No. 15-_____

IN THE

Supreme Court of the United States

POM WONDERFUL, ET AL.,

Petitioners,

v.

FEDERAL TRADE COMMISSION,

Respondent.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the District of Columbia Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The Federal Trade Commission (FTC) deemed several of petitioners' advertisements unprotected by the First Amendment and banned them on the theory that their truthful content nonetheless implied a false or misleading message to a "significant minority" of consumers. Petitioners challenged that ban under the First Amendment. The Court of Appeals upheld the ban in its entirety because—applying only generic principles of administrative law—it gave great deference to the FTC's determination that all of the challenged ads implied the alleged false or misleading messages and for that reason received no First Amendment protection. This Court's cases, including *Peel v. Attorney Registration & Disciplinary Commission of Illinois*, 496 U.S. 91 (1990), and *Ibanez v. Florida Department of Business & Professional Regulation*, 512 U.S. 136 (1994), have expressly held that when a tribunal which traditionally receives fact-finding deference on appeal finds that an advertisement implies a misleading message, that finding must be reviewed *de novo* in order to give meaningful force to the First Amendment. The question presented is:

Whether a finding by the FTC that a truthful advertisement nonetheless implies a misleading message to a minority of consumers, and therefore receives no First Amendment protection, must be reviewed *de novo*?

PARTIES TO THE PROCEEDING

The parties to the proceeding below were POM Wonderful LLC, Roll Global LLC, Stewart A. Resnick, Lynda Rae Resnick, Matthew Tupper, and the Federal Trade Commission. Apart from the Federal Trade Commission, all these parties all join in this petition.

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Petitioners POM Wonderful, LLC, and Roll Global, LLC, are both limited liability companies organized under Delaware law that are wholly owned by the Stewart and Lynda Resnick Revocable Trust. Stewart and Lynda Resnick are the sole trustees and beneficiaries of the Resnick Trust, and are the sole owners of POM Wonderful and Roll Global.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

INTRODUCTION

On the other side of this page are two ads the Federal Trade Commission (FTC) deemed unprotected by the First Amendment and banned as misleading commercial speech. These ads are meant to convey—and so explicitly state—that there is reason to believe that petitioners' pomegranate juice is good for the heart and prostate, a conclusion they say is "supported by $20 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health." Those claims are *undisputedly true*: Because POM contains high levels of antioxidants, which are believed to promote bodily health in many ways, POM invested millions into researching its possible health benefits, with many studies producing encouraging results.

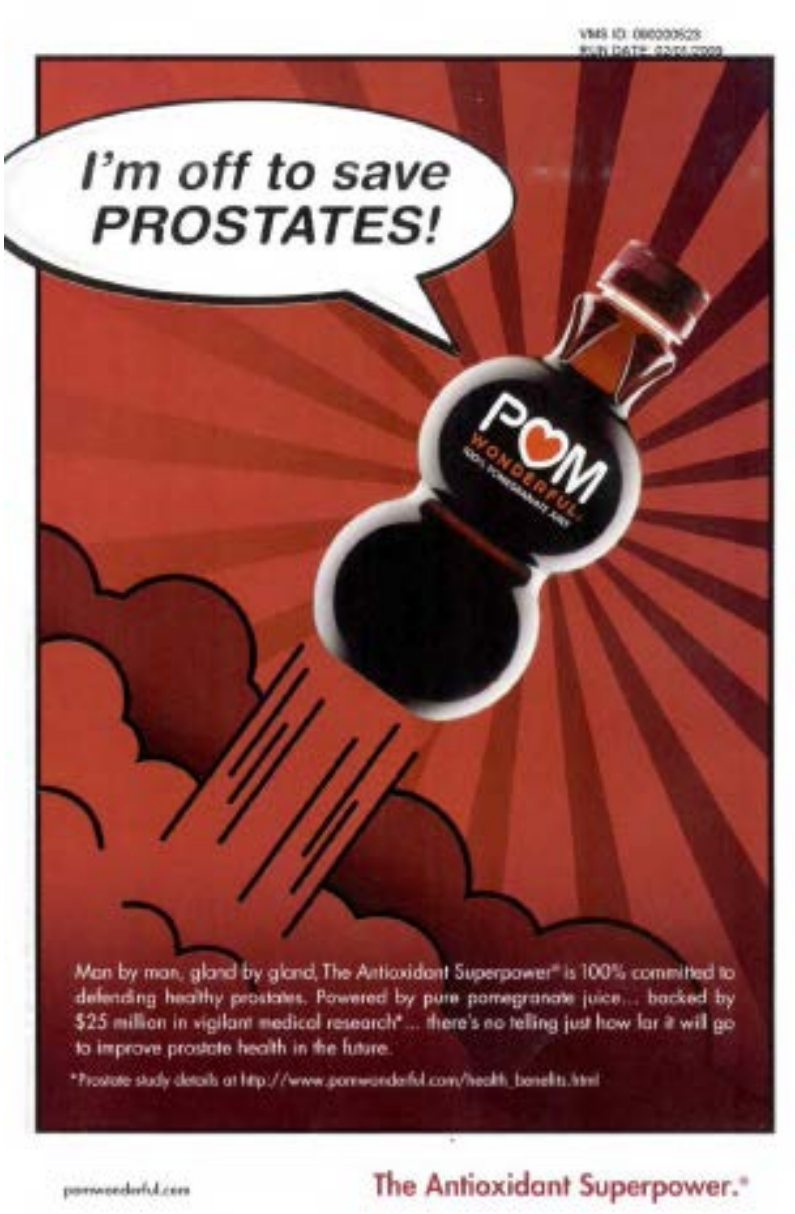
The FTC nonetheless decided that these truthful ads cannot be published, and the public cannot read them, because—based solely on its own, facial analysis—it believed they might *imply* a much stronger claim to a "significant minority" of consumers. More specifically, the FTC concluded that these ads might imply to some that there is *conclusive proof* that POM's juice cures or prevents serious diseases like heart attacks and prostate cancer. At this stage, POM does not dispute that it lacks the scientific evidence the FTC now requires to make such claims—which would ordinarily be associated with pharmaceutical products. But it certainly disputes that the ads convey anything like those claims, and the First Amendment entitles POM to *de novo* review of the FTC's determination that they do.

That *de novo* review would clearly require reversing the FTC's determination that these and other ads receive no First Amendment protection and its prospective ban on running anything like them. Even a cursory glance reveals that their health claims are quotidian; they are plainly

not—as the FTC would have it—claims that pomegranate juice is a proven treatment for heart disease and prostate cancer akin to Lipitor and other FDA-approved drugs.

FIGURE 12

FIGURE 23


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

It's hard to see how these ads can be read to make claims of *scientific proof* that POM treats prostate cancer and heart disease. The words used claim the *opposite* of "proof" (*i.e.*, "emerging science suggests" "encouraging results"), and they refer only to "health" generally, POM's antioxidant content, and the fact that POM is 100% juice (so consumers know nothing is added and that it can only be as good for you as fruit can be). They do not even mention the treatment of any particular disease. For that reason, the ALJ who first evaluated these ads did not find that they imply the FTC's alleged misleading claims, neither did Commissioner Ohlhausen (who wrote separately), and neither did the D.C. Circuit, which declined to exercise *de novo* review. Indeed, the D.C. Circuit pointedly held that while *other* ads banned by the Commission satisfied *de novo* review, it would make no such finding for these ads (and many others), and would instead uphold the FTC's ban only under the exceedingly deferential standard of the Administrative Procedure Act.

The decision that the FTC's ban can be upheld without *de novo* First Amendment review is a plain and critical error of law. This Court has expressly held that the very kind of predicate finding the FTC made here—namely, that a particular instance of commercial speech *implies* a misleading message—must be reviewed *de novo* in order to give compass to First Amendment protections. *See Ibanez v. Florida Department of Business & Professional Regulation*, 512 U.S. 136 (1994); *Peel v. Attorney Registration & Disciplinary Commission of Illinois*, 496 U.S. 91 (1990); *Bose Corp. v. Consumers Union*, 466 U.S. 485 (1984). Otherwise, the scope of the First Amendment would be essentially left to the censor's discretion, because it would always be free to decide that truthful speech implied some misleading message—and to ban it on that theory—subject only to highly deferential, APA review.

Nonetheless, the D.C. Circuit, and the Seventh Circuit along with it, are unwilling to apply this Court's plainly applicable precedent to federal agencies until this Court expressly requires as much. *See Kraft, Inc. v. FTC*, 970 F.2d 311, 317 (7th Cir. 1992) (so holding). In stark contrast, other circuits have recently recognized that, under this Court's precedents, "[w]hether speech is 'inherently misleading' is a question of law that we review *de novo*." *See, e.g.*, *1-800-411-Pain Referral Serv., LLC v. Otto*, 744 F.3d 1045, 1055 (8th Cir. 2014)—a rule other circuits and state supreme courts have applied consistently and uncontroversially. The D.C. Circuit's resolution against *de novo* review will critically affect this issue because of its unique role in agency appeals. Thus, if this Court intends its commercial-speech law to meaningfully curb the speech-restricting choices of federal agencies going forward, it should grant certiorari and resolve this disagreement in favor of the rule its cases already require.

This is an ideal vehicle to do so. Because of the number of ads at issue, the D.C. Circuit distinguished between those on which a ban would survive *de novo* review and those on which it would not so find. As already shown, the latter ads at issue here are a vivid demonstration of how far the agencies can and will go if constrained only by highly deferential, APA review when they choose to ban speech as "implying" a misleading message. The First Amendment requires courts to play a far more meaningful role in evaluating the decision to ban particular instances of truthful speech to consumers on the paternalistic assumption that they will be misled by some lurking implication hiding therein. This Court should grant certiorari, and reverse.

PETITION FOR A WRIT OF CERTIORARI

Petitioners respectfully seek a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit in this case.

OPINIONS BELOW

The D.C. Circuit's opinion (Pet. App. 1a) is published at 777 F.3d 478. Its orders denying rehearing (*id*. 180a-181a) are unpublished. The FTC's opinion (*id.* 45a) and the appendices thereto (*id.* 182a) are available at https://www.ftc.gov/enforcement/cases-proceedings/082-3122/pom-wonderful-llc-roll-global-llc-matter.

JURISDICTION

The D.C. Circuit issued its decision on January 30, 2015, and denied timely rehearing petitions on May 28, 2015. The Chief Justice extended the time for this petition to October 23, 2015. *See* No. 15A173. This Court has jurisdiction under 28 U.S.C. §1254(1).

STATEMENT OF THE CASE

1. Pomegranates have been consumed safely for thousands of years, ID¶77,[1] and have been used by many cultures for medicinal purposes over that time. ID¶986. Petitioners farm pomegranates and produce a variety of products from them—most importantly, POM Wonderful 100% pomegranate juice. There is no dispute that these products are completely safe for consumers and have no adverse health effects. ID¶¶77-88. In fact, pomegranates are not just safe: There is evidence that they are generally quite good for you because (among other things) they are extraordinarily rich in antioxidants. ID¶¶987.

[1] "ID" citations refer to the ALJ's decision, which is available at https://www.ftc.gov/sites/default/files/documents/cases/2012/05/120521pomdecision.pdf. Citations with no "¶" symbol refer to pages.

That evidence comes not only from the recognized benefits of antioxidants in general, but from studies that POM sponsored into the health benefits of pomegranate juice in particular. Working with scientists at leading universities—including field-leading researchers and Nobel laureates—POM spent over $35 million on studies examining the benefits of antioxidants and pomegranate juice for issues like heart, prostate, and erectile function. Pet. App. 4a. The outcomes of that research have been positive, suggesting that POM products may well have benefits for these particular aspects of bodily health.

Many of these studies involved research techniques designed to provide initial, first-stage testing on the possible health benefits of the products. For example, leading scientists conducted laboratory research into the antioxidant effects of POM products on certain kinds of carcinogens, as well as animal studies testing consumption of the products. These studies suggested that POM's products—due at least in part to their high concentration of polyphenol antioxidants—could promote heart and prostate health and improve erectile function by inhibiting oxidative damage to cell tissue, preserving helpful concentrations of nitric oxide in the body, and mitigating arterial inflammation. *See* ID¶¶754, 991-1023, 1310-12.

POM's research sponsorship has great depth and is virtually unparalleled in the food industry. Over the course of more than a decade, POM sponsored more than one hundred studies at more than forty research institutions, *seventy* of which were ultimately published in peer-reviewed scientific journals. *See* ID¶¶128-130.

Among these studies were also some that undertook the notoriously difficult task of studying the effects of POM's nutrient products through basic human trials. Such studies have well-recognized design issues when the product being tested is a natural food like pomegranate

juice or a prevalent dietary nutrient like antioxidants. In that context, randomized controlled trials (RCTs) are often either impossible or prohibitively expensive because, among other things, there are: (1) ethical concerns associated with asking a group of "control" subjects to avoid any consumption of an important nutrient; (2) feasibility concerns associated with trying to "blind" a natural product like fruit juice, which subjects can taste; and (3) cost concerns associated with trying to get a large set of subjects to comply with long-term testing and diet restrictions outside the context of patentable drug treatments. *See* ID¶¶703-705.

For these and other reasons, many scientists have in fact concluded that in vitro trials and animal research can be better suited to study the effects of foods or nutrients on humans (and better able to provide a "control" in the study) than human trials. POM nonetheless decided to try initial human studies and see where they led. And like the laboratory and animal studies, some of these studies also showed encouraging results for heart, prostate, and erectile health. *See, e.g.*, ID¶¶754 (finding basic research suggests POM may benefit heart health), 1142 (finding POM study "supports the conclusion that the POM Products support prostate health"); 1250 (finding erectile dysfunction study had "clinical significance").

Of course, for various reasons including the constraints above, most of these studies were not the sort of large-scale RCTs typically associated with FDA-approved drugs. But because the totality of the science—including human studies, RCTs, and laboratory research—suggested potential benefits, and because pomegranate juice is undisputedly a safe product whose dominant use is as a nutritious fruit juice and not a disease treatment, POM ran a variety of ads, like those above and on the following page, designed to share this promising research with the public.

FIGURE 13


POMx
One small pill for mankind.
"Findings from a small study suggest that pomegranate juice may one day prove an effective weapon against prostate cancer."
The New York Times (July 4, 2006).
Introducing POMx™ – a highly concentrated, incredibly powerful blend of all-natural polyphenol antioxidants made from the very same pomegranates in POM Wonderful 100% Pomegranate Juice. Our method of harnessing astonishing levels of antioxidants is so extraordinary, it's patent-pending. So now you can get all the antioxidant power of an 8oz glass of juice in the convenience of a calorie-free capsule.
Ready to take on free radicals? Put up your POMx and fight them with a mighty 1000mg capsule – that's more concentrated pomegranate polyphenol antioxidants than any other 100% pomegranate supplement. An initial UCLA medical study on POM Wonderful 100% Pomegranate Juice showed hopeful results for men with prostate cancer.[1,2] And preliminary human research suggests that our California-grown pomegranate juice also promotes heart health.[2,3] Take your antioxidants into your own hands. Call 1-888-POM-PILL now, or visit pompills.com/fort and get your first monthly shipment for just $29.95 $24.95 with coupon.
POM IN A PILL™
CALL 1-888-POM-PILL now, or visit pompills.com/fort
Not available in stores | 100% money-back guarantee
SAVE $5 ON YOUR FIRST ORDER.

These ads are generally representative of POM's campaign. In the main, POM either described the possible health benefits of its products only in very general and *highly* qualified terms or endeavored to share the precise results of the studies, together with information on where to find them. Notably, the most prominent text in the ad above is a direct quote from *The New York Times* for the proposition that "[f]indings from a *small* study *suggest* that pomegranate juice *may one day* prove an effective weapon against prostate cancer." *Supra* p.9 (emphasis added).

As these examples further indicate, petitioners' ads made no express claims that POM products treat, prevent, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction, and none claimed that those effects had been "clinically proven." ID¶586. Instead, the vast majority used the kind of heavily qualified language above—describing results as "promising," "hopeful," "preliminary" or "initial"—and made express disclaimers that the products are not intended to treat or prevent any disease. *E.g.*, Pet. App. 234a, 251a, 304a-308a. Indeed, with the exception of a few early ads, POM's approach was to describe precisely what research was done, including where it was done, and to transparently summarize the results with quotes from the published studies themselves. *E.g.*, *id.* 308a. And at all times, POM undisputedly marketed its products as a healthy food product sold in the refrigerated section of grocery stores, never as an alternative to medical treatment. *See* ID, 246.

The entire campaign, however, involved many different ads, some of which characterized the research results more strongly than others. For example, one of POM's early ads depicted a POM bottle with a toothbrush and toothpaste under the headline "Floss your arteries," and contained a sentence stating: "Just eight ounces a day

can reduce plaque by up to 30%!" Pet. App. 208a. A footnote connected that claim to one of POM's early, non-RCT human trials, which it described as a "clinical pilot study." To be sure, ads like these arguably imply stronger claims about POM's effectiveness in promoting human health than some of the foregoing examples (ignoring for the moment their emphasis on naturally occurring antioxidants in 100% fruit juice). Yet, quite notably, even such ads lack any claim of unqualified scientific *proof* and do not remotely market POM as having the effects or testing pedigree of a pharmaceutical product.

2. The FTC's staff nonetheless concluded that many POM ads were misleading because—their truthful text aside—they supposedly *implied* to consumers that pomegranate juice was an unqualifiedly proven means of curing or preventing serious diseases like arteriosclerosis or prostate cancer in the absence of support from gold-standard RCTs. The FTC thus filed an administrative complaint against POM, asserting, *inter alia*, that these ads misleadingly implied that POM had been scientifically established as an effective disease intervention. It did not claim, however, that petitioners' ads placed public health or safety at risk.

Faced with such allegations, the vast majority of advertisers settle with the FTC to avoid the threat of monetary sanctions or follow-on suits by enterprising class-action claimants. But POM was adamant that its ad campaign was intended only to truthfully report the results of its research, and it contested the FTC's allegations in a trial before the Commission's chief administrative law judge. The FTC ultimately alleged that 43 of POM's ads implied a misleading message about POM's status as a proven treatment for serious diseases. Critically, the ALJ determined that only a minority of those ads—nineteen in all—contained any such implied message. Pet. App. 12a. As a result, the ALJ entered only a limited injunction,

instructing POM not to run any future ads making health claims about its products without "competent and reliable scientific evidence." *Id.*

Both petitioners and the FTC staff appealed to the full Commission for review. As relevant, the FTC argued that the ALJ erred in finding that only nineteen ads implied the allegedly misleading claims, and urged the Commission to impose liability on a much broader set of ads. *Id*.

