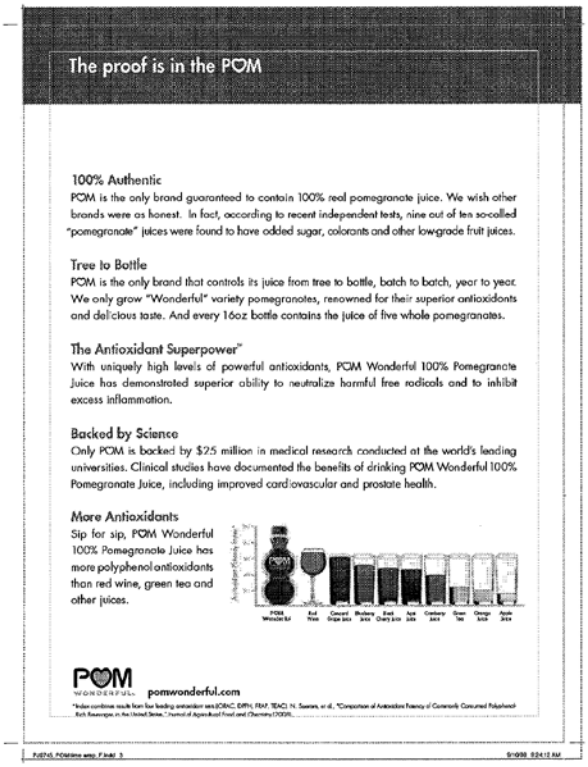

The proof is in the POM

100% Authentic
POM is the only brand guaranteed to contain 100% real pomegranate juice. We wish other brands were as honest. In fact, according to recent independent tests, nine out of ten so-called "pomegranate" juices were found to have added sugar, colorants and other low-grade fruit juices.

Tree to Bottle
POM is the only brand that controls its juice from tree to bottle, batch to batch, year to year. We only grow "Wonderful" variety pomegranates, renowned for their superior antioxidants and delicious taste. And every 16oz bottle contains the juice of five whole pomegranates.

The Antioxidant Superpower*
With uniquely high levels of powerful antioxidants, POM Wonderful 100% Pomegranate Juice has demonstrated superior ability to neutralize harmful free radicals and to inhibit excess inflammation.

Backed by Science
Only POM is backed by $25 million in medical research conducted at the world's leading universities. Clinical studies have documented the benefits of drinking POM Wonderful 100% Pomegranate Juice, including improved cardiovascular and prostate health.

More Antioxidants
Sip for sip, POM Wonderful 100% Pomegranate Juice has more polyphenol antioxidants than red wine, green tea and other juices.

POM WONDERFUL pomwonderful.com

*Index combines results from four leading antioxidant tests (ORAC, FRAP, TEAC) N. Seeram, et al., "Comparison of Antioxidant Potency of Commonly Consumed Polyphenol-Rich Beverages in the United States," Journal of Agricultural Food and Chemistry (2008).

PJ9745, POMtime wrap, F.indd 3 9/19/08 9:24:12 AM

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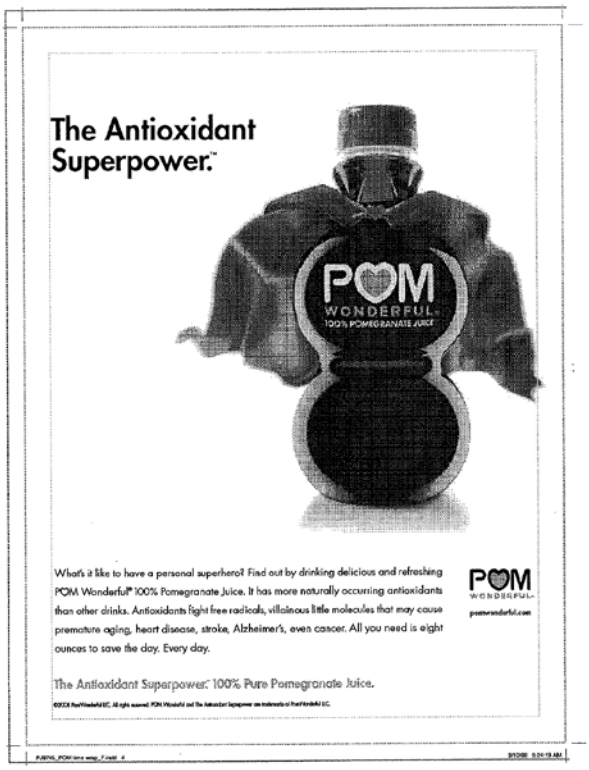

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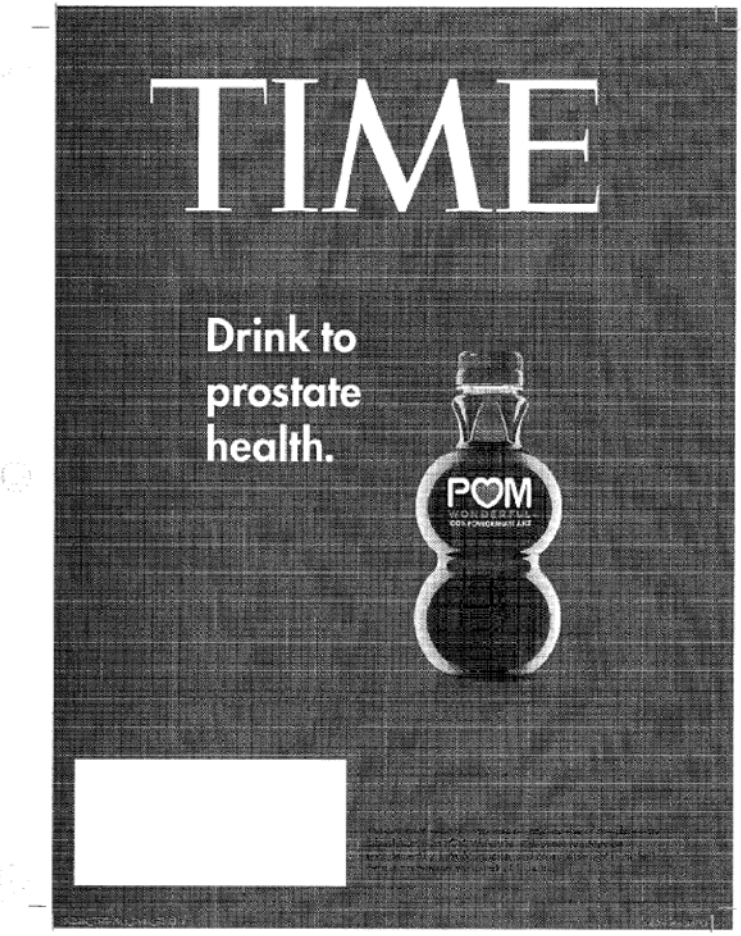

CONFIDENTIAL, SUBJECT TO A PROTECTIVE ORDER POM-OS00001570

CONFIDENTIAL-FTC Docket NO. 9344 **RESP024725**

CX0314_0007

POM Wonderful and Prostate Health

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A recently published medical study involving POM Wonderful 100% Pomegranate Juice followed 46 men previously treated for prostate cancer either with surgery or radiation.

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Learn why POM Wonderful is the only pomegranate juice you can trust.
(See inside back cover of this wrap.)

POM WONDERFUL pomwonderful.com

PJ0225_TIME-Wrap_Dec08_F.indd 2 13:03:08 5:33:02 PM

CONFIDENTIAL, SUBJECT TO A PROTECTIVE ORDER POM-OS00001571

CONFIDENTIAL-FTC Docket NO. 9344 **RESP024726**

CX0314_0008

The proof is in the POM

100% Authentic
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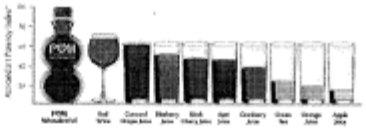


