ORAL ARGUMENT SCHEDULED FOR MAY 2, 2014

NO. 13-1060

In the United States Court of Appeals for the District of Columbia Circuit

POM WONDERFUL LLC, et al.,
Petitioners,

v.

FEDERAL TRADE COMMISSION,
Respondent.

ON PETITION FOR REVIEW
OF AN ORDER OF THE FEDERAL TRADE COMMISSION
(FTC DOCKET NO. 9344)

BRIEF OF RESPONDENT FEDERAL TRADE COMMISSION

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MARCH 25, 2014

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

(A) Parties and Amici.

Except for the following, all parties, intervenors, and amici appearing before the Federal Trade Commission and in this Court are listed in the Brief for Petitioners POM Wonderful LLC, *et al*.:

Public Citizen, Inc. – *Amicus Curiae* in Support of Respondent FTC.

(B) Rulings Under Review.

References to the rulings at issue appear in the Brief for Petitioners POM Wonderful LLC, *et al*.

(C) Related Cases.

This case has not been previously before this Court, and no related cases are pending before this Court or any other court.

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GLOSSARY

For ease of reference, the following abbreviations and citation forms are used in this brief:

ACE	Angiotensin Converting Enzyme
ALJ	Administrative Law Judge
BP	Blood Pressure
CIMT	Carotid Intima-Media Thickness
ED	Erectile Dysfunction
GAQ	Global Assessment Questionnaire
ID	ALJ Initial Decision (page number)
IDF	ALJ Initial Decision Finding (paragraph number)
IIEF	International Index of Erectile Function
IMT	Intima-Media Thickness
JA	Joint Appendix
Op.	Opinion of the Commission of January 10, 2013
Order	The Commission's Final Order (addressing remedial issues)
PSA	Prostate-Specific Antigen
RCT	Randomized and Controlled Trial
Tr.	Transcript of Trial Testimony before the ALJ

Glossary (Cont'd)

In addition, a glossary of technical terms related to the conduct of clinical trials can be found online, at http://clinicaltrials.gov/ct2/about-studies/glossary (a service of the U.S. National Institutes of Health).

PRELIMINARY STATEMENT

POM Wonderful LLC sold one beverage and two dietary supplements derived from its pomegranates: POM Juice, POM_x Pills (one capsule taken daily), and POM_x Liquid (one teaspoon taken daily). POM knew that its target consumers would pay a premium if they believed that these products would combat the diseases they feared most, including heart disease and prostate cancer. POM thus launched an advertising campaign asserting that POM products had been shown effective in fighting those particular diseases.

The FTC found that several dozen of POM's advertisements misled consumers and violated Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45, 52. That decision was as unremarkable as it was reasonable, and it rested on several essential factors. First, POM's advertising campaign was far more aggressive in its medical claims than an ad claiming general health benefits for food products. It did not merely claim that POM products were nutritious or rich in antioxidants. It claimed that POM products were "unique and superior" to other antioxidant sources, CX0355_0001 [JA976]; that they fought "atherosclerosis," "prostate cancer," and other specific diseases; and that rigorous medical research demonstrated and even quantified those supposed disease-fighting benefits.

Second, POM's account of the medical evidence routinely distorted the scientific record and omitted the negative results of POM's own studies. For

example, one ad noted that "98% of heart attacks are due to atherosclerosis, or too much plaque in the arteries," and concluded with this punchline: "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%." CX0029_0002 [JA826]. The ad did not tell consumers that this "clinical pilot study" was tiny and methodologically flawed. Worse, POM's ads continued citing that study and stressing the "30%" claim years after the company's far larger and more rigorous trials showed that POM consumption did *not* significantly reduce arterial plaque in the study groups, let alone by "up to 30%." Op. 43 [JA627]. POM's ads ignored those negative studies, and POM even delayed the publication of the negative results in the medical literature. *Id.*

Third, POM had not substantiated *any* of its disease claims with positive results from even one well-controlled clinical trial. That was not for want of trying. POM in fact conducted controlled, double-blind clinical trials for *both* POM Juice *and* POM_x Pills, which POM claimed were bioequivalent to POM Juice. For POM, the problem with those trials was not that they were hard to conduct, but that their results tended to contradict POM's advertising messages.

