No. 13-1060

United States Court of Appeals for the District of Columbia Circuit

POM WONDERFUL, LLC, et al.

Petitioners

v.

FEDERAL TRADE COMMISSION

Respondent

ON APPEAL FROM THE FEDERAL TRADE COMMISSION CASE NO. 9344

PETITION FOR REHEARING AND REHEARING EN BANC

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STATEMENT RESPECTING REHEARING EN BANC

This case presents the exceptionally important question whether this Court must defer to an agency finding that speech is not protected by the First Amendment. The panel's application of deferential review rests on an ill-considered footnote in prior precedent and conflicts with the Supreme Court's decision in *Peel v. Attorney Registration & Disciplinary Comm'n of Ill.*, 496 U.S. 91 (1990), which requires *de novo* review.

INTRODUCTION

This Petition involves a question of obvious and recurring importance for this Court: When an administrative agency finds that speech is misleading, and bans it on the ground that it thus receives no First Amendment protection, does this Court apply deferential or *de novo* review? Here, an administrative law judge found that a limited number of Petitioner's ads were misleading, but rejected that holding for 17 others. The Federal Trade Commission overturned the latter ruling and banned the larger category of ads, adopting a much broader standard for implying misleading messages into ads and thus denying them any First Amendment protection. A panel of this Court accepted the Commission's broader ban under substantial evidence review, reasoning that it was bound to apply that standard by two ill-considered footnotes in this Court's precedents that do not even cite the Supreme Court's relevant cases.

The *en banc* Court should review this critical aspect of the panel's ruling. The question whether an agency may deem speech on matters of public concern outside the First Amendment, ban that speech, and then shield its decision from serious judicial scrutiny is manifestly important to this Court, which plays a special role in reviewing agency decisions. The FTC and other agencies regularly prohibit ads or other

statements on the ground that they might mislead some consumers—a decision for which this Court is the judiciary's primary backstop. The Supreme Court's decisions, meanwhile, compel *de novo* review of such agency determinations insofar as they purport to place speech outside the First Amendment's protections, precisely because the First Amendment cannot leave its applicability in the hands of the censor itself. Indeed, citing those decisions, the Eight Circuit has recently and specifically held that "[w]hether speech is 'inherently misleading' is a question of law that we review *de novo*." *1-800-411-Pain Referral Service, LLC v. Otto*, 744 F.3d 1045, 1055 (8th Cir. 2014).

This is, moreover, an ideal case in which to confront this important question. The FTC brought this proceeding as a test case, asserting a substantially wider power to prohibit ads that make important claims about the possible health benefits of conventional foods because some consumers might infer far broader, unqualified claims about those products' abilities to treat or prevent disease. As the amicus participation illustrates, industry and consumer groups regard this case as a bell weather of agency authority in that regard. The standard of review, moreover, is outcome determinative with respect to the expanded category of ads targeted by the Commission: There is no serious prospect that a court applying *de novo* review would hold that the speech in question receives no First Amendment protection. Indeed, the FTC's decision to ban the broader set of ads plainly shows that it takes a paternalistic view of whether truthful speech about research into products' health benefits will benefit consumers. And that is just the kind of policy choice that requires *de novo* First Amendment review.

BACKGROUND

Petitioner POM Wonderful makes pomegranate juice and related products that contain very high levels of antioxidants. Because antioxidants have long been associated with health benefits, POM invested more than $35 million into researching a range of potential benefits of its products. To that end, POM sponsored myriad studies conducted by prominent individual scientists at some of the world's finest institutions, resulting in a large body of published research. That included promising, initial results for various risk factors relating to heart, prostate, and erectile health.

Some of these studies, however, did not achieve statistical significance. This was not surprising given that POM's research involved several different types of studies using different measures of potential benefits, some much more difficult than others to utilize—especially in the context of testing the effects of nutrients found in foods. Isolating those effects creates well-recognized problems: To take just one example, it would be unethical and largely impossible to run a study where one group received antioxidants from POM products and another was prohibited from ingesting any antioxidants (which are contained in numerous food sources) for an extended period of time. The results from many of the studies were nonetheless hopeful, indicating that POM products might well be beneficial to consumers' health.

