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No. 13-1060

United States Court of Appeals for the District of Columbia Circuit

POM WONDERFUL, LLC, ET AL

Petitioner

v.

FEDERAL TRADE COMMISSION

Respondent

ON APPEAL FROM THE FEDERAL TRADE COMMISSION
CASE NO. 9344

FINAL JOINT REPLY BRIEF FOR PETITIONERS POM WONDERFUL, LLC, ROLL GLOBAL, STEWART A. RESNICK, LYNDA RAE RESNICK, AND MATTHEW TUPPER

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SUMMARY OF ARGUMENT

The FTC adopted the Order on review to impose strict limits on health-related claims in food advertising throughout the United States. The Commission first adopted a series of rules for broadly construing such ads to impliedly claim: (1) that foods treat or prevent specific diseases ("efficacy" claims); and (2) that those claims are clinically proven ("establishment" claims). JA586-87 (Op. A1-A2). The Commission then adopted another generalized principle: Those implied claims about foods are "actually misleading" unless based on the scientific gold standard of "RCTs": randomized, controlled, human clinical trials using validated endpoints that definitively prove a causal connection between product and benefit. *Id.* JA606-08, 625-26. Absent RCTs, the Commission ruled, those advertisements receive no First Amendment protection *at all*, so the Commission may ban them and sanction the advertiser, including by making future health-related advertisements all but impossible by requiring *two* RCTs. *Id.* JA626, 635-36.

There is no doubt that the Commission's new rules were—as intended—a sea change. In adopting this precedent, the FTC reversed a detailed ALJ ruling applying the Commission's pre-existing "competent and reliable scientific evidence" framework to find: (1) that most of the challenged ads did not convey efficacy or establishment claims; and (2) that RCTs should not be required for the kind of language in POM's ads. *Id.* JA586, 589; JA84 (ALJ Op. 5).

The Petition for Review should be granted. Indeed, the Commission's brief declines to seriously defend half of it. Below, the Commission recognized that its RCT requirement for "efficacy" claims must satisfy its well-settled *Pfizer* factors—a flexible inquiry the Commission adopted to avoid unnecessary restrictions on commercial speech. *See* JA618-19 (Op. 34-35) (applying *In re Pfizer Inc.*, 81 F.T.C. 23 (1972)). But Petitioners' opening briefs demonstrated that the Order in fact arbitrarily departed from *Pfizer* by not accounting for the economic, practical, and ethical infeasibility of conducting RCTs on foods, which make an RCT requirement dramatically disproportionate to the (nonexistent) risks of Petitioners' product and the (very real) prospect of suppressing truthful benefit claims. POM Br. 13-17; Tupper Br. 39-43. In response, the Commission does not even attempt to defend the Order's *Pfizer* analysis; it barely mentions *Pfizer* at all. It relies instead on having found implied *establishment* claims in nearly all the ads, which it says need not be analyzed under *Pfizer*. Br. 48 n.16. But that provides no answer on the supposed *efficacy* claims, which have never been subject to an RCT requirement in food advertisements before the (now-undefended) misapplication of *Pfizer* below.

That leaves the implied establishment claims. But with respect to those—and, indeed, with respect to all the claims at issue—Petitioners' opening briefs demonstrated that the Order violates the First Amendment. As discussed, the

Order holds that implied health-related claims without RCTs receive no constitutional protection. JA626 (Op. 42). But the FTC did not just adopt a very broad standard for implying health-related claims, nor just impose a rigorous RCT requirement for them—it did both, making the Order significantly more than the sum of its parts. The FTC's new and unbalanced standard makes it exceedingly difficult for *any* food advertisers to speak about how scientific studies may support their products' health benefits without risking liability—as the *amicus* briefing here demonstrates. *See, e.g.*, Brief of Counsel for Consumer Healthcare Products Association at 30.

The Order thus conflicts with basic First Amendment principles. Petitioners' speech addresses a matter of public concern: the health effects of foods. In any other context, identical statements would undoubtedly receive *full* constitutional protection. The advertisements, meanwhile, contain measured and accurate depictions of science and repeated disclaimers, and so are at most potentially (not actually) misleading. Yet the Commission says that they are actually misleading commercial speech, and may be banned, because readers are incapable of assessing scientific references in ads or resolving competing claims themselves. That view rests on exactly the paternalistic assumptions that commercial-speech doctrine condemns. And it bans important speech not out of any compelling public-health interest, but because it thinks the public overpays for

juice—juice that is undisputedly safe and healthy. Thus, under even a lenient application of *Central Hudson*, the Order is unconstitutional.

That conclusion is so plainly right that the Commission's lawyers have little choice but to attempt to re-characterize the Order entirely. They deny that the Commission applied any generalized principles, either when it construed the ads as impliedly making super-strong health claims or when it required RCTs for those supposed claims. Rather, they argue (at 35-48), the Commission made case-by-case judgments about these particular advertisements, and found that their particular claims were inadequately supported by particular studies for various reasons not limited to lack of RCTs. Put otherwise, because the Commission's legal rules are dubious, its advocates have tried to make this appeal all about the facts.

Their characterization of the Order does not reflect the Commission's actual reasoning, however, and so is not a basis for affirmance. *SEC v. Chenery*, 318 U.S. 80, 92-95 (1943). Indeed, the assertion that the Commission happened to find that thirty-six diverse advertisements—the great majority of which are heavily qualified and unmentioned in the Commission's brief—*all* run afoul of a supposed narrow, fact-bound inquiry refutes itself. On its face, the Order adopts a series of legal rules—rules that cannot satisfy *Central Hudson* and that will hang over all the nation's food producers if this Court affirms.

For that reason, and because the Order also violates the APA and imposes an overbroad remedial injunction, it must be vacated or reversed.

ARGUMENT

I. The Commission's Order Rests On Broad Legal Principles, Not Fact-Finding About Particular Advertisements

A. The Order depends on broad claim-interpretation principles.

The FTC's brief begins (at 29-33) by faulting POM for failing to plod separately through the Commission's ultimate determinations on each of the thirty-six publications at issue. But POM challenges the legal standards the Commission used to condemn all those advertisements, necessarily challenging its interpretation of the particular ads. It is the FTC that "cherry-picks" the record by focusing on a handful of the most aggressive advertisements—most of which have not been run in over six years. The FTC, not Petitioners, must vindicate the standard the Commission actually adopted and applied in *all* its breadth. *Chenery*, 318 U.S. at 92-95.[1]

Any fair reading of the Order shows that the FTC interpreted POM's ads to make both efficacy and establishment claims on the basis of broad legal

[1] Contrary to the FTC's suggestion (at 33), the Commission's statement that injunctive relief would have been justified based on fewer liable advertisements is irrelevant. The Commission's liability determination for every ad depends on the challenged approach, and there is no other basis for affirmance under *Chenery*. Whether particular ads could be accused under another standard is a matter for another day.

propositions that will apply to all food producers, not nitty-gritty analysis. Petitioners argued to the Commission that the ads made no such claims because they merely reported "accurate descriptions of specific study findings." JA597 (Op. 13). The Commission answered that it was sufficient to imply the relevant claims whenever "these ads drew a logical connection between the study results and effectiveness for the particular diseases." *Id.*

In other words, the Commission adopted 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. *Id.* JA597-98. Commissioner Ohlhausen correctly identified this standard as one where "mere mention of 'health' or healthy functioning can imply a disease-related efficacy [claim]" and "mere mention of scientific evidence can imply a related establishment claim." But, as she continued, once the FTC uses the "mere mention" of "health" to imply a disease claim, and the "mere mention" of "scientific evidence to imply a related establishment claim," it "undermine[s] distinctions between types of claims, and the substantiation appropriate to them." JA770-71.