The Commission broke no new ground in holding POM liable in these circumstances. In contending otherwise, petitioners ignore decades of precedent, including this Court's decision in *Thompson Medical Co. v. FTC*, 791 F.2d 189,

194 (D.C. Cir. 1986). Nor does the Commission's decision raise serious First Amendment concerns. "[M]isleading advertising does not serve, and, in fact, disserves, th[e] interest" of "consumers and society … in the free flow of commercial information." *FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 43 (D.C. Cir. 1985) (internal quotation marks omitted). Petitioners protest that their ads were only "potentially misleading" rather than "inherently misleading." But that distinction is relevant only to prescriptive regulations that prospectively ban categories of commercial messages even if the messages could be presented in non-misleading ways—for example, by qualifying them with effective disclosures. It has no bearing on enforcement decisions that, like this, find that particular advertisements that have already run *were in fact misleading*, despite whatever disclosures they contained. *See*, *e.g.*, *Kraft, Inc. v. FTC*, 970 F.2d 311, 317-18 (7th Cir. 1992).

Finally, petitioners and their amici mischaracterize the Commission's decision when they claim that it suppresses information about emerging science in the absence of rigorous clinical proof. Advertisers remain generally free to inform consumers about a promising body of emerging science so long as they include clear qualifying language that discloses the limitations of the scientific record and the existence of any contrary evidence. But POM's ads included no effective

qualifications and withheld negative clinical results while cherry-picking superficially positive results.

ISSUES PRESENTED FOR REVIEW

Whether the FTC reasonably determined (1) that POM's advertisements were deceptive; (2) that, as a "fencing in" remedy, petitioners should be required to meet rigorous substantiation requirements before making future disease claims; and (3) that petitioner Matthew Tupper is liable for his role in disseminating the deceptive ads.

STATUTES AND REGULATIONS

Pertinent provisions are reproduced in Addendum 1 to this brief.

STATEMENT OF FACTS

A. The Legal Framework

Section 5 of the FTC Act prohibits, and "direct[s]" the FTC "to prevent," "deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45(a)(1). Section 12 of the Act includes within the prohibited category of deceptive acts "any false advertisement" relating to "food" or "drugs" (among other products). *Id.* § 52(a), (b). The Act broadly defines, as a "false advertisement," any "advertisement, other than labeling, which is misleading in a material respect," whether through affirmative "representations made or suggested" by the advertisement or through "a fail[ure] to reveal facts material in the light of such

representations." *Id.* § 55(a)(1); *see Roberts v. Fleet Bank*, 342 F.3d 260, 269 (3d Cir. 2003) ("The FTC Act prohibits … advertisements containing false or misleading representations or material omissions."); *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1099 (9th Cir. 1994) ("a false advertisement need not even be false; it need only be misleading in a material respect").[1]

In a typical deceptive-advertising case, the FTC first addresses *claims interpretation*, determining what messages a reasonable consumer would construe a given advertisement to convey. To that end, the Commission looks to the ad's "net impression." FTC, *Policy Statement on Deception*, 103 F.T.C. 174, 178 (1984) ("*1984 Deception Statement*"); *accord Thompson Med.*, 791 F.2d at 197. That inquiry involves "an evaluation of such factors as the entire document, the juxtaposition of various phrases in the document, the nature of the claim, and the nature of the transaction." *1984 Deception Statement*, 103 F.T.C. at 176. As this Court has held, "the Commission may rely [when interpreting ads] on its own

[1] With respect to "foods," including dietary supplements, the FTC exercises authority over commercial advertising, whereas the Food and Drug Administration exercises authority over product labeling. FTC, *Dietary Supplements: An Advertising Guide for Industry*, at 1 (Apr. 2001) [JA795] ("*2001 Dietary Supplement Guide*"). The two agencies work together to promote consistency in the legal standards they apply, *id.*, but they use different procedures to enforce those standards. The FTC acts mainly through retrospective enforcement actions against individual cases of deception, *see*, *e.g.*, *Thompson Med.*, *supra*, whereas the FDA also adopts general rules that prescribe in advance what nutrient-content and health claims may appear in the labeling of dietary supplements and other "foods," *see*, *e.g.*, *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

reasoned analysis of the advertisements themselves, without resorting to surveys or consumer testimony," and its conclusions are "due special deference owing to the nature of the inquiry and the Commission's expertise in evaluating deception." *Thompson Med.*, 791 F.2d at 197.