POM WONDERFUL pomwonderful.com

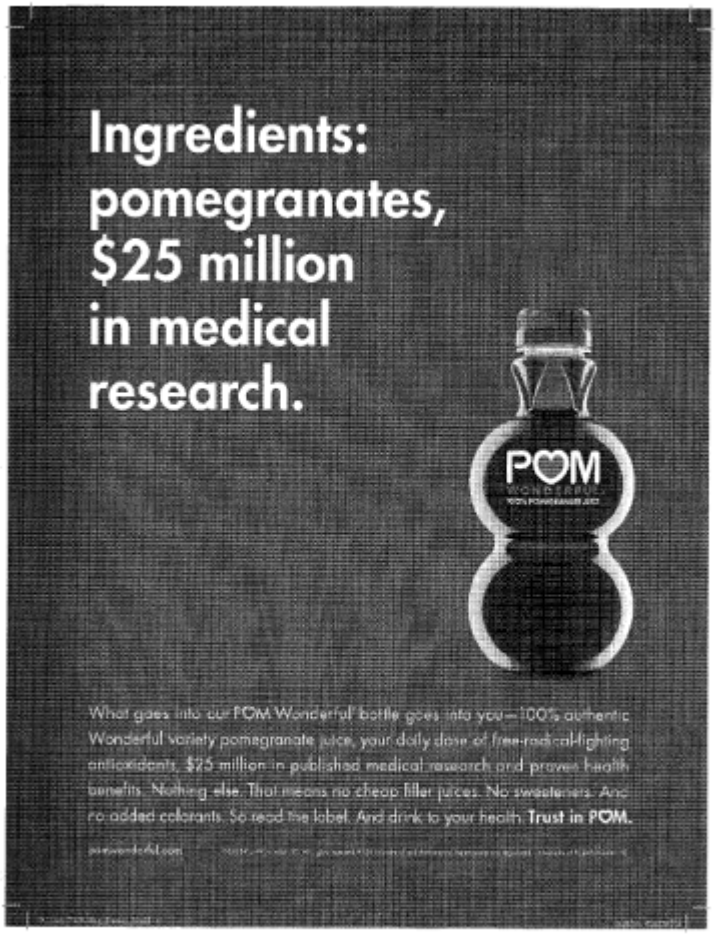
CONFIDENTIAL, SUBJECT TO A PROTECTIVE ORDER

POM-0S00001572

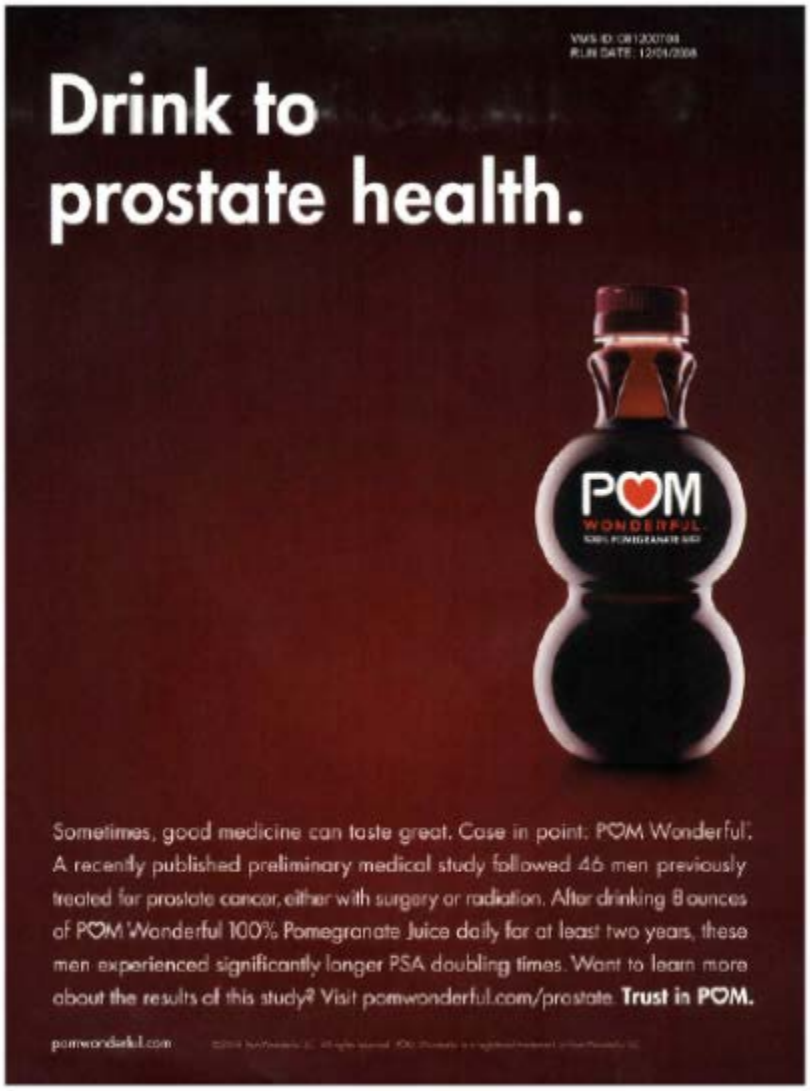
CONFIDENTIAL-FTC Docket NO. 9344

RESP024727

CX0314_0009



APPENDIX B
Figure 22



VMS-0000276

CX0260_0001

Opinion of the Commission

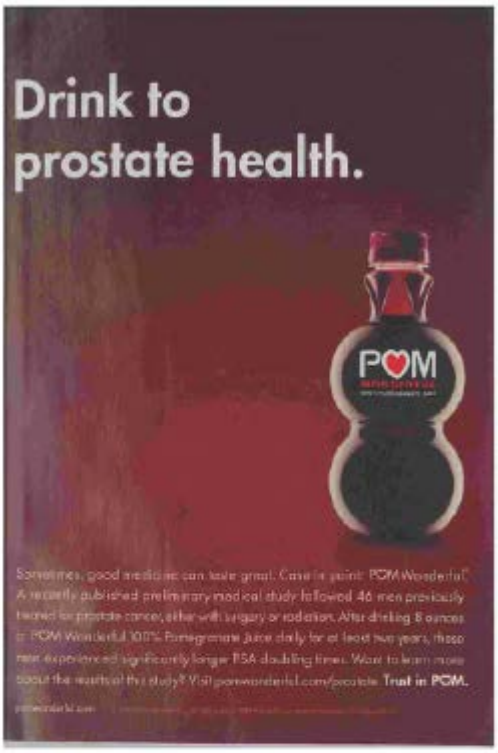
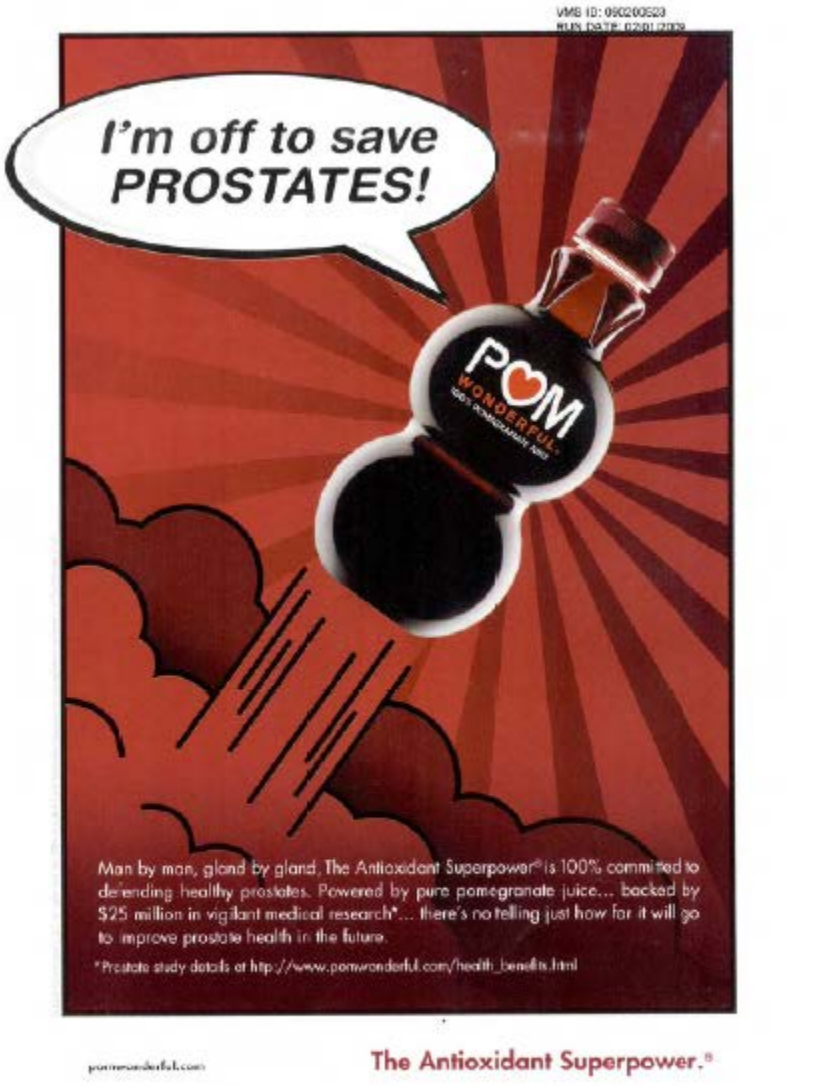


Exhibit B

CX1426_00028

APPENDIX B
Figure 23



VMS-0000281

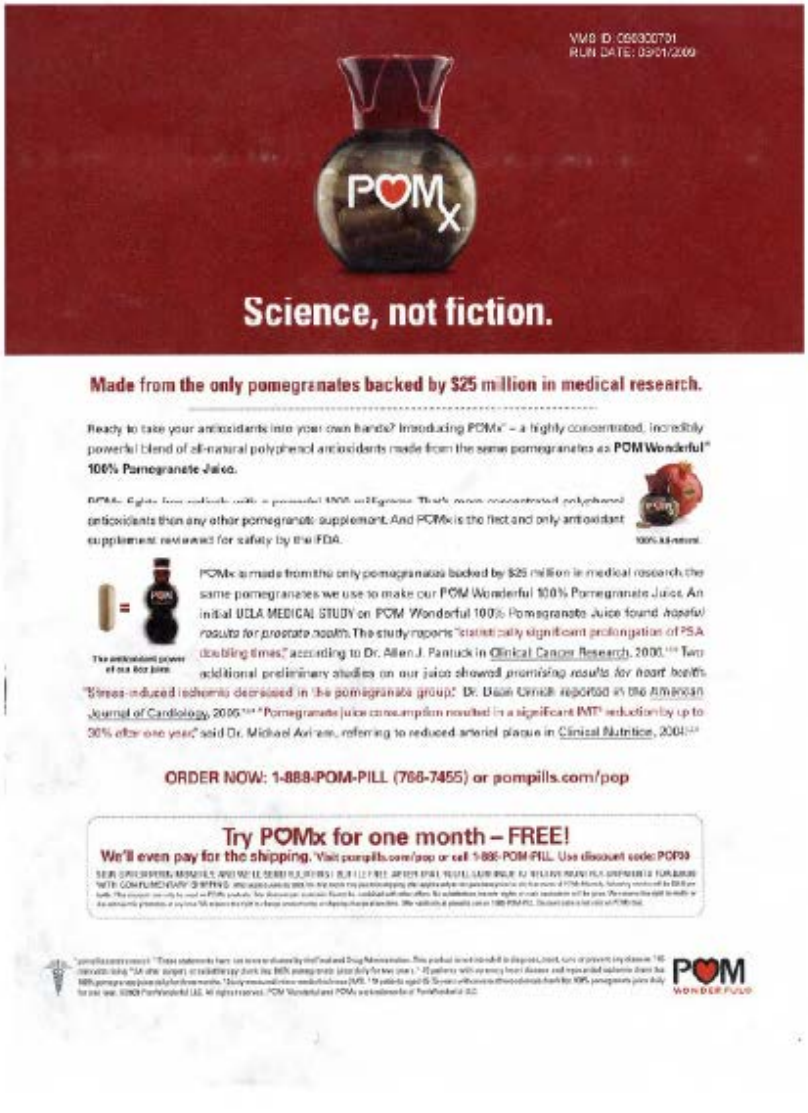
CX0274_0001

Opinion of the Commission

Exhibit C

CX1426_00029

APPENDIX B
Figure 24



VMS-0000291

CX0279_0001

Opinion of the Commission

APPENDIX B
Figure 25

VMS-0000293

CX0280_0001

APPENDIX B
Figure 26

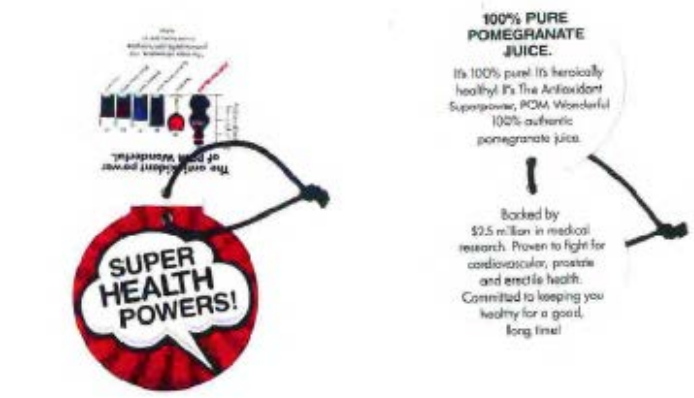
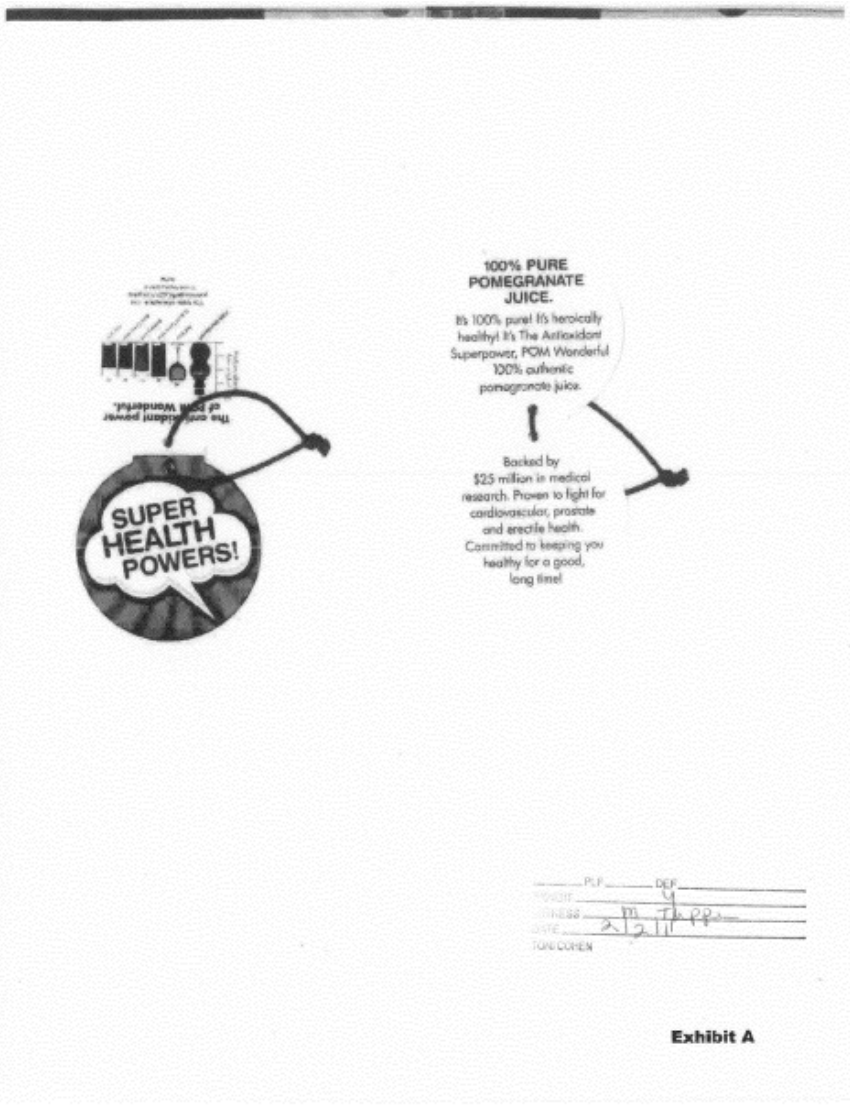