Nonetheless, in its response brief (at 32), the FTC says that POM is looking in the wrong place: Its reasoning is not actually in the body of its opinion but in a separate Appendix A, which supposedly shows that the Commission made a case-

by-case finding that each of POM's advertisements made unsupported health claims. In fact, as the Appendix only confirms, the decision announces a series of legal rules that it applied here and will continue to apply if the Order is affirmed.

The Appendix avowedly rests first and foremost on rules about "Recurring Elements" of advertising in the United States, not individualized assessments of Petitioners' publications. JA638-39 (Op. A1-A2). It states these rules up front, literally identifying each in bold-face type as a basis to broadly construe food producers' advertisements as making efficacy and establishment claims. Thus:

> "**Medical Imagery, Symbols, and Terminology**"—such as "the word 'disease' as well as references to specific diseases and disease symptoms"—are all deemed to "contribute to a net impression" that advertisements "conveyed the disease-related claims";
>
> "**References to Medical Professionals, Scientific Studies, and Medical Journals**"—including accurate statements "quantifying the amount of money spent on research" and accurate "characterization of the research specifically as 'medical'"—are deemed to "contribute to the net impression that the ads conveyed the challenged claims";
>
> "**Performance Results Requiring Scientific Measurement**"—including "references to quantifiable results"—"tend to communicate that the product's attributes are supported by scientific research"; and
>
> "**Qualifying Language**"—"includ[ing] adjectives attached to scientific claims (*e.g.*, '*emerging* science suggests,' '*promising* results,' '*preliminary* studies,' '*initial* scientific research')—"does not neutralize the claims made when the specific results are otherwise described in unequivocally positive terms," notwithstanding the absence of any "extrinsic evidence . . . that an advertisement conveys establishment claims."

Id. JA638-39 & n.3.

As the FTC emphasizes (at 17, 32), Appendix A then does undertake a "Facial Analysis of Individual Exhibits." *Id.* JA640. But that assessment is a far cry from a case-by-case study of each advertisement—a study that, if genuinely undertaken, could not declare nearly every ad misleading.[2] Instead, with respect to each ad, the Order either adopts the ALJ's adverse findings without explanation, *e.g.*, JA646 (Figures 21 and 27), or applies the Commission's just-adopted rules to reverse nearly all the determinations favorable to POM. The Order's actual operation is easily illustrated with three examples reproduced at the back of this brief.

First, the Commission reversed the ALJ and sanctioned Petitioners on the theory that Figure 11 (Addendum 1) falsely claims *clinical proof* that POM "treats heart disease" without an RCT. The Commission's finding of an implied establishment claim here rests on rote invocation of its just-adopted rules. It consists of just three sentences, none of which disputes that the advertisement's text is accurate. First, the Commission says the ad includes "medical imagery"—*i.e.*, "a blood pressure cuff." Second, it asserts that:

[2] The sole "case-specific" analysis below went to whether POM's studies represented positive RCT results. *Id.* JA610-18. The FTC draws liberally from that discussion even though the conclusion that POM lacked RCTs is uncontested here.

> 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."

Third, the Commission recounts without explanation that "[t]he ad also states that POM Juice will help '[k]eep your ticker ticking.'" JA643 (Op. A6). Consistent with the Commission's rule holding most health-claim disclaimers irrelevant as a matter of law, the Appendix not only accords no weight to the quoted cautionary words—"helps," "contribute," and "encouraging results"—but literally ellipses out the accurate and qualified statement that "*emerging* science *suggests*" that free radicals have the described effect.

Likewise, consider Figure 13 (Addendum 2), where the FTC again reversed the ALJ. Here, the FTC's brief discussion points to the *New York Times* excerpt saying that "[f]indings from a small study suggest that pomegranate juice may one day prove an effective weapon against prostate cancer." It acknowledges qualifying language but, as always under the Commission's generalized rules, finds that it "fail[s] to counteract the net impression conveyed." And it points to the mere mention of "hopeful results for men with prostate cancer" from an "initial UCLA medical study" as sufficient to conclude that POM was making a *clinically proven* cancer-treatment claim. JA643-44 (Op. A6-A7). There is nothing defensibly case-specific about this analysis: It takes an obviously rule-based approach to interpret an accurate newspaper quote about what a "small" study

"suggests" might "one day" be possible as implying an *unqualified* claim of existing clinical proof.

Finally, consider Figure 23 (Addendum 3). Here, the Commission's Appendix states that "[t]he headline … read in conjunction with the text … implies that POM Juice protects men from prostate cancer," because "the word 'defend[]' in conjunction with 'save' gives the impression that the ad is conveying information about a serious threat to prostates—prostate cancer." The Commission continues: "The message of 'defense' is one of warding off danger, *i.e.*, preventing or reducing the risk of prostate cancer." And finally, "the language that POM Juice is 'backed by $25 million in vigilant medical research' communicates that these claims are scientifically established." JA646 (Op. A9).

This daisy chain of reasoning refutes the FTC's claim of a case-by-case approach, because *this advertisement does not mention prostate cancer*. The Commission's result instead tracks its broad rules, which regard accurately "quantifying" the amount spent on "medical" research as implying an efficacy and establishment claim. *Id.* JA638. By contrast, a case-by-case analysis would be at least sensitive enough to recognize that ads that do not even *mention* cancer are not claiming *clinically proven* prostate-*cancer* effects.

The broad and precedential standard embodied in these claim interpretations is unmistakable. It was best described by Commissioner Ohlhausen: "Based on

the majority's views about these exhibits, it is difficult to imagine any structure/function claims that POM could associate with its products in the marketplace without such claims being interpreted, *under the FTC precedent set in this case*, as disease-related claims." JA772 (emphasis added). Indeed, in a subsequent case, Commissioner Ohlhausen has highlighted the precedential effect of the broad claim-interpretation rules adopted here as potentially "prevent[ing] useful information from reaching consumers in the marketplace and ultimately mak[ing] consumers worse off." Statement Dissenting In Part, *In the Matter of GeneLink, Inc. and foru International Corporation* (FTC Jan. 7, 2014), JA1295-96 & nn.1, 6 (citing POM order).

B. The Commission further adopted an inflexible rule for food advertising requiring RCTs for all its implied claims.

There should be no question that the Order's sole liability theory was that POM lacked RCTs backing the claims the Commission implied into the ads. Yet here, again, the FTC's appellate brief gives the misimpression that the Commission adopted no legal rules; it instead goes on at length about some of POM's studies, comparing them to POM's ads and then suggesting that the science contradicted the ads' specific text. *See* FTC Br. 35-48, 49-50. This line of argument has nothing to do with the Order's rationale, which relied entirely on adopting an RCT requirement for the implied claims, and thus cannot support affirmance. *Chenery*, 318 U.S. at 92-95.

The Order itself *expressly* adopts a categorical rule: RCTs are necessary to substantiate every one of POM's claims, without regard to the actual content or qualifications of any particular ad. JA622 (Op. 38) ("Having determined that [Petitioners] are required to have RCTs to support their claims … and based upon our prior review of the substantiation that [Petitioners] possess, we conclude they lack support for each of their claims."); *id.* JA587 (the "basis of [Petitioners'] liability is their lack of … RCTs … to substantiate the claims that we found").

In fact, the FTC's fixed rule is that if its legal standards deem an assertion to be an implied efficacy or establishment claim, then an RCT is required, without looking back to an ad's context, qualifications, the nature of the product offered, the feasibility of RCTs, or any other factor. The FTC justifies its RCT requirement on that very basis. JA604 (Op. 20) ("We consider *only* the claims … that the Challenged POM products treat, prevent, or reduce the risk of heart disease, prostate cancer, and ED, and that such claims are scientifically established. The expert evidence was clear that RCTs are necessary for adequate substantiation of *these* representations." (emphasis added)); *id.* JA606, 608 (similar); FTC Br. 34 & n.11 (RCTs are necessary to "justify these causal claims"). In other words, the RCT requirement treats each of the ads reproduced above the same as an unqualified *express* claim that pomegranate juice is a *clinically proven* cure for heart disease or cancer. That is why the Order carefully describes general

standards for RCT research, JA607-09 (Op. 23-25), but never compares particularized research findings to particular advertising text, as the FTC's new effort at back-filling here does. *See* FTC Br. 35-47.