The Commission then turns to whether the claims are deceptive. "[I]n general an advertisement is considered deceptive if the advertiser lacks a 'reasonable basis' to support the claims made in it." *Id*. at 193. The FTC thus determines whether an advertiser in fact had evidentiary substantiation, sufficient under the circumstances, for making the claims its ads have been found to convey. *See id.*; *see also FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 8 (1st Cir. 2010) (when "advertisers lack adequate substantiation evidence, … their ads are deceptive as a matter of law"). In making that determination, the Commission often relies on case-specific expert testimony. This Court has recognized—and accordingly extends deference to—the FTC's "special expertise in determining what sort of substantiation is necessary to assure that advertising is not deceptive." *Thompson Med.*, 791 F.2d at 196.

Advertising claims fall into two basic categories for substantiation purposes. An *efficacy* claim is a message that a given product successfully performs the advertised benefit, such as preventing or treating a medical condition. The FTC applies the multifactor *Pfizer* analysis to determine, on a case-by-case basis, the

level of substantiation needed for an efficacy claim.[2] In contrast, an *establishment* claim is a message that the advertiser has scientific evidence backing up its efficacy claim. The Commission does *not* apply the multifactor *Pfizer* analysis in determining the substantiation needed for establishment claims. Instead, "[i]f an advertisement represents that a particular claim has been scientifically established, the advertiser must possess a level of proof sufficient to satisfy the relevant scientific community of the claim's truth." *In re Removatron Int'l Corp.*, 111 F.T.C. 206, 297-99 (1988), *aff'd*, 884 F.2d 1489 (1st Cir. 1989). In this case, the FTC determined that nearly all of the POM advertisements at issue here—34 out of 36—made both establishment and efficacy claims. *See* Op. 41 & Summary Table [JA625, 765-767].

It is particularly important to enforce substantiation requirements in the area of medical-benefit claims. For centuries, many sellers of health products have made highly misleading claims that their products fight particular diseases, and they often cite ostensibly promising medical experiments that turn out to have been

[2] The *Pfizer* factors are "(1) the type of claim; (2) the type of product; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a false claim; and (6) the amount of substantiation experts in the field would agree is reasonable." Op. 34-35 [JA618-619]; *see In re Pfizer Inc.*, 81 F.T.C. 23 (1972).

flawed or nonprobative.[3] Such claims have nonetheless duped millions of consumers, in part because products sold for their medical benefits are "credence goods"—products whose efficacy consumers cannot easily ascertain before or even after purchasing them. As the FTC explained in 1984, in a decision ultimately upheld by this Court, "the inability of consumers to evaluate [health] effect[s] by themselves in an uncontrolled environment is a persuasive reason for consumers to expect (and us to require) appropriate scientific testing" for claims of medical benefit. *In re Thompson Med. Co.*, 104 F.T.C. 648, 826 (1984), *aff'd*, *Thompson Med.*, 791 F.2d 189.

The FTC thus has long cautioned that it "will closely scrutinize the scientific support" that an advertiser cites as substantiation for a disease claim—*i.e.*, for an advertisement that "suggest[s], either directly or indirectly," that a product "will provide a disease benefit." *2001 Dietary Supplement Guide* at 21 [JA815]; *see also id.* at 8 [JA802] ("products related to consumer health or safety require a relatively high level of substantiation"). In 1986, for example, this Court noted approvingly that "[t]he FTC has usually required two well-controlled clinical tests" to substantiate generalized claims that scientific evidence supports a product's

[3] *See generally* Simon Singh and Edzard Ernst, *Trick or Treatment: The Undeniable Facts About Alternative Medicine* (2008) (discussing the long history of misleading claims, many of them based on supposedly promising experimental results, for alternative medical treatments such as homeopathy, acupuncture, and herbal supplements).

purported medical benefits. *Thompson Med.*, 791 F.2d at 194. The Court then affirmed the FTC's decision to extend that substantiation requirement to simple efficacy claims for the product in question (a topical pain-relief cream). *Id.* at 195-96; *see* pp. 54-56 and note 22, *infra*.