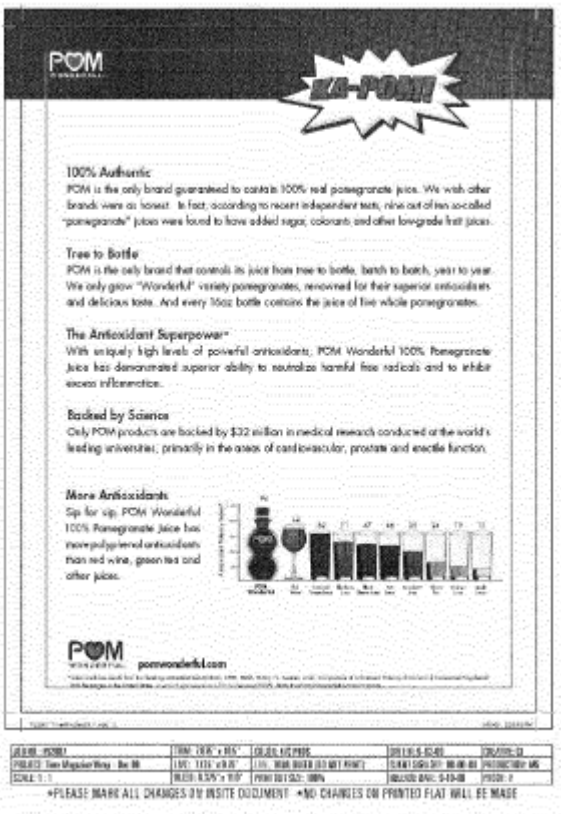
Exhibit A

CX1426_00027


SUPER HEALTH POWERS!
100% PURE POMEGRANATE JUICE.
It's 100% pure! It's heroically healthy! It's The Antioxidant Superpower, POM 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!
PLF
DEF
Exhibit A
CX0475_0001

APPENDIX B
Figure 27

Opinion of the Commission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With uniquely high levels of powerful antioxidants, POM Wonderful 100% Pomegranate Juice has demonstrated superior ability to neutralize harmful free radicals and to inhibit excess inflammation.
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POM
pomwonderful.com
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Opinion of the Commission

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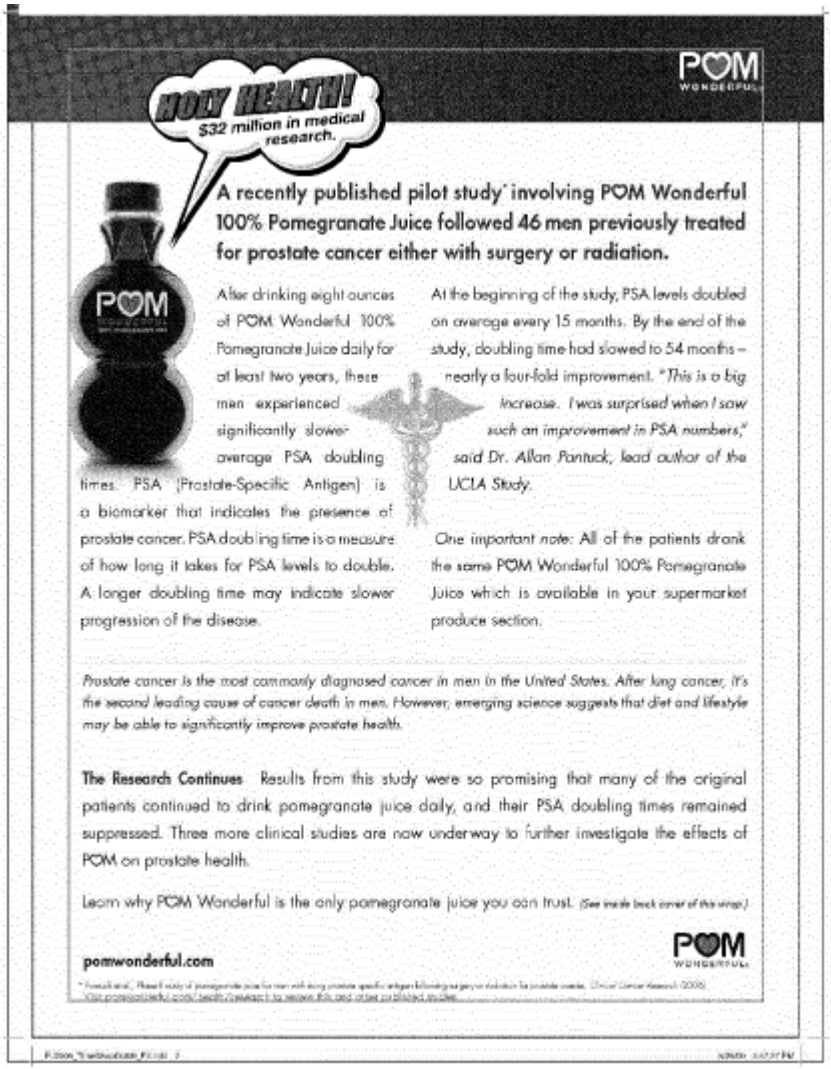
Opinion of the Commission



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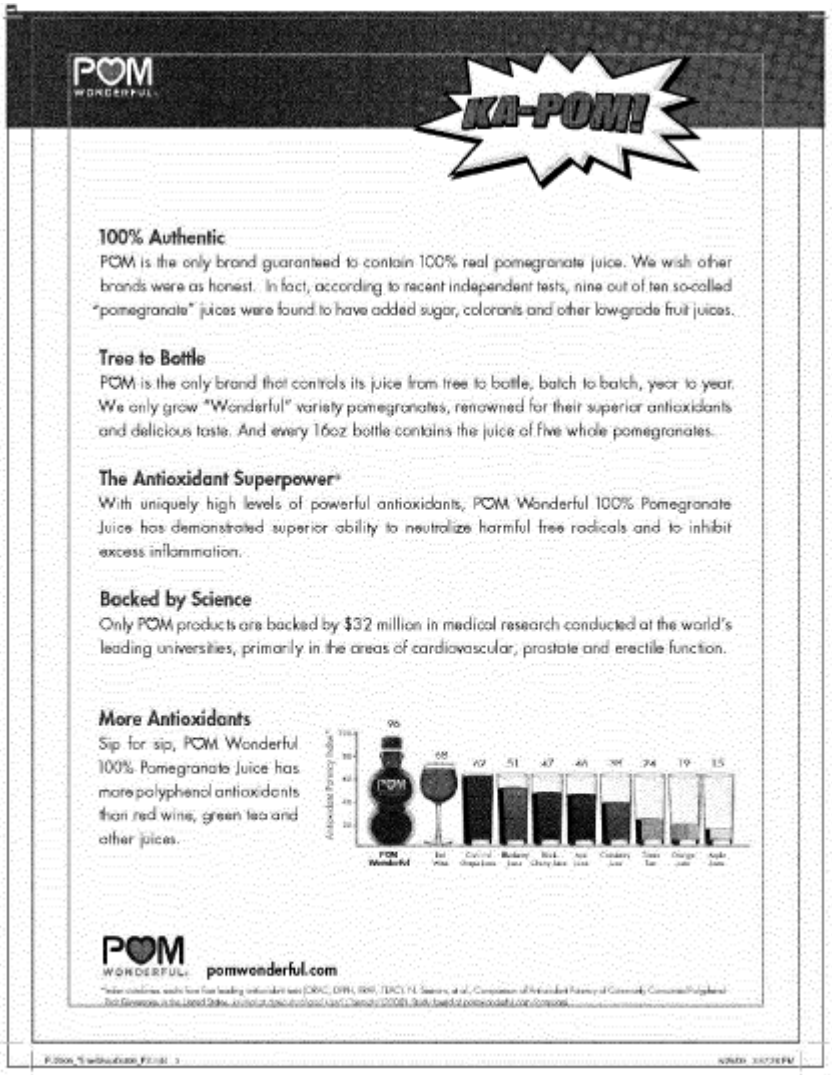

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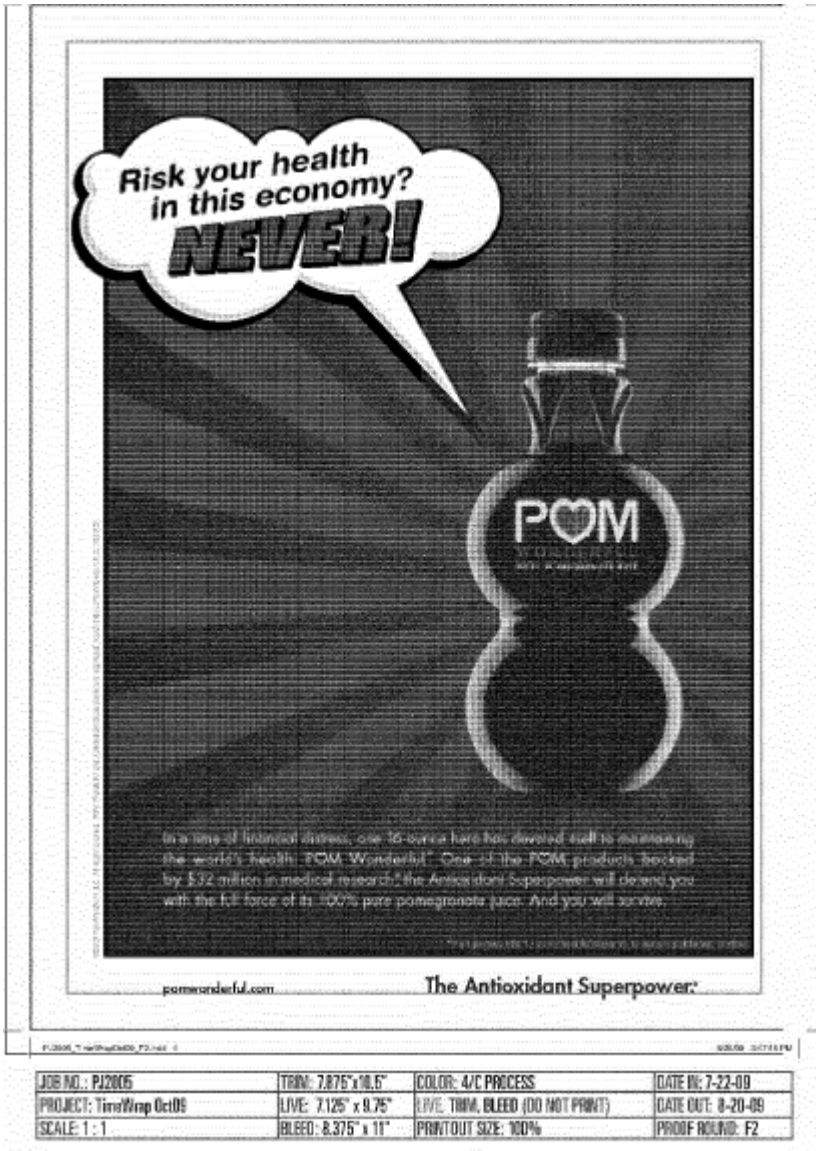
Opinion of the Commission