C. The FTC's allegations that POM distorted the science are irrelevant, false, and only demonstrate the dangers of suppressing speech.

The FTC likewise gains nothing by suggesting throughout its brief (*e.g.*, at 25, 34-48) that POM somehow suppressed or "distorted" the scientific record. Astoundingly, it fails to mention that the Commission made no such finding.[3] This new, post-hoc effort to portray POM's world-recognized researchers as junk scientists only backfires, demonstrating the dangers of relegating scientific disputes to bureaucratic central planning rather than the marketplace of ideas. In several respects, the FTC's newfound allegations reflect no more than a one-sided approach to complicated scientific debates best aired in public, not suppressed on the theory that consumers are too easily confused to decide for themselves.

To begin, the FTC's allegation that Petitioners' distorted the scientific record actually rests on the Commission's own distorted focus on a handful of studies.

[3] The FTC's brief repeatedly cites to a few sentences from one isolated paragraph in the Order about how certain POM ads were not "verifiable" for First Amendment purposes because they did not discuss other studies the FTC regards as adverse. JA627 (Op. 43). That language makes little sense as a First Amendment matter. *See, e.g.*, *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1214 (D.C. Cir. 2012) (government has heavy burden in compelling a party to include contrary views in its speech). But the relevant point here is that this language has *nothing* to do with the Commission's liability finding.

POM has invested $35 million in research by accomplished independent researchers at leading universities, leading to seventy published studies, much of it in animal and laboratory work that confirms biological mechanisms through which antioxidants could promote heart, prostate, and erectile function. Tupper Br. 5-9. It is undisputed that these studies suggest possible benefits. It would thus be a heroic achievement for any one or two studies to *disprove* that such benefits may exist, as the FTC now suggests.

Indeed, the brief of the FTC's lawyers illustrates why the Commissioners were wise not to rely on allegations that POM distorted science. The primary new allegation (at 37-41) is that POM ignored "negative" studies that disproved any connection between POM products and arterial plaque, allegedly making it "profoundly deceptive" for POM to ever mention again the small, earlier study by Dr. Aviram showing a 30% decrease in a group of patients with severe stenosis. The FTC omits that the ads that supposedly "continued" to make this "claim" clearly did so in very different language than the decade-old advertisements the Commission hopes this Court will find misleading. The initial ads did state that "eight ounces a day can reduce plaque by up to 30%," JA664 (Fig. 4), but POM scaled those ads back thereafter. *See* Tupper Br. 10. The later ads that allegedly "continued" to make this claim were not even accused in this proceeding—another fact unmentioned in the Commission's brief—and are very different: They contain

a direct quotation from Dr. Aviram accurately reporting his results, along with footnotes that explain the experimental design, direct readers to the study itself, and expressly disclaim any intent to "treat, cure or prevent any disease." *See* FTC Br. Addendum 2.

The FTC's re-reading of the science surrounding the 30% claim is worse. It begins with the erroneous claim (at 37-38) that the Ornish CIMT study showed that "the treatment group fared no better than the control group in any measurement concerning arterial plaque"—attempting to imply that this study showed no effects and proved earlier positive studies a "sham." False: There was a positive effect measured in the study, and the odds were 87% that it was not due to chance. JA1281 (Ornish, Tr. 2456). The problem with the study wasn't that it showed no effect, but that it was too small to achieve 95% statistical significance, *id.* JA1279 (Tr. 2352-54), which is why the Commission did not even *discuss* it. *See* JA611-12 (Op. 27-28).[4] It takes a wholly unsophisticated approach to statistics to call this proof that POM's products had *no effects*, especially given the positive research the FTC omits. *See, e.g.*, *Pearson v. Shalala*, 130 F. Supp. 2d 105, 115 (D.D.C. 2001) (in this context, "[t]he mere absence of significant affirmative evidence … does not

[4] The FTC's expert conceded that his criticism was that this study was "underpowered" and—as the study's designer explained—could have achieved statistical significance at the higher sample sizes that were intended but ultimately impossible to achieve JA1245-47 (Sacks, Tr. 1606-08); JA1201 (Sacks); JA1279 (Ornish, Tr. 2352).

translate into negative evidence"). All this discussion actually proves is that—even when there are possible positive effects—it is difficult and uneconomical to conduct studies of the size and rigor necessary to satisfy the FTC's standard.

The FTC also wrongly claims (at 38-41) that the Davidson CIMT study disproved earlier results because, while it *did* show statistically significant effects from POM products at twelve months, the effect did not last until the final, eighteen-month follow-up. The FTC omits that this study was published in a peer-reviewed journal, JA992 (Davidson); JA1011-12 (Heber), that the results *were* significant for a high-risk subgroup even at eighteen months, JA888-89 (study); JA1256-57 (Herber, Tr. 1981-82), and that Dr. Davidson testified that his results were consistent with both the other researchers'. JA989-91. Instead, it accuses POM of trying to "spin" or "gerrymander" the science by focusing on the statistically significant results rather than the FTC's preferred interpretation. But there is nothing remotely untoward about focusing on particular statistically significant results even though that level of certainty was not achieved throughout. Post-hoc analysis at the end of a study is routine, and the FTC's expert admitted to having done it himself. JA1203-05 (Sacks); JA1246 (Sacks, Tr. 1614); JA1257 (Heber, Tr. 1984); JA985, 987 (Davidson).

The haphazard analogy in the FTC's brief again shows its lack of sophistication. The FTC (at 39) likens subsequent analysis of the positive results

of the Davidson study to calling a coin unfair if it showed statistically significant bias after sixty flips but was fair after one hundred. But seeing statistically significant evidence of bias at a given follow-up (sixty flips) is significant *by definition*, and the odds that bias will just disappear thereafter by chance are rarer still. The FTC apparently believes that a researcher seeing that remarkable result should just conclude the coin is fair, chalk the earlier result up to chance, and call it a day. In reality, the only sound approach is to acknowledge both results and try to explain them, as the researchers did. And in any event, the existence of only *some* statistically significant results is miles from proving *no* effects and thus disproving previous work—as the Commission's brief newly claims.

Similarly, the FTC errs badly in suggesting (at 40) that this study somehow disproved the Aviram study's 30%-reduction finding because, in the group that *did* achieve a significant result, the effect size was only 5%. These two studies covered different people: The subjects in the first had severe build-up, while the second actively excluded such individuals. JA1251, 1254-57 (Heber, Tr. 1819, 1975-76, 1983-84). One would thus expect different effect sizes, as the researchers testified. *Id.* Tellingly, the FTC cites no contrary testimony on this point—hoping, again, that non-scientific musings on appeal will be enough. And in any event, the FTC here contradicts its own claim interpretation: It sanctioned POM not for making a 30%-reduction claim when only a 5%-reduction claim could be

substantiated, but for (impliedly) suggesting that its products have *any* possible heart-health benefits.

The FTC fares no better when it bemoans POM's reliance on PSA-doubling times as a marker for prostate cancer recurrence and death. FTC Br. 43 (accusing POM of presenting "the medical jargon 'PSA doubling time' as though changes … would closely correspond to changes in life expectancy"). Here is what the FTC's own expert, Dr. Eastham, said in a 2005 article: "PSA doubling time can also be used as a surrogate marker for prostate cancer-specific death." JA856. In fact, pomegranate research, including the very POM-sponsored study at issue, is shared with patients at Memorial Sloan-Kettering, where Dr. Eastham works, through its website *on cancer care*. *See* JA1298 (http://www.mskcc.org/cancercare/herb/pomegranate). Meanwhile, the federal government spends untold millions covering annual PSA-screening tests under Medicare. *See* JA1308 (http://www.medicare.gov/coverage/prostate-cancer-screenings.html). There may be a scientific dispute about PSA markers, but it only confirms that POM's ads contribute to an important public debate in which more information, not FTC prohibitions on speech, should decide the winners and losers.