The FTC has long applied its general substantiation standards to food-derived products. In a 2001 industry guide, the FTC explained that even three clinical trials would be inadequate to substantiate disease claims about a hypothetical "compound extracted from fruit" if each trial was inadequately controlled or otherwise only marginally probative. *2001 Dietary Supplement Guide* at 13 [JA807]. And in 2011, this Court cited that guide in rejecting a First Amendment challenge to an FTC order against a dietary-supplement manufacturer that had advertised various disease benefits without adequate substantiation. *Daniel Chapter One v. FTC*, 405 Fed. Appx. 505, 506 (D.C. Cir. 2011).

This does *not* mean that an advertiser must always wait until initially promising scientific evidence becomes conclusive before it may inform consumers that such evidence exists. An advertiser may cite genuinely promising scientific developments, even if they have not yet been confirmed by rigorous clinical proof, so long as the ad conveys whatever "qualifying information is necessary to prevent [the] ad from being deceptive." *2001 Dietary Supplement Guide* at 6 [JA800]. To that end, "[t]he advertiser should make sure consumers understand both the extent

of scientific support and the existence of any significant contrary evidence." *Id.* at 7 [JA801]. Accordingly, "[v]ague qualifying terms—for example, that the product 'may' have the claimed benefit or 'helps' achieve the claimed benefit—are unlikely to be adequate." *Id*. Rather, the FTC requires "a disclosure that clearly describes the limitations of the research" and "states unambiguously that additional research is necessary to confirm the preliminary results." *Id.* at 8 [JA802]. *See generally 1984 Deception Statement*; FTC, *Policy Statement Regarding Advertising Substantiation*, 104 F.T.C. 839 (1984).

As the FTC has explained, disease claims that are inadequately substantiated and inadequately qualified can harm consumers in two respects even if the advertised product is "safe" to use. First, like victims of any marketing fraud, consumers deceived into believing that a product will help prevent or treat diseases are more likely to buy the product and pay a premium for it than if they knew the whole truth. *See*, *e.g.*, *Thompson Med. Co.*, 104 F.T.C. at 824; *see also FTC v. QT, Inc.*, 512 F.3d 858, 863 (7th Cir. 2008) ("One important reason for requiring truth is so that competition in the market will lead to appropriate prices."); *Pantron*, 33 F.3d at 1100 (deceptive advertising "create[s] a substantial economic cost"). Second, unfounded disease claims may "lead consumers to forego other treatments that have been validated by scientific evidence, or to self-medicate for potentially serious conditions without medical supervision." *2001 Dietary Supplement Guide*

at 21 [JA815]. That concern can be present even if a product is not explicitly marketed as an alternative to conventional medical treatments. Consumers who believe that a product is medically effective are at least somewhat more likely to forgo the expense and side effects of conventional treatment options or resist necessary dietary and lifestyle changes. Both concerns—financial and medical—underlie the Commission's enforcement regime, and each concern independently justifies the Commission's longstanding insistence on rigorous scientific evidence for disease claims.

B. POM's Products and Advertising

This case involves ads for three distinct POM products: one beverage (POM Juice) and two dietary supplements (POM_x Pills and Liquid). POM Juice is manufactured by pressing whole pomegranates into a concentrate, filtering it or enzyme-treating it, and later re-constituting it to make juice. IDF 58-62 [JA91].[4] POM separately extracts POM_x Liquid and POM_x Pills from "discarded, mashed-up pomegranates left over from the juicing process." IDF 67-71 [JA92]. POM advertised these three products as bioequivalent for all relevant purposes. For example, POM told consumers that they "can get all the antioxidant power of an

[4] Because that process eliminates fiber and Vitamin C from the finished juice product, *see* IDF 62 [JA91], POM Juice fails to meet the nutritional criteria that FDA has established for a food to be labeled as "healthy." 21 C.F.R. § 101.65(d)(2)(i)(F).