POM thus ran a variety of ads publishing the encouraging results. The FTC's legal staff interpreted these ads very broadly, however, construing them as if they assured consumers that POM products treated, cured, or prevented heart disease, pros-

tate cancer, and/or erectile dysfunction. The staff further believed that POM's ads implied that clinical research "proved" these disease effects, and that both sets of claims were misleading unless they were supported by the scientific gold standard of statistically significant, randomized controlled trials (RCTs). It thus filed an administrative complaint accusing 43 POM ads of being false or misleading. Op. 12.

The ALJ found that only 19 of those ads made the relevant disease claims in the absence of adequate scientific proof. Both sides appealed to the Commission. *Id.*

Over the dissent of Commissioner Ohlhausen, the Commission adopted a substantially broader interpretation of health claims in advertisements. It then applied that standard to ban significantly more of POM's ads, and enjoined POM from making any such statements in the absence of support from two RCTs. Op. 13-14. Many of the 36 ads in this expanded category contained qualified language signaling that the research findings were not conclusive. For example, one ad for POM pills began with the following bolded quotation, taken directly from the *New York Times*: "Findings from a *small* study *suggest* that pomegranate juice may *one day prove* an effective weapon against prostate cancer." *See* Fig. 13 (appended; emphasis added). Other ads contained similarly limited claims, stating only that POM's juice "is supported by $20 million of *initial* scientific research" which "has uncovered *encouraging* results in prostate and cardiovascular *health*." Fig. 11 (appended; emphasis added); *see also* Fig. 12 (appended). Simply put, many of POMs ads truthfully conveyed only that there were "initial" and "preliminary" results that were "hopeful" and "encouraging," rather than

any claim of definitive proof. *Id.* Moreover, many of these ads referred only to bodily *health*, and did not refer at all to *diseases* like cancer that POM could possibly treat or prevent. *See, e.g.*, Fig. 23 (appended).

The Commission nonetheless read the ads—quite remarkably—as if they claimed unqualified scientific proof of POM's efficacy in addressing diseases. POM sought this Court's review, arguing that the Commission misconstrued the ads as making unqualified claims of clinical proof that POM's products had disease effects.

A panel of this Court affirmed in relevant part.[1] It did so for all the ads prohibited by the Commission—including 17 ads that the ALJ found were not subject to sanction—based on the "deferential" standard of review. Op. 34. As to those 17 ads, the panel held only that there was "substantial evidence in the record" to sustain the FTC's finding; put otherwise, it did not find that the FTC 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. *See id.* 16, 34-35 (describing FTC's "significant minority" standard). The panel further opined that it would reach

[1] The panel ruled for POM insofar as it viewed the FTC's injunction requiring two RCTs as overly onerous under *Central Hudson*'s test for commercial speech. It did so recognizing that, under the FTC's ruling, 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 POM products treated or prevented a disease. Op. 36. If even such limited language would be read so broadly, the panel held, then requiring two RCTs was a more onerous restriction than necessary to serve any compelling purpose, and could prevent dissemination of important, useful information to consumers. Op. 38-45.

the same conclusion on *de novo* review, but *only* "at least with respect to the nineteen ads determined misleading" by the ALJ in the initial FTC proceeding—conspicuously failing to make such a finding with respect to the additional 17 ads the Commission prohibited under its significantly more sweeping standard for implying health claims into food advertisements. *Id.* 34. Both the FTC and the panel relied exclusively on the face of the ads for these findings; in fact, most of the ads on which the ALJ declined to find liability are not discussed in the panel opinion at all. *See id.* 34-35.