To be sure, there are potential criticisms of these studies (and most others) and various interpretations of their results can and should be aired by interested parties. But the FTC's appellate brief wrongly transforms these narrow scientific

disagreements into allegations that POM's publicly expressed view of the science is "profoundly deceptive." FTC Br. 41. While, again, those allegations have nothing to do with the Order on review, they do confirm how important it is to resolve such debates with more public information, not less.

II. The FTC's Legal Rules For Claim Interpretation And RCT Substantiation Violate The First Amendment

As the foregoing demonstrates, POM's ads squarely address a matter of significant public concern. The possible benefits of the antioxidants and other nutrients in pomegranate juice for heart and prostate health are very real—the FTC has never argued otherwise; all the in vitro and animal research is undisputed; the human clinical research likewise suggests a benefit; and Complaint Counsel expressly told the ALJ that it was accusing POM only of lacking the necessary RCTs, not "selling snake oil." JA1210 (Tr. 69:12-19). POM's ads thus accurately share research results that Americans should see, while carefully qualifying those results to (undisputedly) refrain from holding POM products out as a substitute for medical treatment. Accordingly, against the public's interest in airing a debate about possible health benefits, the FTC places only the concern that some consumers might overpay for juice. As POM's opening brief explained, the FTC's broad legal rules thus violate the First Amendment: They proscribe commercial speech that is, at most, only potentially misleading, and do not satisfy the *Central Hudson* balancing test for such proscriptions—most fundamentally, because they

rely on the paternalistic assumption that consumers will be too bamboozled by the mere mention of science to decide the debate for themselves.

The FTC does not contest POM's showing that, under *Central Hudson*, the Order neither directly advances the asserted interest in ensuring accurate information about "premium" fruit juice, POM Br. 39-48, nor is adequately tailored to avoid unnecessary suppression of speech. *Id.* 48-52. It relies, instead, on a single, supposedly "complete answer"—because the FTC labeled the ads "actually misleading," the First Amendment is inapplicable and the courts can butt out. FTC Br. 63, 68. It claims that the category of constitutionally protected "potentially misleading" speech exists only when a prospective rule restricts speech *ex ante*, and never when the agency has deemed speech misleading *ex post*. *Id.* 67-68. This effort to shut the First Amendment out of every FTC adjudication on deceptive advertising cannot be accepted; it is both contrary to precedent and an existential threat to settled First Amendment values.

A. Ex post adjudications are subject to *Central Hudson*.

The Commission does not cite a single case or commentator for the remarkable proposition that *Central Hudson*'s test for regulating "potentially misleading" speech is irrelevant to the application of legal rules in adjudication—relying, instead, on a description of a subset of the cases as arising in the context of *ex-ante* regulation. FTC Br. 68-69 & n.30. It would be exceptional for such a

critical constitutional principle to have thus far gone unnoticed by a single person in the entire legal profession save the regulators at the FTC. In fact, the Commission's theory is an invention.

First, in the context of administrative adjudication, the distinction between *ex-ante* proscription and *ex-post* regulation is nonsensical. The FTC itself stresses (at 83-84 & n.36) its power to announce new substantive standards through adjudication, including by using a proceeding like this for "development of agency policy." Announcing a method for implying claims and requiring RCTs for them has the same effect on regulated parties whether done by rule or adjudication: The amicus briefs show that the regulated community is deeply troubled precisely because it must comply with this decision's standards going forward. And, like Petitioners, each advertiser will be subject to a series of rules requiring RCTs whenever science is mentioned, rather than a case-by-case weighing of studies against advertising text. Particularly from the First Amendment perspective of chilling protected speech, the decision on review is no less "prospective" than any other agency rule.

Moreover, when it comes to assessing "implied" claims, the cases simply refute the FTC's suggestion that there is no category of "potentially misleading" speech in an *ex-post* posture. It would perhaps make sense to say that *express* claims can be found either "actually misleading" or not—and never "potentially"

so. But that is not true here, where the agency found both an implied disease claim and an implied level of support, and then concluded that this doubly-implied claim *might* make POM's ads misleading. Indeed, the FTC's *own citations* confirm that such implied claims are routinely considered under the rubric of protected, "potentially misleading" speech.

Take the Supreme Court's decision in *Peel v. Attorney Registration and Disciplinary Commission of Illinois*, 496 U.S. 91 (1990). There, the Illinois Supreme Court sanctioned an attorney for his letterhead because, by claiming NBTA certification as a trial specialist, it "implied" three additional claims the state court found "misleading." *Id.* at 98-99. The Illinois Supreme Court's decision was based on case-specific factors, such as the letterhead's juxtaposition of its certification claim against state-bar admissions. *Id.* at 98-99, 101. Recognizing that it faced the question whether Illinois's lawyer-advertising rules were unconstitutional "as applied to petitioner Peel," *id.* at 107 n.15, the Supreme Court first determined that Peel's letterhead could not be condemned as actually or inherently misleading, *id.* at 99-106, and then considered whether it could be forbidden as potentially misleading under commercial-speech doctrine, *id.* at 106-111. Likewise, in *Ibanez v. Florida Department of Business & Professional Registration*, 512 U.S. 136 (1994), the Court rejected the argument that a particular advertisement's use of CPA and CFP designations could be sanctioned as actually

misleading based on what those labels "implied," and went on to subject the state court's *ex-post* analysis to First Amendment scrutiny as a regulation of potentially misleading speech. *Id.* at 144-148.

That analysis shows that the Commission regulated POM's speech as "potentially misleading" at best, so the FTC's concession that it cannot survive First Amendment scrutiny under *Central Hudson* resolves the case. As in *Peel*, the FTC has no "empirical evidence to support its claim of deception," 496 U.S. at 108, and there is "no contention that any … person was actually misled or deceived," *id.* at 100-101—the FTC relies exclusively on its own facial reading of the ads, as did the Illinois Supreme Court. And as in *Peel*, the FTC also "focused not on [any ad's] facial accuracy, but on its implied claim[s]," which "confuses the distinction between statements of opinion or quality and statements of objective facts that may support an inference of quality." *Id.* at 101. Like Peel's letterhead, many of the ads condemned by the FTC's standard state facts that "are true and verifiable," *id.* at 100, such as the amount spent on research, the benefits of antioxidants, their high levels in pomegranate juice, and the existence of "encouraging" results. *See* POM Br. 24-26.

The Supreme Court rejected the view that Peel's letterhead implied an inherently misleading claim of state certification as a trial specialist because "it seem[ed] unlikely that petitioner's statement about his certification as a 'specialist'

… *necessarily* would be confused with formal state recognition," and the contrary view would make an unduly "paternalistic assumption" about the audience. 496 U.S. at 104-105 (emphasis added). So too here: The FTC's action plainly rests on a paternalistic view of American consumers; it "seems unlikely that [POM's] statement" that "an initial medical study … showed hopeful results for men with prostate cancer" "*necessarily* would be confused" with a claim that POM possesses clinical proof that pomegranate juice is a cancer cure. Indeed, this case has always been about what POM's ads *might* mean to *some* consumers, not how they would "necessarily" be read. *See* POM Br. 23-34. Thus, as in *Peel*, the FTC's action might be justified as prohibiting potentially misleading commercial speech, but not as a restriction on actually misleading content.