8oz glass of juice in the convenience of a calorie-free capsule." CX0120_0001 [JA872]; *accord* CX0355_0001 [JA976]; *see also* CX0348_0001 [JA968] (entitled "24 scientific studies[,] now in one easy-to-swallow pill"; claiming that POM_x Pills were "so concentrated that a single capsule has the antioxidant power of a full glass" of POM Juice); CX0280_0001 [JA895] (similar).

POM charged high prices for these products. A 16-ounce bottle of POM Juice sold for "$4+/bottle, roughly a 30% premium to … pomegranate competitors." Op. 38 n.31 [JA622]. And POM_x Pills sold for approximately one dollar per capsule. IDF 101 [JA95]. POM confidently charged such prices because it knew that, in its own words, certain consumers would "put up with the price" if they believed that the products offered unique "[h]ealth benefits." Op. 38 n.31 [JA622]. POM thus ran dozens of advertisements targeting, among others, consumers "who are very health-conscious (hypochondriacs)" and who are "seeking a natural cure for current ailments" or who wish to "prevent future ailment[s]," such as older men "who are scared to get prostate cancer." IDF 176-178 [JA104]. For example, one ad told consumers that POM Juice "can help prevent … heart disease, stroke, Alzheimer's, even cancer" and that "[e]ight ounces a day is all you need" to "[c]heat death." CX0036_0001 [JA830].

POM also sought to differentiate its products from the competition by claiming that its pomegranates had not only *more* but *better* ("unique and

superior") antioxidants as compared to other fruits and vegetables. *E.g.*, CX0355_0001 [JA976]. POM's ads further implied that its products were medically superior even to rival pomegranate products. For example, the ads claimed that "POM Wonderful is the only pomegranate juice you can trust" (ID Appx. 9) [JA424] because, among other things, "[o]ur juice comes from a unique pomegranate variety (the Wonderful), which is grown in a unique location (California), and which is juiced with proprietary technology (ours!)" (ID Appx. 41) [JA456]. Another ad stressed that "[t]he Wonderful variety of pomegranate is a type of pomegranate rather than a brand" and that most "[o]f the many published peer-reviewed medical papers that speak to the health benefits of pomegranate … were conducted using juice or pomegranate extract from this variety of pomegranate." CX0065-002 [JA867]; *accord* CX0279_0001 [JA893] (stating, twice, that POM_x Pills are "made from the only pomegranates backed by $25 million in medical research").

POM's advertising claimed that this supposedly "unique pomegranate variety" would combat several very specific diseases. First, in most of the ads at issue here, POM claimed that its products would treat, prevent, or reduce the risk of heart disease. For example, many ads claimed that POM would treat atherosclerosis—*i.e.*, plaque in the arteries. One such ad, citing a "clinical pilot study," promised: "Ace your EKG…. A glass a day can reduce plaque by up to

30%! Trust us, your cardiologist will be amazed." CX0034 (footnote omitted) [JA828]. As discussed below, that 30% figure was highly problematic from the start. Yet POM's ad campaign continued to cite it through 2010, years after POM learned that the much larger, double-blind studies it had commissioned showed no significant plaque-reducing benefits at all, let alone 30%. *See* Op. 43 [JA627]; *e.g.*, CX0280, CX0328 (attached as Addenda 2 and 3) [JA895, 957]. *See generally* Section I.B.1, *infra*.

Second, POM claimed that its products would treat prostate cancer by, for example, substantially slowing the disease's progress in patients who had undergone treatment for that disease. One ad, portraying a POM bottle as a medical superhero, proclaimed, "I'm off to save prostates … [m]an by man, gland by gland," and noted that this claim was "backed by $25 million in vigilant medical research." CX0274_0001 [JA891]. Other ads claimed that recovering prostate cancer patients who consumed POM products after surgery or radiation treatment enjoyed a dramatic ("four-fold") slowing in doubling times for PSA ("prostate-specific antigen"), a protein marker for prostate cancer. *E.g.*, CX0379_0002 (attached as Addendum 4) [JA910]. As discussed below, that seemingly impressive claim was clinically meaningless for reasons that POM did not disclose in its ads.