Over the disagreement of Commissioner Ohlhausen, the Commission adopted a far broader interpretation of health claims in advertising and used it to reverse much of the ALJ's reasoning—banning a substantially larger category of ads. *Id.* 12a-13a. Under the Commission's reasoning, 34 different ads (including all three of those above) made implied, *unqualified* claims that POM was a *scientifically proven* treatment for serious human ailments including heart disease, prostate cancer, and erectile dysfunction. (The FTC refers to these claims of proof as "establishment claims.") For two other ads, it agreed with the ALJ that they claimed that POM was an effective disease treatment, but did not discuss whether these ads made claims of clinical proof. (Claims of effectiveness without claims of proof are called "efficacy claims," and together with establishment claims, are called "disease claims.") *See id.* 182a-195a (FTC appendix with findings for various ads); 309a-311a (FTC summary table of ad-by-ad findings by FTC and ALJ). Thus, in contrast with the ALJ, the Commission imposed liability based on 36 ads in total, in the process demonstrating that it would, going forward, imply much stronger disease claims into any ads purporting to discuss the possible health benefits of natural food products like juice. *Id.* 12a-13a.

It avowedly did so without any evidence regarding how consumers actually read these ads, relying solely on

its own facial analysis instead. *Id.* 60a-72a. At the same time, it relied on testimony from experts about what kind of evidence scientists in the field would require to make the disease claims the FTC inferred into the ads—finding that they would require RCTs. *Id.* 82a-86a. This allowed the Commission to vastly expand the set of banned ads to include all those that *laypeople* would perceive as making disease claims if they were not substantiated by the evidence *experts* would require to make such claims. The FTC did not care, for example, what evidence experts would demand for a "small study" to "suggest" that POM might "one day" provide a health benefit. *See supra* p.13; Pet App. 85a ("Although there is substantial testimony regarding the level of support required for generalized nutritional and health benefit claims, such evidence does not address the issue before us."). Nor did it ask *any* questions of laypeople, including what kind of scientific evidence *they* would expect from the actual ads at issue. *Id.* 73a (explaining that FTC offered no extrinsic evidence of its own).

The Commission's decision to apply a much broader standard for facially implying disease claims into POM's ads without any extrinsic evidence dramatically affected the injunctive relief it imposed on POM. The FTC's injunction forbids POM from making any disease claims without support from an RCT. Pet. App. 13a, 44a.[2] The scope of that injunction thus turns entirely on what counts as a disease claim. For example, under the ALJ's ruling, there are seventeen specific ads POM would be able to run tomorrow, because they make no disease claims. But

[2] The Commission initially attempted to prevent POM from making any such claims without support from *two* RCTs. But the D.C. Circuit held that this ban on future speech could not be justified under the First Amendment. *See* Pet. App. 44a.

under the Commission's view, these ads *do* make the impermissible "implied" claims, and POM cannot run them or anything like them now or in the future.

The same is true for the industry as a whole. The precedential effect of the Commission's order in this case is that any natural-food advertiser cannot make a disease claim in the absence of RCT support. Indeed, the FTC clearly intended this case to serve as a precedent-setting decision expanding a requirement for RCT testing in the natural-food context, and the industry and its counsel have seen it just that way. *See, e.g.*, *The D.C. Circuit's* POM Wonderful *Decision*, Crowell & Moring (Feb. 19, 2015), https://goo.gl/A71AIz. But, again, the meaning of that rule depends entirely on what counts as a disease claim. Under the ALJ's standard, substantially fewer ads would be interpreted as making the kind of unqualified, pharmaceutical-style claim that the Commission now forbids in the absence of RCT support. But if the Commission is correct that a far broader set of ads make the impermissible claims, then other commercial speakers must rein in their speech severely to avoid transgressing the Commission's new standard.

Commissioner Ohlhausen's separate opinion emphasized this problem and refused to agree that many of the ads at issue made efficacy or establishment claims. She emphasized that the Commission was finding *implied* disease claims when the ads largely discussed only "continued healthy functioning," Pet. App. 151a, and that the Commission was eliding that well-recognized distinction without any evidence "that consumers viewing the exhibits would actually perceive [the] stronger claims." *Id.* 151a-156a (further noting that "Congress and the Food and Drug Administration have created carefully drawn boundaries between different types of claims," and expressing "concern[] that the majority's interpretation of certain exhibits blurs these boundaries"). In her view, it

was inappropriate to make such strong conclusions from the face of the ads themselves because it would throw off the balance between requiring appropriate substantiation for health claims and getting useful information to consumers. She urged the Commission to "keep in mind … that if we are too quick to find stronger claims than the ones reasonable consumers actually perceive, then we will inadvertently, but categorically, require an undue level of substantiation for those claims." *Id.* 155a. She then proceeded, on an ad-by-ad basis, to explain why the Commission had over-read many of POM's claims—especially by ignoring their qualified language. *Id.* 160a-161a (discussing Fig.12, *supra* p.2, and noting that "the text is qualified with references such as 'emerging science'"), 161a (discussing Fig.13, *supra* p.9, and noting that the ad contains "heavily qualified descriptions of studies").

Notably, Commissioner Ohlhausen also recognized the First Amendment implications of the Commission's decision. As she noted, its broad willingness to imply unqualified disease claims into commercial speech—without any extrinsic evidence to support the proposition that consumers would actually be misled—"raises questions about whether this approach qualifies as a case-by-case analysis or is more like a broad prohibition on certain categories of speech, which has implications for First Amendment review of our actions." Pet. App. 154a & n.8. And she further clarified the "broad prohibition" that she saw at work in the Commission's facial analysis: Pointing to some of the same ads identified above, she concluded that, under the precedent set in this case, "the mere mention of 'health' or healthy functioning can imply a disease-related efficacy [claim] … and the mere mention of scientific evidence can imply a related establishment claim." *Id.* 157a. Accordingly, she noted that, "[b]ased on the majority's views about these exhibits, it is difficult

to imagine any structure/function claims that POM could associate with its products in the marketplace without such claims being interpreted, under the FTC precedent set in this case, as disease-related claims." *Id.*[3] Simply put, her concern was that the decision would function as a broad gag order on the industry going forward.

3. POM appealed to the D.C. Circuit, arguing that the Commission's aggressive interpretation of its ads led it to ban them in violation of the First Amendment and the balancing test for commercial speech imposed by *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980). POM explained that the ads were only *potentially* misleading because the Commission had no evidence that consumers were actually misled and was instead proceeding based solely on its facial judgment that a "significant minority" would misperceive unqualified disease claims that the ads did not actually make. Forbidding language that is true but might *imply* something misleading to consumers is the kind of action that must be balanced against the First Amendment costs of withholding information from the marketplace. And because, as POM explained, there was no risk to health or safety from POM's products, the FTC's broad ban on making any kind of health-related claims in natural-food ads violated *Central Hudson* and the First Amendment.

Of course, *Central Hudson*'s balancing test only applies if commercial speech is truthful and non-misleading, raising the predicate issue whether the speech in question

[3] "Structure/function" claims are a term of art for claims that relate merely to the continued healthy functioning of a body structure, rather than a claim to treat or prevent a particular disease, and have always required less scientific substantiation than disease claims or claims of scientific proof.

satisfies that standard. *See* 447 U.S. at 566. But this Court has made very clear that when an agency or lower court determines that a particular advertisement cannot be shown to consumers because it may mislead them, the appellate court must scrutinize that claim *de novo* to avoid placing the ad outside the First Amendment's protections at the discretion of the censor. *See Ibanez*, 512 U.S. at 144-148; *Peel*, 496 U.S. at 108; *Bose*, 466 U.S. at 503-511. These cases include the decision to withhold deference from state supreme courts acting in their capacity as regulators of the state bar and preventing lawyers from running particular, individual ads *ex post* on the theory that they implied, on their face, a misleading message to the public. *Peel*, 496 U.S. at 101, 104-105, 108. POM thus asked the D.C. Circuit to review *de novo* the determination that its ads implied that there was unqualified proof that pomegranate juice could cure or prevent diseases.

Notably, the FTC declined to defend its order under *Central Hudson*, and instead rested its argument entirely on the theory that it had determined that POM's ads contained a misleading message that it had concluded received no First Amendment protection whatsoever. It urged the court to review those determinations only with substantial deference, and to end the First Amendment inquiry there.

The D.C. Circuit agreed, and affirmed in relevant part. Importantly, it did so for all of the ads prohibited by the Commission—including the seventeen ads the ALJ found not to include the alleged misleading claims—based on the "deferential" standard of review. Pet. App. 33a. As to those seventeen ads, it held only that there was "substantial evidence in the record" to sustain the FTC's finding; put otherwise, it found it sufficient to affirm that the FTC had not acted *arbitrarily* in finding that "at least a significant minority of reasonable customers" would have

read POM's ads to convey misleadingly unqualified disease claims. *Id.* 15a, 33a (describing FTC's "significant minority" standard).

The panel made clear, however, that it had reached that conclusion on *de novo* review only "with respect to the nineteen ads determined misleading" by the ALJ—conspicuously failing to make such a finding with respect to the seventeen further ads the Commission prohibited under its more sweeping standard. *Id.* 33a. Like the FTC, the panel relied exclusively on the face of the ads for these findings. Among the seventeen ads whose ban the D.C. Circuit affirmed only under deferential review—and without any substantial discussion—are all three of those above.

Indeed, the Court of Appeals decided to apply only deferential review even though it recognized that the standard the Commission had settled on for implying claims of *unqualified* clinical proof into health ads would have quite broad effect going forward. Elsewhere in its opinion, the court recognized that the "evident leeway to make 'effectively qualified' disease claims … appears to be highly circumscribed," in the sense that "[r]epresentations characterizing a study's results as 'preliminary' or 'initial'" would be read by the FTC as completely unqualified claims of clinical proof that a product treats or prevents disease. *Id.* 35a-36a. Put otherwise, the panel fully recognized that the FTC found POM's ads to contain misleading messages of unqualified clinical proof according to a standard that broadly implies such claims into ads that contain the *opposite* words. But it still determined that the First Amendment permits a court to affirm an FTC decision applying that standard solely under the APA's highly deferential standard of review.

4. POM sought rehearing en banc, emphasizing that the decision conflicted with this Court's cases. In

particular, POM emphasized that the decision had relied on circuit precedent that had never even considered *Peel*. Rehearing was denied. Pet App. 181a.

REASONS FOR GRANTING THE WRIT

The question of the proper standard of review when an agency bans speech by reading an implied, misleading message into otherwise truthful commercial speech plainly merits certiorari review for four reasons. First, the D.C. Circuit's determination that review must be deferential is clearly contrary to this Court's precedent. Second, there is a division of authority in the courts on this question, and the few courts that have refused to follow this Court's cases are expressly waiting for this Court's guidance. Third, the issue is important and necessary to resolve now because the decision itself will frustrate future vehicles. And fourth, any such future vehicles that do arise are unlikely to be as good as this one: This is the rare case in which the Court of Appeals (and decisions below) distinguished among a large set of ads meeting different standards of review. Accordingly, this case provides a golden opportunity to clarify the standard in a situation where it makes a difference, and the broad record of ads at issue allows that question to be resolved in a concrete fashion that gives guidance to future courts.

I. The Decision Below Conflicts With This Court's Precedent.

As an initial matter, the D.C. Circuit's decision in this case is wrong. This Court has insisted that appellate courts review the kind of predicate factual finding at issue *de novo* in the First Amendment context precisely because a contrary rule leaves the First Amendment's application almost entirely in the hands of the censor. And the D.C. Circuit's rule here does just that: By affirming a speech ban whenever the FTC can survive deferential, arbitrary-and-capricious review on the proposition that a

"substantial minority" of consumers will be misled by an ad, the D.C. Circuit leaves the Commission (and other agencies) free to read broad claims into everyday examples of commercial speech, with the end of keeping them from the public on the very kind of paternalistic grounds that this Court's doctrine condemns.

Accordingly, over 30 years ago, this Court made clear that "factual" determinations by lower tribunals that go to the protected character of the speech in question are reviewed *de novo*. *See Bose*, 466 U.S. at 503-511. And not long thereafter, this Court applied that rule to require *de novo* review in two indistinguishable situations where regulators determined that particular ads could imply a misleading message and should be sanctioned as a result. *See Peel*, 496 U.S. at 108; *Ibanez*, 512 U.S. at 144-148.

The Court's seminal decision in this area is *Bose*, which held that a finding of "actual malice" in defamation cases is subject to *de novo* appellate review because it goes to the protected character of the speech. 466 U.S. at 503-511. *Bose* noted that such "factual" determinations are always reviewed *de novo* by successive courts—including in such various contexts as whether the allegedly unprotected speech is knowingly false, fighting words, likely to incite violence, obscenity, or child pornography. *Id.* at 504-08. That broad holding, and its reasoning, strongly suggest that *de novo* review is likewise required in the analogous context where the FTC claims that speech is in an unprotected category because it implies a misleading message to a minority of consumers.

Indeed, it is worth noting how emphatic a holding *Bose* laid down. *Bose* was a defamation case, in which the relevant evidentiary issue was whether the speaker knew that the statements he was making were false. After a nineteen-day bench trial, *id.* at 489, an Article III judge concluded that the speaker knew the statements were

false, expressly relying on credibility findings. *Id.* at 497. This Court recognized that, under Rule 52(a), "[f]indings of fact shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses." *Id.* at 498. And it openly acknowledged that "an inquiry into what a person knew at a given point in time" easily falls within the findings of "fact" on which Rule 52(a) requires deference. *Id.* Nonetheless, *Bose* held that "Rule 52(a) … does not prescribe the standard of review," and instead "reaffirm[ed] the principle of independent appellate review that we have applied uncounted times before," when the "factual" question goes to the constitutionally protected character of the speech. *Id.* at 514.

Further, this Court recognized the importance of laying down that rule by both reaching out to do so and giving it remarkable breadth. The *Bose* Court noted that it could well have reversed even "under the clearly-erroneous standard of review." *Id.* at 514. It likewise recognized that the "actual malice" standard of *New York Times v. Sullivan*, 376 U.S. 254 (1964), did not even obviously apply, as the allegedly defamatory statements in *Bose* concerned only the quality of Bose loudspeakers. *See* 466 U.S. at 514. But this Court nonetheless took the opportunity to emphasize that "[a]ppellate judges in such a case *must exercise independent judgment*," even though "the question presented reaches us on a somewhat peculiar wavelength." *Id.* (emphasis added). And this Court even emphasized that "the rule of independent review assigns to judges a constitutional responsibility that cannot be delegated to the trier of fact," even if the fact-finding at issue falls within the province of "a jury" as constitutional factfinder. *Id.* at 501.

The Court in *Bose* also carefully explained why independent judicial review on such "factual findings"

was required—namely, because it is the responsibility of the judiciary under the First Amendment to establish the breadth of any category of unprotected speech. As the Court explained, "[p]roviding triers of fact with a general description of the type of communication whose content is unworthy of protection has not, in and of itself, served sufficiently to narrow the category, nor served to eliminate the danger that decisions by triers of fact may inhibit the expression of protected ideas." *Id.* at 505. Indeed, *Bose* emphasized the ever-present risk in the First Amendment context that an alleged factual finding may represent bias against the speech at issue: "The principle of viewpoint neutrality that underlies the First Amendment itself also imposes a special responsibility on judges *whenever* it is claimed that a particular communication is unprotected." *Id.* (emphasis added, citation omitted).

Although a passing footnote in *Bose* led to questions whether this Court would apply the same rule to commercial speech cases, *see id.* at 504 n.22, those questions were rapidly put to rest in *Peel*. 496 U.S. at 108. There, the Illinois Supreme Court sanctioned certain attorney advertisements on the theory that they could imply a set of misleading messages to some consumers. Citing *Bose*, this Court expressly held that, in that commercial-speech context as well, "[w]hether the inherent character of a statement places it beyond the protection of the First Amendment is a question of law over which Members of this Court should exercise *de novo* review." *Id.* That was particularly so because the issue was not any ad's "facial accuracy, but … its implied claim[s]." *Id.* at 101. This Court thus rigorously scrutinized the ads and their supposed implied claims and determined that—where the ads did not "necessarily" imply the misleading message—it would not permit banning them based on "paternalistic assumption[s]" about the audience. *Id.* at 104-05.

Finally, this Court reaffirmed its *de novo* approach to deceptive-advertising determinations in *Ibanez*. 512 U.S. at 144-48. There, the Florida Board of Accountancy sanctioned Ibanez for using designations in her promotional materials it believed would deceive the public into thinking that she was certified by the state. *Id.* at 144-45. This Court reaffirmed *Peel*, gave no deference to the Board's finding that consumers would be *actually* misled by the ads into believing petitioner was state certified, and proceeded to apply the First Amendment's balancing analysis to ultimately reject the proposition that such designations could be regulated as "potentially misleading" commercial speech. *Id.* at 145-148.

These cases—particularly *Peel*—are remarkably on point. In *Peel*, as here, the Court had before it an *ex post* determination that *particular* advertisements implied a misleading message. 496 U.S. at 101. There, as here, the lower tribunal found that the allegedly misleading implied messages existed based solely on a facial analysis of the ads, with "no contention that any person was actually misled or deceived." *Id.* at 101, 106, 108; *see also Ibanez*, 512 U.S. at 145 (noting that there, as in *Peel*, the regulator did not rely on "any evidence of deception"). And in those cases, as here, the regulator who found the implied, misleading message was a fact-finding tribunal *and* subject-matter expert ordinarily entitled to great deference on appeal. *Peel*, 496 U.S. at 108 (rejecting deference to Illinois Supreme Court in its capacity as regulator of the state bar); *Ibanez*, 512 U.S. at 144-45 (giving no deference to state board specifically charged with regulating accountancy). Indeed, *Peel* specifically rejected the dissent's call for deference to the Illinois Supreme Court on the ground that it was "in a far better position … to determine which statements are misleading or likely to mislead," 496 U.S. at 108, holding instead that where such a tribunal "[l]ack[s] empirical evidence to support its

claim of deception," the question "[w]hether the inherent character of a statement places it beyond the protection of the First Amendment" requires "*de novo* review." *Id.* That exact holding determines the outcome here.

Indeed, there is no meaningful way to distinguish these cases, which perhaps explains why the D.C. Circuit did not even try to do so—instead relying on footnotes from its own, plainly outdated circuit precedent. Pet. App. 33a; *infra* pp.28-29. In particular, a federal agency like the FTC is entitled to no more deference in this area than a state agency or state supreme court regulating the state bar, and it is largely backwards for *First Amendment purposes* to give a political body like the FTC greater "fact-finding" deference than an Article III court or jury of the kind at issue in *Bose.* As this Court noted, one of the principal First Amendment concerns that leads to the *de novo* review requirement is that a decision-maker's "factual" determination placing speech in an unprotected category may not really be value or viewpoint neutral. *Bose*, 466 U.S. at 505. Surely, that risk is far *lesser* where the decision-maker is a neutral, life-tenured judge rather than an agency avowedly free to pursue its own policy preferences. Choosing to defer to the facial analysis of a political agency, when this Court has instructed courts not even to defer to a neutral court's analysis of a nineteen-day trial record, represents an indefensible refusal to apply this Court's settled law.