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SCALE: 1 : 1	BLEED: 8.375" x 11"	PRINTOUT SIZE: 100%	PROOF ROUND: F2


TIME
Lucky I have super
HEALTH POWERS!
POM
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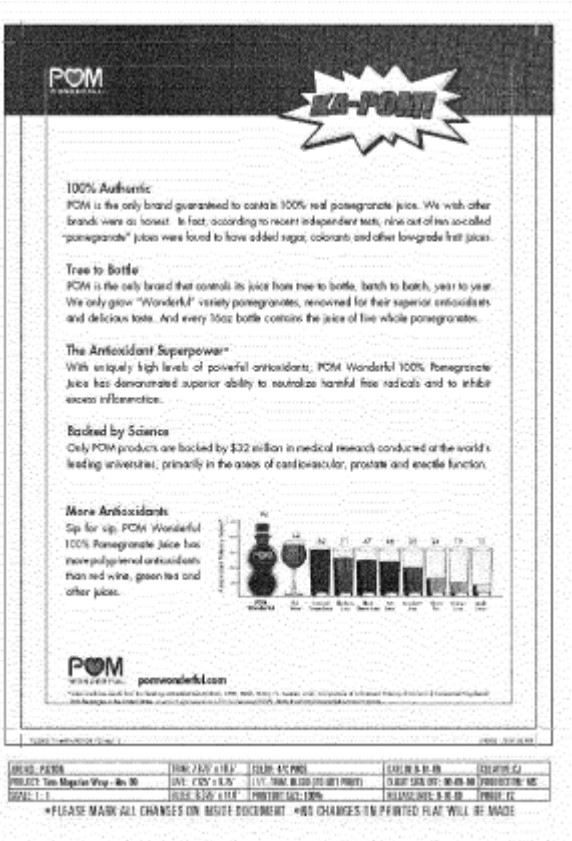
Opinion of the Commission

*PLEASE MARK ALL CHANGES ON INSIDE DOCUMENT *NO CHANGES ON PRINTED PLATE WILL BE MADE


POM
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POM
pomwonderful.com
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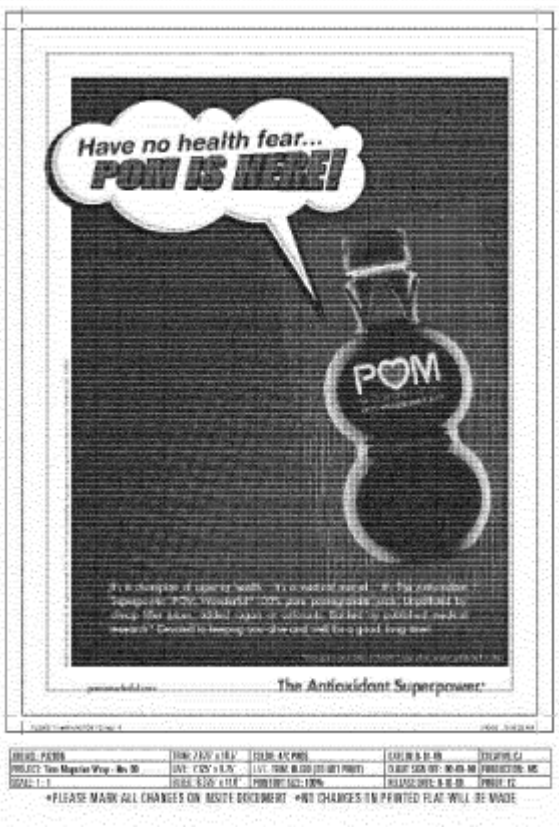
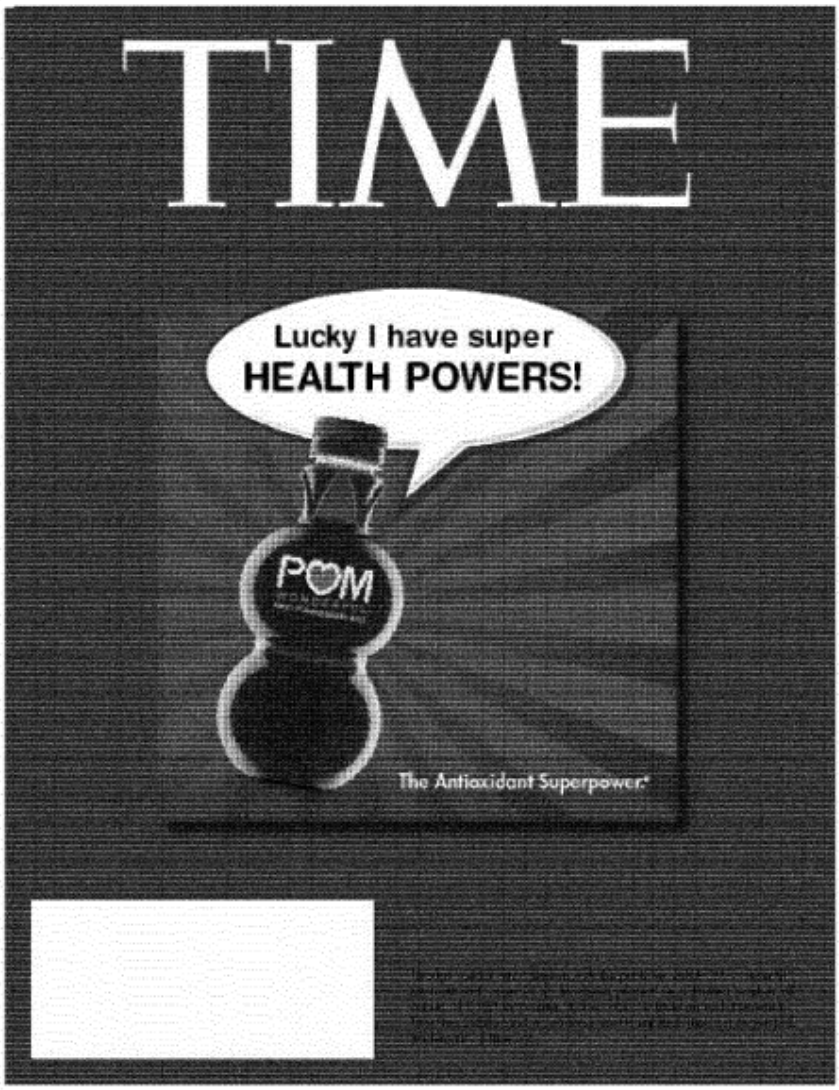
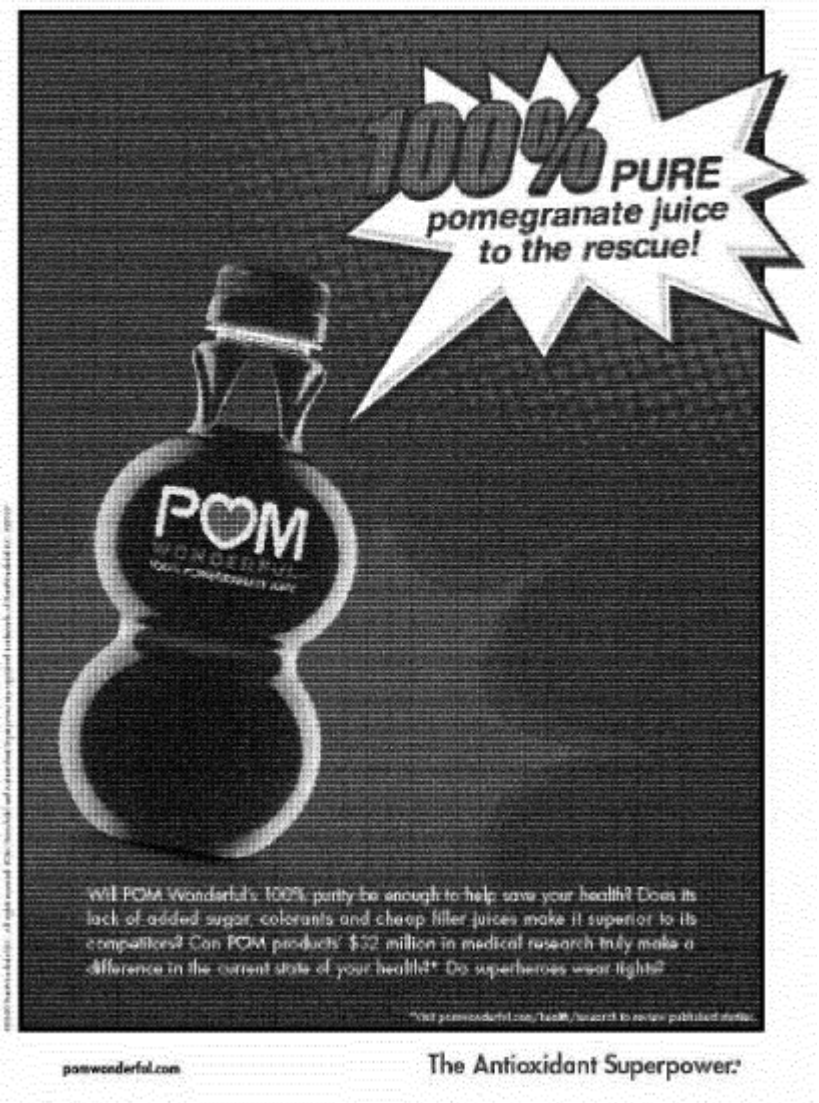