The panel recognized and accepted the FTC's holding that it would have imposed the same remedy even considering only the 19 ads found liable by the ALJ. *See* Op. 34. But even if the *en banc* Court accepts that view, the decision to sustain the Commission's order only under deferential review with respect to the *17 additional ads* remains extremely significant, because it determines the scope of the Commission's injunction. As the panel noted, that injunction requires POM to have RCT support for *unqualified* disease claims—a category that, under the panel's ruling, broadly sweeps in the 17 additional ads. *See* Op. 36. In stark contrast, if *de novo* review determines that any of these ads do not make such claims—as POM argued, the ALJ and Commissioner Ohlhausen found, and the panel did not contest—then the ads are protected speech and POM has an uncontested right to publish them. It moreover has the right to make other equivalent statements without the FTC prohibiting those ads and sanctioning POM on the ground that they impliedly make unqualified disease claims. The upshot is that the standard of review alone supports a ban on 17 instances of

protected speech that cannot possibly be banned unless they really do communicate the allegedly misleading, "implied" messages. In all other respects, those ads inform consumers about important information, including the precise outcomes of scientific studies and the possible benefits of POM's antioxidant-rich and entirely safe products.

REASONS FOR GRANTING REHEARING EN BANC

The standard of review that the panel applied—which was previously adopted via a passing holding in one of this Court's footnotes—requires this Court's collective attention. First, it is inconsistent with Supreme Court precedents that this Court has *never* discussed in applying substantial-evidence review. Second, it is entirely too lax, allowing the FTC to censor speech unless this Court can find it *arbitrary* to believe that a significant *minority* of people will read it in a misleading way. Indeed, the ads in this case are a perfect indication of just how far this doubly deferential rule can be stretched in banning truthful speech. Third, the standard of review is vitally important: The permissive standard alone supports a prospective gag order on many instances of protected speech in this case, and will do so in many future cases as well.

I. Supreme Court Precedent Never Considered By This Court Requires *De Novo* Review Of The First Amendment's Application In Deceptive Advertising Cases

The panel held that Circuit "precedents 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." Op. 34. It did not discuss the merits of that legal rule, however—apparently believing itself bound by precedent

to endorse it. Because a deferential standard has now been firmly established in panel precedent, only *en banc* review can bring this Court in line with the Supreme Court.

The Supreme Court's decision in *Bose Corp. v. Consumers Union*, 466 U.S. 485 (1984), compels the application of *de novo* review. The Court there 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. *Id.* at 503-11. The Court 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 imminent violence, prurient obscenity, or child pornography. *Id.* at 504-08. That broad holding, and its reasoning, strongly suggest that *de novo* review is required in the analogous context where the FTC claims that speech is in an unprotected category because it implies a misleading message.

Nonetheless, shortly after *Bose*, this Court said (in a footnote) that it would not read that decision to change the standard of review in the FTC's deceptive advertising cases. *FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 41 n.3 (D.C. Cir. 1985). Judge Bork's reasoning was that *Bose* left open the question whether it should apply to commercial speech. *Id.* Nonetheless, this Court recognized that the language and rationale of *Bose* appeared to cover FTC advertising cases no less than other contexts where the question is whether the speech falls into an unprotected category. *Id.*

Five years later, the Supreme Court confirmed that this Court erred, and ought to have applied *Bose*'s facially applicable holding. In *Peel,* 496 U.S. at 108, the Illinois

Supreme Court sanctioned certain attorney ads on the theory that they could imply a set of misleading messages to some consumers. Citing *Bose*, the Supreme 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.* There, as here, the issue was not any ad's "facial accuracy, but … its implied claim[s]." *Id.* at 100-01. And there, as here, the lower tribunal implied the allegedly misleading messages solely from the face of the ads, with "no contention that any person was actually misled or deceived." *Id.* at 101, 108. There, the Supreme Court rigorously scrutinized the supposed implied claims and determined that—where the ads did not "necessarily" imply the misleading message—it would not allow them to be banned based on "paternalistic assumption[s]" about the audience. *Id.* at 104-05. That is exactly the kind of rigorous, *de novo* review that the panel refused to apply here. *See also Ibanez v. Florida Dep't of Business & Professional Registration*, 512 U.S. 136, 144-48 (1994) (applying similar, rigorous, *de novo* analysis to holding that a particular ad implied a misleading message, and holding the ad to be protected speech).

