

**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION**

COMMISSIONERS: **Jon Leibowitz, Chairman**
 J. Thomas Rosch
 Edith Ramirez
 Julie Brill
 Maureen K. Ohlhausen

In the Matter of)	
)	
POM WONDERFUL LLC and)	
ROLL GLOBAL LLC,)	Docket No. 9344
as successor in interest to Roll International)	
Corporation, companies, and)	January 10, 2013
)	
STEWART A. RESNICK,)	
LYNDA RAE RESNICK, and)	
MATTHEW TUPPER, individually and as)	
officers of the companies,)	
)	
Respondents.)	

OPINION OF THE COMMISSION

By OHLHAUSEN, Commissioner:

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, “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.

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

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

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.

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.

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 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

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/0823122/100927pomagreee.pdf>.

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 "[I]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 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).

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.

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 Commission finds that 36⁸ 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

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.

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.

(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.

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

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

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 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* 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

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

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

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

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 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

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

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.

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.

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 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.

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.”).

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 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

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.

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

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

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*”).

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.

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 (“[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 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

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.”

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).

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 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 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.

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>.

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 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;

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.

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

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)).

weight of expert testimony in 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.

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

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.”).

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

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.

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 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

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>.

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.

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 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

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”).

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.

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 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

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.

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.

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 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 than 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 advertiser made limited claims or provided appropriate disclaimers, neither bars nor discourages

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.

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 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

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).

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 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

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 *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)).

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 “[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 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.

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.

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.

XI. 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.

Opinion of the Commission, Final Order, and Concurring Statements of Commissioner Rosch and Commissioner Ohlhausen Issued On January 10, 2013