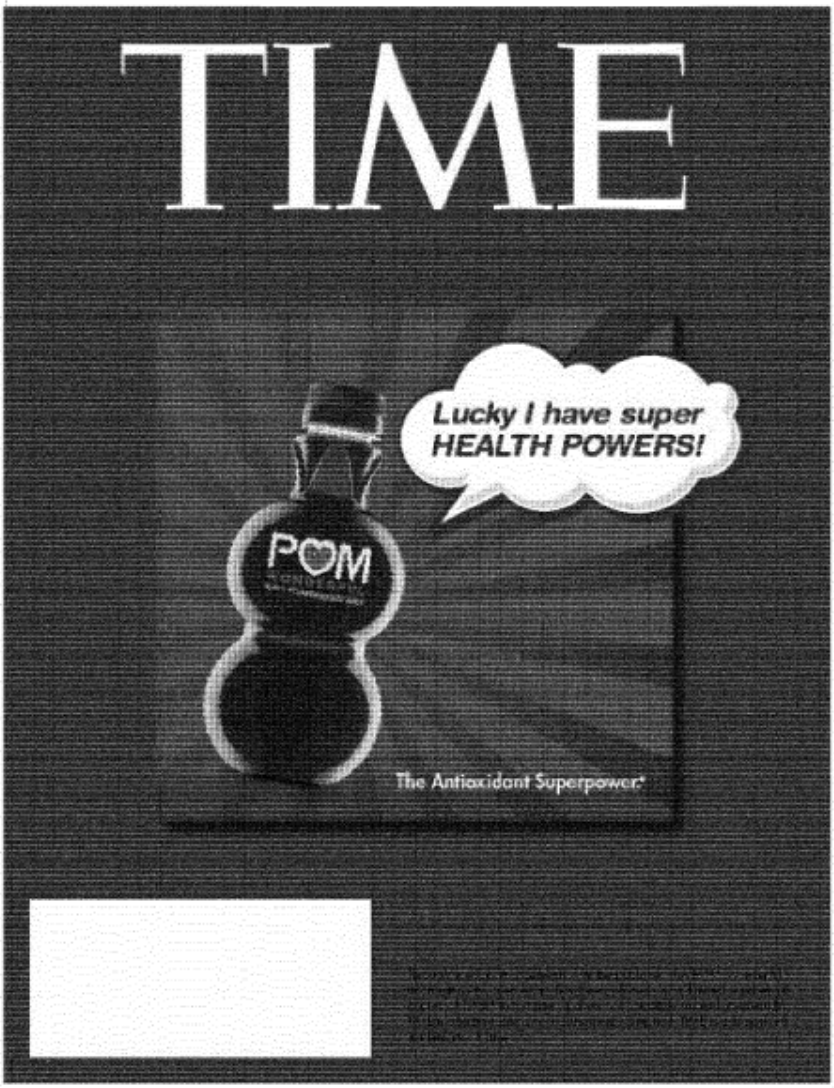


CONFIDENTIAL-FTC Docket NO. 9344 RESP023825

CX0380_0005

Opinion of the Commission





CONFIDENTIAL-FTC Docket NO. 9344 RESP023827

CX0380_0007

APPENDIX B
Figure 28

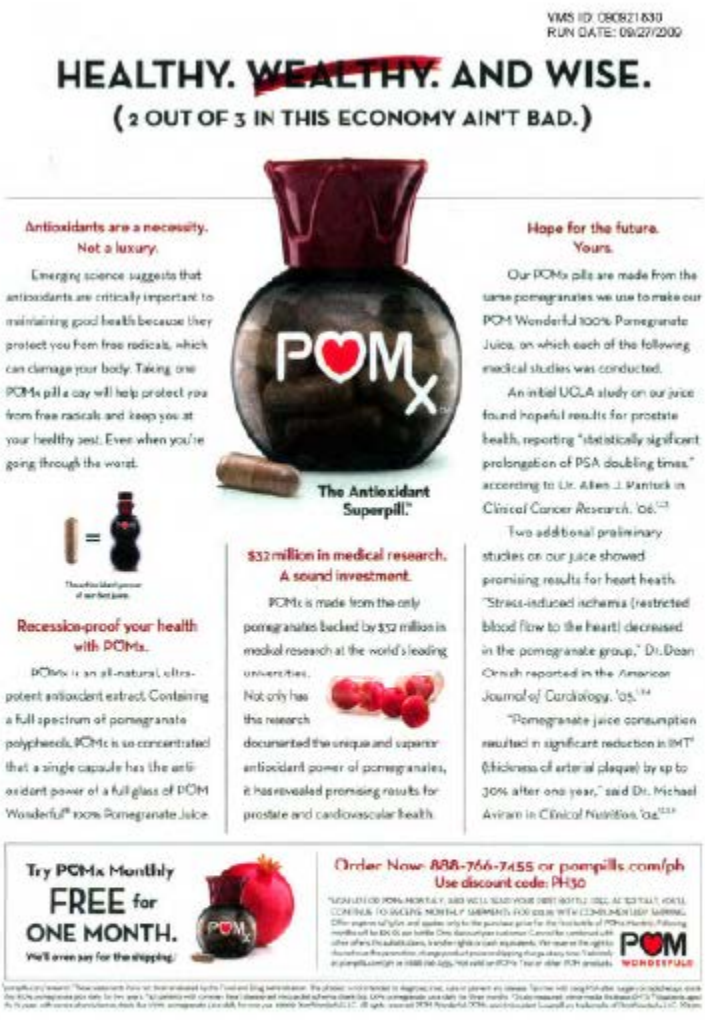


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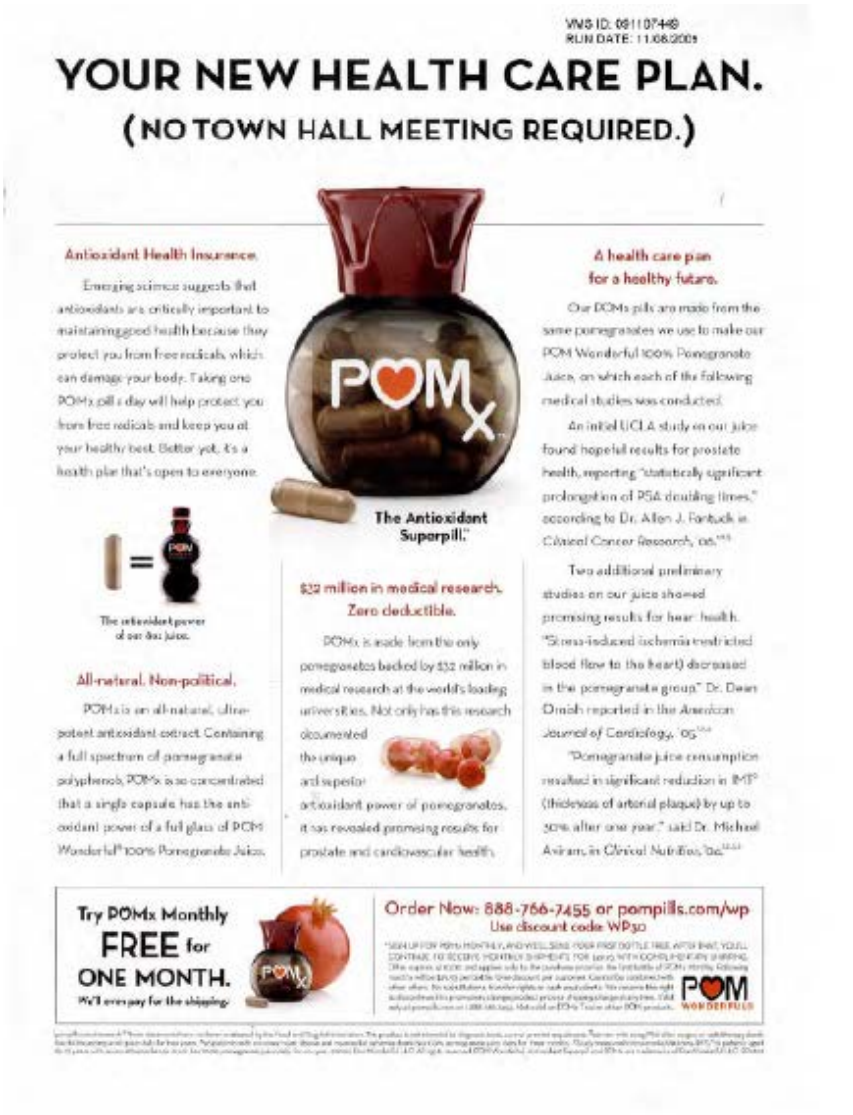
Exhibit J

CX1426_00043

APPENDIX B
Figure 29



VMS-0000303

CX0328_0001

APPENDIX B
Figure 30

VMS-0000304

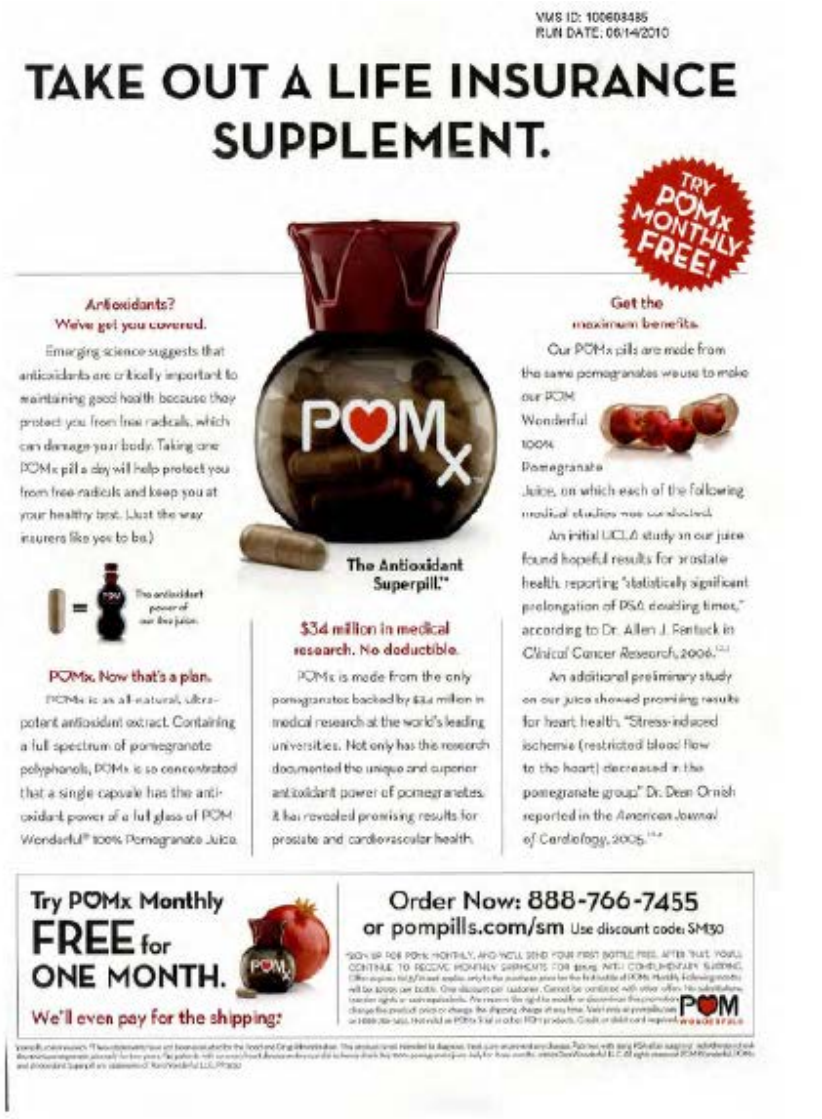
CX0337_0001

Opinion of the Commission

APPENDIX B
Figure 31

VMS-0000306

CX0342_0001



VMS-0000320

CX0353_0001

APPENDIX B
Figure 32

VMS-0000312

CX0348_0001

VMS-0000313

CX0350_0001

Opinion of the Commission

APPENDIX B
Figure 33

VMS-0000319

CX0351_0001

VMS-0000323

CX0355_0001

APPENDIX C
Summary Table of Commission Findings
Regarding POM Exhibits

Note:
- "y" means that the Commission finds an exhibit to make a challenged claim.
- "n" means that the Commission does not have sufficient evidence to find an exhibit to make a challenged claim.
- "(y)" or "(n)" means the Commission overrules a specific finding by the ALJ.
- Shaded box means the claim was not challenged by Complaint Counsel.