Thereafter, this Court decided *Novartis v. FTC*, 223 F.3d 783 (D.C. Cir. 2000), a case in which the FTC found that certain ads falsely implied that Novartis's over-the-counter analgesic was superior to others in relieving back pain. Novartis challenged only whether the misleading claims were material, *id.* at 786, but nonetheless argued for *de novo* review under *Bose*. In yet another footnote, this Court held that *Brown &*

Williamson had already resolved broadly against *de novo* review, with no analysis whatsoever of the import of the intervening Supreme Court decisions in *Peel* and *Ibanez*. *See id.* at 787 n.4. This *Novartis* footnote, in turn, was the sole basis on which the panel here held that deferential review was compelled by Circuit precedent. Op. 34.

Thus, this Court has now definitively held that the standard of review for determining whether speech is unprotected is more deferential in FTC deceptive advertising cases than in *every* other First Amendment context—including commercial speech more generally. It has done so exclusively in footnotes that do not even mention the Supreme Court's binding precedents. *Peel*, in particular, is on all fours: It similarly involved a regulator ordinarily treated with deference by the federal courts (there, the Illinois Supreme Court as regulator of the state bar), in an *ex-post* adjudicatory posture, concluding based exclusively on the facial evidence that certain ads implied a misleading message. The Eighth Circuit thus recently held, citing *Peel*, that "[w]hether speech is 'inherently misleading' is a question … we review *de novo*." *Otto*, 744 F.3d at 1055. Before definitively rejecting a Supreme Court holding in such a closely analogous case, and departing from the related holdings of other Circuits, this Court should at least *consider* the question. Now, only the *en banc* Court can do so.

II. This Court Cannot Defer To The FTC On Whether FTC Decisions Are Subject To First Amendment Scrutiny

It would largely defeat the purpose of the First Amendment for this Court to allow the FTC to deem its own censorship not subject to First Amendment review.

The truthful and non-misleading ads on health matters of obvious public concern that the Commission chose to ban here show precisely why: These ads convey important information to consumers, and are plainly protected speech unless they imply the (unlikely) message that POM juice can treat or prevent life-threatening diseases. And, in fact, the only distinctions between this case and *Peel* recommend in favor of *more* searching review than the heavy scrutiny applied there.

The theory of the FTC's ban in this case is that virtually all of the ads at issue might mislead consumers by implying that POM's products were *unqualifiedly proven* by science to treat, prevent, or reduce the risk of heart or prostate *disease*, even though POM did not have RCT support for that statement. *See* JA587. In overruling the ALJ, the Commission found that super-strong claim lurking in quotidian text. In addition to the ads noted above, *see supra* p.4, the Commission found that an ad with a POM juice bottle on a therapist's couch conveyed this claim by saying that POM juice is "supported by $20 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health." Fig. 12 (attached). This ad does not mention "proof" or "disease" and its only medical imagery is a tongue-in-cheek reference to psychotherapy. But, nevertheless, governed by the doubly deferential standard, the panel felt bound to affirm that this innocuous text falsely implied that POM is unqualifiedly proven to prevent heart disease.

Indeed, the most remarkable aspect of the FTC's approach to its ban—which necessarily goes unaddressed under this standard of review—is how little it is willing

to accept by way of accurate qualification. Even the panel remarked on this fact, *see supra* n.1; Op. 36-37, and it is readily demonstrated. For POM's ads that truthfully quoted the *New York Times* about "a small study suggest[ing] that pomegranate juice may one day prove an effective weapon against prostate cancer," the FTC acknowledged that the ads "include language that attempts to qualify the claims conveyed." *See* JA643-44. But it found that these plain qualifications could not "counteract the net impression" that POM *treats cancer*, which it found to be conveyed in sentences like: "Our method of harnessing astonishing levels of antioxidants is so extraordinary, it's patent pending." *Compare id. with* Figure 13 (appended). The Commission's self-evident theory for extending its ban so far is that consumers are easily confused, and may be potentially misled by accurate descriptions of science or scientific research.