Third, although the great majority of ads at issue involve claims about heart disease or prostate cancer, several ads also claimed that consumption of POM products would successfully treat erectile dysfunction. For example, one advertisement for POM_x Pills claimed that "[i]n a preliminary study on erectile function," men who consumed POM products "reported a 50% greater likelihood of improved erections as compared to placebo," an effect POM attributed to "enhanc[ed] … actions of nitric oxide in vascular endothelial cells." CX0355_0001 [JA976]. As the FTC and ALJ later found, that claim, too, was based on unreliable science and non-probative metrics, facts that POM's ads withheld from consumers. Op. 33 [JA617]; IDF 1231-1232. [JA256]

C. Administrative Proceedings Before the Commission

On September 24, 2010, the FTC issued an administrative complaint against petitioners, claiming that 43 of POM's advertisements were false or misleading and thus violated Sections 5 and 12 of the FTC Act. CX1426 [JA15-64]. As relief, the complaint sought to enjoin petitioners from making disease claims in their advertisements without first securing FDA approval. CX1426_021-022 [JA35-36]

An ALJ conducted an administrative hearing that generated some 3300 pages of trial transcript and involved 14 expert witnesses and nearly 2000 exhibits. ID 2 [JA81]. In the end, the ALJ found that 20 of the challenged ads made specific

disease efficacy claims and that 16 of those 20 also made establishment claims. IDF 580-583 [JA163-164]. Turning to substantiation, the ALJ found that "experts in the relevant fields would agree that competent and reliable scientific evidence" for disease claims "must include clinical studies, although not necessarily double-blind, randomized, placebo-controlled clinical trials." ID 328 [JA407]. Even under that lenient standard, however, the ALJ concluded that every one of the 20 ads that made disease claims was materially false or misleading in that POM lacked adequate substantiation for each such claim. ID 5-6 [JA84-85]. The ALJ thus entered injunctive relief against petitioners but rejected Complaint Counsel's request for an FDA-preapproval requirement for disease claims in future POM ads. ID 6, 332 [JA85, 411].

Both sides appealed the ALJ's order to the Commission. In such appeals, the Commission reviews the trial record *de novo* and owes no deference to the ALJ's findings, on claims interpretation or any other issue. Op. 3, 6 [JA587, 590]; *see* 16 C.F.R. § 3.54(a). On January 10, 2013, the FTC issued the order under review, which agreed with the ALJ that petitioners had all violated the FTC Act. The Commission also found that petitioners had run "a larger number of advertisements containing false and misleading claims than the ALJ [had] found." Op. 3 [JA587].

Claims Interpretation. In interpreting the claims made by the challenged advertisements, the FTC relied mainly on its own facial analysis, *see* Op. 8-14 [JA592-598], but it also considered consumer surveys and other extrinsic record evidence where it was proffered. *See* Op. 14-17 [JA598-601]. The Commission found that 36 of the 43 charged advertisements contained "efficacy" claims that POM's products could treat, prevent, or reduce the risk of disease. And it found that 34 of those 36 ads also contained "establishment" claims that clinical evidence substantiated the efficacy claims. Op. 9, 41 & Summary Table [JA593, 625, 765-767]. The Commission detailed those findings in a fourteen-page ad-by-ad analysis set forth in Appendix A to the opinion. *See* Op. A1-A14 [JA638-651]. The Commission also found that petitioners "inten[ded] to convey" the disease claims that the Commission found deceptive. Op. 17 [JA601].

Deception. The FTC then turned to the question of whether these disease claims were adequately substantiated.[5] Relying in large part on case-specific

[5] Op. 17-38 [JA601-622]. The Commission found that the ALJ had adopted an erroneously undemanding standard because he had mistakenly "relied on expert testimony about the level of substantiation necessary for broad, generalized health and nutritional benefits when he determined the level of substantiation needed to address the specific disease treatment, prevention and risk reduction claims at issue in this case." Op. 18 [JA602]. And the Commission further observed that the ALJ appeared in some passages to have applied the multifactor *Pfizer* analysis to the establishment claims that appear in 34 out of the 36 ads at issue, thereby contradicting decades of settled precedent confining that analysis to basic efficacy claims. *Id.* As "the agency entrusted by Congress with the responsibility for making findings under the statute," the Commission may "reach[] a result contrary