B. The FTC's theory poses a fundamental threat to First Amendment values.

Accepting the FTC's contrary view would leave entirely too much power in the hands of the agency claiming the power to punish speech in the past and censor it in the future. The Commission would be able to condemn essentially any speech *ex post* subject only to APA review applied with "special deference." And relatedly, this would leave the agency free to imply claims and ban speech on the very kinds of paternalistic assumptions that the First Amendment forbids. So long as its view of what some consumers might believe was reasonable, it could cure

that "problem" by forbidding speech, in exactly the way commercial-speech doctrine condemns.

Relying on a pair of three-decade-old cases, the FTC argues that this Court cannot decide the First Amendment question itself but must grant it "special deference" on the question of what claims the challenged ads imply and what is necessary to substantiate those implied claims, FTC Br. 23 (citing *Thompson Med. Co. v. FTC*, 791 F.2d 189 (D.C. Cir. 1986)), and that "the FTC's antecedent finding that a particular advertisement is misleading, and thus warrants no constitutional protection, is entitled to substantial deference and will be upheld if reasonable," *id.* 65 (citing *FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35 (D.C. Cir. 1985)). In other words, the FTC may by adjudication adopt and employ a standard for "misleading" advertising under which certain kinds of ads imply certain kinds of claims that can only be made with certain kinds of evidence and the *only* opportunity to contest that standard, however onerous its restriction on commercial speech, is under one of the law's least rigorous standards of review.

This is not—indeed, cannot be—the law. First, *Brown & Williamson* does not say that once the FTC's facial analysis implying a misleading claim survives APA review, then otherwise protected speech is *ipso facto* subject to being banned and sanctioned by regulators. *Brown & Williamson* upheld a district court's facial finding of an implied, deceptive message because it "th[ought] that the likely

public reaction [wa]s *unambiguous*." 778 F.2d at 41 (emphasis added). *See also Peel*, 496 U.S. at 104-105 (addressing what the challenged ad "necessarily" implied to consumers). Indeed, it strongly suggested that relying on facial analysis alone was appropriate only when "the alleged deception rises to a commonplace" or is "self-evident." 778 F.2d at 41 (quotation marks omitted).[5]

Moreover, even if *Brown & Williamson* said what the FTC thinks, it would no longer be the law. The *Brown & Williamson* Court recognized that *Bose v. Consumers Union*, 466 U.S. 485 (1984), could be read to call for a more searching form of appellate review in First Amendment cases, but it declined to extend *Bose* to the commercial-speech context. *See Brown & Williamson*, 778 F.2d at 41, n.3. Five years later in *Peel*, the Supreme Court made clear that *Brown & Williamson* was wrong: Citing *Bose*, it held—in the commercial-speech context—that "[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." 496 U.S. at 108. Indeed, almost all the Supreme Court's modern commercial-speech doctrine post-dates *Brown & Williamson* and *Thompson Medical*, the two cases the FTC relies on most. This Court should

[5] While the FTC liberally paraphrases a footnote suggesting that the standard might be lower in cases litigated before the agency (*e.g.*, at 65), the Court expressly said it would "not decide" that question. *Brown & Williamson*, 778 F.2d at 40, n.1.

accordingly reject a regime in which the existence of First Amendment protection is left to the "expert" opinion of the FTC.

That is especially so because accepting the FTC's theory invites the fundamental evil that commercial-speech doctrine resists. The cases uniformly condemn government 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). But the claim-interpretation standards for which the FTC now claims "special deference" are fundamentally paternalistic—they rest upon the premise that American consumers will jump from any "logical connection" between studies and health benefits to the conclusion that specific disease benefits have been clinically proven.

As POM has explained and the cases consistently state, the right answer for that concern is more speech, not less. POM Br. 41-42 (collecting cases). But if the FTC is free to apply categorical rules that turn any ad into an actually misleading statement, based solely on a facial analysis of its "implications," we will get less speech, not more. Indeed, the FTC's unambiguous position in this case is that consumers will be better off *never hearing* truthful accounts of the studies in POM's ads because they might get the wrong idea—except, perhaps, if the speech comes from favored speakers like the government, which makes indistinguishable health-related statements without RCT support. *Id.* 44-45.

In this respect, *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), is precisely on point and by far this Court's most relevant decision. In *Pearson*, the FDA carefully considered very particular health claims about folic acid supplements and rejected some as "misleading" because they contradicted its view of the best available science. *See* 61 Fed. Reg. 8752, 8760 (1996). It then argued to this Court that "health claims lacking 'significant scientific agreement' are *inherently* misleading" because of their likely impact on consumers. *Pearson*, 164 F.3d at 656. The Court rejected that paternalistic argument out of hand as "almost frivolous." *Id.* (citing *Peel*, 496 U.S. at 105). But that is exactly the approach the FTC has taken here: It decided that certain "health claims lacking [RCT support] are inherently misleading" because of their likely impact on consumers—*i.e.*, a "significant minority" of consumers might misread them as implying a much stronger claim than they state, and those consumers must be protected against their own misreading. *Pearson* holds that avoiding such implications involves regulating "potentially misleading" speech, not actually misleading speech, and so must satisfy *Central Hudson*'s rigorous test.

The FTC fundamentally misunderstands *Pearson* in this regard (at 66-67) as a case involving only the consideration of disclaimers. To be sure, *Pearson* held that the FDA could not satisfy *Central Hudson* because it had failed to consider disclaimers as a less-restrictive alternative than foreclosing the speech entirely.

164 F.3d at 657. But before it made that determination about whether the FDA could *satisfy* the First Amendment, it first concluded that the First Amendment *applied*. *Pearson* (like *Peel*) thus demonstrates that when an agency looks at a claim on its face and regulates it based on what it likely implies to consumers, the agency will typically be regulating only "potentially misleading" speech subject to First Amendment scrutiny.

Nor can the FTC save its approach from *Pearson* by arguing that it is willing to permit advertisements using science with appropriate qualifications. As demonstrated by the examples above, its legal rules rely on forbidden paternalistic assumptions to deem such qualifiers almost always worthless. According to the FTC, phrases conveying that studies suggest possible benefits, not conclusive proof of treatment—words like "initial," "small study," "pilot study, "preliminary," "encouraging," "hopeful," "suggests"—are too complicated for consumers to understand, even if they appear in large print at the top of the page. *See, e.g.*, JA690. In particular, its categorical position that such terms do "nothing to alter the net impression that clinical studies prove POM's claims," and "if anything … provide a positive spin," JA597, 639-40 (Op. 13, A2-A3), just gives consumers no credit: When it comes to finding an *establishment* claim, words like "promising," "encouraging" and "hopeful" are *antonyms* for "clinical proof." One cannot fairly read the statement that a product is "supported by $20 million of initial scientific

research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health," as an unqualified claim that "$20 million in research proves this product prevents heart disease." *Compare* JA684 (Fig. 11) *with* JA643 (Op. A6). But under its categorical legal rules, that is exactly what the Commission does.

Similar assumptions underlie the FTC's extended discussion (at 60-62) about the font size of POM's disclaimer that its products are "not intended to treat, prevent, or cure any disease"—language used in many thousands of ads. The Commission's rules of construction read the ads to imply *exactly* the opposite of that language. And in many instances, this absolute disclaimer hangs as a numerical footnote from the quoted studies, precisely to prevent readers from jumping from one study to the conclusion that POM is claiming a proven, causal relationship. But the FTC now says that this disclaimer is not clear enough because footnotes are too small. Here—as with so many arguments—the FTC omits that the Commission neither adopted nor even discussed this rationale. But even were this argument before the Court, it would still reflect a fundamentally paternalistic view of consumers: They are so interested in science that they will over-read an ad describing any single study as making an establishment claim, but they aren't quite interested enough to bother reading footnotes.[6]

[6] Interested readers regularly do read footnotes.