That theory of speech restriction is just the sort that requires *de novo* scrutiny under the First Amendment. As this Court has clarified, commercial-speech doctrine looks with disfavor on efforts to "prohibit[] certain kinds of speech on the premise that consumers need government to protect them from accurate information." *Spirit Airlines v. USDOT*, 687 F.3d 403, 415 (D.C. Cir. 2012). To be sure, some accurate information has the *potential* to mislead—which is all the FTC can be fairly said to find when it holds that such ads, considered exclusively on their face, could be misleading to some *minority* of consumers. *See, e.g.*, *Peel*, 496 U.S. 104-05 (First Amendment and *Central Hudson* balancing test applies if ad considered on its face does not "necessarily" imply misleading message). But *Peel* and *Ibanez* conclusively demonstrate that a ban

on accurate commercial speech that is only potentially misleading is subject to *de novo* First Amendment review, even when an agency considers the particular ads at issue and decides to sanction them in an *ex-post* adjudication. *See, e.g.*, *id.* at 100-01, 108-09.

In short, deference is inappropriate here because all the FTC did was apply its own facial judgment to how "reasonable" people might interpret POM's ads. For the ads now specifically at issue, it reached a different conclusion from the ALJ who heard the evidence and one objecting Commissioner, reading ads that do not mention "proof" or "disease" to make *unqualified* claims that POM is a *proven* treatment for life-threatening *diseases*. This kind of judgment is no more likely to be reliably made by the FTC than this Court, and at the very core of First Amendment review.

III. This Question Is Important And This Case Is A Good Vehicle For *En Banc* Review

In addition to the foregoing, there are three reasons why this case is an ideal vehicle for this Court to consider an issue important enough to merit *en banc* review.

First, the Court is very unlikely to get another chance. These food advertising cases are already overwhelmingly likely to settle: Only a small number of companies will shoulder the expense of taking deceptive advertising cases to trial, given that the trial and primary appeal all occur before the agency itself. And if this Court adheres to the holding that the only review in those cases will be exceedingly deferential, trials presenting this question will be more unlikely still. In fact, while there have been many consent decrees on this issue in the 30 years since *Brown & Williamson*, *see* Op.

42-43, there have only been a handful appeals. Given the disincentive created by this very decision, future cases will be even fewer and further between.

Second, the chilling effect of definitively endorsing the weak standard of review in this case will be immense. Given the FTC's free hand under the doubly deferential standard, companies will avoid saying anything that could even approach a claim about health or nutrition. The amicus participation in this case is indicative of how seriously the industry takes the FTC's increasing effort to police the use of any scientific results in food advertising—however qualified the claims may be. Definitively endorsing deferential review will amplify that chill several times over.

Finally, vehicles as concrete as this one are unlikely to arise. The typical case involves one relevant claim; this case presents 36 separate and distinct ads, the ALJ and Commission read many of them differently, and the panel opinion itself suggests that the standard of review could require different outcomes among them. 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. This Court should accordingly grant *en banc* review and give this question—and POM's protected speech—the judicial scrutiny that it deserves.

REASONS FOR GRANTING REHEARING

In the alternative, POM asks the panel to reconsider its opinion in one narrow respect. The opinion suggests that the Commission held POM liable for misleading

consumers by "selectively touting" some studies, *see* Op. 23-24, or failing to disclose studies that found no statistically significant results, *see id.* 6-12. But that was *not* the agency's theory and the record would not support that theory: As to liability, the FTC held only that POM's ads were misleading because they made unqualified disease claims in the absence of RCT support. *See* JA587 (the "basis of [Petitioners'] liability is their lack of … RCTs … to substantiate the claims that we found"); POM Reply Br. 11-13. The Commission's liability discussion does not accuse POM of withholding science or misdescribing the results of studies in particular ads. Notably, the panel's factual recitation—which arguably suggests such a theory—does not contain a single citation to the Commission's findings. *See* Op. 6-12.

The panel is of course bound to the Commission's theory, and cannot expand it or defend the result on other grounds. *See, e.g.*, *SEC v. Chenery Corp.*, 318 U.S. 80, 88, 95 (1943). The panel likely did not intend to do so; the relevant discussion appears almost exclusively in the factual narrative, and in two paragraphs that begin by discussing the theory of liability that the Commission in fact adopted. *See* Op. 6-12, 23-24. Removing those two paragraphs, beginning with the word "Moreover" on the last line of page 23, would more accurately conform the opinion's liability rationale to the Commission's. This request does not affect the result in the case; indeed, it is important only because this limited portion of the Court's discussion might be mischaracterized by future litigants to vastly expand the conduct that actually underlies POM's administratively adjudicated liability.