Exhibit	Heart Disease			Prostate Cancer			Erectile Dysfunction			Estab.
	Treat	Prevent	Reduce Risk	Treat	Prevent	Reduce Risk	Treat	Prevent	Reduce Risk	
1. CX0013 2003 Press Release	y	y	y							y
2. CX0016 Drink and Be Healthy		y	y							y
3. CX0029 10 Out of 10 People	y	y	y							y
4. CX0031 Floss Your Arteries	y	y	y							(y)
5. CX0033 Life Support		y	y							
6. CX0034 Amaze Your Cardiologist	y	y	y							(y)
7. CX0036 Cheat Death		(y)	y							
8. CX0044 2005 Press Release	y	y	y							y

9. CX0065 2006 Press Release		(y)	(y)	y						y
10. CX1426 Ex. I Antioxidant Superpill Brochure	y	y	y	y	y	y				y
11. CX0103 Decompress	n	(y)	(y)							(y)
12. CX0109 Heart Therapy		(y)	(y)							(y)
13. CX0120 One Small Pill				(y)	n	n				(y)
14. CX0122 Science, Not Fiction				(y)	n	n				(y)
15. CX0128 2007 Press Release							y			y
16. CX1426 Ex. M POMx Heart	y	y	y							y
Exhibit	Heart Disease			Prostate Cancer			Erectile Dysfunction			Estab.
	Treat	Prevent	Reduce Risk	Treat	Prevent	Reduce Risk	Treat	Prevent	Reduce Risk	
17. CX1426 Ex. N POMx Prostate				y	y	y				y
18. CX0169/ CX1426 Ex. L Power of POM	(y)	(y)	(y)	(y)	(y)	(y)				(y)
19. CX0180/ CX1426 Ex. K Antioxidant Superpill	(y)	(y)	(y)	(y)	(y)	(y)				(y)
20. CX0192 Heart Pumping		(y)	(y)							(y)
21. CX0314 Drink to Prostate Health				y	y	y				y
22. CX0260/ CX1426 Ex. B Prostate Health				(y)						(y)

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23. CX0274/ CX1426 Ex. C Off to Save Prostates					(y)	(y)				(y)
24. CX0279 Science, Not Fiction	(y)	(y)	(y)	(y)	(y)	(y)				(y)
25. CX0280 Live Long Enough	(y)	(y)	(y)	(y)	(y)	(y)				(y)
26. CX0475/ CX1425 Ex. A Juice Bottle Hang Tag	n	n	n	n	n	n	n	n	n	n
27. CX0372/ CX0379/ CX0380 Super Health				y	y	y				y
28. CX0331/ CX1426 Ex. J Healthy Wealthy	(y)	(y)	(y)	(y)	(y)	(y)				(y)
29. CX0328 Your New Health Care Plan	(y)	(y)	(y)	(y)	(y)	(y)				(y)
30. CX0337 First Bottle You Should Open	(y)	(y)	(y)	(y)	(y)	(y)				(y)
31. CX0342/CX0353 Life Insurance Supplement	(y)	(y)	(y)	(y)	(y)	(y)				(y)

Exhibit	Heart Disease			Prostate Cancer			Erectile Dysfunction			Estab.
	Treat	Prevent	Reduce Risk	Treat	Prevent	Reduce Risk	Treat	Prevent	Reduce Risk	
32. CX0348/CX0350 24 Scientific Studies	(y)	(y)	(y)	(y)	(y)	(y)				(y)
33. CX0351/CX0355 Only Antioxidant Pill Rated X	(y)	(y)	(y)	(y)	(y)	(y)	y	y	y	(y)
34. CX0463 Heart Therapy		n	n							
35. CX0466/ CX1426 Ex. H Off to Save Prostates					n	n				
36. CX0473 Capture of POMWonderful .com Community Website	(y)	(y)	(y)	(y)	(y)	(y)	(y)	(n)	(n)	(y)
37. CX0473 Capture of POMWonderful .com Website	y	y	y	y	y	y	y	**(n)**	(n)	y
38. CX0473 Capture of PomegranateTruth .com Website	y	y	y	(y)	n	n	(y)	n	n	y
39. CX0473 Capture of POMPills.com Website	y	y	y	y	y	y	y	(n)	(n)	y
40-43. CX0473 Media Interviews	The Commission does not reach the challenged media interviews. See section IX. of the Commission's Opinion.									

FINAL ORDER

DEFINITIONS

For purposes of this Order, the following definitions shall apply:

1. Unless otherwise specified, "Individual Respondents" means Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper, individually and as officers of POM Wonderful LLC ("POM Wonderful") and Roll Global LLC ("Roll").

2. Unless otherwise specified, "Respondents" means POM Wonderful and Roll, their successors and assigns; the Individual Respondents; and each of the above's officers, agents, representatives, and employees.

3. "Commerce" means as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

4. "Covered Product" means any food, drug, or dietary supplement, including, but not limited to the POM Products.

5. "Food" and "drug" means as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.

6. "Endorsement" means as defined in 16 C.F.R. § 255.0(b).

7. "POM Product" means any food, drug, or dietary supplement containing pomegranate or its components, including, but not limited to, POM Wonderful 100% Pomegranate Juice and pomegranate juice blends, POMx Pills, POMx Liquid, POMx Tea, POMx Iced Coffee, POMx Bars, and POMx Shots.

8. The term "including" in this Order means "without limitation."

9. The terms "and" and "or" in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

IT IS ORDERED that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not make any representation in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, illustration, trademark, or trade name, that such product is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, including, but not limited to, any representation that the product will treat, prevent or reduce the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, or improving blood flow to the heart; treat, prevent or reduce the risk of prostate cancer; or treat, prevent or reduce the risk of erectile dysfunction; unless the representation is non-misleading and, at the time of making such representation, Respondents possess and rely upon competent and reliable scientific evidence that, when considered in light of the entire body of relevant and reliable scientific evidence, is sufficient to substantiate that the representation is true. For purposes of this Part I, competent and reliable scientific evidence shall consist of at least two randomized and controlled human clinical trials (RCTs) of the Covered Product that are randomized, well controlled, based on valid end points, and conducted by persons qualified by training and experience to conduct such studies. Such studies shall also yield statistically significant results, and shall be double-blinded unless Respondents can demonstrate that blinding cannot be effectively implemented given the nature of the intervention.

II.

IT IS FURTHER ORDERED that Respondents, directly or through any corporation, partnership, subsidiary, division, trade

name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, trademark, or trade name, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

III.

IT IS FURTHER ORDERED that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, illustration, trademark, or trade name, about the health benefits, performance, or efficacy of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, Respondents possess and rely upon 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 scientific evidence, to substantiate that the representation is true. For purposes of this Part III, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.

IV.

IT IS FURTHER ORDERED that:

A. Nothing in Parts I through III of the Order shall prohibit Respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990; and

B. Nothing in Parts I through III of the Order shall prohibit Respondents from making any representation for any drug that is permitted in the labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

V.

IT IS FURTHER ORDERED that POM Wonderful, Roll, and their successors and assigns, and Individual Respondents shall, for five (5) years after the last date of dissemination of any representation covered by this Order, maintain and upon request make available to the Commission for inspection and copying:

A. All advertisements, labeling, packaging, and promotional materials containing the representation;

B. All materials that were relied upon in disseminating the representation;

C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations; and

D. All acknowledgments of receipt of this Order, obtained pursuant to Part VI.

VI.

IT IS FURTHER ORDERED that POM Wonderful, Roll, and their successors and assigns, and Individual Respondents shall deliver a copy of this Order to all of their current and future principals, officers, directors, and managers, and to all of their current and future employees, agents, and representatives having managerial responsibilities with respect to the subject matter of

this Order, and shall secure from each such person a signed and dated statement acknowledging receipt of the Order. POM Wonderful, Roll, and their successors and assigns, and Individual Respondents shall deliver this Order to such current personnel within thirty (30) days after the effective date of this Order, and to such future personnel within thirty (30) days after the person assumes such position or responsibilities.

VII.

IT IS FURTHER ORDERED that POM Wonderful, Roll, and their successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporations or any business entity that POM Wonderful, Roll, and their successors and assigns, and Individual Respondents directly or indirectly control, or have an ownership interest in, that may affect compliance obligations arising under this Order, including but not limited to formation of a new business entity; a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor entity; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order; the proposed filing of a bankruptcy petition; or a change in the business or corporate name or address. Provided, however, that, with respect to any proposed change about which POM Wonderful, Roll, and their successors and assigns, and Individual Respondents learn less than thirty (30) days prior to the date such action is to take place, POM Wonderful, Roll, and their successors and assigns, and Individual Respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line FTC v. POM Wonderful. *Provided, however*, that, in lieu of overnight courier, notices may be sent by first class mail, but only if electronic versions of such notices are contemporaneously sent to the Commission at DEbrief@ftc.gov.

VIII.

IT IS FURTHER ORDERED that each Individual Respondent, for a period of ten (10) years after the date of issuance of this Order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include the Individual Respondent's new business address and telephone number and a description of the nature of the business or employment and his or her duties and responsibilities. Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line FTC v. POM Wonderful. Provided, however, that, in lieu of overnight courier, notices may be sent by first-class mail, but only if electronic versions of such notices are contemporaneously sent to the Commission at DEbrief@ftc.gov.

IX.

IT IS FURTHER ORDERED that POM Wonderful, Roll, and their successors and assigns, and Individual Respondents within sixty (60) days after the effective date of this Order, shall each file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of their compliance with this Order. Within ten (10) days of receipt of written notice from a representative of the Commission, they shall submit additional true and accurate written reports.

X.

This Order will terminate on January 10, 2033, or twenty (20) years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the Order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

A. Any Part in this Order that terminates in less than twenty (20) years;

B. This Order's application to any proposed respondent that is not named as a defendant in such complaint; and

C. This Order if such complaint is filed after the Order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that Respondents did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Part as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

CONCURRING STATEMENT OF COMMISSIONER MAUREEN K. OHLHAUSEN

I disagree with the majority's findings of implied disease efficacy and establishment claims with regard to the exhibits detailed below for several reasons. First, several of these exhibits contain claims about the general effects of the POM products on the continued healthy functioning of the body but do not make references to diseases or health-related conditions.[1] Despite the absence of such references or of other suggestive indicators (*e.g.*, strong medical imagery), the majority finds that these exhibits contain *implied* disease-related claims without extrinsic evidence that consumers viewing the exhibits would actually perceive such stronger claims and not simply perceive healthy functioning claims (akin to "structure/function" or "S/F" claims under Food

[1] *See* Figs. 4, 12, 18-20, 23-25, and 28-33.

and Drug Administration regulations).[2] I am concerned that, if the Commission too easily finds implied disease efficacy or establishment claims in advertisements for foods, absent extrinsic evidence, then it may tend to undermine an important balance that is struck in the regulation of food, supplement, and drug advertising under the FTC Act and other federal laws.[3]

Second, for a number of advertisements, I believe the majority conflates disease treatment claims with prevention/risk reduction claims. In one instance, they find implied disease treatment claims where the exhibit appears only to claim or suggest that the risk of disease is, or may be, reduced by POM products.[4] Conversely, in several others, they find implied prevention/risk reduction claims (not solely disease treatment claims) for exhibits that describe studies of subjects already suffering from prostate cancer or ED.[5] For all of these exhibits, we lack extrinsic evidence that consumers would perceive all the various claims that the majority finds are implied by the exhibits. Because it seems unlikely that a consumer would assume that any food or food product that lowers the risk of disease is also a viable treatment for that disease, I disagree with the majority's conclusions that such claims are facially present in certain exhibits. Likewise, because it seems unlikely that a consumer would assume that a treatment for existing cancer or heart disease would necessarily prevent the onset of these conditions, I disagree with the majority's conclusion that such claims are facially present in certain other exhibits.

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[2] The fact that I find these claims more akin to structure/function claims does not mean I take a position on whether Respondents possessed adequate substantiation or otherwise met the requirements to make structure/function claims.

[3] The FTC has long recognized "the importance of consistent treatment of nutrient content and health claims in food advertising and labeling and [sought] to harmonize its advertising enforcement program with FDA's food labeling regulations to the fullest extent possible under the statutory authority of the FTC Act." FTC Enforcement Policy Statement on Food Advertising, (1994), *available at* http://www.ftc.gov/bcp/policystmt/ad-food.shtm.

[4] *See* Fig. 6.

[5] *See* Figs. 10, 17, and 36-39.

Finally, because a number of exhibits contain descriptions of studies that are highly qualified with terms such as "small study," "initial scientific research," and "promising," "hopeful" or "encouraging" results, I disagree with the conclusion that these exhibits make establishment claims in the absence of extrinsic evidence supporting such a conclusion.[6] Moreover, the majority argues that the challenged ads reinforce the disease-related establishment claims by mentioning that POM spent millions on research.[7] However, the references to the money spent on research appear to be significantly related to demonstrating the amount of antioxidants in the POM products and the general effects of those antioxidants on the human body. Therefore, we need extrinsic evidence to show that consumers would also take away the impression that the research supporting the disease claims is established and not merely preliminary.