Even standing alone, the D.C. Circuit's vast departure from this Court's binding precedent requires review. But, as explained below, the case for certiorari is far stronger than that because review of federal agency cases appears to be the *sole* context in which *any* courts have departed from *Bose* and *Peel*, creating a clear split on how false-advertising cases are reviewed under the First Amendment.

II. There Is A Circuit Conflict On The Question Presented, And The Lower Courts Are Awaiting This Court's Guidance.

The D.C. Circuit here joined the Seventh Circuit as the only court since *Bose* and *Peel* to deny that independent judicial review applies to the question whether a given ad's language on its face implies a misleading message to consumers. In various, closely related contexts, other courts have routinely recognized that *Bose* and *Peel* govern. And, importantly, it is clear from both the decisions of the D.C. and Seventh Circuits that they are awaiting a definitive holding from this Court on the question presented. This Court should provide the guidance these courts evidently need.

Many courts have recognized that *Bose* and *Peel* uncontroversially require *de novo* review in this context. This includes multiple holdings from state supreme courts, which frequently encounter this issue when state boards enforce advertising standards for regulated professions. In a recent example, the Virginia Supreme Court considered whether certain blog posts by an attorney were misleading commercial speech because they discussed his victories without a disclaimer that results in legal cases cannot be guaranteed. *Hunter v. Va. State Bar*, 285 Va. 485, 492 (2013). The state bar claimed the posts were actually or inherently misleading and unprotected by the First Amendment. *Id.* at 500. Citing *Peel* and *Bose*, the Virginia Supreme Court recognized that it would have to review that suggestion *de novo* because "[a]n appellate Court must independently examine the entire record in First Amendment cases to ensure that a 'a forbidden intrusion on the field of free expression' has not occurred." *Id.* at 495-496. And it found that the posts were *not* inherently or actually misleading, and were instead protected speech

that was only potentially misleading and thus subject to *Central Hudson*'s balancing test. *Id.* at 499-500.

Other state supreme courts are in accord. In *Snell v. Engineered Systems & Designs, Inc.*, 669 A.2d 13, 19 (Del. 1995), the Delaware Supreme Court considered a lower court finding about whether a given trade name misleadingly implied to consumers that the company at issue involved state-licensed engineers. Again, citing *Peel*, the court recognized that the question whether the speech at issue was "actually or inherently misleading, although resembling a factual question, is actually a matter of law, subject to this Court's *de novo* review." *Id*. And the court then refused to find that the trade name at issue was actually or inherently misleading commercial speech absent some *evidence* that reasonable people were actually being misled. *Id.* at 21.

Likewise, in *Appeal of Sutfin*, 141 N.H. 732, 736 (1997), the New Hampshire Supreme Court considered a decision by the Board of Dental Examiners that had reviewed a dentist's ad and determined that his truthful advertisement for a surgical procedure implied various misleading messages about its superiority. The court recognized that, because the Board had no actual evidence of deception, its facial judgment amounted to a claim that the ad was "inherently misleading" because of its implied messages. And, again citing *Peel*, it recognized that this is manifestly a question "that an appellate court must review *de novo*." *Id.* at 736. Undertaking that review, the court reversed. *Id.* at 736-737.

Decisions like these plainly demonstrate that the supreme courts of the several states recognize that they cannot, under *Bose* and *Peel*, show their state agencies the First Amendment deference as censors of commercial speech that the D.C. Circuit here extended to the FTC. And no court has ever articulated a rationale under which

state subject-matter experts governing particular, long-regulated professions would be shown *less* deference than federal agencies purporting to regulate advertising far more generally.

Federal court decisions likewise adhere to the plain meaning of *Peel* and *Bose* and routinely note the broad rule that "in cases involving First Amendment claims, an appellate court must undertake independent review of the record." *Braun v. Soldier of Fortune Magazine, Inc.*, 968 F.2d 1110, 1120-21 (11th Cir. 1992). They have applied that rule to a jury finding that a particular ad would have implied to reasonable people that it advertised illegal services, *id.*; to a Texas rule that it would mislead consumers for non-licensed individuals to refer to themselves as interior designers, *Byrum v. Landreth*, 566 F.3d 442, 447-48 & n.5 (5th Cir. 2009); to district court fact-findings regarding a ban on direct mail solicitation of personal-injury victims, *Revo v. Disciplinary Bd. of Supreme Court of N.M.*, 106 F.3d 929, 932 (10th Cir. 1997); to a civil enforcement action based on fraudulent commodity marketing, *CFTC v. Vartuli*, 228 F.3d 94, 108 n.7 (2d Cir. 2000); and—quite recently—to a district court judgment that particular ads by a health-care referral service misled consumers regarding the source and nature of potential compensation for medical injuries. *Otto*, 744 F.3d at 1055.

In contrast, only the D.C. and Seventh Circuits have denied the application of *Bose* and *Peel* in this context. And to the extent they even offer a defense of that decision, it only further demonstrates the need for this Court's intervention.

In particular, the Seventh Circuit has made clear that it is only waiting for this Court's guidance. In *Kraft*, the FTC had found Kraft liable for running misleading ads regarding the calcium content of cheese slices, and Kraft appealed, seeking *de novo* review under *Bose* and *Peel*. *See*

970 F.2d at 313. The case arose shortly after *Peel* and before *Ibanez*, and the Seventh Circuit concluded that while "*Peel* arguably extended *de novo* review to … commercial advertising," it was not clear that this Court intended that result, so it would "decline to apply *de novo* review in [the FTC] context." *Id.* at 317. *Kraft*'s core reasoning was that—in a decision long predating *any* of this Court's commercial-speech cases—this Court had applied deferential review in an FTC false-advertising case, *see id.* at 316 (citing *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 385 (1965)), and the Seventh Circuit believed it was compelled to wait for this Court to overturn that precedent before it did so itself based on *Bose* and *Peel*. *See id. at* 317 (quoting *Rodriquez de Quijas v. Shearson/American Express, Inc.*, 490 U.S. 477, 484 (1989), for the proposition that "[i]f a precedent of this Court has a direct application in a case, yet appears to rest on reasons rejected in some other line of decisions, [Courts] of Appeals should follow the case which directly controls, leaving to [the Supreme] Court the prerogative of overruling its own decisions"). So, while "*Colgate-Palmolive* preceded the extension of first amendment protection to commercial speech," and "one might argue that *Bose* and *Peel* operating in tandem effectively overrule *Colgate-Palmolive*," the Seventh Circuit refused to take that step absent this Court's guidance. *Id.* at 316-317.

The D.C. Circuit's endorsement of deferential review is likewise rooted entirely in the stickiness of outdated precedents. Shortly after *Bose*, and before *Peel*, a footnote in a D.C. Circuit decision expressed doubt whether *Bose* would apply to commercial-speech cases. *See FTC v. Brown & Williamson Tobacco Corp.,* 778 F.2d 35, 41 n.3 (D.C. Cir. 1985). Then, *after Peel*, the Seventh Circuit relied on that footnote to reject *de novo* review in *Kraft*. *See* 970 F.2d at 317. Thereafter, yet another D.C. Circuit footnote would rely on these precedents to reject an

argument for *de novo* review in an FTC false-advertising case *without even acknowledging* that *Peel* had intervened. *See Novartis v. FTC*, 223 F.3d 783, 787 n.4 (D.C. Cir. 2000). And in this case, the D.C. Circuit once again rejected an argument for *de novo* review under *Bose* based entirely on its own previous footnotes and the decision in *Kraft*—again omitting any mention of *Peel* and its application of *Bose* in the commercial-speech context.

These outlier decisions refusing to follow *Bose* and *Peel* where they obviously apply are rooted in no more than outdated precedent that this Court's decisions have passed by. Perhaps it is understandable that these courts would wait for this Court to acknowledge that its own, ancient precedents regarding review of FTC decisions have been eclipsed not only by *Bose* and *Peel*, but also by *Central Hudson* and the entire doctrine of commercial-speech protection. But if this Court is going to instruct lower courts to await its specific guidance before jettisoning outdated precedent, that guidance should be swiftly provided—especially when those courts *expressly say* they are waiting for it. Otherwise, a bizarre divergence of authority will persist where findings of misleading advertising are reviewed *de novo* when they come from courts, juries, and expert state regulators, but not federal agencies, for a reason no court has even tried to explain.

III. The D.C. Circuit's Error Is Critical And Requires Prompt Correction.

Allowing agencies to imply purportedly misleading messages into truthful commercial speech, subject only to deferential review, is also enormously consequential.

As an initial matter, the outcome of this case is of critical, nationwide importance for two reasons. First, the FTC brought this action as a test case, *supra* p.14, and the Commission's precedential opinion will govern the entire industry nationwide. That rule has never been subjected

to independent First Amendment analysis. If anything, the D.C. Circuit's refusal to uphold the ban on nearly half the ads at issue under *de novo* review strongly suggests that the FTC has in fact banned POM's protected speech and chilled the protected speech of others going forward. This Court should not allow a major, precedent-setting, nationwide speech restriction to go into effect without any independent First Amendment review.

Separately, the question presented has huge practical significance. Subject only to APA review, the FTC (and *any* other agency, state or federal) will have essentially a free hand to ban certain kinds of truthful commercial statements in *any* industry on the theory that a substantial minority of consumers will misunderstand them, even if the underlying motive is likely political. A commission that believes daily fantasy sports games are too close to gambling—perhaps after lobbying from casinos—could sanction a company for prominently discussing large pay-outs on the theory that some substantial minority of consumers are misled regarding the likelihood of winning. A commission that thinks guns are more dangerous than people believe could fine manufacturers for advertising their safety features. A commission that believes in organic farming could forbid use of the word "natural" by any foods containing conventionally farmed products on the theory that some minority of consumers would understand organic and natural as synonyms. And a commission that disfavors certain medical procedures can find that claims regarding those procedures are misleading because of what they "imply" and sanction providers accordingly. Subjecting such speech-restrictive decisions only to highly deferential, arbitrary-and-capricious review is an invitation to First Amendment mischief.

Moreover, the nature of this rule is that leaving it in place will itself restrict this Court's opportunities for review. Speakers who know independent judicial review

is unavailable will avoid making any statements that could come within the arguable orbit of agency prohibitions—however unjustified those prohibitions might be. And when they do raise regulators' hackles, they are very unlikely to go to trial and appeal all the way to this Court. That's particularly true because "trial" here involves expensive litigation before the agency, which is then appealed to the full agency, which (as this case shows) can then do pretty much anything within its discretion, unconstrained by ALJ factual findings or the prospect of meaningful judicial review.

The FTC's experience in this regard is instructive. Cases like these are already overwhelmingly likely to settle: While there have been many consent decrees on this issue in the thirty-plus years since *Bose*, *see* Pet. App. 41a-42a (citing many), petitioners have found only six Court of Appeals cases in that span concerning implied claims in FTC false-advertising suits—half of which arose in the D.C. Circuit. And the disincentive created by the D.C. Circuit's holding in this case will only make future cases even fewer and further between. That is particularly so because contested findings of liability from the agency give rise to follow-on class action suits aggregating a tremendous number of (largely dubious) claims, where the company will be held up for a large settlement. This Court can safely assume that, if the D.C. Circuit's grant of enormous deference to the FTC in this case remains in place, the agencies' settlement leverage will derail most future vehicles before they leave the station.

This is not to say the issue arises infrequently—far from it. The FTC is active in seeking to enforce its rules and has in fact vastly increased its activity in this area. *Supra* p.14. The point is merely that, given deferential review in the courts, vehicles that actually take this issue through the appellate process are unlikely.

That effect is further multiplied by the unique role the D.C. Circuit plays in agency review. It will be the forum in most or all cases arising from many federal agencies—including the FTC, FCC, FDA, USDA, DOT, and others that routinely purport to regulate the way companies can communicate with consumers. This case thus confirms to the entire breadth of the federal regulatory state that it has a highly favorable forum for defending any decision it might make to condemn a company for how it chooses to speak in the marketplace. This Court's intervention is therefore merited.

IV. This Is A Uniquely Good Vehicle For The Question Presented.

For the reasons given, it would be appropriate to grant certiorari on the question presented now even if this were an ordinary vehicle for reviewing it. But, in fact, this case presents a particularly good vehicle for considering the appropriate standard of review. Even leaving aside the chilling effect of this decision on the already infrequent vehicles that make it all the way through an administrative trial and appeal, future vehicles as strong as this one are unlikely to arise.

The typical case involves one relevant claim; this case presents 36 separate and distinct ads which—given both the various administrative opinions and the approach taken by the D.C. Circuit—allow this Court to articulate the standard of review is a concrete fashion that will provide guidance to the lower courts. Not only is there a breadth of different ads at issue, but many of them were read quite differently by the ALJ and Commission, and Commissioner Ohlhausen's separate opinion carefully explains how an independent judgment on most of those ads should reach a different result. Moreover, the D.C. Circuit's opinion itself suggests that the standard of review would likely require different outcomes among those ads

by refusing to say that it would affirm the ban on nearly half the ads at issue under *de novo* review. Accordingly, this set of facts will allow this Court to demonstrate the importance and application of the standard of review in a concrete setting that will clarify future cases and permit POM to run several constitutionally protected ads that the Commission has banned.

The Commission will no doubt protest that the standard is not outcome-determinative here because the D.C. Circuit did not affirmatively say it would strike down the FTC's ban on the seventeen additional ads under *de novo* review, and in fact suggested that the FTC's remedial injunction could be affirmed even if liability was assessed on a smaller number of ads. *See* Pet. App. 33a. But this overlooks the critical point that the *scope* of that remedial injunction depends entirely on what counts as an ad making an impermissible disease claim, which—in turn—is certainly dependent on the standard for reviewing the FTC's suggestion that the ads found innocuous by the ALJ and Commissioner Ohlhausen and reproduced above really imply that POM is a scientifically proven cure for heart disease and cancer. Indeed, it is rare to be presented with a vehicle in which there is so strong an indication that the standard of review will make a difference in evaluating a prohibition on protected speech. This Court should take this opportunity and clarify that *Bose* and *Peel* apply to First Amendment review of federal agency orders no less than they do to indistinguishable orders arising from expert state regulators and Article III courts.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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October 23, 2015

APPENDIX

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued May 2, 2014 Decided January 30, 2015

No. 13-1060

POM WONDERFUL, LLC, ET AL.,
PETITIONERS

v.

FEDERAL TRADE COMMISSION,
RESPONDENT

On Petition for Review of an Order
of the Federal Trade Commission

Thomas C. Goldstein argued the cause for petitioners POM Wonderful, LLC, et al. With him on the briefs were John Graubert, Megan L. Rodgers, and Erik S. Jaffe.

Erik S. Jaffe was on the brief for petitioner Matthew Tupper.

Bilal K. Sayyed was on the brief for amici curiae Consumer Healthcare Products Association and Council for Responsible Nutrition in support of petitioners.

Jonathan W. Emord was on the brief for amici curiae Alliance for Natural Health USA and TechFreedom in support of petitioners.

Jonathan E. Nuechterlein, General Counsel, Federal Trade Commission, argued the cause for respondent. With him on the brief were *Joel Marcus*, Assistant General Counsel, and *Imad D. Abyad*, Attorney. John F. Daly, Attorney, Federal Trade Commission, entered an appearance.

Julie A. Murray, Scott L. Nelson, Allison M. Zieve, and *Stephen Gardner* were on the brief for amici curiae Public Citizen, Inc. and Center for Science in the Public Interest in support of respondent.

Before: GARLAND, *Chief Judge*, SRINIVASAN, *Circuit Judge*, and GINSBURG, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge* SRINIVASAN.

SRINIVASAN, *Circuit Judge*: POM Wonderful, LLC produces, markets, and sells a number of pomegranate-based products. In a series of advertisements from 2003 to 2010, POM touted medical studies ostensibly showing that daily consumption of its products could treat, prevent, or reduce the risk of various ailments, including heart disease, prostate cancer, and erectile dysfunction. Many of those ads mischaracterized the scientific evidence concerning the health benefits of POM's products with regard to those diseases.

In 2010, the Federal Trade Commission filed an administrative complaint charging that POM and related parties had made false, misleading, and unsubstantiated representations in violation of the Federal Trade Commission Act. After extensive administrative proceedings, the full Commission voted to hold POM and the associated parties liable for violating the FTC Act and ordered them to cease and desist from making misleading and inadequately supported claims about the health benefits of POM products. The Commission's order also bars POM and the related parties from running future ads asserting that their products treat or prevent any disease unless armed with at least two randomized, controlled, human clinical trials demonstrating statistically significant results.

POM and the associated parties petition for review of the Commission's order, arguing that the order runs afoul of the FTC Act, the Administrative Procedure Act, and the First Amendment. We deny the bulk of petitioners' challenges. The FTC Act proscribes—and the First Amendment does not protect—deceptive and misleading advertisements. Here, we see no basis for setting aside the Commission's conclusion that many of POM's ads made misleading or false claims about POM products. Contrary to petitioners' contentions, moreover, the Commission had no obligation to adhere to notice-and-comment rulemaking procedures before imposing liability in its adjudicatory proceeding. Additionally, we affirm the Commission's remedial order insofar as it requires POM to gain the support of at least one randomized, controlled, human clinical trial study before claiming a causal relationship between consumption of POM products and the treatment or prevention of any disease. We find inadequate justification, however, for the Commission's blanket requirement of at least two such studies as a precondition to any disease-related claim. In all other respects, we deny the petition for review.

I.

A.

Since 1987, entrepreneurs Stewart and Lynda Resnick have acquired and planted thousands of acres of pomegranate orchards in California. In 1998, they began to collaborate with doctors and scientists to investigate the potential health benefits of pomegranate consumption. They formed POM Wonderful, LLC to make, market, and sell pomegranate-based products. The products include POM Wonderful 100% Pomegranate Juice and two dietary supplements, POMx Pills and POMx Liquid, which contain pomegranate extract in concentrated form. The Resnicks are the sole owners of POM Wonderful and

an affiliated company, Roll Global LLC, which provides advertising and other services to POM. Those entities have engaged in a broad array of advertising campaigns promoting POM products through various media including magazine ads, newspaper inserts, billboards, posters, brochures, press releases, and website materials.

POM's promotional materials regularly referenced scientific support for the claimed health benefits of its pomegranate products. By 2010, the Resnicks, POM, and Roll had spent more than $35 million on pomegranate-related medical research, sponsoring more than one hundred studies at forty-four different institutions. This case involves studies examining the efficacy of POM's products with regard to three particular ailments: heart disease, prostate cancer, and erectile dysfunction.

1. POM sponsored a number of studies examining the capacity of its products to improve cardiovascular health. One such study, led by Dr. Michael Aviram of the Technion Israel Institute of Technology, examined the effect of pomegranate juice consumption by patients with carotid artery stenosis. Carotid artery stenosis is the narrowing of the arteries that supply oxygenated blood to the brain, usually caused by a buildup of plaque inside the arteries.