expert testimony, it concluded that "experts in the relevant fields would require RCTs (*i.e.*, properly randomized and controlled human clinical trials …) to establish a causal relationship" between POM's products and "the treatment, prevention, or reduction of risk of the serious diseases at issue in this case," "two of which are potentially fatal." Op. 22, 25 [JA606, 609]. As the name suggests, RCTs should be both well-controlled and randomized—*i.e.*, "subjects should be randomly assigned to the test and control groups" to "increase[] the likelihood that the treatment and control groups are similar in relevant characteristics" and to "prevent[] the investigator from introducing bias into the study." Op. 23 (internal quotation marks and brackets omitted) [JA607]. The studies should also show "statistically significant" effects on either "disease endpoints" or "validated surrogate markers that have been shown to be so closely linked to a direct endpoint that a change in the surrogate marker is confidently predictive of a change in the disease." *Id.* (internal quotation marks omitted).

Finally, although RCTs "should be double-blinded when feasible," the Commission concluded that "some flexibility in the double-blind requirement" is warranted for food products, given that it "may not always be feasible" to keep

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to that of the ALJ when there is substantial evidence in support of each result, and is free to substitute its judgment for the ALJ's." *Kiewit Power Constructors Co. v. NLRB*, 652 F.3d 22, 26 (D.C. Cir. 2011) (internal quotation marks, alterations, and citation omitted).

study participants from knowing what foods they are consuming. Op. 24 [JA608]. But that feasibility concern did not arise here because POM_x Liquid and Pills should be no more difficult than any other syrup or capsule to simulate with a placebo. *Id.* And even with respect to POM Juice, POM in fact "submitted several studies with pomegranate juice that were described as double blind RCTs." *Id.*

As discussed in greater detail below, POM did not support its disease claims with probative science, and POM's sponsored RCTs yielded no statistically significant positive results; indeed, they tended to produce negative results. The FTC thus concluded that the relevant ads were deceptive. The Commission suggested that POM might have stopped short of misleading consumers in a number of ads if it "had made disclaimers such as those described in *Pearson* [*v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999)] (*i.e.*, 'the evidence in support of this claim is inconclusive,' *id.* at 659)." Op. 44 [JA628]. But POM had included no such disclaimers; indeed, its purported qualifications often "provide[d] a positive spin on the studies rather than a substantive disclaimer." Op. 13 [JA597]. The FTC similarly observed that POM's ads were deeply misleading because they contained "many omissions of material facts." Op. 43 [JA627]. For example, some ads relied on a particular clinical study to establish certain disease claims without noting the shortcomings that had led multiple peer reviewers to reject that study,

and they omitted any discussion of the contrary results of a "much larger, well-designed, well-controlled study." *Id.*

Constitutional defenses. Turning to petitioners' First Amendment arguments, the Commission found that, because POM's advertising was "actually misleading," it was "not protected by the First Amendment." Op. 41-42 [JA625-626]. The Commission also explained that petitioners' reliance on *Pearson* was unavailing. *Pearson* addressed prescriptive regulations that had prospectively banned certain types of health claims because, the Court found, the FDA had not considered whether hypothetical disclaimers could have kept such claims from misleading consumers. In contrast, this enforcement action targeted only *actual advertisements* that were misleading because, in fact, they did *not* contain effective disclaimers. Op. 44 [JA628].

Remedy. Having found liability, the FTC imposed a cease-and-desist remedy against petitioners. Although it had based liability on a greater number of advertisements than the ALJ had, the Commission emphasized that this injunctive remedy would have been justified "even if based only on the smaller number of ads where the ALJ found [petitioners] conveyed the claims." Op. 50 [JA634].

The remedy includes "fencing-in" provisions, which, under longstanding precedent, may be (and often are) "broader than the conduct that is declared unlawful." Op. 50 (citing, *inter alia*, *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374,

394-95 (1965)) [JA634]. Here, although the Commission declined Complaint Counsel's request to impose an FDA pre-approval requirement, it ordered that petitioners "must have at least two RCTs" that demonstrate a product's effectiveness in the diagnosis, treatment, or prevention of any disease before making such a representation. Op. 51 [JA635].