The FTC is quite candid as to what its version of an effective disclaimer or qualification requires. And it is not pretty. Take the RCT that showed a relationship between consuming pomegranate juice and improved erectile function, but only to a 94% probability, not the FTC's 95% standard. POM Br. 20-21. The FTC is willing to permit sharing this result with consumers, but with a huge catch: "to avoid deceiving consumers, POM would have needed, *at a minimum*, to qualify its … claim with the information that the cited study results rested on an unvalidated metric, that they fell short of statistical significance even under that metric, and that the results did not even approach statistical significance under the validated metric accepted by the relevant medical community." FTC Br. 47 (emphasis added; quotation marks and brackets omitted). The notion that a consumer would understand the words of *that* wandering legalism, but not POM's accurate and qualified recitation of the results, is bizarre. And no regulated entity would feel "free to inform consumers about an emerging body of science," *id.* 59-60, where the FTC would require that kind of disclaimer "at a minimum" before construing a report of the qualified results of one study as an unqualified establishment claim.

In sum, the FTC's Order bans speech that is only potentially misleading without disputing that it cannot satisfy *Central Hudson*. The Commission importantly has never explained why its own long-standing, flexible *Pfizer* test is

inadequate to protect consumers, and why it needs a bright-line rule that restricts so much more speech. The Order must therefore be reversed.

III. The Commission's RCT Requirement For The Implied Claims Violates The APA

The opening briefs explain that an RCT requirement is far too onerous as applied to the nutrient effects of foods—like the antioxidants in pomegranate juice—because of practical, ethical, and economic constraints on RCT testing in that context. POM Br. 13-17; Tupper Br. 39-43. Here the proof is in the pudding: The ALJ found that RCTs are almost unheard-of in the food context, JA182 (¶701), and not even the Commission disputed the difficulty in doing them, JA621 (Op. 37). The witnesses overwhelmingly confirmed that the barriers to RCT testing for foods recommended a lower substantiation standard, even for particularized disease claims. So long as a food is safe and not marketed as a replacement for medical treatment, the evidence demonstrated (and the ALJ found) that it would be appropriate to advertise its possible health benefits, even absent RCTs. Tupper Br. 41-44 & nn.7-8. The Order prevents consumers from learning about potentially beneficial diet choices by requiring evidence that will almost never be available—a risk identified by the cases that have come closest to considering this issue. *See, e.g.*, *Matrixx Initiatives v. Siracusano*, 131 S. Ct. 1309, 1320 (2011) (neither medical professionals nor the federal government "limit the data they consider to the results of randomized clinical trials"); *FTC v. QT, Inc.*

(7th Cir. 2008) (RCT requirement tends to "prevent vendors from making truthful statements that will help consumers locate products that will do them good").

The FTC makes a half-hearted effort (at 52) to demonstrate that the RCT requirement is not too onerous by suggesting that POM was able to conduct "repeated[]" RCTs with its own products.[7] This argument is at least ironic, for in the next breath the FTC criticizes POM's experimental designs. But it also fails to take seriously the burdens experienced in trying—and *failing*—to develop RCTs for pomegranate juice that could achieve statistically significant results. For example, the Ornish CIMT study discussed above could not economically recruit and retain a big enough sample to achieve statistical significance. Likewise, the disappearance of statistically significant results at eighteen months in the Davidson study could reflect the difficulty in consistently controlling for nutrient effects when study participants inevitably consume antioxidants and other nutrient compounds throughout their diets. Indeed, even when the research can follow an RCT model and achieve significant results, the FTC may reject it based on its contrary interpretation of those results (as with the Davidson study) or its own views about which metrics are best validated as disease endpoints (as with the Padma-Nathan study). POM has invested over $35 million in dozens of published

[7] The FTC's suggestion (at 52) that POM's *non*-juice products were more amenable to RCTs is irrelevant. Those products represent less than one percent of POM's business and advertising, and no part of the Commission's Order distinguished the requirements for those products from those for POM's juice.

studies, and yet the FTC finds one way or another to reject them all. That confirms just how onerous the FTC's standards really are.

The FTC thus primarily responds (at 53-56) by focusing on its finding of establishment claims, and claiming that it has always required RCTs in that context. It cites *Thompson Medical* and *Daniel Chapter One v. FTC*, 405 F. App'x. 505 (D.C. Cir. 2010), as evidence that it has consistently required RCTs for establishment and disease claims, even when the product is "safe." Accordingly, the FTC says, its decision to impose an RCT requirement here cannot be arbitrary or unsupported.

Preliminarily, the court's remark in dicta in *Thompson Medical* that "[t]he FTC has usually required two well-controlled clinical tests" for establishment claims, 791 F.2d at 193—on which the FTC's brief heavily relies (*e.g.*, at 54)—misreads the administrative record in that case. The relevant reference was to the *FDA's standards* for drug approval. *See* 104 F.T.C. 684, 1984 WL 565377, at *97 (1984) ("As the Commission has explicitly recognized …, the FDA requires … two or more well-controlled clinical studies."). Both before and after *Thompson Medical*, the FTC has never required two RCTs for any product not marketed as a medical treatment.

Indeed, the claims in *Thompson Medical* and *Daniel Chapter One* lack the very features that led the witnesses to conclude that RCTs should not be required

here. Most importantly, both involved products that were expressly marketed as replacements for traditional medical treatments. *Thompson Medical* concerned an "over-the-counter" medication that expressly claimed to deliver aspirin's pain-fighting power even though it "contain[ed] no aspirin." 791 F.2d at 191 ("When you suffer from arthritis, imagine putting the strong relief of aspirin right where you hurt."). That is not this case: The FTC has never contested the ALJ's finding that POM products were not marketed as replacements for medical treatment, JA325 (ALJ Op. 246); and all of the claims at issue here are implied, not express. JA594 (Op. 10).

This Circuit's unpublished opinion in *Daniel Chapter One* is even further afield. That case concerned a shark-cartilage pill expressly marketed as a viable alternative treatment for cancer. Brief for Respondent, *Daniel Chapter One v. FTC*, 405 F. App'x. 505 (D.C. Cir. 2010) (No. 10-1064), 2010 WL 5647058, *11-*12 (company "urge[d] consumers who 'suffer from any type of cancer' 'to buy the products' they describe as 'Daniel Chapter One's Cancer solutions,' assuring consumers that 'How to fight cancer is your choice!'"). Indeed, the FTC relied on this express claim as its core theory of the case. *Id*. *38 ("[C]onsumers would reasonably assume that, when DCO touts its products … as an alternative to products marketed by drug manufacturers, DCO has first subjected those products to scientific testing."). And in any event, *Daniel Chapter One* only required

"clinical trials" for these hyperbolic claims, not RCTs—which the company lacked because it relied exclusively on "experience" and the teachings of the Bible. 405 F. App'x at 506. An opinion generally requiring "clinical trials" before holding shark cartilage out as a cancer cure in no way supports holding all food-product advertisers to an RCT requirement before holding their products out as a nutritious option with possible benefits for heart and prostate health.

It is particularly disingenuous for the FTC to criticize POM for failing to distinguish this unpublished decision (at 56) because Complaint Counsel affirmed that it was not accusing POM of selling "snake oil" and, after a discussion of the allegations, the ALJ recognized that the case was "in no way, shape or form comparing [POM] to *Daniel Chapter One*." JA1210, 1249 (Tr. 69:11-19, 1802:20-1803:20). Nor does the FTC anywhere explain how cases about products that have *no use* apart from their deceptively advertised medical effects bear upon a product like pomegranate juice that is, first and foremost, a nutritious food with only collateral health benefits.

In any event, *Thompson Medical* actually refutes the FTC's suggestion that its decision to apply an RCT requirement in this case broke no new ground. As *Thompson Medical* makes clear, the FTC's typical approach to establishment claims is to require the level of proof that the advertisement itself claims to have. 791 F.2d at 194. Put otherwise, if an ad claims to have "one small study"—as

POM's did—then only one small study is required. *Thompson Medical* thus *hurts* the Commission; it can only embrace that precedent by wrongly using its claim-construction standards to turn specific establishment claims into general ones.