In Dr. Aviram's study, ten patients with carotid artery stenosis consumed concentrated pomegranate juice daily for a year, while nine patients with carotid artery stenosis served as a control group and consumed no pomegranate juice. The investigators measured the change in the patients' carotid intima-media thickness (CIMT), an indicator of plaque buildup. They found that patients who consumed pomegranate juice every day experienced a reduction in CIMT of "up to 30%" after one year, while CIMT for patients in the control group increased by 9% after one year. *POM Wonderful LLC*, No. 9344, Initial

Decision of ALJ at 115 ¶ 791 (U.S. Fed. Trade Comm'n May 17, 2012) (ALJ Initial Decision). As one of POM's experts would later testify, the Aviram study, while "suggest[ing] a benefit" from pomegranate juice consumption for patients with carotid artery stenosis, was "not at all conclusive," in part because of the study's small sample size. Id. at 118 ¶ 802 (quoting expert testimony). In 2004, the journal *Clinical Nutrition* published the study. See M. Aviram et al., *Pomegranate Juice Consumption for 3 Years by Patients with Carotid Artery Stenosis Reduces Common Carotid Intima-Media Thickness, Blood Pressure and LDL Oxidation*, 23 Clinical Nutrition 423 (2004).

Subsequently, in 2005, a larger study, led by Dr. Dean Ornish of the University of California, San Francisco and the Preventative Medicine Research Institute, followed seventy three patients with at least one cardiovascular risk factor for one year. The patients were randomly assigned either to drink one cup of pomegranate juice daily or to drink a placebo beverage. At the end of the study, Dr. Ornish and his coinvestigators found no statistically significant difference between the treatment group and the placebo group in CIMT change or any other heart-related measure.

In 2006, a third, still larger study, led by Dr. Michael Davidson of the University of Chicago, followed 289 patients with one or more coronary heart disease risk factors. As in the Ornish study, the patients were randomly assigned to drink either pomegranate juice or a placebo beverage each day. At the end of eighteen months, Dr. Davidson and his coinvestigators found no statistically significant difference in the rate of carotid intima-media thickening between patients in the treatment group and those in the placebo group. POM initially delayed publication of the adverse findings, but ultimately allowed publication of the study in 2009. See Michael H.

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

In their final report, Dr. Davidson and his coinvestigators noted that they had found some evidence of an association between pomegranate juice consumption and decreased CIMT among subgroups of patients with high triglyceride levels and low levels of HDL ("good") cholesterol. Dr. Davidson and his co-authors emphasized, however, that the findings for those subgroups were based on "post hoc exploratory analyses" unanticipated in the study protocol. As Dr. Davidson and his co-authors noted, "post hoc exploratory analyses . . . should be interpreted with caution" because of an increased risk of "type I errors" (i.e., false positives). *See id.* at 941. Even for patients in the high-risk subgroups, moreover, the reduction in arterial thickness was between 4% and 9% (depending on the measurement), substantially below the 30% decrease reported by Dr. Aviram.

Although Drs. Ornish and Davidson completed their arterial thickness studies in 2005 and 2006, respectively, a consumer reading POM's promotional materials after 2006 would not have known of those studies or that they cast doubt on Dr. Aviram's prior findings. In June 2007, for example, POM distributed a brochure featuring a statement by Dr. Aviram that "POM Wonderful Pomegranate Juice has been proven to promote cardiovascular health," along with a description of his arterial thickness study, but with no mention of Drs. Ornish's and Davidson's contrary findings. *POM Wonderful LLC*, No. 9344, Opinion of the Commission, App. B fig.10, at 5 (U.S. Fed. Trade Comm'n Jan. 10, 2013) (FTC Op.). That same summer, POM published a newsletter in which it asserted that "NEW RESEARCH

OFFERS FURTHER PROOF OF THE HEART-HEALTHY BENEFITS OF POM WONDERFUL JUICE." *Id.* App. B fig.16, at 3. The newsletter claimed a "30% DECREASE IN ARTERIAL PLAQUE" on the basis of Dr. Aviram's limited study but again omitted any mention of the Ornish and Davidson findings. *Id.* And in 2008 and 2009, POM conducted a $1 million promotional campaign, with seventy ads in newspapers and magazines across the country, in which it trumpeted Dr. Aviram's findings—including the 30% figure—without any acknowledgement of the contrary Ornish and Davidson studies. *Id.* App. B fig.25; *see also id.* App. B fig.19.

Dr. Ornish also conducted a separate study examining the relationship between pomegranate juice and blood flow. The study followed forty-five patients with coronary heart disease and myocardial ischemia (insufficient blood flow to the heart due to narrowing of the arteries). The patients were randomly assigned to drink either pomegranate juice or a placebo beverage daily. Dr. Ornish later testified that, although his protocol called for a twelve-month study, he terminated the study abruptly after three months because the Resnicks did not follow through on their previous commitment to fund a twelve-month trial.

At the end of three months, patients in the treatment group outperformed patients in the placebo group on one measure of blood flow to the heart, known as the "summed difference score." The study, however, found no statistically significant difference between the treatment and control groups on two other measures of blood flow (the "summed rest score" and the "summed stress score"), nor did it find any statistically significant differences in blood pressure, cholesterol, or triglycerides. Medical experts later noted a number of shortcomings of the study, including that patients in the placebo group began the

study with significantly worse blood flow than patients in the treatment group, potentially skewing the outcomes.

POM touted the results of the second Ornish study in its ads and promotional materials without noting the study's limitations or acknowledging that patients in the treatment group showed no statistically significant improvement in blood flow on two of three measures. In September 2005, for instance, POM issued a press release announcing the study in which it asserted that "blood flow to the heart improved approximately 17% in the pomegranate juice group" and that differences in blood flow between the two groups were "statistically significant." *Id.* App. B fig.8. POM continued to make similar statements in its promotional materials through 2009. *See id.* App. B fig.10, at 5 (June 2007 brochure claiming that "[p]atients who consumed 8oz of POM Wonderful 100% Pomegranate Juice daily for three months experienced a 17% improvement in blood flow"); *id.* App. B fig.16, at 3 (summer 2007 newsletter claiming "17% IMPROVED BLOOD FLOW"); *id.* App. B figs.37, 38, 39 (similar claims on POM websites in 2009).

2. In addition to the cardiovascular studies, petitioners sponsored research on the effect of pomegranate juice consumption in prostate cancer patients. One study, led by Dr. Allan Pantuck of the University of California, Los Angeles Medical School, followed forty-six patients who had been diagnosed with prostate cancer. All of the patients had already been treated by radical prostatectomy, radiation therapy, or cryotherapy. The study called for them to drink eight ounces of pomegranate juice daily. There was no control group. The study concluded that the patients' "PSA doubling time," a measure of the rapidity of growth in prostate tumor cells, increased from fifteen months at the beginning of the study to fifty-four months at the end. But

as Dr. Pantuck himself noted, patients who have undergone radical prostatectomy or radiation therapy for prostate cancer commonly experience a lengthening in PSA doubling time regardless of whether they consume pomegranate juice.

POM, however, made no mention of the limitations of the Pantuck study in its public statements. In a July 2006 press release, POM claimed that "drinking 8 ounces of POM Wonderful pomegranate juice daily prolonged post-prostate surgery PSA doubling time from 15 to 54 months," without noting that some or all of the increase in the patients' PSA doubling times may have resulted from the radical prostatectomies or radiation treatments undergone by the patients. *Id.* App. B fig.9, at 2. POM advanced similar claims in a June 2007 brochure and in a fall 2007 newsletter, again with no disclosure of the study's limitations. *See id.* App. B figs.10, 17. In 2008 and 2009, POM ads in the New York Times Magazine and TIME Magazine asserted that prostate cancer patients who drank eight ounces of POM Wonderful 100% Pomegranate Juice a day for at least two years experienced "significantly slower" PSA doubling times, once again without any acknowledgment that the patients' PSA doubling times may have slowed regardless of whether they consumed pomegranate juice. *Id.* App. B figs.21, 27; *see also id.* figs.36, 37, 38, 39 (similar claims on POM websites in 2009).

3. Petitioners additionally sponsored research of the effects of pomegranate juice consumption in men with mild to moderate erectile dysfunction. One study, led by Dr. Harin Padma-Nathan, a urologist in Beverly Hills, California, followed fifty-three patients over eight weeks. The study used a "crossover" design: one group of patients consumed pomegranate juice for the first four weeks and then consumed a placebo beverage for the next

four, while a second group consumed the placebo beverage for the first four weeks and pomegranate juice for the next four. Dr. Padma-Nathan and co-investigators evaluated the results using two measures: the International Index of Erectile Function (IIEF), a fifteen-question instrument, and the Global Assessment Questionnaire (GAQ), a one-question test. The IIEF is a "validated" tool, which means that the measure has been shown to have statistical reliability, while the one-question GAQ is not a validated measure for assessing erectile function. *See generally* R. C. Rosen et al., *The International Index of Erectile Function (IIEF): A State-of-the-Science Review*, 14 Int'l J. Impotence Res. 226, 226 (2002).

Dr. Padma-Nathan's study showed some evidence that patients scored higher on the GAQ measure after drinking pomegranate juice. But the *p*-value—the probability of observing at least as strong an association between pomegranate juice consumption and GAQ scores due to random chance—was 0.058, falling just short of statistical significance at the conventional $p<0.05$ level. On the scientifically validated IIEF measure, however, the difference between patients' scores after drinking pomegranate juice and after drinking the placebo beverage came nowhere near statistical significance: there was nearly a 3/4 likelihood of observing as strong an association due to random chance ($p=0.72$). *See* C.P. Forest, H. Padma-Nathan & H.R. Liker, *Efficacy and Safety of Pomegranate Juice on Improvement of Erectile Dysfunction in Male Patients with Mild to Moderate Erectile Dysfunction: A Randomized, Placebo-Controlled, Double-Blind, Crossover Study*, 19 Int'l J. Impotence Res. 564, 566 (2007).

In its public statements about Dr. Padma-Nathan's study, POM made no mention of the negative results with respect to the validated IIEF measure. POM instead touted the study outcomes based exclusively on the non-

validated GAQ measure. A 2007 POM press release thus described Dr. Padma-Nathan's study as follows:

> At the end of . . . each four week period, efficacy was assessed using the International Index of Erectile Function (IIEF) and Global Assessment Questionnaire (GAQ). The IIEF is a validated questionnaire that has been demonstrated to correlate with ED intensity. The GAQ elicits the patient's self-evaluation of the study beverages' effect on erectile activity. Forty seven percent of the subjects reported that their erections improved with POM Wonderful Pomegranate Juice, while only 32% reported improved erections with the placebo (p=0.058).

FTC Op. App. B fig.15, at 2. That press release, while referencing IIEF and thus suggesting that its description of the findings would account for that measure, in fact promoted the results based solely on the GAQ measure with no acknowledgment of the adverse findings on IIEF scores. In 2009 and 2010, POM similarly touted the GAQ findings— again without any mention of the negative IIEF results—on websites and in print ads. *See id.* App. B figs.33, 36, 37, 38, 39.

B.

In September 2010, the Federal Trade Commission filed an administrative complaint alleging that POM, Roll, the Resnicks, and POM's then-President Matthew Tupper had made false, misleading, and unsubstantiated representations in violation of the FTC Act. *See* FTC Act § 5(a)(1), 15 U.S.C. § 45(a)(1); FTC Act § 12(a), 15 U.S.C. § 52(a). The complaint identified forty-three advertisements or promotional materials containing claims alleged to be false, misleading, or unsubstantiated.

In May 2012, following an administrative trial, the Commission's chief administrative law judge found that nineteen of POM's advertisements and promotional

materials contained implied claims that POM products treat, prevent, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction. He further concluded that POM and the related parties lacked sufficient evidence to substantiate those claims, and that the claims were material to consumers. He therefore held the POM parties liable under the FTC Act and ordered them to cease and desist from making further claims about the health benefits of any food, drug, or dietary supplement unless the claims are non-misleading and supported by competent and reliable scientific evidence.

Both sides appealed to the full Commission. POM and the related parties argued that they should not have been held liable at all, while the Commission's complaint counsel argued that additional ads and promotional items (beyond the nineteen identified by the administrative law judge) made false or misleading claims. The complaint counsel also urged the Commission to impose an injunctive order barring POM from claiming that any of its products is effective in the treatment or prevention of any disease unless POM first gains pre-approval from the Food and Drug Administration.

In January 2013, the Commission unanimously affirmed the administrative law judge's decision to impose liability on POM and the other parties. Four of the five commissioners found that thirty-six of POM's ads and promotional items made false or misleading claims, but the Commission specified that injunctive relief would be justified even if based solely on the nineteen ads found by the administrative law judge (and affirmed by the Commission) to be false or misleading. Commissioner Ohlhausen filed a concurring statement saying that she, like the administrative law judge, would have found a smaller number of POM ads to be false or misleading. But

she agreed that POM and the related parties should all be held liable for violating the FTC Act.

The Commission also broadened the scope of the injunctive order against POM and the other parties, although it declined complaint counsel's request to require FDA pre-approval. Part I of the Commission's final order prohibits POM, Roll, the Resnicks, and Tupper from representing that any food, drug, or dietary supplement "is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease"—including but not limited to heart disease, prostate cancer, and erectile dysfunction—unless the representation is non-misleading and supported by "competent and reliable scientific evidence that, when considered in light of the entire body of relevant and reliable scientific evidence, is sufficient to substantiate that the representation is true." The order goes on to say:

> For purposes of this Part I, competent and reliable scientific evidence shall consist of at least two randomized and controlled human clinical trials (RCTs) . . . that are randomized, well controlled, based on valid end points, and conducted by persons qualified by training and experience to conduct such studies. Such studies shall also yield statistically significant results, and shall be double-blinded unless [POM, Roll, the Resnicks, or Tupper] can demonstrate that blinding cannot be effectively implemented given the nature of the intervention.

POM Wonderful LLC, No. 9344, Final Order at 2 (U.S. Fed. Trade Comm'n Jan. 10, 2013) (FTC Final Order).

Part II of the order prohibits POM and the related parties from misrepresenting the results of scientific studies in their ads. Part III bars them from making any claim about the "health benefits" of a food, drug, or

dietary supplement unless the representation is non-misleading and supported by "competent and reliable scientific evidence." But unlike Part I, which applies specifically and solely to *disease*-related claims, Part III contains no requirement that randomized, controlled, human clinical trials support more general claims about health benefits.

POM, Roll, the Resnicks, and Tupper petitioned this court for review. We have jurisdiction under sections 5(c) and 5(d) of the FTC Act, 15 U.S.C. § 45(c)-(d).

II.

Per our usual practice, we first address petitioners' statutory challenges to the Commission's order before turning to their constitutional claims. *See In re Fashina*, 486 F.3d 1300, 1302-03 (D.C. Cir. 2007). On review of an order under the FTC Act, "[t]he findings of the Commission as to the facts, if supported by evidence, shall be conclusive." FTC Act § 5(c), 15 U.S.C. § 45(c). That standard is "essentially identical" to the familiar "substantial evidence" test under the Administrative Procedure Act. *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454 (1986). The Commission "is often in a better position than are courts to determine when a practice is 'deceptive' within the meaning of the [FTC] Act," and that "admonition is especially true with respect to allegedly deceptive advertising since the finding of a § 5 violation in this field rests so heavily on inference and pragmatic judgment." *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 385 (1965).

A.

In determining whether an advertisement is deceptive in violation of section 5 of the FTC Act, the Commission engages in a three-step inquiry, considering: (i) what claims are conveyed in the ad, (ii) whether those claims

are false, misleading, or unsubstantiated, and (iii) whether the claims are material to prospective consumers. *See Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992); *see also Thompson Med. Co.*, 104 F.T.C. 648, 660-61 (1984), *aff'd*, 791 F.2d 189, 197 (D.C. Cir. 1986). At the first step, 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." *Thompson Med. Co.*, 104 F.T.C. at 788. The Commission "examines the overall net impression" left by an ad, *Kraft*, 970 F.2d at 314, and considers whether "at least a significant minority of reasonable consumers" would "likely" interpret the ad to assert the claim, *Telebrands Corp.*, 140 F.T.C. 278, 291 (2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006).

In identifying the claims made by an ad, the Commission distinguishes between "efficacy claims" and "establishment claims." *See Thompson Med. Co. v. FTC*, 791 F.2d 189, 194 (D.C. Cir. 1986). An efficacy claim suggests that a product successfully performs the advertised function or yields the advertised benefit, but includes no suggestion of scientific proof of the product's effectiveness. *See id.*; *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1492 n.3 (1st Cir. 1989). An establishment claim, by contrast, suggests that a product's effectiveness or superiority has been scientifically established. *See Thompson Med. Co.*, 791 F.2d at 194; *Sterling Drug, Inc. v. FTC*, 741 F.2d 1146, 1150 (9th Cir. 1984).

The distinction between efficacy claims and establishment claims gains salience at the second step of the Commission's inquiry, which calls for determining whether the advertiser's claim is false, misleading, or unsubstantiated. If an ad conveys an efficacy claim, the advertiser must possess a "reasonable basis" for the claim. *See Pfizer Inc.*, 81 F.T.C. 23, 62 (1972). The FTC examines

that question under the so-called "*Pfizer* factors," including "the type of product," "the type of claim," "the benefit of a truthful claim," "the ease of developing substantiation for the claim," "the consequences of a false claim," and "the amount of substantiation experts in the field would consider reasonable." *Daniel Chapter One*, No. 9329, 2009 WL 5160000, at *25 (U.S. Fed. Trade Comm'n Dec. 24, 2009) (citing *Pfizer*, 81 F.T.C. at 64), *aff'd*, 405 F. App'x 505 (D.C. Cir. 2010); *see also Thompson Med. Co.*, 104 F.T.C. at 821.

For establishment claims, by contrast, the Commission generally does not apply the *Pfizer* factors. *See Removatron Int'l Corp.*, 111 F.T.C. 206, 297 (1988), *aff'd*, 884 F.2d 1489 (1st Cir. 1989). Rather, the amount of substantiation needed for an establishment claim depends on whether the claim is "specific" or "non-specific." *See Thompson Med. Co.*, 791 F.2d at 194. If an establishment claim "states a specific type of substantiation," the "advertiser must possess the specific substantiation claimed." *Removatron*, 884 F.2d at 1492 n.3. If an ad instead conveys a non-specific establishment claim—e.g., an ad stating that a product's efficacy is "medically proven" or making use of "visual aids" that "clearly suggest that the claim is based upon a foundation of scientific evidence"—the advertiser "must possess evidence sufficient to satisfy the relevant scientific community of the claim's truth." *Bristol-Myers Co.*, 102 F.T.C. 21, 321 (1983), *aff'd*, 738 F.2d 554 (2d Cir. 1984). The Commission therefore "determines what evidence would in fact establish such a claim in the relevant scientific community" and "then compares the advertisers' substantiation evidence to that required by the scientific community." *Removatron*, 884 F.2d at 1498.

