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

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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,

At trial, Complaint Counsel challenged a total of 43 items, including print

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 Challeng

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,

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*

The ALJ further determined that the appropriate level of substantiation for such claims is

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

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.*

> 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

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.

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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 th

2. Bovitz Survey

Here, we only consider whether Respondents intended to make the disease claims

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,

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* *Reipyonh,0.4he claimg the am18Tw(4F.T.2a-8esie)7.0t adexpsnt Counsel 0.1t the Challenged POM PrD.3Tical*

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

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

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

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

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

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.

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, preven

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 ex

Having fully considered and weighed all of the evidence and the expert testimony on Respondents' basic science and clt,4[(ofical trials,d th

(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

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

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

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." 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).

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

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advertising where the regulatory bodies found advertising to be misleading based on simple affirmative representations, such as stating the jurisdictions where the attorney was licensed or certifications that the attorney held. The Court struck down the regulations because it found that, for example, so long as the attorney was still licensed in the jurisdiction, providing the information to the public was not misleading because consumers could easily confirm the licensing or certification.

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

C. Potentially Misleading

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

In *Pearson*, manufacturers of dietary supplements sought pre-approval from the FDA for four health claims that the manufacturers wanted to make in labeling for their products. The FDA refused to approve the claims on the grounds that they were not supported by the "significant scientific agreement" standard of evidence under that agency's regulatory scheme. The FDA, consistent with agency practice, refused to consider the manufac

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

. . .

In evaluating health claims, the Commission looks to a number of factors to determine

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.

> 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

ordered by Judge Chappell, is justified even if

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

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[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)).

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],