The FTC's second defense of its RCT requirement fares worse. It argues (at 51) that the administrative testimony unanimously endorsed an RCT requirement for specific disease claims, and that POM's contrary testimony was in fact addressed only to more general claims of "health benefits." This is textbook arbitrariness: reading the exact same words differently to suit a preferred result. According to the FTC, when it comes to the testimony, statements that clearly pertain to disease claims are treated as relating only to general health. But when it comes to POM's advertisements, statements that are far more general are aggressively construed as disease claims.

A simple, side-by-side comparison makes this clear. This is a piece of testimony the FTC construes as irrelevantly discussing only "general health":

> "[I]t is not appropriate to require the use of double-blind placebo-controlled studies for evaluating the health benefits of foods …' and 'there is credible scientific evidence that pomegranate juice and pomegranate extracts have significant health benefits for human cardiovascular systems, including: 1) decreases in arterial plaque; 2) lowering of blood pressure; and 3) improvement of cardiac blood flow."

JA610 (Op. 26). This, on the other hand, is what the FTC calls an unqualified establishment claim:

> 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.

JA686 (Fig. 12). The idea that the former passage discusses the weaker form of claim is utter nonsense. If POM put the testimony the FTC now construes as related only to "general health claims" in one of its ads, there is no question the FTC would have used its new rules of claim interpretation to sanction it.

Indeed, the FTC's reading of the record is so capricious that it is impossible to predict what will count as a disease claim requiring an RCT. One of the few ads the FTC correctly found not to convey any efficacy or establishment claim was the point-of-sale bottle tag reproduced as Addendum 4 (Fig. 26). The Commission rightly found that this ad, reporting $25 million in medical research and that POM is "proven to fight for" various forms of health, makes no disease or establishment claim. But meanwhile, it regards language stating that "$20 million of initial scientific research … has uncovered *encouraging* results in prostate and cardiovascular health," JA684 (Fig. 11), as making both kinds of claims. If there is a rational basis for these distinctions, it is impossible to locate in the FTC's opinion. Such an unpredictable and irrational approach to finding implied disease claims will certainly suffice to chill advertisers from making anything that approaches a scientific claim of health benefits in the future, especially because FTC liability findings can bring follow-on disgorgement suits by the Commission,

see, e.g., *QT*, 512 F.3d at 860, or class actions seeking exorbitant damages (such as the $450 million suit now pending against POM). But it does not satisfy the APA, to say nothing of the vagueness standards of the First Amendment.

Finally, even if the Commission could treat language consistently, its Order would still rely on an irrationally inconsistent view of consumers themselves. Although the FTC justifies its RCT standard with the testimony of *scientists*, it recognizes that the question is the level of proof *consumers* would expect. *See* JA610 (Op. 21); POM Br. 28-29. That requires the Commission to hold two opposite views of consumers at once: When they see any positive scientific study, they are unsophisticated, and hear a claim of clinical proof; but having heard a claim of clinical proof, they immediately transform into experts, and think not of any study, but only of RCTs. This sleight of hand is at the very core of the FTC's rationale for the RCT requirement. But if anything counts as irrational, that would be it.

IV. The FTC's Overbroad Remedial Order Violates The First Amendment

At a minimum, the FTC's fencing-in remedy is unconstitutionally overbroad. It prohibits Petitioners from making "any representation in any manner, expressly or by implication" that any of its products have disease effects unless that representation is both "non-misleading" and supported by two RCTs. Here, at least, the FTC concedes (at 74) that the First Amendment applies, and its

Order must satisfy *Central Hudson*. But its suggestion (at 76) that its broad injunction is actually "narrowly tailored" to advance its substantial interest "in ensuring the accuracy of commercial information" is plainly mistaken.

First, the FTC cannot consistently state the government interest its Order serves. It must concede there is no public-health concern because pomegranate juice is safe and not advertised or regarded by consumers as a substitute for medical treatment. Thus, the FTC begins (at 75) by discussing the government interest in ensuring the accuracy of marketplace information, to the end of preventing consumers from overpaying. But when it turns to *Central Hudson*'s narrow-tailoring prong, it claims that "the Order's scope is narrowly tailored to serve the government's interest in preventing recidivism." *Id.* It then goes on to argue (at 76-77) that the Order is justified essentially as a punishment, without even considering whether narrower alternatives would adequately vindicate the asserted interest in getting accurate information to consumers.

This rationale overlooks that the FTC's injunction is not even theoretically confined to misleading speech. In particular, the FTC did not consider allowing POM to get concededly non-misleading information to consumers by strengthening its qualifications or in any way modifying its ads to suit the FTC's newly expansive view of what constitutes an unqualified establishment claim. Contrary to the FTC's suggestion (at 72-73), this argument does not attempt to "confine" the

FTC to "orders merely directing wrongdoers to stop violating the law"; the FTC could have considered strong mandatory disclaimers or other remedies that favor disclosure over public ignorance. But the FTC instead decided to proceed with a broad, prospective ban on non-misleading speech, and bears a heavy burden to justify that approach.

The FTC also fails to explain why an injunction requiring one RCT, rather than two, would not have completely vindicated its interests, as Commissioner Ohlhausen concluded, *see* JA587 (Op. 3 n.3). Indeed, a requirement of two RCTs is indisputably overbroad. For example, it would prevent POM from publicizing a prize-winning, iron-clad RCT demonstrating that POM helps to fight flu symptoms, no matter how beneficial to consumers or whether there was even a shadow of a prospect that any consumer might be misled.

Discovering such a result is (or was) a realistic possibility for a company committed to funding further public research into its non-patented products, but the FTC's overbroad injunction now makes that research unjustifiable. Indeed, as the *amicus* briefing here suggests, the natural consequence of the FTC's approach is that food companies simply will not invest in research that could uncover possible benefits, nor disseminate potentially life-changing information based on others' research for fear of prosecution. That is true even of research and advertising the FTC has *itself* defended in the past, such as the (not-RCT-tested) connection

between fiber-rich diets and cancer prevention that Kellogg disseminated regarding its products. *See* CHPA Br. 5-8.

The FTC's injunction here clearly runs afoul of this Court's remedial holding in *Brown & Williamson*, 778 F.2d at 43-45. There, the Court rejected a remedial injunction for deceptive advertising insofar as it prohibited the company from providing information about test results in a way that "would eliminate consumer confusion." *Id.* at 45. In that circumstance, it held, the "FTC must bear the affirmative burden of demonstrating any inadequacy, and thus deceptiveness, of the results … advertised in the manner described." *Id.* That is because, even when it comes to remedial orders, "[t]he restriction imposed … may not place an absolute prohibition on potentially misleading information if the information also may be presented in a way that is not deceptive." *Id.* at 43 (quotation marks and alterations omitted). Because the Commission's remedy here unabashedly extends to speech that is not even theoretically deceptive, it cannot satisfy the First Amendment inquiry that *Brown & Williamson* requires.

Finally, the Commission cannot justify its decision to extend its injunction to the entire Roll family of companies, even though it does not dispute that those companies have never produced a single misleading ad. The FTC's theory (at 77-78) is that this extension is reasonable because of Roll's common ownership over various brands. But while it points to a case where the Commission extended its

injunction from Kraft singles to other Kraft *Cheese* products, *Kraft Inc. v. FTC*, 970 F.2d 311, 326-327 (7th Cir. 1992), there is no precedent for extending such an injunction to every product a common parent company makes—or will make for twenty years—as it did so cavalierly here.