Even if the Commission concludes at the first step that an advertiser conveyed efficacy or establishment

claims and determines at the second step that the claims qualify as false, misleading, or unsubstantiated, it can issue a finding of liability 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. 136, 368 (1981), *enforced as modified*, 695 F.2d 681 (3d Cir. 1982); *see also Colgate-Palmolive*, 380 U.S. at 386-88. Here, petitioners do not dispute the materiality of POM's disease-related claims. We therefore confine our analysis to the first and second steps of the Commission's determination: its findings that petitioners' ads conveyed efficacy and establishment claims and that those claims were false, misleading, or unsubstantiated.

B.

At the first step of its inquiry, the Commission determined that thirty-six of petitioners' advertisements and promotional materials conveyed efficacy claims asserting that POM products treat, prevent, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction. The Commission further concluded that thirty-four of those ads also conveyed establishment claims representing that clinical studies substantiate the efficacy of POM products in treating, preventing, or reducing the risk of the same ailments. The Commission set forth the basis for those findings in considerable detail in an appendix to its opinion, with a separate explanation for each ad.

Those ads, as described earlier, *see supra* Part I.A, repeatedly claimed the benefits of POM's products in the treatment or prevention of heart disease, prostate cancer, or erectile dysfunction, and consistently touted medical studies ostensibly supporting those claimed benefits. The question whether "a claim of establishment is in fact made is a question of fact the evaluation of which is within the FTC's peculiar expertise." *Thompson Med. Co.*, 791 F.2d at

194; *see also Removatron*, 884 F.2d at 1496. Here, we perceive no basis for setting aside the Commission's carefully considered findings of efficacy and establishment claims as unsupported by substantial evidence.

Petitioners argue that the Commission applied overly broad claim interpretation principles by "adopt[ing] a rule that if an advertisement *correctly* references research connecting a food product to possible health benefits, it necessarily implies the vastly broader claim that there is 'clinical proof' that the product treats, cures, or prevents a disease." Joint Reply Br. 6 (emphasis in original). We disagree with that characterization of the Commission's approach. As the Commission made clear in its opinion, "[n]ot 'every reference to a test or study necessarily gives rise to an establishment claim.'" FTC Op. at 12 (alteration omitted) (quoting *Bristol-Myers*, 102 F.T.C. at 321 n.7). Here, however, the advertisements go beyond merely describing specific research in sufficient detail to allow a consumer to judge its validity. The study results are referenced in a way that suggests they are convincing evidence of efficacy.

As the Commission separately set forth for each ad, "these ads drew a logical connection between the study results and effectiveness for the particular diseases." *Id.* at 13. Moreover, they invoked medical symbols, referenced publication in medical journals, and described the substantial funds spent on medical research, fortifying the overall sense that the referenced clinical studies establish the claimed benefits. *Id.* at 13-14. As the Commission explained, "[w]hen 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." *Id.* at 14.

Petitioners accuse the Commission of "'cherry-pick[ing]' the record by focusing on a handful of the most aggressive advertisements—most of which have not been run in over six years." Joint Reply Br. 5. There is no meaningful difference, however, between the more recent ads' reliance on medical studies and that of the earlier ads. Consider, for instance, the advertisement for POMx Pills appearing in Playboy magazine in July 2010, less than three months before the Commission filed its complaint. *See* FTC Op. App. B fig.33. According to that ad, POMx is "backed by $34 million in medical research at the world's leading universities" revealing "promising results for erectile, prostate and cardiovascular health." *Id.* The ad goes on to discuss three specific studies: Dr. Padma-Nathan's erectile dysfunction study, Dr. Pantuck's PSA doubling time study, and Dr. Ornish's blood flow study. Of the first, the ad says that, "[i]n a preliminary study on erectile function, men who consumed POM Juice reported a 50% greater likelihood of improved erections as compared to placebo." The ad next asserts that "[a]n initial UCLA study on our juice found hopeful results for prostate health, reporting 'statistically significant prolongation of PSA doubling times.'" Finally, the ad states that "[a] preliminary study on our juice showed promising results for heart health"—specifically, improved "blood flow to the heart."

Materials appearing on POM websites in 2009-2010 convey substantially similar claims. The pomwonderful.com site described POM juice as "backed by" $25 million in "medical research" and clinical testing. ALJ Initial Decision at 55 ¶ 370. The website pointed to "medical results" in the categories of "cardiovascular health," "prostate health," and "erectile function." *Id.* For cardiovascular health, the webpage characterized Dr. Ornish's blood flow study as showing "improved blood flow to the heart," and Dr. Aviram's CIMT study as

showing a decrease in arterial plaque from daily consumption of POM juice. *Id.* at 56 ¶ 373. Further links contained descriptions of studies "demonstrat[ing] that pomegranate juice lowers blood pressure in patients with hypertension," and "clearly demonstrat[ing] for the first time that pomegranate juice consumption by patients with carotid artery stenosis possesses anti-atherosclerotic properties." *Id.* at 56-57 ¶¶ 375-76. In the category of prostate health, the webpage described Dr. Pantuck's study as showing that men with prostate cancer who drank pomegranate juice daily "experienced significantly slower PSA doubling times," *id.* at 56 ¶ 371, with PSA doubling time described as "an indicator of prostate cancer progression," *id.* at 58 ¶ 381. And with regard to erectile function, the webpage described Dr. Padma-Nathan's study as demonstrating that men who drank pomegranate juice "were 50% more likely to experience improved erections." *Id.* at 56 ¶ 372.

The Commission reviewed the claims in POM's ads "in light of any disclaimers or disclosures that [petitioners] actually made." FTC Op. at 44. For the 2010 Playboy ad, for instance, the Commission concluded that "at least a significant minority of reasonable consumers" would construe the ad to claim that drinking eight ounces of POM juice or ingesting one POMx pill a day can treat, prevent, or reduce the risk of erectile dysfunction, prostate cancer, and heart disease. *Id.* App. A at A10-A11. The ad's references to the described studies as "promising," "initial" or "preliminary" did not detract from the Commission's conclusion. The Commission considered the effect of such adjectives "in the context of each ad in its entirety," explaining that those sorts of modifiers do "not neutralize the claims made when the specific results are otherwise described in unequivocally positive terms." *Id.* App. A at A2. The Commission concluded that the "use of one or two adjectives does not alter the net

impression," especially "when the chosen adjectives" (such as "promising") "provide a positive spin on the studies rather than a substantive disclaimer." *Id.* at 13.

The Commission noted, though, that it might reach a different result if an ad were to incorporate an effective disclaimer, such as a statement that the "evidence in support of this claim is inconclusive." *Id.* at 44 (quoting *Pearson v. Shalala*, 164 F.3d 650, 659 (D.C. Cir. 1999)). Because POM's ads contained no such qualifier, the Commission held petitioners to the general substantiation standard for non-specific establishment claims—i.e., the requirement that petitioners possess evidence sufficient to satisfy the relevant scientific community of the truth of their claims. Petitioners advance no persuasive ground for rejecting that approach as beyond the Commission's discretion.

C.

At the second stage of its analysis, the Commission found petitioners' efficacy and establishment claims to be deceptive due to inadequate substantiation. "In reviewing whether there is appropriate scientific substantiation for the claims made, our task is only to determine if the Commission's finding is supported by substantial evidence on the record as a whole." *Removatron*, 884 F.2d at 1497 (internal quotation marks omitted). When conducting that inquiry, we are mindful of the Commission's "special expertise in determining what sort of substantiation is necessary to assure that advertising is not deceptive." *Thompson Med. Co.*, 791 F.2d at 196.

1. For both petitioners' efficacy claims and their non-specific establishment claims, the Commission found that "experts in the relevant fields" would require one or more "properly randomized and controlled human clinical trials"— "RCTs"—in order to "establish a causal

relationship between a food and the treatment, prevention, or reduction of risk" of heart disease, prostate cancer, or erectile dysfunction. FTC Op. at 22. Without at least one such RCT, the Commission concluded, POM's efficacy claims and its non-specific establishment claims were inadequately substantiated.

In reaching that conclusion, the Commission emphasized a distinction between "generalized nutritional and health benefit claims" and "the specific disease treatment and prevention claims at issue in this case," i.e., "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." *Id.* at 20. The Commission declined to address the level of support required for general health or nutritional claims. *See id.* at 20-21. It instead confined its analysis to the specific disease prevention and treatment claims in question, concluding that the "expert evidence was clear that RCTs are necessary for adequate substantiation of these representations." *Id.*

The Commission additionally explained that lesser substantiation might suffice for "claims that do not assert a causal relationship." *Id.* at 23. POM's ads, though, "convey the net impression that clinical studies or trials show that a causal relation has been established between the consumption of the Challenged POM Products and its efficacy to treat, prevent or reduce the risk of the serious diseases in question." *Id.* at 22; *see, e.g.*, *id.* App. B fig.2 ("Medical studies have shown that drinking 8oz. of POM Wonderful pomegranate juice daily minimizes factors that lead to atherosclerosis, a major cause of heart disease."); *id.* App. B fig.7 ("POM Wonderful Pomegranate Juice . . . can help prevent premature aging, heart disease, stroke, Alzheimer's, even cancer."); *id.* App. B fig.20 ("Eight ounces a day is enough to keep your heart pumping.").

The Commission found that "experts in the relevant fields would require RCTs . . . to establish" such a "causal relationship." *Id*. at 22-23.

The Commission examined each of the studies invoked by petitioners in their ads, concluding that the referenced studies fail to qualify as RCTs of the kind that could afford adequate substantiation. *Id.* at 28-34. Petitioners' claims therefore were deceptive. *Id.* at 34, 38. Moreover, in light of petitioners' selective touting of ostensibly favorable study results and nondisclosure of contrary indications from the same or a later study, the Commission found that there were "many omissions of material facts in [the] ads that consumers cannot verify independently." *Id.* at 43; *see* FTC Act § 15(a)(1), 15 U.S.C. § 55(a)(1) ("[I]n determining whether any advertisement is misleading, there shall be taken into account . . . the extent to which the advertisement fails to reveal facts material in the light of such representations."). Petitioners, the Commission observed, "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 [they] refer in their ads." FTC Op. at 49.

With regard to heart disease, for instance, petitioners repeatedly touted the results of Dr. Aviram's limited CIMT study without noting the contrary findings in Drs. Ornish's and Davidson's later and larger studies. *See supra* p. 7. For prostate cancer, petitioners consistently relied on Dr. Pantuck's study of PSA doubling times but with no indication of the study's limitations, including, for instance, that the study's subjects all had undergone radical treatments associated with prolonged PSA doubling times regardless of consumption of pomegranate juice. *See supra* pp. 9-10. And in connection with erectile

dysfunction, petitioners promoted the results of Dr. Padma-Nathan's study based exclusively on the non-validated, one-question GAQ measure, without acknowledging that the study showed no improvement according to the only scientifically validated measure used to assess the results (the IIEF). *See supra* pp. 11-12.

2. Petitioners challenge the Commission's factual finding that experts in the relevant fields require RCTs to support claims about the disease-related benefits of POM's products. We conclude that the Commission's finding is supported by substantial record evidence. That evidence includes written reports and testimony from medical researchers stating that experts in the fields of cardiology and urology require randomized, double-blinded, placebo-controlled clinical trials to substantiate any claim that a product treats, prevents, or reduces the risk of disease. *See* J.A. 1018 (expert report of Dr. James Eastham of Memorial Sloan-Kettering Cancer Center); *id*. at 1048-49 (expert report of Dr. Frank Sacks of Harvard Medical School and Harvard School of Public Health); *id*. at 1081 (expert report of Dr. Arnold Melman of Albert Einstein College of Medicine); *id*. at 1104 (expert report of Dr. Meir Jonathan Stampfer of Harvard Medical School and Harvard School of Public Health).

The Commission drew on that expert testimony to explain why the attributes of well-designed RCTs are necessary to substantiate petitioners' claims. FTC Op. at 23-24. A control group, for example, "'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') [and] the passage of time.'" *Id.* at 23 (quoting ALJ Initial Decision at 90 ¶ 611). Random assignment of a study's subjects to treatment and control groups "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." *Id.* (quoting ALJ Initial Decision at 90 ¶ 612). And when a study is "double-blinded" (i.e., when neither the study participants nor the investigators know which patients are in the treatment group and which patients are in the control group), it is less likely that participants or investigators will consciously or unconsciously take actions potentially biasing the results. *Id.* at 24.

Petitioners assert that certain of the Commission's experts "admit[ted]" that RCTs are not always necessary to substantiate claims about the health benefits of foods and nutrients. Tupper Br. 41. Petitioners take the experts' remarks out of context. For example, Dr. Meir Jonathan Stampfer acknowledged having made recommendations concerning diet and exercise "even when the data are not supported by randomized clinical trials," but he also emphasized that a health recommendation based on the "best available evidence" is "not the same as stating that a causal link has been established." J.A. 1218 (deposition testimony). Dr. Frank Sacks likewise acknowledged that "well-conducted, well-executed observational research is very important" for evaluating foods and nutrients, but he emphasized that a causal link between a food or nutrient and a reduction in disease risk "cannot be proven from an observational [i.e., non-RCT] study." *Id.* at 1240 (deposition testimony). POM nonetheless claimed a scientifically established, causal link between its products and various disease-related benefits on the basis of studies that were not randomized or placebo-controlled. *See, e.g.*, FTC Op. App. B fig.2 (asserting, on basis of Dr. Aviram's non-randomized and non-placebo-controlled CIMT study, that "[m]edical studies have shown that drinking 8oz. of POM Wonderful pomegranate juice daily minimizes factors that lead to atherosclerosis (plaque buildup in the arteries), a major cause of heart disease"); *id.* App. B fig.3

(stating, on basis of same study, that "a clinical pilot study shows that an 8 oz. glass of POM Wonderful 100% Pomegranate Juice, consumed daily, reduces plaque in the arteries up to 30%"); *id.* App. B fig.9 (claiming, on basis of Dr. Pantuck's non-controlled study, that pomegranate juice consumption "prolonged post-prostate surgery PSA doubling time").

Petitioners observe that some of their own experts offered divergent views about the need for RCTs to substantiate disease-related claims for food products. But section 5(c) of the FTC Act, 15 U.S.C. § 45(c), which addresses judicial review, "forbids a court to 'make its own appraisal of the testimony, picking and choosing for itself among uncertain and conflicting inferences.'" *Ind. Fed'n of Dentists*, 476 U.S. at 454 (quoting *FTC v. Algoma Lumber Co.*, 291 U.S. 67, 73 (1934)). The standard set forth in section 5(c) is "essentially identical" to the "'substantial evidence' standard for review of agency factfinding," *id.*, and "does not permit the reviewing court to weigh the evidence, but only to determine that there is in the record such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Am. Home Prods. Corp. v. FTC*, 695 F.2d 681, 686 (3d Cir. 1982) (quoting *Steadman v. SEC*, 450 U.S. 91, 99 (1981)). In asking us to substitute our own appraisal of the expert testimony for the Commission's, petitioners ask us to do what section 5(c) forbids. *See Thompson Med. Co.*, 791 F.2d at 196.

3. Petitioners contend that it is "too onerous" to require RCTs to substantiate disease-related claims about food products "because of practical, ethical, and economic constraints on RCT testing in that context." Joint Reply Br. 32. The Commission was unpersuaded by that argument, *see* FTC Op. at 24-25, and so are we.

As for the practical constraints on double-blinded, placebo-controlled, randomized trials, petitioners say that

it is "difficult, if not impossible, to 'blind' a fruit." POM Br. 13. But that argument does not apply to two of the three products at issue—POMx Liquid and POMx Pills—which are dietary supplements amenable to blinding. And as applied to POM juice, petitioners' argument is called into question by the fact that several juice studies they sponsored were double-blinded and placebo-controlled, including studies led by Dr. Ornish, Dr. Davidson, and Dr. Padma-Nathan. *See, e.g.*, Davidson et al., *supra*, at 937 (explaining that beverage with "similar color and energy content" as pomegranate juice could be "labeled so that neither subjects nor staff members were aware" whether beverage was placebo). In any event, the Commission required double-blinding only "when feasible," acknowledging that, "in some instances . . . it may not be possible to conduct blinded clinical trials of food products." FTC Op. at 24.

As for the ethical constraints on randomized controlled trials, petitioners say that it is "impossible to create a zero intake group for nutrients in an ethical manner—doctors cannot, for example, ethically deprive a control group of patients of all Vitamin C for a decade to determine whether Vitamin C helps prevent cancer." POM Br. 15 (internal quotation marks omitted). Many of the challenged ads, however, made claims about the short-term benefits of consuming POM products. *See, e.g.*, FTC Op. App. B fig.1 (asserting, on basis of ten-patient study with no control group, that "[p]omegranate juice inhibited [angiotensin converting enzyme (ACE)] by 36% after two weeks of consumption" and that "[i]nhibition of ACE lessens the progression of atherosclerosis"). And whether or not it may be unethical to tell patients in a control group to stop consuming vitamin C, petitioners give us no reason to believe that it would be unethical to create a zero intake group for pomegranate juice.

We acknowledge that RCTs may be costly, although we note that the petitioners nonetheless have been able to sponsor dozens of studies, including several RCTs. Yet if the cost of an RCT proves prohibitive, petitioners can choose to specify a lower level of substantiation for their claims. As the Commission observed, "the need for RCTs is driven by the claims [petitioners] have chosen to make." *Id.* at 25. An advertiser who makes "express representations about the level of support for a particular claim" must "possess the level of proof claimed in the ad" and must convey that information to consumers in a non-misleading way. *Thompson Med. Co.*, 791 F.2d at 194. An advertiser thus still may assert a health-related claim backed by medical evidence falling short of an RCT if it includes an effective disclaimer disclosing the limitations of the supporting research. Petitioners did not do so.

D.

Petitioners argue that the substantiation standard applied by the Commission to POM's establishment and efficacy claims amounts to a new legal rule adopted in violation of the Administrative Procedure Act's notice-and-comment requirements for rulemaking. *See* Administrative Procedure Act § 4, 5 U.S.C. § 553; FTC Act § 18(a)-(b), 15 U.S.C. § 57a(a)-(b) (APA notice-and-comment requirements apply to FTC rules). We disagree. The Commission proceeded in this case via adjudication rather than rulemaking. And it "is well settled that an agency 'is not precluded from announcing new principles in an adjudicative proceeding,'" and that "'the choice between rulemaking and adjudication lies in the first instance within the agency's discretion.'" *Cassell v. FCC*, 154 F.3d 478, 486 (D.C. Cir. 1998) (alteration omitted) (quoting *NLRB v. Bell Aerospace Co. Div. of Textron Inc.*, 416 U.S. 267, 294 (1974)); *see also Qwest Servs. Corp. v. FCC*, 509 F.3d 531, 536-37 (D.C. Cir. 2007).