Virtually none of the claims found by the Commission in the challenged exhibits is express – they are deemed to be implied. The Commission may undertake a net impression analysis and find implied claims when it can "conclude with confidence after examining the interaction of all the different elements in [an advertisement] that they contain a particular implied claim." *In re Thompson Med. Co.,* 104 F.T.C. 648, 788-89 (1984); *Telebrands Corp.,* 140 F.T.C. 278, 290 (2004) (citing *Thompson Medical*). When such confidence is lacking (*e.g.,* due to well-qualified claims or contradicting statements), however, "we will not find the ad to make the implied claim unless extrinsic evidence allows us to conclude that such a reading of the ad is reasonable." *Thompson Med. Co.*, 104 F.T.C at 789; *Telebrands,* 140 F.T.C. at 291 (citing *Thompson Med. Co.*).

With respect to the claims described below, such extrinsic evidence is unavailable or inadequate. Although Complaint Counsel offered the expert testimony of Dr. Stewart, he did not conduct his own facial analysis of the challenged advertisements and could not opine on what they meant. IDF 513. Also, unlike in

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[6] *See* Figs. 4, 6, 12-14, 18-20, 24, 25, and 28-33.

[7] "When an ad represents that tens of millions of dollars have been spent on medical research, it tends to reinforce the impression that the research supporting product claims is established and not merely preliminary." *See* Section IV.A. of the opinion.

cases such as *Thompson Medical* and *Telebrands*, Complaint Counsel did not introduce copy testing evidence to demonstrate what claims consumers may perceive from well-qualified or contradictory statements in advertisements. Because a number of exhibits contain references to the continued healthy functioning of the body without mentioning disease or health-related conditions, discuss only treatments for patients already suffering certain diseases, discuss risk reduction without mentioning treatment of certain diseases, or contain extensive qualifying language, I do not share the majority's ability to "conclude with confidence," that no extrinsic evidence is needed to read stronger claims between the lines. I am concerned with, and thus disagree with, these particular majority findings.[8]

As our opinion today observes, the Commission has paid particular attention to the balancing of pertinent consumer interests in describing the *Pfizer* factors applicable to the question of what constitutes a reasonable basis for a claim.[9] The Commission also has been clear that our substantiation standards and claims interpretation are inextricably linked. Hence, in delineating standards for prior substantiation, we state "[t]he Commission will take care to assure that it *only* challenges *reasonable interpretations* of advertising claims."[10] As a procedural matter, we may begin by asking what particular claims – and categories of claims – are being made, and then ask what evidence should be required to substantiate such claims. We must keep in mind, however, that if we are too quick to find stronger claims than the ones reasonable consumers actually perceive, then we will inadvertently, but categorically, require an undue level of substantiation for those claims.

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[8] Engaging in broad claim interpretation also raises questions about whether this approach qualifies as a case-by- case analysis or is more like a broad prohibition on certain categories of speech, which has implications for First Amendment review of our actions.

[9] *See In re Pfizer Inc.*, 81 F.T.C. 23, 91-2 (1972); *see FTC Policy Statement Regarding Advertising Substantiation*, 104 F.T.C. 839 (1984) (appended to *Thompson Med. Co.*, 104 F.T.C. 648 (1984)) ("*Substantiation Statement*").

[10] *Substantiation Statement* at 840 n. 3 (emphasis added) ("Notwithstanding … variations in approach, the focus of all Commissioners on reasonable interpretations of claims is intended to ensure that advertisers are not required to substantiate claims that were not made.")

In particular, Congress and the Food and Drug Administration have created carefully drawn boundaries between different types of claims regarding the effect of food and dietary supplement products on nutrition and health. FDA regulations distinguish between various categories of claims that may be associated with food products and dietary supplements – including "qualified health claims," "health claims," and "structure/function" claims – and the level of substantiation required for each category of claim.[11] According to FDA guidance, health claims and qualified health claims expressly or by implication characterize the relationship of a substance to a disease (*e.g.*, heart disease) or health-related condition (*e.g.*, high blood pressure).[12] By contrast, structure/function claims describe the effect that a substance has on the structure or function of the body for maintenance of good health and nutrition but do not make reference to a disease.[13] The FDA imposes different and more stringent requirements on health claims than it does on structure/function claims.[14]

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[11] *See generally* FDA, Guidance for Industry: A Food Labeling Guide (September 1994; Revised April 2008; Revised October 2009), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm; FDA, Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims – Final (2009), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm; FDA Guidance for Industry: FDA's Implementation of "Qualified Health Claims": Questions and Answers; Final Guidance (May 12, 2006), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053843.htm.

[12] FDA, Guidance for Industry: A Food Labeling Guide, at 8.Claims H1, Q1.

[13] *Id.* at 8.Claims S1, S7.

[14] "Health claims are required to be reviewed and evaluated by FDA prior to use." FDA, Guidance for Industry: A Food Labeling Guide, at 8.Claims H1. FDA also distinguishes "health claims that meet the Significant Scientific Agreement (SSA) standard," from "S/F claims [that] must be truthful and not misleading and are not pre-reviewed or authorized by FDA."). *id.* at 8.Claims H3. In addition, "FDA does not require conventional food manufacturers to notify FDA about their S/F claims and disclaimers are not required for conventional foods." FDA, Structure/Function Claims, *available at* http://www.fda.gov/Food/LabelingNutrition/LabelClaims/StructureFunctionClaims/ucm2006881.htm. Structure/function claims were specifically authorized by the Dietary Supplement Health and Education Act of 1994, 108 Stat. 4325

I am concerned that the majority's interpretation of certain exhibits blurs these boundaries and creates an inconsistency between FTC advertising requirements and FDA food labeling and advertising requirements by concluding that the mere mention of "health" or healthy functioning can imply a disease-related efficacy (*i.e.,* a health claim in FDA terms) and that the mere mention of scientific evidence can imply a related establishment claim. For instance, Figures 12, 20, and 23 seem limited to addressing the product's general health benefits by providing antioxidants and fighting free radicals, and thus potentially reducing the risk of disease, while claiming that these benefits are backed by significant scientific or medical research about prostate or cardiovascular health. Based on the majority's views about these exhibits, it is difficult to imagine any structure/function claims that POM could associate with its products in the marketplace without such claims being interpreted, under the FTC precedent set in this case, as disease-related claims.[15]

(codified as amended in scattered sections of 21 U.S.C.); *see also* Dep't Health & Human Servs., Food & Drug Admin., Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, Final Rule, 65 Fed. Reg. 1000 at 1034-35 (Jan. 6, 2000).

[15] I am concerned that, for these exhibits, the majority readings are in conspicuous tension with the express findings and intent of Congress in enacting the Dietary Supplement Health and Education Act of 1994 (DSHEA), wherein Congress provides for structure/function claims that may be made on behalf of dietary supplements. In the statute itself are express findings that healthful diets may reduce the risk of disease and the need for medical intervention; that "consumers should be empowered to make choices about preventive health care programs," *id.* at § 2(8), based on available scientific evidence; and that, "although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers." *Id.* at § 2(13). Moreover, although the DSHEA regards dietary supplements in particular, FDA has concluded that "structure/function claims may be made on a conventional food provided the effects are derived from the nutritive value of the food." FDA, Guidance for Industry: A Food Labeling Guide, at 8.Claims S1. Hence, "[o]n December 20, 2002, the agency announced its intention to extend its approach to implementing the *Pearson* decision to include health claims for conventional foods (67 Fed. Reg. 78002)." FDA, Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims – Final, at § II (background).

A possible (though not plausible) argument for the majority's position is that these exhibits are somehow infused with messages from other ads included in some of POM's advertising campaigns that mentioned specific diseases or health conditions. However, we should not reach such a conclusion in the absence of extrinsic evidence in the record. *Thompson Med. Co.*, 104 F.T.C. at 789; *Telebrands*, 140 F.T.C. 379, 436 (2004) (ALJ Decision), *adopted by* the Commission in *Telebrands*, 140 F.T.C. 278, 281 (2004) (requiring extrinsic evidence even though the ads at issue contained express references to other ads). More generally, we should be careful not to interpret claims so broadly that we undermine distinctions between types of claims, and the substantiation appropriate to them, that Congress and our sister agency have found important to the public's health and wellbeing.

In sum, the majority's findings with regard to the exhibits detailed below in the absence of extrinsic evidence leave questionable room for marketers to make well-qualified and substantiated structure/function type efficacy or establishment claims because of the high risk that such claims will be found to imply the treatment, prevention, or risk-reduction of a disease, or that they are clinically proven.

I incorporate these arguments by reference to my views for specific exhibits in my comments below.

Figure 4. CX0031: "Floss Your Arteries" print advertisement

I disagree with the majority view that this print ad conveyed to a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily treats – rather than prevents or reduces the risk of – heart disease. I also disagree with the majority and would uphold the ALJ's finding that the evidence fails to show that this print ad conveys to a significant minority of reasonable consumers that the claims contained in the advertisement are clinically proven. The advertisement's language qualifies that drinking POM Juice "*can* reduce plaque by up to 30%" (emphasis added) and the citation to a study appears in a footnote too small to be clear and conspicuous under our own standards.[16] *See* ID at

[16] Advertisers cannot use fine print to contradict other statements in an ad or to clear up misimpressions the ad would otherwise leave. *FTC Deception Policy Statement*, appended to *Cliffdale Associates, Inc.*, 103 F.T.C. 110, 180-

¶ 447. Further, the imagery in the advertisement is that of regular hygiene, such as tooth brushing and flossing, not medical imagery related to heart disease that appears in other challenged advertisements where the Commission unanimously found an implied establishment claim.

Figure 6. CX0034: Amaze Your Cardiologist

I disagree with the majority view that this print ad conveys to a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily treats – rather than prevents or reduces the risk of – heart disease. I also disagree with the majority and would uphold the ALJ's finding that the evidence fails to show that this exhibit conveys to a significant minority of reasonable consumers that the claims contained in the advertisement are clinically proven because the statement regarding plaque reduction is well-qualified ("*can* reduce plaque by up to 30%" (emphasis added)) and the reference to a study appears in a footnote too small to be clear and conspicuous under our own standards. *See* ID at ¶¶ 465-468.

Figures 10 and 17. CX1426 Ex. I: Antioxidant Superpill Brochure; CX1426 Ex. N: POMx Prostate Newsletter

I disagree with the majority's view that these exhibits convey to a significant minority of reasonable consumers that daily consumption of POM products prevents or reduces the risk of prostate cancer, as opposed to treating prostate cancer. All references to that disease in the exhibit appear rooted in a study of 46 men age 65 to 70 who had been treated for prostate cancer. Further, CX1426 Ex. I specifically references "new studies are under way … in patients *with* prostate cancer" (emphasis added).

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81 (1984). To be effective, Commission orders require such disclosures to be clear and conspicuous. *E.g., Thompson Med. Co.,* 104 F.T.C. at 842-43. For print ads, for instance, past Commission orders have defined "clear and conspicuous" to mean in a type size and location sufficiently noticeable for an ordinary consumer to read and understand it and in print that contrasts with the background against which it appears. *See, e.g.*, *FTC v. Green Millionaire, LLC,* No. 1:12-cv-01102-BEL (D. Md. filed Apr. 12, 2012) (proposed order granting stipulated permanent injunction), *available at* http://www.ftc.gov/os/caselist/1023204/120416greenmillstip.pdf.

Figure 12. CX0109: Heart Therapy

I disagree with the majority and would uphold the ALJ's findings that the evidence fails to show that this print ad conveys to a significant minority of consumers that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease or that such claims are clinically proven. The imagery in this ad, which is a POM bottle reclining on a couch, suggests psychotherapy, not treatment for heart disease. The text is qualified with references such as "emerging science," "initial scientific research," and "encouraging results in prostate and cardiovascular health." There is also an exhortation to "keep your heart healthy," without mention of or linkage to a specific disease, which seems more indicative of general structure/function type claims rather than health claims involving disease prevention or risk reduction.