Respectfully Submitted.

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici.

Petitioners in this action are POM Wonderful, LLC, Roll Global, LLC, Stewart A. Resnick, Lynda Rae Resnick. Respondent is the United States Federal Trade Commission.

The amici who filed on behalf of Petitioners in this matter include the Consumer Healthcare Products Association, the Council for Responsible Nutrition, the Alliance for Natural Health-USA, and Tech Freedom. Public Citizen Inc. and the Center for Science in the Public Interest filed as amici supporting respondents.

B. Rulings Under Review.

The Rulings under review in this matter are the FTC's Final Order and Opinion *In the Matter of POM Wonderful, LLC, et al.,* FTC Docket No. 9344, which are reported at 2013-1 Trade Cases P 78220, 2013 WL 268926 (Jan. 16, 2013). They appear in the joint appendix and relevant excerpts appear as an addendum to this Petition.

C. Related Cases.

Petitioners certify that this case has not previously been before this Court and that there are no related cases pursuant to Circuit Rule 28.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure and Circuit Rule 26.1, Petitioners make the following disclosures:

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.

CERTIFICATE OF COMPLIANCE

I, Thomas C. Goldstein, hereby certify that this Petition for Rehearing and Rehearing En Banc complies with the page limitations of Federal Rules of Appellate Procedure 35(b)(2) and 32(a)(5) because it is prepared in 14-point Garamond, a proportionally spaced font.

/s/Thomas C. Goldstein
Thomas C. Goldstein

CERTIFICATE OF SERVICE

I, Thomas C. Goldstein, hereby certify that on April 6, 2015, I served a copy of the foregoing Petitioner for Rehearing and Rehearing En Banc on counsel for all parties using the Court's CM/ECF system. Counsel for all parties are registered users of that system.

/s/Thomas C. Goldstein
Thomas C. Goldstein

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, POM_x Pills and POM_x 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 co-investigators 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 co-investigators 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 co-investigators 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 POM_x 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, POM_x 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 POM_x 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—POM_x Liquid and POM_x 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.

Figure 11

Decompress.

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

POM Wonderful Pomegranate Juice. The Antioxidant Superpower.™

POM WONDERFUL®
pomwonderful.com

Figure 12

Heart therapy.

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

POM WONDERFUL®
pomwonderful.com

POM Wonderful Pomegranate Juice. The Antioxidant Superpower.™

Figure 13

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.[1,3] 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.