Petitioners point to *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1024 (D.C. Cir. 2000), where we said that "an agency may not escape the notice and comment requirements . . . by labeling a major substantive legal addition to a rule a mere interpretation." *Appalachian Power*, however, involved a guidance document that "in effect amended" a regulation, which the agency could not "legally do without complying with the rulemaking procedures." *Id.* at 1028. Here, the Commission did not effectively amend a notice-and-comment regulation. It instead validly proceeded by adjudication. As we have explained, the "fact that an order rendered in an adjudication may affect agency policy and have general prospective application does not make it rulemaking subject to APA section 553 notice and comment." *Conference Grp., LLC v. FCC*, 720 F.3d 957, 966 (D.C. Cir. 2013) (citation and internal quotation marks omitted).

The Commission's decision, in any event, does not involve a "major substantive legal addition" to its substantiation standards. *Appalachian Power Co.*, 208 F.3d at 1024. With respect to POM's establishment claims, the substantiation standard applied by the Commission is consistent with Commission precedent. When an advertiser represents that claims have been "scientifically established," the FTC has long held the advertiser to "the level of evidence required to convince the relevant scientific community of the claim's truthfulness." *Bristol-Meyers*, 102 F.T.C. at 317-18; *accord Removatron*, 111 F.T.C. at 297-99; *Thompson Med. Co.*, 104 F.T.C. at 821-22 & n.59. And the Commission has required RCTs to substantiate establishment claims in other contexts. *See, e.g.*, *Am. Home Prods. Corp.*, 98 F.T.C. at 200-06. With respect to POM's efficacy claims, the Commission arrived at its RCT substantiation requirement by applying the traditional *Pfizer* factors. That conclusion coheres with past Commission decisions applying *Pfizer*, including *Pfizer*

itself. *See Pfizer*, 81 F.T.C. at 66 (finding that "for a test, standing alone, to provide a reasonable basis" for a claim that a nonprescription product is effective in treating minor burns and sunburns, "the test should be an adequate and well-controlled scientific test," and noting "strong desirability" that the test be "double-blind"); *Thompson Med. Co.*, 104 F.T.C. at 826 (applying "six *Pfizer* factors" and concluding that the "proper level of substantiation for . . . efficacy claims" for topical analgesic marketed to treat minor arthritis is "two well-controlled clinical tests").

E.

Matthew Tupper, for his part, challenges the Commission's decision to hold him individually liable (along with the Resnicks) for POM's deceptive acts and practices. Tupper, who became POM's chief operating officer in 2003 and served as its president from 2005 to 2011, contends that he should not be held individually liable because Lynda Resnick, not he, had the "final say" on the ads. Tupper Br. 33.

Tupper cites no decisions supporting his assertion that individual liability under the FTC Act extends only to those with "final say" over deceptive acts or practices. The other circuits to address the issue have determined that "[i]ndividuals may be liable for FTC Act violations committed by a corporate entity if the individual 'participated directly in the deceptive practices or acts or had authority to control them.'" *FTC v. IAB Mktg. Assocs., LP*, 746 F.3d 1228, 1233 (11th Cir. 2014) (alteration omitted) (quoting *FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 573 (7th Cir. 1989)); *accord FTC v. QT, Inc.*, 512 F.3d 858, 864 (7th Cir. 2008); *FTC v. Freecom Commc'ns, Inc.*, 401 F.3d 1192, 1204 (10th Cir. 2005); *FTC v. Publ'g Clearing House, Inc.*, 104 F.3d 1168, 1170 (9th Cir. 1997). It is undisputed that Tupper participated directly in meetings

about advertising concepts and content, reviewed and edited ad copy, managed the day-to-day affairs of POM's marketing team, and possessed hiring and firing authority over the head of POM's marketing department. Even assuming that "authority to control" is a prerequisite for individual liability under the FTC Act, we would still affirm based on the Commission's unchallenged finding that Tupper "had the authority to determine which advertisements should run." FTC Op. at 53.

Tupper next argues that the Commission failed to prove his *knowledge* that POM's ads conveyed misleading claims. But the FTC has been required to demonstrate an individual's knowledge only when seeking equitable monetary relief. *See FTC v. Network Servs. Depot, Inc.*, 617 F.3d 1127, 1138 (9th Cir. 2010); *Freecom Commc'ns*, 401 F.3d at 1197-203, 1207. In this case, the sole remedy imposed by the FTC was injunctive relief. And when the Commission does not seek restitution or monetary penalties, the FTC Act "imposes a strict liability standard" and "creates no exemption . . . for unwitting disseminators of false advertising." *Porter & Dietsch, Inc. v. FTC*, 605 F.2d 294, 309 (7th Cir. 1979); *see Feil v. FTC*, 285 F.2d 879, 896 (9th Cir. 1960); *Koch v. FTC*, 206 F.2d 311, 317 (6th Cir. 1953); *Parke, Austin & Lipscomb, Inc. v. FTC*, 142 F.2d 437, 440 (2d Cir. 1944).

Finally, Tupper contends that there is "no justification" for applying the Commission's order to him because he has "voluntarily retired from his position at POM." Tupper Br. 37. That argument occupied just two sentences of his opening brief, and he referenced no precedent supporting it until his reply brief. Joint Reply Br. 43-44 (citing *FTC v. Accusearch Inc.*, 570 F.3d 1187, 1201 (10th Cir. 2009); *Borg-Warner Corp. v. FTC*, 746 F.2d 108, 110 (2d Cir. 1984)). When a litigant's opening brief presents an argument "in conclusory fashion and without

visible support," we have discretion to deem the argument forfeited. *See Bd. of Regents of the Univ. of Wash. v. EPA*, 86 F.3d 1214, 1221 (D.C. Cir. 1996). Tupper's argument fails on the merits in any event. Injunctive relief may be inappropriate if the affected parties "have not shown a propensity toward violating" the statute and "nothing in the record . . . suggests the likelihood or even the possibility" of further violations. *Borg-Warner*, 746 F.2d at 110-11. But the Commission found that petitioners, including Tupper, "have a demonstrated propensity to misrepresent to their advantage the strength and outcomes of scientific research" and "engaged in a deliberate and consistent course of conduct—no mere isolated incident or mistake." FTC Op. at 51. Additionally, there is no assurance that Tupper will not return to POM or join another company that markets food products or dietary supplements.

III.

Having rejected petitioners' statutory claims, we now turn to their constitutional arguments. Petitioners challenge both the Commission's liability determination and its remedy on First Amendment grounds. We reject both challenges except insofar as the Commission in its remedial order imposed an across-the-board, two-RCT substantiation requirement for any future disease-related claims by petitioners.

A.

"For commercial speech to come within [the First Amendment], it at least must concern lawful activity and not be misleading." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980). Consequently, "[m]isleading advertising may be prohibited entirely." *In re R. M. J.*, 455 U.S. 191, 203 (1982).

In imposing liability against petitioners, the Commission found that POM's ads are entitled to no First Amendment protection because they are "deceptive and misleading." FTC Op. at 44. Petitioners ask us to review that finding de novo in light of the First Amendment context, *see Bose Corp. v. Consumers Union of U.S.*, 466 U.S. 485, 505 (1984), and to overturn the Commission's decision to impose liability. Our precedents, however, call for reviewing the Commission's factual finding of a deceptive claim under the ordinary (and deferential) substantial-evidence standard, even in the First Amendment context. *Novartis Corp. v. FTC*, 223 F.3d 783, 787 n.4 (D.C. Cir. 2000); *FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 41 n.3 (D.C. Cir. 1985); *see also Kraft,* 970 F.2d at 316 (cited in *Novartis Corp.*, 223 F.3d at 787 n.4). We conclude that the Commission's findings of deception are supported by substantial evidence in the record; and we would reach the same conclusion even if we were to exercise de novo review, at least with respect to the nineteen ads determined misleading by the administrative law judge and held by the Commission to form a sufficient basis for its liability determination and remedial order.

We have addressed eighteen of those nineteen ads in the course of our earlier discussion, and we affirm the Commission's determination that those ads were deceptive for the reasons set forth above and in the FTC's opinion. *See* FTC Op. App. A at A3-A7, A9-A14; *id*. App. B figs.1, 2, 3, 4, 6, 7, 8, 9, 10, 15, 16, 17, 21, 27, 33, 37, 38, 39. The sole remaining ad is one carried in two magazines in 2004 and 2005. It features an intravenous tube running through a bottle of POM juice alongside the headline "Life support." *Id*. App. B fig.5. The ad says that POM juice "has more naturally occurring antioxidants than any other drink," and that "[t]hese antioxidants fight hard against free radicals that can cause heart disease" and

"even cancer." *Id.* The ad then tells readers that, if they "[j]ust drink eight ounces a day," they will "be on life support—in a good way." *Id.*

The administrative law judge concluded that, "[b]ased on the overall, common-sense, net impression" of the ad, "a significant minority" of "reasonable" consumers "would interpret [the ad] to be claiming that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease." ALJ Initial Decision at 69 ¶ 455. The full Commission adopted the administrative law judge's findings about the net impression conveyed by the ad, and we see no basis to overturn that conclusion. At the time, there was insufficient support for an unqualified efficacy claim of a link between daily consumption of pomegranate juice and prevention of heart disease. As a result, insofar as the FTC imposed liability on petitioners for the nineteen ads found to be deceptive by the administrative law judge, the Commission sanctioned petitioners for misleading speech unprotected by the First Amendment.

B.

Finally, we address petitioners' First Amendment challenge to the Commission's injunctive order. Part III of the order imposes a baseline requirement applicable to all of petitioners' ads. It bars representations about a product's general health benefits "unless the representation is non-misleading" and backed by "competent and reliable scientific evidence that is sufficient in quality and quantity" to "substantiate that the representation is true." FTC Final Order at 3. For purposes of that baseline requirement, "competent and reliable evidence" means studies that are "generally accepted in the profession to yield accurate and reliable results." *Id.*

Part I of the order, meanwhile, imposes heightened requirements in the specific context of claims about the treatment or prevention of "any disease" (including, but not limited to, heart disease, prostate cancer, and erectile dysfunction). *Id.* at 2. Such disease-related claims, like the broader category of health claims covered by Part III, must be "non-misleading" and supported by "competent and reliable scientific evidence." *Id.* But "competent and reliable scientific evidence" is more narrowly defined for purposes of Part I to consist of "at least two randomized and controlled human clinical trials (RCTs)" that "yield statistically significant results" and are "double-blinded" whenever feasible. *Id.* In short, Part III's baseline requirement for all health claims does not require RCT substantiation, whereas the specific requirements in Part I for disease-related claims not only contemplate RCT substantiation, but call for—as a categorical matter—two RCTs.

The Commission clarified in a footnote of its brief that Part I's blanket, two-RCT-substantiation requirement for disease claims attaches only to *unqualified* representations. FTC Br. 73 n.33. But the evident leeway to make "effectively *qualified*" disease claims without two RCTs, *id.*, appears to be highly circumscribed. Representations characterizing a study's results as "preliminary" or "initial"—even if describing a gold-standard RCT yielding results with an extremely high degree of statistical significance—would fail to count as adequately qualified and thus would be prohibited. *See* FTC Op. App. A at A2. Rather, an ad apparently would need to contain a disclaimer stating "unambiguously" that the evidence is "inconclusive" or that "additional research is necessary," FTC Br. 10, 19, even if the ad is substantiated by a well-designed RCT that experts uniformly consider to be conclusive, and regardless of the amount and quality of additional supporting evidence

other than RCTs. Short of such a disclaimer, a disease-related claim faces a categorical bar unless substantiated by two RCTs.

Petitioners challenge the remedial order's blanket, two-RCT-substantiation requirement under the First Amendment. They contend, and the Commission accepts, that their challenge should be examined under the general test for commercial speech restrictions set out in *Central Hudson*, 447 U.S. at 566. *See* Joint Reply Br. 39-40; FTC Br. 74.

Central Hudson first requires that the "asserted governmental interest [be] substantial." 447 U.S. at 566. The Supreme Court has made clear that the governmental "interest in ensuring the accuracy of commercial information in the marketplace is substantial." *Edenfield v. Fane*, 507 U.S. 761, 769 (1993). The Commission asserts that its remedial order aims to advance that concededly substantial interest, satisfying *Central Hudson*'s first prong.

With regard to the means by which the Commission seeks to further its asserted interest, *Central Hudson* requires that a challenged restriction "directly advance[] the governmental interest" and that it "is not more extensive than is necessary to serve that interest." 447 U.S. at 566. Here, insofar as the Commission's order imposes a general RCT-substantiation requirement for disease claims—i.e., without regard to any particular number of RCTs—the order satisfies those tailoring components of *Central Hudson* review.

In finding petitioners liable for deceptive ads, the Commission determined that petitioners' efficacy and establishment claims were misleading because they were unsubstantiated by RCTs. We have upheld that approach in this opinion. Requiring RCT substantiation as a forward-looking remedy is perfectly commensurate with

the Commission's assessment of liability for petitioners' past conduct: if past claims were deceptive in the absence of RCT substantiation, requiring RCTs for future claims is tightly tethered to the goal of preventing deception. To be sure, the liability determination concerned claims about three specific diseases whereas the remedial order encompasses claims about any disease. But that broadened scope is justified by petitioners' demonstrated propensity to make deceptive representations about the health benefits of their products, and also by the expert testimony supporting the necessity of RCTs to establish causation for disease-related claims generally. *See* FTC Op. at 22, 35-36. For purposes of *Central Hudson* scrutiny, then, the injunctive order's requirement of *some* RCT substantiation for disease claims directly advances, and is not more extensive than necessary to serve, the interest in preventing misleading commercial speech.

We reach the opposite conclusion insofar as the remedial order mandates *two* RCTs as an across-the-board requirement for any disease claim. *Central Hudson* "requires something short of a least-restrictive-means standard," *Board of Trustees v. Fox*, 492 U.S. 469, 477 (1989), but the Commission still bears the burden to demonstrate a "reasonable fit" between the particular means chosen and the government interest pursued, *id.* at 480. *See Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 26-27 (D.C. Cir. 2014) (en banc). Here, the Commission fails adequately to justify a categorical floor of two RCTs for any and all disease claims. It of course is true that, all else being equal, two RCTs would provide more reliable scientific evidence than one RCT, affording added assurance against misleading claims. It is equally true that three RCTs would provide more certainty than two, and four would yield more certainty still. But the Commission understandably does not claim a myopic interest in

pursuing scientific certitude to the exclusion of all else, regardless of the consequences.

Here, the consequences of mandating more than one RCT bear emphasis. Requiring additional RCTs without adequate justification exacts considerable costs, and not just in terms of the substantial resources often necessary to design and conduct a properly randomized and controlled human clinical trial. If there is a categorical bar against claims about the disease-related benefits of a food product or dietary supplement in the absence of two RCTs, consumers may be denied useful, truthful information about products with a demonstrated capacity to treat or prevent serious disease. That would subvert rather than promote the objectives of the commercial speech doctrine. *See Edenfield*, 507 U.S. at 766.

Consider, for instance, a situation in which the results of a large-scale, perfectly designed and conducted RCT show that a dietary supplement significantly reduces the risk of a particular disease, with the results demonstrated to a very high degree of statistical certainty (i.e., a very low *p*-value)—so much so that experts in the relevant field universally regard the study as conclusively establishing clinical proof of the supplement's benefits for disease prevention. Perhaps, moreover, a wealth of medical research and evidence apart from RCTs—e.g., observational studies—reinforces the results of the blue-ribbon RCT. In that situation, there would be a substantial interest in assuring that consumers gain awareness of the dietary supplement's benefits and the supporting medical research (and without any qualifiers stating, misleadingly, that the evidence is "inconclusive," *see supra* p. 38). After all, as the Food and Drug Administration has explained in past guidance to the industry, "[a] single large, well conducted and controlled clinical trial could provide sufficient evidence to establish a substance/disease

relationship, provided that there is a supporting body of evidence from observational or mechanistic studies." U.S. Food & Drug Admin., *Guidance for Industry: Significant Scientific Agreement in the Review of Claims for Conventional Foods and Dietary Supplements* 5 (Dec. 1999), 1999 WL 33935287 (withdrawn 2009).

The two-RCT requirement in the Commission's order brooks no exception for those circumstances. No matter how robust the results of a completed RCT, and no matter how compelling a battery of supporting research, the order would always bar any disease-related claims unless petitioners clear the magic line of two RCTs. The Commission has elsewhere explained to industry advertisers that, "[i]n most situations, the quality of studies will be more important than quantity." U.S. Fed. Trade Comm'n, *Dietary Supplements: An Advertising Guide for Industry* 10 (Apr. 2001), *available at* http://www.business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry. The blanket, two-RCT substantiation requirement at issue here is out of step with that understanding.

The Commission fails to demonstrate how such a rigid remedial rule bears the requisite "reasonable fit" with the interest in preventing deceptive speech. *Fox*, 492 U.S. at 480; *see also Am. Meat Inst.*, 760 F.3d at 26. In the liability portion of its opinion, the Commission went to great lengths to explain why RCTs, rather than less demanding studies, are required to substantiate the sorts of causal claims petitioners asserted in the past. But the Commission stressed that it "need not, and does not, reach the question of the number of RCTs needed to substantiate the claims made." FTC Op. at 3. The Commission nonetheless imposed a categorical, two- RCT substantiation requirement in the remedial portion of its opinion. *Id.* at 51. As justification for that decision, the

Commission tendered two grounds, in a brief, five-sentence explanation. Neither of the grounds (nor both together) adequately justifies the Commission's blanket two-RCT requirement.

First, the Commission asserts that a two-RCT requirement is consistent with its precedent. The fact that the Commission may have imposed a remedy in the past, however, does not necessarily establish the closeness of its fit to a new set of facts. And here, we view the Commission's history with a two-RCT remedy to cut against, not in favor of, its imposition of a two-RCT requirement for all disease claims. It is true that this Court observed, almost thirty years ago, that the "FTC has usually required two well-controlled clinical tests" before certain "non-specific establishment claim[s] may be made." *Thompson Med. Co.*, 791 F.2d at 194. But all of the cases cited in support of that observation, like *Thompson* itself, involved a highly specific type of representation: establishment claims about the comparative efficacy of over-the-counter analgesics. *See Sterling Drug, Inc.*, 741 F.2d at 1152-53; *Bristol Myers Co. v. FTC*, 738 F.2d 554, 558-59 (2d Cir. 1984); *Am. Home Prods. Corp.*, 695 F.2d at 691-93. The decision to require two well-controlled clinical studies was confined to a particular type of claim about a particular product—the comparative ability of analgesics to afford pain relief. *See, e.g.*, *Thompson Med. Co.*, 791 F.2d at 192. And the decision came after extended analysis of considerations specific to that context. *See Am. Home Prods. Corp.*, 98 F.T.C. at 201-06.