Figures 13-14. CX0120: One small pill for mankind; CX0122: Science Not Fiction

I disagree with the majority and would uphold the ALJ's conclusion that the record does not support a finding that these exhibits convey to a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats prostate cancer or that such claim is clinically proven. The exhibits contain conflicting elements and heavily qualified descriptions of studies, thus suggesting the need for extrinsic evidence to determine what consumers take away. For instance, the exhibits state that "[f]indings from *a small study suggest* … pomegranate juice *may one day prove* an effective weapon" or "[a]n *initial* UCLA medical study … showed *hopeful results* for men with prostate cancer" (emphasis added).

Figures 18-19 and 24. CX0169/CX1426 Ex. L: "The Power of POM;" CX0180/CX1426 Ex. K: "The antioxidant Superpill;" and CX0279: "Science, Not Fiction" print advertisement

I disagree with the majority and would uphold the ALJ's conclusion that the evidence fails to show that these print ads convey to a significant minority of reasonable consumers that taking a POMx Pill daily treats, prevents, or reduces the risk of heart disease and prostate cancer or that these claims are clinically proven. The ads mention the potential benefits for "prostate health" and "heart health," and exhort the consumer to "invest in your health," which are statements likely more correlated to

structure/function type claims than to health/disease claims. Moreover, the exhibits discuss the available science with qualifiers such as "preliminary studies," "hopeful results," or "suggests anti-atherosclerosis benefits." In addition, the caduceus symbol in CX0169 is next to the tag line "Reviewed for Safety by the FDA." Further, the text of any statements at the bottom of these exhibits is too small to qualify any claims adequately. Thus, extrinsic evidence would be necessary to conclude that consumers would take away health/disease claims or establishment claims from these ads.

Figure 20. CX0192: What Gets Your Heart Pumping print advertisement

I disagree with the majority and would uphold the ALJ's conclusion that the evidence fails to show that this print ad conveys to a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease or that these claims are clinically proven. In contrast to certain other exhibits, this ad's imagery, a POM bottle in a bikini top, does not include medical imagery but rather invokes sexual attraction. Moreover, the ad contains statements such as "healthy arteries" and "cardiovascular health," which seem similar to structure/function type claims rather than health/disease claims. Further, the ad's references to science are qualified as "initial" scientific research that has uncovered "encouraging" results. Thus, extrinsic evidence would be necessary to conclude that consumers would take away health/disease claims or establishment claims from this ad.

Figure 23. CX0274/CX1426 Ex. C: "I'm Off to Save Prostates" print advertisement

I disagree with the majority and would uphold the ALJ's conclusion that the evidence fails to show that this print ad conveys to a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily prevents or reduces the risk of prostate cancer or that these claims are clinically proven. Statements such as "defending healthy prostates" and "improve prostate health" are more akin to structure/function type claims than to health/disease claims. Moreover, the mention of research in this ad is not tied to any disease generally or cancer specifically. Further, the ad lacks any medical imagery. Thus, the

Commission should require extrinsic evidence to find implied health/disease or establishment claims.

Figures 25 and 28-33. CX0280: Live Long Enough; CX0331/CX1426 Ex. J: Healthy Wealthy; CX0328: Your New Health Care Plan; CX0337: First Bottle You Should Open; CX0342/CX0353: Life Insurance Supplement; CX0348/CX0350: 24 Scientific Studies; CX0351/CX0355: Only Antioxidant Supplement Rated X

I disagree with the majority and would uphold the ALJ's conclusion that the evidence in the record fails to show that these print ads convey to a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats, prevents or reduces the risk of heart disease or prostate cancer or that these claims are clinically proven. These ads state "keep you at your healthy best" and "prostate and cardiovascular health" and do not refer to any disease, making the claims akin to structure/function type claims. The imagery regarding pills is linked to the antioxidant power of the product. The studies referenced are strongly qualified, stating that "*preliminary* studies … showed *promising* results for heart health" or that an "*initial* UCLA study … found *hopeful* results for prostate health" (emphasis added). Moreover, any disclaimers at the bottom of the ad are too small to be interpreted in conjunction with other messages. For similar reasons, I also disagree with the majority's view that exhibits CX0351 and CX0355 convey to a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats, prevents, or reduces the risk of erectile dysfunction or that those claims are clinically proven. The statements about the studies referenced are qualified; for instance, the ad refers to a "*preliminary* study on erectile function" (emphasis added) and notes that "further studies are warranted." Thus, the Commission should require extrinsic evidence to find implied health/disease or establishment claims.

Figures 36 and 39. CX0473: Capture of POMWonderful.com Community Website; CX0473: Capture of POMPills.com Websites

I disagree with the majority's view that these exhibits convey to a significant minority of reasonable consumers that taking eight ounces of POM Juice or one POMx Pill daily prevents or reduces

the risk of – rather than treats – prostate cancer. Because the science referenced in these exhibits consists of subjects who had already been diagnosed with that disease, I would require extrinsic evidence before finding implied claims of disease prevention or risk reduction.

Figure 37. CX0473: Capture of POMWonderful.com Website
For the same reasons noted for exhibits 36 and 39, I disagree with the majority's view that this exhibit conveys to a significant minority of reasonable consumers that taking eight ounces of POM Juice or one POMx Pill daily prevents or reduces the risk of – rather than treats – prostate cancer. Because the science referenced in this exhibit consists of subjects who had already been diagnosed with cancer, I would require extrinsic evidence before finding such implied claims.

CONCURRING STATEMENT OF COMMISSIONER J. THOMAS ROSCH

The Commission Opinion states that "[t]here are two analytical routes by which Complaint Counsel can prove that Respondents' ads are deceptive or misleading and both arise in this case." Commission Opn. at 17. The first is to demonstrate that the claims in the ads are false. The second approach relies on the "reasonable basis" theory; that is, that an objective claim about a product's performance or efficacy carries with it a representation that the advertiser had a reasonable basis of support for the claim. *Id.* I agree with these assertions.

Using this framework, the Commission Opinion separately analyzes the efficacy claims and the level of substantiation claimed by those advertisements. More specifically, the Commission first determines for itself whether and to what extent the ads make efficacy claims (*see, e.g.*, *id.* at 9); but the Commission relies on extrinsic evidence (the testimony of experts) to determine the level of substantiation required to support the claims made by the ads in that respect. The

Commission ends up concluding on the basis of the testimony of those experts that the highest level of well-controlled studies (the "gold standard" of RCTs) is required to support the latter claims. *Id*. at 20, 22-23, 25-26, 30, 32, 35, and 38.

I agree with the Commission's conclusion. Moreover, I agree that the Commission reached that conclusion by using the most traditional (that is to say the safest) analytical route. However, that route entails a discussion of both the expert testimony and how the *Pfizer* factors should apply in this case. *Id.* at 20-38. I consider that lengthy discussion to be unnecessary. Beyond that, having served as a Commissioner for seven years and having been a trial lawyer for nearly 40 years before that, I am somewhat skeptical of relying so heavily on the opinions of experts who are paid by both Complaint Counsel and Respondents. Fortunately, I do not have to do so.

Instead, I would decide that the "net impression" left by the ads includes claims about what level of substantiation the advertiser is purporting to have; that a net impression may be conveyed both expressly and by implication; and that the substantiation claims in these ads are false.

First, let me emphasize that I, like my colleagues, have examined the ads myself. There can be no dispute that the net impression of the ads is what counts in determining what impression is conveyed to consumers. The case law has long held that. *See, e.g., American Home Prods. v. FTC*, 695 F.2d 681, 687 (3d Cir. 1982); *FTC v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir. 1963). Moreover, there can be no quarrel with the proposition that the net impression conveyed by an ad includes implied claims, as well as express claims. The Commission itself has repeatedly been held to have the common sense and expertise to determine the net impression conveyed, "so long as those claims are reasonably clear." *Kraft, Inc. v. FTC*, 970 F.2d 311, 319 (7th Cir. 1992);[1] *accord FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1189-90 n.12 (N.D. Ga. 2008); *see also FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 391-92 (1965).

[1] It is worth noting that all of the appellate authority respecting the need for the Commission to consider expert opinions *predates* the *Kraft* case.

Second, neither *Kraft* nor *Colgate-Palmolive* contains any suggestion that the Commission itself lacks the common sense and expertise to determine whether any false substantiation claims are conveyed by the ads, as part of its examination of the ads' net impression. Nor do other cases require that there ordinarily be any form of extrinsic evidence in that inquiry. *See, e.g.*, *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1189 (extrinsic evidence "is only necessary when the asserted claims fall on the 'barely discernible' side of the continuum"); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 958 (N.D. Ill. 2006), *aff'd*, 512 F.3d 858 (7th Cir. 2008). Indeed, as the Commission Opinion acknowledges, *Sterling Drug*, 102 F.T.C. 395, 436 (1983), stands for the straightforward notion that "when an advertiser represents in its ad that there is a particular level of support for a claim, the absence of that support makes the claim false." Commission Opn. at 16, 20. Thus, I would hold that claims about the level of substantiation, no less than any other net impression conveyed by the ads, can be false, and that the Commission itself can make that determination.

Third, I would agree that if POM's ads simply made health claims, standing alone, they could not properly be challenged as false or deceptive. But they do not stand alone. In some instances the alleged health claim is expressly linked to a claim that the POM products treat, prevent or reduce the risk of heart disease or prostate cancer. The link between POM and the treatment, prevention or reduction of risk of those very serious diseases is at least implicit in many other instances. Those express and implicit links create a net impression that the highest possible level of substantiation exists for the POM product being advertised, and that claim is false.

More specifically, many of the advertisements expressly link POM to the treatment, prevention or reduction of the risk of heart disease or prostate cancer. *See, e.g.,* POM Claims Appendix, ads numbered 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 12, 14, 16, 19, 20, 28, 29, 30, 31, 32, and 33. Other ads at least implicitly link POM or POMx to the treatment, prevention, or the reduction of risk of those very serious diseases by liberally quoting physicians. *See id.*, ads numbered 16, 18, 19, 21, 24, 25, 27, 28, 29, 30, 31, 32, and 33 in the Claims Appendix. Another set of ads implicitly link POM to

the treatment, prevention, or the reduction of risk of heart disease or prostate cancer by equating POM with POMx (which is depicted as a prescription drug), or by depicting POM itself as a medicine. *See id.*, ads numbered 10, 13, 14, 16, 17, 18, 19, 22, 25, 28, 29, 30, 31, and 32. Furthermore, ads implicitly link POM to the treatment, prevention, or reduction of risk of these life-threatening diseases by describing POM as a life insurance supplement or a healthcare plan. *See id.*, ads numbered 29 and 31. Each of these claims creates the net impression that the highest form of substantiation exists to support the claims linking POM to the treatment, prevention or reduction of risk from these serious diseases.

Fourth, I do not consider erectile dysfunction to be as serious as heart disease or prostate cancer. For example, while erectile dysfunction afflicts many men, it is generally not life-threatening. Thus, I do not think that linking POM with the treatment, prevention or reduction of risk of erectile dysfunction, standing alone, creates a net impression that claims respecting that malady are supported by the highest level of substantiation. But that does not mean the Commission Opinion is wrong in requiring that level of substantiation for erectile dysfunction as well. The Commission has long considered so-called "establishment" claims to be binding on the advertisers that make them. *See FTC Policy Statement Regarding Advertising Substantiation*, appended to *Thompson Med. Co.*, 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986) (for ads that "contain express or implied statements regarding the amount of support the advertiser has for the product claim . . ., the advertiser must possess the amount and type of substantiation the ad actually communicates to consumers"). In this case, those associated with POM have made such claims. *See, e.g.,* POM Claims Appendix, ad numbered 33.