V. Mr. Tupper Should Not Be Held Individually Liable

The Commission ignores the argument that because Mr. Tupper has permanently retired from his position, "there is no justification for applying the Commission's injunction to Mr. Tupper personally." Tupper Br. 37. "An injunction is a drastic and extraordinary remedy," unwarranted if a narrower remedy would adequately protect the public. *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2761 (2010). Thus, "[w]hen, as in this case, a defendant has ceased offending conduct, the party seeking injunctive relief must demonstrate to the court 'that there exists some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive.'" *FTC v. Accusearch Inc.*, 570 F.3d 1187, 1201 (10th Cir. 2009) (quoting *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953)); *see also Borg-Warner Corp. v. FTC*, 746 F.2d 108, 110-11 (2d Cir. 1984).

The *Borg-Warner* court held that the Commission could not maintain an injunction against a party that had exited the business that gave rise to the violations when the Commission presented no evidence that the party might restart

it. *See* 746 F.2d at 110-111. By seeking to enforce its cease-and-desist order against Mr. Tupper, the Commission has again abused its remedial discretion.

The Commission's argument that an injunction is nevertheless warranted because Mr. Tupper participated in POM's allegedly misleading advertisements is unpersuasive. Although the Commission points to its findings that Mr. Tupper had control over some aspects of POM's advertising, it does not contest—and in fact concedes—that Mr. Tupper's role was merely to "implement POM's direction." FTC Br. 80 (quoting Op. 53). Whatever role Mr. Tupper played in POM's advertising does not indicate that he could continue to engage in any conduct the Commission finds objectionable.

The Commission is also incorrect to suggest that any degree of participation in prohibited advertising establishes a basis for individual liability. Such a sweeping rule would permit the Commission to sanction individuals, like Mr. Tupper, who relied in good faith on information they believed to be correct. Individual liability is especially inappropriate because, although the Commission strains (at 80-81) to make it appear that Mr. Tupper had knowledge that POM's ads could be misleading, the Commission made no finding to that effect. Where, as here, an individual merely participated in the creation of the allegedly misleading advertisements, and where, as here, it is undisputed that he will have no control over *any* advertisements in the future, individual liability is inappropriate.

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March 25, 2014

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rules of Appellate Procedure and the Clerk's Order of March 25, 2014, I hereby certify that the relevant portions of the foregoing brief contain 10,500 words, as determined by the word counting feature of Microsoft Word 2010.

/s/Thomas C. Goldstein
Thomas C. Goldstein

CERTIFICATE OF SERVICE

Pursuant to this Court's Circuit Rule 25(c), I hereby certify that on this 25th day of March, 2014, I electronically filed the foregoing Corrected Brief with the Court by using the CM/ECF system. All participants in the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/Thomas C. Goldstein
Thomas C. Goldstein

ADDENDUM 1
(Figure 11)

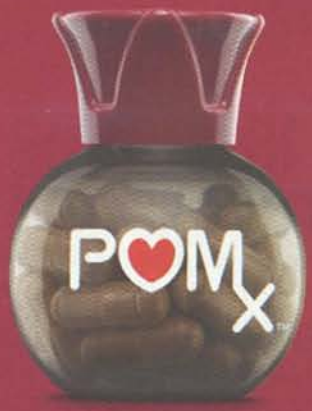
Decompress.

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
pomwonderful.com

POM Wonderful Pomegranate Juice. The Antioxidant Superpower.™

ADDENDUM 2
(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.

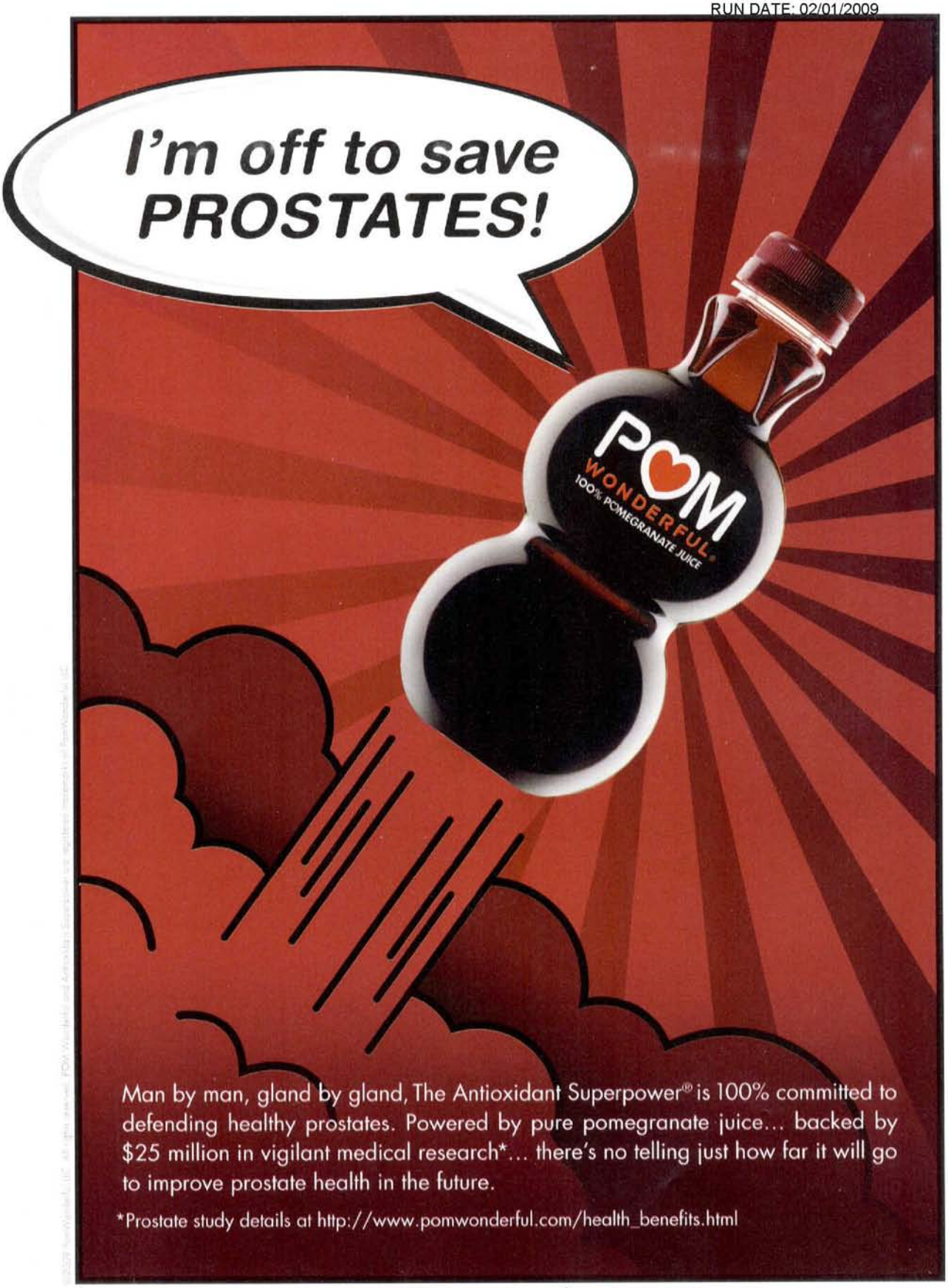
Call 1-888-POM-PILL or visit pompills.com/fort and mention or enter code **FORT5** at checkout. To pay by check, call 1-888-POM-PILL for instructions. Hurry, offer expires July 31, 2007.

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.

ADDENDUM 3
(Figure 23)

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



pomwonderful.com

The Antioxidant Superpower.®

ADDENDUM 4
(Figure 26)

100% PURE POMEGRANATE JUICE.

It's 100% pure! It's heroically healthy! It's The Antioxidant Superpower, POM Wonderful 100% authentic pomegranate juice.

Backed by $25 million in medical research. Proven to fight for cardiovascular, prostate and erectile health. Committed to keeping you healthy for a good, long time!