In particular, due to the subjective nature of pain sensitivity, the Commission concluded that "the elements of a well-controlled clinical trial" are especially important in the case of analgesics. *Thompson Med. Co.*, 104 F.T.C. at 720. That is even more true in a "comparative drug trial," in which the subjectivity of pain is compounded by the

need to qualify the relative effect of two or more alternate treatments. *See id.* at 719-25. The Commission also found significant that FDA panels on analgesics (as well as the medical scientific community) "require[] replication of the results of a clinical test involving an analgesic drug." *Id.* at 720-21. For all of those reasons, the Commission concluded that "[t]wo or more independently conducted, well-controlled clinical studies are required to establish the comparative efficacy of [over-the-counter] analgesics for the relief of mild to moderate pain." *Am. Home Prods. Corp.*, 98 F.T.C. at 201; *see also Thompson Med. Co.*, 104 F.T.C. at 719. Rather than supporting the imposition of a two-RCT mandate as routinely necessary to prevent the misleading of consumers, *Thompson* suggests that the Commission has imposed two-RCT requirements only in narrow circumstances based on particularized concerns.

More recent Commission action does not demonstrate otherwise. After being asked at oral argument to identify two-RCT remedial orders other than those discussed in *Thompson*, the Commission produced a handful of examples in a post-argument submission. *See* FTC 28(j) Letter at 2 (May 5, 2014). Most of the examples are consent orders—entered without litigation or explanation of the Commission's reasoning—providing little insight into why two RCTs would be required to prevent a claim from being misleading. *See L'Occitane, Inc.*, No. C-4445, 2014 WL 1493613 (U.S. Fed. Trade Comm'n Mar. 27, 2014); *Dannon Co., Inc.*, No. C-4313, 2011 WL 479884 (U.S. Fed. Trade Comm'n Jan. 31, 2011); *Nestle Healthcare Nutrition, Inc.*, No. C-4312, 2011 WL 188928 (U.S. Fed. Trade Comm'n Jan. 12, 2011). The other examples impose two RCTs for only some subset of future claims, while requiring less support for other claims. *See Schering Corp.*, 118 F.T.C. 1030, 1122-23 (1994) (requiring generally acceptable scientific evidence for some claims and two RCTs for others); *Jerome Milton, Inc.*, 110 F.T.C.

104, 116 (1987) (requiring one RCT or generally acceptable scientific evidence for some claims and two RCTs for others).

Outside of those examples, several orders over the past decade require only "competent and reliable scientific evidence"—not necessarily RCTs, let alone two RCTs—to substantiate disease claims akin to those made by petitioners. *See, e.g.*, *Tropicana Prods., Inc.*, 140 F.T.C. 176, 184-85 (2005); *Unither Pharma, Inc.*, 136 F.T.C. 145, 295-96 (2003). And in other recent orders, the Commission has imposed a one-RCT remedy. *See, e.g.*, *FTC v. Reebok Int'l Ltd.*, No. 1:11-cv-02046-DCN, slip op. at 5-6 (N.D. Ohio Sept. 29, 2011). Indeed, in *Removatron* the Commission itself modified an ALJ's initial order to require one RCT rather than two. 111 F.T.C. at 206. In short, the Commission's precedents suggest that two-RCT remedial provisions are only selectively imposed in specific circumstances based on particular concerns.

The Commission observes that certain expert testimony in this case "recognized the need for consistent results in independently-replicated studies," with one of its experts noting the possibility that the results of a single RCT "may be due to chance or may not be generalizable due to the uniqueness of the study sample." FTC Op. at 51 (internal quotation marks omitted). But insofar as the results of any particular RCT may be suspect due to deficiencies in the sample or trial, the baseline requirement for health-related claims independently bars any representations unless supported by "competent and reliable scientific evidence that . . . is sufficient to substantiate that the representation is true," which in turn requires that a study be "generally accepted in the profession to yield accurate and reliable results." FTC Final Order at 3. In any event, the Commission's own expert testimony—as described by the Commission

itself—weighs against imposing a categorical, two-RCT-substantiation requirement for all disease claims. As the Commission explained, expert testimony about the need for two RCTs was addressed to one particular disease, whereas one RCT could suffice for the other two examined diseases: "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." FTC Op. at 3. The Commission nonetheless imposed a categorical, two-RCT requirement for *all* disease claims, regardless of the quality of any single RCT or the strength of other medical evidence.

Finally, the Commission justifies its two-RCT requirement on the ground that petitioners "have a demonstrated propensity to misrepresent to their advantage the strength and outcomes of scientific research" and "have engaged in a deliberate and consistent course of conduct." *Id.* at 51. But by definition, every party subjected to a final FTC order has been found to have engaged in some unlawful advertising practice. The Commission does not explain how the two-RCT requirement is reasonably linked to the particular history of petitioners' wrongdoing. The Commission does highlight petitioners' history of selectively drawing on favorable studies while disregarding unfavorable results. *Id*. at 49. To the extent the two-RCT remedy aims to prevent petitioners from misleadingly highlighting favorable results alone, however, the order separately requires petitioners to base any representations on "competent and reliable scientific evidence that, *when considered in light of the entire body of relevant and reliable scientific evidence*, is sufficient to substantiate that the representation is true." FTC Final Order at 2 (emphasis added). With that baseline already established by the

order, the contribution of the two-RCT requirement to the order's effectiveness in this regard is far from clear.

For those reasons, we hold that the Commission's order is valid to the extent it requires disease claims to be substantiated by at least one RCT. But it fails *Central Hudson* scrutiny insofar as it categorically requires two RCTs for all disease-related claims. That is not at all to say that the Commission would be barred from imposing a two-RCT-substantiation requirement in any circumstances. *See Thompson Med. Co.*, 791 F.2d at 193-96. Rather, the Commission has failed in this case adequately to justify an across-the-board two-RCT requirement for all disease claims by petitioners.

* * * * *

For the foregoing reasons, Part I of the Commission's remedial order will be modified to require petitioners to possess at least one RCT before making disease claims covered by that provision and, as modified, enforced. We deny the petition for review in all other respects.

So ordered.

APPENDIX B

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, as successor in interest to Roll International Corporation, companies, and	)	**Docket No. 9344** **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.

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[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

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 having3 a reasonable basis to substantiate these claims. The Complaint also alleged that Respondents disseminated advertising and promotional materials representing that clinical studies, research, and/or trials prove that consumption of the Challenged POM Products in certain doses treats, prevents or reduces the risk of heart disease, prostate cancer, or ED, when in fact clinical studies, research, or trials do not so prove.

At trial, Complaint Counsel challenged a total of 43 items, including print advertisements, newsletters, separate "web captures" of Respondents' websites, Internet banner advertisements, press releases, and media interviews. Respondents denied that such materials make the claims alleged and argued that the claims that were made in their advertising and promotional materials were substantiated adequately by scientific research. Some of POM's ads and marketing materials stated that the Challenged POM Products were supported by over $30 million in medical research.

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

an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *Id.* at 331.

Respondents' principal claims on appeal are that the ALJ erred in (1) finding that any of the challenged advertising and promotional materials contain implied efficacy or establishment claims (*i.e.*, those asserting that the efficacy claims are established scientifically) that the Challenged POM Products treat, prevent or reduce the risk of heart disease, prostate cancer, or ED; (2) holding that substantiation for such claims required clinical studies; and (3) finding the foregoing claims to be material. Respondents also allege that the relief ordered is impermissibly broad and runs afoul of the First and Fifth Amendments.

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

Based on our consideration of the entire record in this case and the arguments of counsel, we deny Respondents' appeal and grant in part, and deny in part, Complaint Counsel's cross- appeal. We find Respondents liable on the basis of a larger number of advertisements containing false and misleading claims than the ALJ found. The

basis of Respondents' liability under the FTC Act is their lack of sufficiently reliable evidence — namely, RCTs (as described more fully below in this opinion) — to substantiate the claims that we found. Complaint Counsel's experts testified that two RCTs are necessary to substantiate the heart disease claims at issue, while the prostate cancer and ED claims can be substantiated with at least one RCT. *See* CX1291 at 15 (Sacks Expert Report) (for heart disease "most scientists and researchers . . . believe that at least two-well designed studies . . . showing strong results are needed to constitute reliable evidence"); CX1287 at 6 (Eastham Expert Report) (stating "qualified experts in the field of urology, including the prevention and treatment of prostate cancer, . . . would require that Respondents' claims be supported by at least one well-conducted, randomized, double-blind, placebo-controlled clinical trial with an appropriate endpoint"); and CX1289 at 4 (Melman Expert Report) ("[t]o constitute competent and reliable scientific evidence, experts in the field of erectile dysfunction would require at least one clinical trial, involving several investigatory sites, that is well-designed, randomized, placebo-controlled, and double-blinded"). The Commission need not, and does not, reach the question of the number of RCTs needed to substantiate the claims made because, as discussed below, Respondents failed to proffer even one RCT that supports the challenged claims that we found they made.[2] The Final Order we issue today differs from that proposed by the ALJ and contains fencing-in relief by providing that any disease-related establishment or efficacy claims made about the Challenged POM Products or in connection

[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.

with Respondents' sale of any food, drug, or dietary supplement must be supported by at least two RCTs.[3] However, we do not reach the question of liability based on the four challenged media interviews, and today's Final Order does not include a provision requiring FDA pre- approval of any future claims made by Respondents.

II. Factual Background and Proceedings Below

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

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.

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[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.

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

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

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 outreach, radio and television ads, and press releases. IDF 171. POM Wonderful considers health-conscious, educated, affluent consumers to be its target audience. IDF 172, 176, 178, 181.

The POM Juice print advertisements at issue were disseminated in a wide variety of publications, including

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

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

and (6) treats ED (Compl. ¶ 16.B). In sum, the Complaint alleges that Respondents made six different claims regarding the efficacy of the Challenged POM Products.

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

Following an administrative trial that began on May 24, 2011, and concluded on November 4, 2011, the ALJ filed a 335-page Initial Decision, with 1,431 findings of fact and a 108-page appendix on May 17, 2012. The ALJ found that 19 of the 43 challenged advertisements and promotional materials contained implied claims that the Challenged POM Products treat, prevent or reduce the risk of heart disease, prostate cancer, or ED, and that 14 of these ads also contained implied claims that these effects on disease were clinically proven. ID at 211-34. The ALJ also found that the claims at issue are material to consumers. *Id.* at 290-96. The ALJ further determined that the appropriate level of substantiation for such claims is competent and reliable scientific evidence, which for claims that a food or food-derived product treats, prevents or reduces the risk of disease must include adequate clinical studies, though not necessarily RCTs. *Id.* at 234-50. The ALJ determined that Respondents did not have such evidence to substantiate their claims, rendering them false or misleading under Sections 5(a) and 12 of the FTC Act. *Id.* at 250-290. According to the ALJ's cease and

desist order against the corporate and individual Respondents pursuant to Section 5(b) of the FTC Act, Respondents would be prohibited from engaging in deceptive advertising practices with respect to any food, drug, or dietary supplement that may be advertised by Respondents in the future. *Id.* at 309-25. The ALJ did not require that Respondents seek FDA pre-approval for any future disease claims with respect to the Challenged Products. *See id*. at 314-23.

III. Legal Standard

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

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

[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.

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).

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

[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.

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

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[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.

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, 52-353, 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 issing elements, but instead such analysis is strictly constrained by what actually appears in ad. We disagree. When conducting a facial analysis of an advertisement, the advertisement must be viewed as a whole "without emphasizing isolated words or phrases apart from their context[.]" *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1496 (1st Cir. 1989) (quoting *Am. Home Prods. Corp. v. FTC*, 695 F.2d 681, 687 (3d Cir. 1982)); *FTC v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir. 1963) (explaining "[t]he entire mosaic should be viewed rather than each tile separately"). Respondents' ads drew a logical connection between the antioxidant claims and the specific disease treatment or prevention claims through the associated explanatory text, the specific findings of the study results, and references to diseases or medical conditions. Ultimately, we assess the net impression of each ad, and we find that for many of Respondents' ads, the net impression is more than any individual element of the ad.

The ALJ did not individually analyze those exhibits for which he did not find the claims alleged by Complaint Counsel. Instead, he summarized generally a variety of factors explaining why he did not find such claims,

including that the "advertisements . . . do not mention heart disease, prostate cancer, or erectile dysfunction; use vague, non-specific, substantially qualified, and/or otherwise non-definitive language; use language and/or images that, in the context of the advertisement, are inconsistent with the alleged claim; and/or do not draw a connection for the reader, such as through associated explanatory text, between health benefits, or study results, and effectiveness for heart disease, prostate cancer, or erectile dysfunction." ID at 222.

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

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

We also overrule some of the ALJ's findings with regard to Figure 11 ("Decompress" print ad) because we find that this ad conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease. The ad containing medical imagery depicts the

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

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

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

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 particular ads, "the foregoing language fails

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

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

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[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.

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 advertising campaigns related to a number of the advertisements challenged by Complaint Counsel. ID at 222. Except where noted here and in the accompanying Claims Appendix, we agree with the ALJ's conclusions with respect to the extrinsic evidence provided in this case.

Extrinsic evidence can include results from methodologically sound surveys about the ads in question, the common usage of language, accepted principles from market research concerning consumers' response in general to ads, and the opinions of expert witnesses on

how an advertisement might reasonably be interpreted. *See Kraft Inc.*, 114 F.T.C. at 121 (explaining extrinsic evidence includes "reliable results from methodologically sound consumer surveys"); *Thompson Med. Co.*, 104 F.T.C. at 790.

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

Dr. Butters examined the challenged ads and offered his opinion that none of them conveyed that scientific research proves that the use of the Challenged POM Products successfully treats, prevents or reduces the risk of heart disease, prostate cancer, or ED. IDF 264, 480-83; PX0158 (Butters Expert Report at 0003). He concluded that, at most, the ads would convey that pomegranate juice is a health beverage and that preliminary research suggests there may be health benefits. IDF 486; PX0158 (Butters Expert Report at 0003, 0043.) Additionally, Dr. Butters opined that what people might infer with respect to a food product may differ from what they might infer with respect to a drug regarding treatment claims. IDF 491-92; Butters, Tr. 2817-18. During trial, Dr. Butters testified and proffered his opinion on the interpretation of many of the challenged ads. *See* IDF 496-511. Dr. Stewart provided a useful analysis of Dr. Butters' expert report, but Dr. Stewart did not conduct his own facial analysis of the challenged ads, and because he could not opine on what the ads meant, his analysis has inherent limitations. IDF 513. He explained that Dr. Butters' linguistic approach to ad interpretation fails to take into account the characteristics of the viewer and how consumers use information. Stewart, Tr. 3170-73.

We agree with the ALJ's conclusion that, notwithstanding Dr. Butters' opinion to the contrary, the use of qualified language such as "may" or "can" with respect to the effects of the Challenged POM Products on

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

2. Bovitz Survey

In 2009, POM engaged the Bovitz Research Group to design a consumer survey to evaluate the relative effectiveness of the then-running "Super Hero" advertising campaign compared to POM's earlier "Dressed Bottle" campaign. The survey exposed survey respondents to POM's billboard advertising, which included taglines related to antioxidants but contained no additional text. Four of the billboard advertisements share headlines and imagery that appear in certain challenged ads in this case.

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[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.

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.

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,

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[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.").

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]

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

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[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.

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

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[17] "'[C]ompetent and reliable scientific evidence' has been more specifically defined in Commission orders addressing health claims for food products to mean: tests, analysis, research, studies or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *FTC Enforcement Policy Statement on Food Advertising*, (1994), *available at* http://www.ftc.gov/bcp/policystmt/ad-food.shtm (citing *Gracewood Fruit Co.*, 116 F.T.C. 1262, 1272 (1993); *Pompeian, Inc.*, 115 F.T.C. 933, 942 (1992)) ("*Food Advertising Statement*").

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.*,

[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.

104 F.T.C. at 821-22 n.59; *Removatron Int'l Corp.*, 111 F.T.C. at 297.

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

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[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).

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 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

[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).

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.

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.

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[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.

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

[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

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

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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.

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; 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

[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.

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.

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

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[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.

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

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

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

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

But our consideration of the type of claim goes beyond merely identifying Respondents' claims broadly as health claims. Here, the evidence in the record shows that many of Respondents' claims went beyond structure/function claims to represent that the Challenged POM Products treat, prevent or reduce the risk of serious diseases. As previously discussed, Respondents' specific disease claims require proof of causation. As the Commission has found in other cases (*see, e.g.*, *Thompson Med. Co.*, 104 F.T.C. at 321), and as demonstrated by the weight of expert testimony in this case, proof of causation requires RCTs. *See* discussion *supra*, Section V.A.[28]

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[28] 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

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

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substance in a food and a disease or health-related condition is adequately supported by the scientific evidence.").

that where the product is safe and where the advertisement does not suggest that the product be used as a substitute for conventional medical care or treatment, it is appropriate to favor disclosure. *Id*. at 248. But the ALJ's failure to distinguish Respondents' particular disease treatment and prevention claims from those asserting some general health benefits led him to an incorrect conclusion. A determination that RCTs are necessary to support Respondents' specific claims that the Challenged POM Products treat, prevent or reduce the risk of particular diseases will not erect a barrier that will prevent the disclosure to the public of useful nutritional information. We have not determined the level of substantiation that is required to support all health and nutritional claims.[29] Thus, while our reasoning may be informative about our likely approach to evaluate other

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

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 economic injuries."). Consumers pay a higher price for POM products at least in part because of their ostensible health benefits.[31]

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[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.

[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").

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

[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.

is deceptive for failure to have a reasonable basis. Thus, Respondents' advertising violates Sections 5(a) and 12 of the FTC Act. *See Removatron Int'l Corp.*, 884 F.2d at 1498 (finding that where advertisers lack a reasonable basis, their ads are deceptive as a matter of law).

VI. Respondents' False and Misleading Claims are Material

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

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

[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.

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

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

A. Actually Misleading

Contrary to Respondents' claim, empirical or extrinsic evidence is not necessarily required for the Commission to conclude that Respondents' ads are actually misleading. Respondents mischaracterize the law in arguing that the Commission is limited to finding an advertisement is actually misleading only in instances

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

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

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

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

that have evaluated lawyers' advertisements of their certifications as civil trial specialists by NBTA have concluded that the statements were not misleading or deceptive *on their face*, and that, under our recent decisions, they were protected by the First Amendment") (emphasis added).

Once the Commission has determined that Respondents' ads are actually misleading, no further analysis is necessary because misleading commercial speech is not protected by the First Amendment. Each of the cases cited by Respondents acknowledges that '[t]he Federal Government [is] free to prevent the dissemination of commercial speech that is false, deceptive, or misleading." *Zauderer*, 471 U.S. at 638. The three-part analysis for determining whether regulation of commercial speech is constitutional under *Central Hudson* – whether the regulation is based on a substantial governmental interest, whether the regulation directly advances the governmental interest asserted, and whether the regulation is not more extensive than necessary to serve that interest – is applicable only if a threshold inquiry determines that the speech in question is not false or misleading. *See Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 566; *Edenfield v. Fane*, 507 U.S. 761, 768 (1993); *Daniel Chapter One*, 2009 WL 5160000 at *19-20. We nonetheless address Respondents' additional First Amendment arguments.