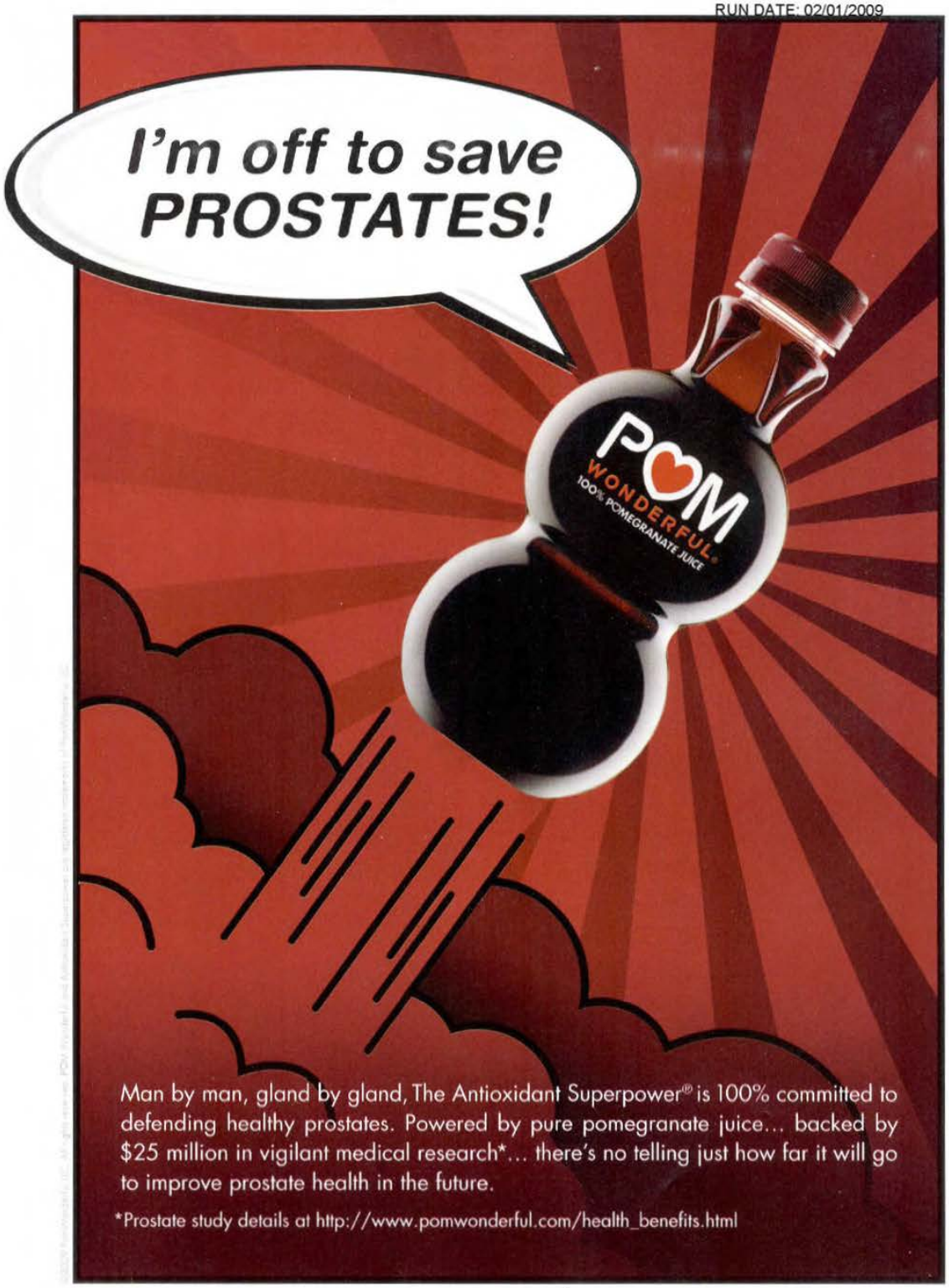
Call 1-888-POM-PILL or visit pompills.com/fort and mention or enter code **FORT5** at checkout. To pay by check, call 1-888-POM-PILL for instructions. Hurry, offer expires July 31, 2007.

CONSUMER: This offer expires July 31, 2007. Mention or enter coupon code FORT5 at checkout. This coupon can only be used on POMx products. One coupon redemption per customer. Cannot be combined with other offers. No substitutions, transfer rights or cash equivalents will be given. We reserve the right to modify or discontinue this promotion at any time. Coupon code valid only at pompills.com/fort or 1-888-POM-PILL.

[1] **pomwonderful.com/cancer.html** [2] **pomwonderful.com/heart_health.html** [3] These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Figure 23

VMS ID: 090200523
RUN DATE: 02/01/2009



pomwonderful.com

The Antioxidant Superpower.®


I'm off to save PROSTATES!
POM WONDERFUL
100% POMEGRANATE JUICE
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.®

Exhibit C

Excerpts from Commission Decision

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

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

controlled clinical trials (referred to in this opinion as "RCTs"); and (4) in his order, the ALJ should have required pre-approval by the Food and Drug Administration ("FDA") of any future disease claims made by Respondents with respect to the Challenged POM Products.