B. Inherently Misleading

Respondents contend that "an advertisement cannot be inherently misleading on its face when it states objectively accurate and verifiable facts," but also admit "[a]n advertisement that states accurate and verifiable facts may, in some instances, be potentially misleading." RA at 20. Indeed, Respondents' admission is the more accurate description of the law. Courts have regularly

found "that even literally true statements can have misleading implications" and challenging such deception does not violate the First Amendment. *Kraft Inc.*, 970 F.2d at 322 (citing *Zauderer*, 471 U.S. at 652; *Thompson Med. Co.*, 791 F.2d at 197; *Removatron Int'l Corp.*, 111 F.T.C. at 292-95; *Am. Home Prods. Corp.*, 695 F.2d at 687).

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

Respondents assert that the statements in their ads also are objectively accurate and verifiable facts. Respondents point to statements in their ads that the Challenged POM Products are high in antioxidants and to the citations of their studies to explain that the studies were conducted by world-renowned researchers, the results were published in peer-reviewed journals, and the statements about the disease-specific findings as proof the statements, like those in *R.M.J.*, are objectively are accurate and verifiable. We agree that many of the facts in Respondents' ads are verifiable. However, there are many omissions of material facts in Respondents' ads that

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

C. Potentially Misleading

Finally, Respondents argue that, because their ads are not actually misleading or inherently misleading, a position that this opinion has already rejected, then their

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

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

these claims and the government's interest in preventing fraud. *Id.* at 657. The D.C. Circuit concluded that potentially misleading claims could be remedied by "prominent" disclaimers. *Id.* at 658, 659.

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

In addition, the Commission's approach to address misleading advertising, which is a case-by-case adjudication *after* ads have been disseminated, differs from regulatory efforts that prohibit categories of speech or rely on *prior* approval of the language to be used. The latter serve as illustrations of "bars" on commercial speech and are inapplicable to the detailed *ex post* analysis we engage in here, based on a full record about the ads in question. *See Kraft Inc.*, 970 F.2d at 317 (explaining that "a prophylactic regulation applicable to all lawyers, completely prohibiting an entire category of potentially misleading commercial speech" at issue in *Peel*, is

[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.

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 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

[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).

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 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

[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

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

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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)).

substantiating RCTs before they again advertise that one of their products prevents, reduces the risk, or treats any disease.

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

[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.

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. 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

APPENDIX C

Concurring Statement of Commissioner Maureen K. Ohlhausen In the Matter of POM Wonderful

Docket No. 9344
January 10, 2013

I disagree with the majority's findings of implied disease efficacy and establishment claims with regard to the exhibits detailed below for several reasons. First, several of these exhibits contain claims about the general effects of the POM products on the continued healthy functioning of the body but do not make references to diseases or health-related conditions.[1] Despite the absence of such references or of other suggestive indicators (*e.g.,* strong medical imagery), the majority finds that these exhibits contain *implied* disease-related claims without extrinsic evidence that consumers viewing the exhibits would actually perceive such stronger claims and not simply perceive healthy functioning claims (akin to "structure/function" or "S/F" claims under Food and Drug Administration regulations).[2] I am concerned that, if the Commission too easily finds implied disease efficacy or establishment claims in advertisements for foods, absent extrinsic evidence, then it may tend to undermine an important balance that is struck in the regulation of

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

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

food, supplement, and drug advertising under the FTC Act and other federal laws.[3]

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

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

[4] *See* Fig. 6.

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

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

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

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

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

claim unless extrinsic evidence allows us to conclude that such a reading of the ad is reasonable." *Thompson Med. Co.*, 104 F.T.C at 789; *Telebrands,* 140 F.T.C. at 291 (citing *Thompson Med. Co.*).

With respect to the claims described below, such extrinsic evidence is unavailable or inadequate. Although Complaint Counsel offered the expert testimony of Dr. Stewart, he did not conduct his own facial analysis of the challenged advertisements and could not opine on what they meant. IDF 513. Also, unlike in cases such as *Thompson Medical* and *Telebrands*, Complaint Counsel did not introduce copy testing evidence to demonstrate what claims consumers may perceive from well-qualified or contradictory statements in advertisements. Because a number of exhibits contain references to the continued healthy functioning of the body without mentioning disease or health-related conditions, discuss only treatments for patients already suffering certain diseases, discuss risk reduction without mentioning treatment of certain diseases, or contain extensive qualifying language, I do not share the majority's ability to "conclude with confidence," that no extrinsic evidence is needed to read stronger claims between the lines. I am concerned with, and thus disagree with, these particular majority findings.[8]

As our opinion today observes, the Commission has paid particular attention to the balancing of pertinent consumer interests in describing the *Pfizer* factors applicable to the question of what constitutes a reasonable

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

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

In particular, Congress and the Food and Drug Administration have created carefully drawn boundaries between different types of claims regarding the effect of food and dietary supplement products on nutrition and health. FDA regulations distinguish between various categories of claims that may be associated with food products and dietary supplements – including "qualified health claims," "health claims," and "structure/function" claims – and the level of substantiation required for each category of claim.[11] According to FDA guidance, health

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

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

[11] *See generally* FDA, Guidance for Industry: A Food Labeling Guide (September 1994; Revised April 2008; Revised October 2009),

claims and qualified health claims expressly or by implication characterize the relationship of a substance to a disease (*e.g.,* heart disease) or health-related condition (*e.g.,* high blood pressure).[12] By contrast, structure/function claims describe the effect that a substance has on the structure or function of the body for maintenance of good health and nutrition but do not make reference to a disease.[13] The FDA imposes different and more stringent requirements on health claims than it does on structure/function claims.[14]

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available at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm; FDA, Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims – Final (2009), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm; FDA Guidance for Industry: FDA's Implementation of "Qualified Health Claims": Questions and Answers; Final Guidance (May 12, 2006), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053843.htm.

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

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

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

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

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specifically authorized by the Dietary Supplement Health and Education Act of 1994, 108 Stat. 4325 (codified as amended in scattered sections of 21 U.S.C.); *see also* Dep't Health & Human Servs., Food & Drug Admin., Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, Final Rule, 65 Fed. Reg. 1000 at 1034-35 (Jan. 6, 2000).

[15] I am concerned that, for these exhibits, the majority readings are in conspicuous tension with the express findings and intent of Congress in enacting the Dietary Supplement Health and Education Act of 1994 (DSHEA), wherein Congress provides for structure/function claims that may be made on behalf of dietary supplements. In the statute itself are express findings that healthful diets may reduce the risk of disease and the need for medical intervention; that "consumers should be empowered to make choices about preventive health care programs," *id.* at § 2(8), based on available scientific evidence; and that, "although the Federal

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

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

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Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers." *Id.* at § 2(13). Moreover, although the DSHEA regards dietary supplements in particular, FDA has concluded that "structure/function claims may be made on a conventional food provided the effects are derived from the nutritive value of the food." FDA, Guidance for Industry: A Food Labeling Guide, at 8.Claims S1. Hence, "[o]n December 20, 2002, the agency announced its intention to extend its approach to implementing the *Pearson* decision to include health claims for conventional foods (67 Fed. Reg. 78002)." FDA, Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims – Final, at § II (background).

prevention, or risk-reduction of a disease, or that they are clinically proven.

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

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

I disagree with the majority view that this print ad conveyed to a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily treats – rather than prevents or reduces the risk of – heart disease. I also disagree with the majority and would uphold the ALJ's finding that the evidence fails to show that this print ad conveys to a significant minority of reasonable consumers that the claims contained in the advertisement are clinically proven. The advertisement's language qualifies that drinking POM Juice "*can* reduce plaque by up to 30%" (emphasis added) and the citation to a study appears in a footnote too small to be clear and conspicuous under our own standards.[16] *See* ID at ¶ 447. Further, the imagery in the advertisement is that of regular hygiene, such as tooth brushing and flossing, not medical imagery related to heart disease that appears in other

[16] Advertisers cannot use fine print to contradict other statements in an ad or to clear up misimpressions the ad would otherwise leave. *FTC Deception Policy Statement*, appended to *Cliffdale Associates, Inc.,* 103 F.T.C. 110, 180-81 (1984). To be effective, Commission orders require such disclosures to be clear and conspicuous. *E.g., Thompson Med. Co.,* 104 F.T.C. at 842-43. For print ads, for instance, past Commission orders have defined "clear and conspicuous" to mean in a type size and location sufficiently noticeable for an ordinary consumer to read and understand it and in print that contrasts with the background against which it appears. *See, e.g.*, *FTC v. Green Millionaire, LLC,* No. 1:12-cv-01102-BEL (D. Md. filed Apr. 12, 2012) (proposed order granting stipulated permanent injunction), *available at* http://www.ftc.gov/os/caselist/1023204/120416greenmillstip.pdf.

challenged advertisements where the Commission unanimously found an implied establishment claim.

Figure 6. CX0034: Amaze Your Cardiologist

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

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

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

Figure 12. CX0109: Heart Therapy

I disagree with the majority and would uphold the ALJ's findings that the evidence fails to show that this print ad conveys to a significant minority of consumers that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease or that such claims are

clinically proven. The imagery in this ad, which is a POM bottle reclining on a couch, suggests psychotherapy, not treatment for heart disease. The text is qualified with references such as "emerging science," "initial scientific research," and "encouraging results in prostate and cardiovascular health." There is also an exhortation to "keep your heart healthy," without mention of or linkage to a specific disease, which seems more indicative of general structure/function type claims rather than health claims involving disease prevention or risk reduction.

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

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

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

I disagree with the majority and would uphold the ALJ's conclusion that the evidence fails to show that these print ads convey to a significant minority of reasonable consumers that taking a POMx Pill daily treats, prevents, or reduces the risk of heart disease and prostate cancer or

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

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

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

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

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

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

I disagree with the majority and would uphold the ALJ's conclusion that the evidence in the record fails to show that these print ads convey to a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats, prevents or reduces the risk of heart disease or prostate cancer or that these claims are clinically proven. These ads state "keep you at your healthy best" and "prostate and cardiovascular health" and do not refer to any disease, making the claims akin to structure/function type claims. The imagery regarding pills is linked to the antioxidant power of the product. The studies referenced are strongly qualified, stating that "*preliminary* studies … showed

promising results for heart health" or that an "*initial* UCLA study … found *hopeful* results for prostate health" (emphasis added). Moreover, any disclaimers at the bottom of the ad are too small to be interpreted in conjunction with other messages. For similar reasons, I also disagree with the majority's view that exhibits CX0351 and CX0355 convey to a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats, prevents, or reduces the risk of erectile dysfunction or that those claims are clinically proven. The statements about the studies referenced are qualified; for instance, the ad refers to a "*preliminary* study on erectile function" (emphasis added) and notes that "further studies are warranted." Thus, the Commission should require extrinsic evidence to find implied health/disease or establishment claims.

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

I disagree with the majority's view that these exhibits convey to a significant minority of reasonable consumers that taking eight ounces of POM Juice or one POMx Pill daily prevents or reduces the risk of – rather than treats – prostate cancer. Because the science referenced in these exhibits consists of subjects who had already been diagnosed with that disease, I would require extrinsic evidence before finding implied claims of disease prevention or risk reduction.

Figure 37. CX0473: Capture of POMWonderful.com Website

For the same reasons noted for exhibits 36 and 39, I disagree with the majority's view that this exhibit conveys to a significant minority of reasonable consumers that taking eight ounces of POM Juice or one POMx Pill daily prevents or reduces the risk of – rather than treats –

prostate cancer. Because the science referenced in this exhibit consists of subjects who had already been diagnosed with cancer, I would require extrinsic evidence before finding such implied claims.

APPENDIX D

Concurring Statement of
Commissioner J. Thomas Rosch
In the Matter of POM Wonderful
Docket No. 9344
January 10, 2013

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

Using this framework, the Commission Opinion separately analyzes the efficacy claims and the level of substantiation claimed by those advertisements. More specifically, the Commission first determines for itself whether and to what extent the ads make efficacy claims (*see, e.g., id*. at 9); but the Commission relies on extrinsic evidence (the testimony of experts) to determine the level of substantiation required to support the claims made by the ads in that respect. The Commission ends up concluding on the basis of the testimony of those experts that the highest level of well-controlled studies (the "gold standard" of RCTs) is required to support the latter claims. *Id.* at 20, 22-23, 25-26, 30, 32, 35, and 38.

I agree with the Commission's conclusion. Moreover, I agree that the Commission reached that conclusion by using the most traditional (that is to say the safest) analytical route. However, that route entails a discussion of both the expert testimony and how the *Pfizer*

factors should apply in this case. *Id*. at 20-38. I consider that lengthy discussion to be unnecessary. Beyond that, having served as a Commissioner for seven years and having been a trial lawyer for nearly 40 years before that, I am somewhat skeptical of relying so heavily on the opinions of experts who are paid by both Complaint Counsel and Respondents. Fortunately, I do not have to do so.

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

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

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

also *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 391-92 (1965).

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

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

highest possible level of substantiation exists for the POM product being advertised, and that claim is false.

More specifically, many of the advertisements expressly link POM to the treatment, prevention or reduction of the risk of heart disease or prostate cancer. *See, e.g.,* POM Claims Appendix, ads numbered 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 12, 14, 16, 19, 20, 28, 29, 30, 31, 32, and 33. Other ads at least implicitly link POM or POMx to the treatment, prevention, or the reduction of risk of those very serious diseases by liberally quoting physicians. *See id.*, ads numbered 16, 18, 19, 21, 24, 25, 27, 28, 29, 30, 31, 32, and 33 in the Claims Appendix. Another set of ads implicitly link POM to the treatment, prevention, or the reduction of risk of heart disease or prostate cancer by equating POM with POMx (which is depicted as a prescription drug), or by depicting POM itself as a medicine. *See id.*, ads numbered 10, 13, 14, 16, 17, 18, 19, 22, 25, 28, 29, 30, 31, and 32. Furthermore, ads implicitly link POM to the treatment, prevention, or reduction of risk of these life-threatening diseases by describing POM as a life insurance supplement or a healthcare plan. *See id.*, ads numbered 29 and 31. Each of these claims creates the net impression that the highest form of substantiation exists to support the claims linking POM to the treatment, prevention or reduction of risk from these serious diseases.

Fourth, I do not consider erectile dysfunction to be as serious as heart disease or prostate cancer. For example, while erectile dysfunction afflicts many men, it is generally not life- threatening. Thus, I do not think that linking POM with the treatment, prevention or reduction of risk of erectile dysfunction, standing alone, creates a net impression that claims respecting that malady are supported by the highest level of substantiation. But that does not mean the Commission Opinion is wrong in requiring that level of substantiation for erectile

dysfunction as well. The Commission has long considered so-called "establishment" claims to be binding on the advertisers that make them. *See FTC Policy Statement Regarding Advertising Substantiation, appended to Thompson Med. Co.,* 104 F.T.C. 648, 839 (1984), *aff'd,* 791 F.2d 189 (D.C. Cir. 1986) (for ads that "contain express or implied statements regarding the amount of support the advertiser has for the product claim . . ., the advertiser must possess the amount and type of substantiation the ad actually communicates to consumers"). In this case, those associated with POM have made such claims. *See, e.g.,* POM Claims Appendix, ad numbered 33.

APPENDIX E

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, as successor in interest to Roll International Corporation, companies, and	)	**Docket No. 9344**
STEWART A. RESNICK, LYNDA RAE RESNICK, and MATTHEW TUPPER, individually and as officers of the companies,	)	
Respondents.	)	

FINAL ORDER

DEFINITIONS

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

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

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

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

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

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

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

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

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

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

I.

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

II.

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

III.

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

objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.

IV.

IT IS FURTHER ORDERED that:

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

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

V.

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

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

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

C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the

representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations; and

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

VI.

IT IS FURTHER ORDERED that POM Wonderful, Roll, and their successors and assigns, and Individual Respondents shall deliver a copy of this Order to all of their current and future principals, officers, directors, and managers, and to all of their current and future employees, agents, and representatives having managerial responsibilities with respect to the subject matter of this Order, and shall secure from each such person a signed and dated statement acknowledging receipt of the Order. POM Wonderful, Roll, and their successors and assigns, and Individual Respondents shall deliver this Order to such current personnel within thirty (30) days after the effective date of this Order, and to such future personnel within thirty (30) days after the person assumes such position or responsibilities.

VII.

IT IS FURTHER ORDERED that POM Wonderful, Roll, and their successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporations or any business entity that POM Wonderful, Roll, and their successors and assigns, and Individual Respondents directly or indirectly control, or have an ownership interest in, that may affect compliance obligations arising under this Order, including but not limited to formation of a new business entity; a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor entity; the

creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order; the proposed filing of a bankruptcy petition; or a change in the business or corporate name or address. *Provided, however*, that, with respect to any proposed change about which POM Wonderful, Roll, and their successors and assigns, and Individual Respondents learn less than thirty (30) days prior to the date such action is to take place, POM Wonderful, Roll, and their successors and assigns, and Individual Respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line FTC v. POM Wonderful. *Provided*, *however*, that, in lieu of overnight courier, notices may be sent by first class mail, but only if electronic versions of such notices are contemporaneously sent to the Commission at DEbrief@ftc.gov.

VIII.

IT IS FURTHER ORDERED that each Individual Respondent, for a period of ten (10) years after the date of issuance of this Order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include the Individual Respondent's new business address and telephone number and a description of the nature of the business or employment and his or her duties and responsibilities. Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier to the Associate Director for Enforcement, Bureau of Consumer

Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line FTC v. POM Wonderful. Provided, however, that, in lieu of overnight courier, notices may be sent by first-class mail, but only if electronic versions of such notices are contemporaneously sent to the Commission at DEbrief@ftc.gov.

IX.

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

X.

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

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

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

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

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

By the Commission

Donald S. Clark
Secretary

ISSUED: January 10, 2013
SEAL:

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 13-1060 September Term, 2014

FTC-9344

Filed On: May 28, 2015

POM Wonderful LLC, et al.,

Petitioners

v.

Federal Trade Commission,

Respondent

BEFORE: Garland, Chief Judge; Srinivasan, Circuit Judge; and Ginsburg, Senior Circuit Judge

O R D E R

Upon consideration of petitioners' petition for panel rehearing filed on April 6, 2015, it is

ORDERED that the petition be denied.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Ken R. Meadows
Deputy Clerk

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 13-1060 September Term, 2014

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POM Wonderful LLC, et al.,
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v.

Federal Trade Commission,
Respondent

BEFORE: Garland, Chief Judge; Henderson, Rogers, Tatel, Brown, Griffith, Kavanaugh, Srinivasan, Millett, Pillard, and Wilkins, Circuit Judges; Ginsburg, Senior Circuit Judge

O R D E R

Upon consideration of petitioners' petition for rehearing en banc, the response thereto, and the absence of a request by any member of the court for a vote, it is

ORDERED that the petition be denied.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Ken R. Meadows
Deputy Clerk