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

II. Factual Background and Proceedings Below

Respondent POM Wonderful is a limited liability company wholly owned by the Stewart and Lynda Resnick Revocable Trust dated December 27, 1988. IDF 1, 3. In 2002, POM Wonderful launched the first of the Challenged POM Products, POM Wonderful Juice, and currently sells all of the Challenged POM Products. IDF 5, 6. Respondent Roll Global is a separate corporation wholly owned by the same trust; Roll Global owns a number of companies, including POM Wonderful LLC, FIJI Water, Suterra, Paramount Farms, Paramount Citrus, Teleflora, Neptune Shipping, Paramount Farming, and Justin Winery. IDF 7, 9, 11. Roll

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

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

APPENDIX A
POM Claims Appendix[1]

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

A. Recurring Elements

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

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

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

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

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

diseases." The ad also states that: "Science tells us that pomegranate antioxidants neutralize free radicals, helping to prevent the damage that can lead to disease," and that POM "promotes heart and prostate health" and "guards your body against free radicals." These statements contributed to the net impression that the POMx Pill or POM Juice will prevent or reduce the risk of heart disease and prostate cancer in addition to treating these diseases.

Figure 11. CX0103: "Decompress" print advertisement

The Commission adopts the findings and conclusions of the ALJ that the evidence fails to show that CX0103 conveyed to a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily treats heart disease. *See* ID at ¶ 587. However, we find that this exhibit conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease and that these claims have been scientifically established. In this regard, the decision of the ALJ is reversed. The ad containing medical imagery depicts the POM Juice bottle wrapped in a blood pressure cuff. Moreover, express language in the ad establishes a link between POM Juice, which "helps guard … against free radicals [that] … contribute to disease," and the $20 million of "scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health." The ad also states that POM Juice will help "[k]eep your ticker ticking." In combination, these elements communicate the message that POM Juice prevents or reduces the risk of heart disease, and that those efficacy claims are scientifically established.

Figure 12. CX0109: "Heart Therapy" print advertisement

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

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

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

However, the Commission finds that these exhibits conveyed to at least a significant minority of consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats prostate cancer. The text in CX0120 and CX0122 specifically states that a study showed "hopeful results for men with prostate cancer." Further, in CX0120, the advertising copy, indicating that it is a

quote from the *New York Times*, states that "[f]indings from a small study suggest that pomegranate juice may one day prove an effective weapon against prostate cancer." While the ads include language that attempts to qualify the claims conveyed, the Commission finds that these attempts to qualify fail to counteract the net impression conveyed through the use of strong descriptive language such as "incredibly powerful," "astonishing levels of antioxidants," and "so extraordinary, it's patent pending." In this regard, the decision of the ALJ is reversed.

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

Figure 15. CX0128: June 2007 press release
The Commission adopts the findings and conclusions of the ALJ with regard to CX0128. Accordingly, we conclude that this exhibit conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats erectile dysfunction and that this claim has been scientifically established. *See* ID at ¶¶ 432-439.

Figure 16. CX1426 Ex. M: POMx Heart Newsletter
The Commission adopts the findings and conclusions of the ALJ with regard to CX1426 Ex. M. Accordingly, we conclude that this exhibit conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats, prevents or reduces the risk of heart disease, and that these claims have been scientifically established. *See* ID at ¶¶ 346-350.

Figure 17. CX1426 Ex. N: POMx Prostate Newsletter
The Commission adopts the findings and conclusions of the ALJ with regard to CX1426 Ex. N. Accordingly, we conclude that this exhibit conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats, prevents or reduces the risk of prostate cancer, and that these claims have been scientifically established. *See* ID at ¶¶ 351-354. The Commission finds, as the ALJ did, that this newsletter draws a clear link between antioxidants and a reduction in the risk of prostate cancer. After noting that prostate cancer is "the second leading cause of cancer related to death in the United States," the newsletter addresses "risk factors" for prostate cancer, including "diet," and advises a diet that is rich in antioxidants. The newsletter also expressly informs readers of medical research in "top peer-reviewed medical journals that document the pomegranate's antioxidant health benefits such as heart and prostate health."

Figure 18. CX0169/CX1426 Ex. L: "The Power of POM" print advertisement
Based on the overall net impression of CX0169/CX1426 Ex. L, the Commission finds that this exhibit conveyed to at least a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking a POMx Pill daily treats, prevents or reduces the risk of heart disease and prostate cancer, and that these claims are scientifically established. This ad includes