This two-RCT order requirement is the Commission's choice of *remedy*. In the underlying *liability* ruling, the Commission had concluded that POM lacked positive results from even one RCT, and it thus declined to decide whether POM should have had positive results from more than one RCT. Op. 3 [JA587]. In its remedial order, however, the Commission concluded that petitioners should be subject to a two-RCT substantiation requirement for *future* disease claims because, unlike other advertisers, they have "demonstrated [a] propensity to misrepresent to their advantage the strength and outcomes of scientific research … about serious diseases." Op. 51 [JA635]. That said, this two-RCT requirement "applies only to [petitioners' future] claims for disease prevention, risk reduction, and treatment," not to any future claims of general health benefits, *see* Op. 52 [JA636], and not even to disease claims that are effectively qualified, *see* note 33, *infra.*

The FTC further concluded that this requirement should apply to all foods, drugs, or dietary supplements sold by POM and its corporate affiliate Roll Global LLC, which helped POM design the ads in question. Op. 50 [JA634]. Finally, the

FTC upheld the ALJ's conclusion that injunctive relief should extend to petitioner Matthew Tupper, who had been closely involved in the relevant advertising campaign and had the authority to control its challenged practices. Op. 53 [JA637].[6]

STANDARD OF REVIEW

Under the FTC Act, "[t]he findings of the Commission as to the facts, if supported by evidence, shall be conclusive." 15 U.S.C. § 45(c). This formulation is "essentially identical [to the] 'substantial evidence' standard for review of agency factfinding." *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 454 (1986). That standard "requires more than a scintilla, but … less than a preponderance of the evidence." *Florida Gas Transmission Co. v. FERC*, 604 F.3d 636, 645 (D.C. Cir. 2010) (internal quotation marks omitted); *see also Arkansas v. Oklahoma*, 503

[6] Except as indicated in several footnotes in the Commission's principal opinion, that opinion was unanimous. Commissioner Ohlhausen, who wrote that opinion, disagreed with the other four Commissioners on two discrete issues: claims interpretation and remedy. First, she concluded that a number of the advertisements at issue did not make the cited disease claims or were sufficiently ambiguous as to require extrinsic evidence that the claims were conveyed to consumers. But she confirmed that, "[f]or most of the challenged advertisements, [she] agree[d] with the majority of the Commission about the claims conveyed." Op. 9 n.9 [JA593]. Second, whereas the majority's fencing-in relief imposed a two-RCT requirement on any future disease claims by petitioners as viewed in the context of all other reliable evidence, Commissioner Ohlhausen "would [have] require[d] only one RCT." Op. 51 n.36 [JA635]. But all five Commissioners agreed that, for *liability* purposes, POM lacked adequate substantiation for its disease claims because it had no clinically significant positive results from even one RCT.

U.S. 91, 113 (1992); *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1496 (1st Cir. 1989). The standard "is not modified in any way when [an agency] and its [ALJ] disagree." *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 496 (1951).

In deceptive advertising cases, this Court extends special deference to the Commission's longstanding "expertise" on the following issues:

- "assessing whether advertisements are misleading or deceptive" (*Thompson Med.*, 791 F.2d at 193);
- determining "whether a claim of establishment is … made" in a given advertisement" (*id.* at 194);
- "determining what sort of substantiation is necessary to assure that advertising is not deceptive" (*id.* at 196); and
- "determining the type of [remedial] order that is necessary to cope with the unfair practices found" (*Colgate-Palmolive*, 380 U.S. at 392).

More generally, "an FTC finding [of deceptive advertising] is 'to be given great weight by reviewing courts' because it 'rests so heavily on inference and pragmatic judgment' and in light of the frequency with which the Commission handles these cases." *Kraft*, 970 F.2d at 316 (quoting *Colgate-Palmolive*, 380 U.S. at 385, and reaffirming *Colgate*'s continued validity); *accord Removatron*, 884 F.2d at 1496.

SUMMARY OF ARGUMENT

1. This is a garden-variety enforcement action against unscrupulous advertising. POM told consumers that its products would combat specific diseases, two of which are life-threatening, and that clinical studies backed up those claims. In fact, POM had no scientific basis for these claims. And the clinical studies

POM sponsored, when they were at all rigorous, tended only to contradict those claims. The FTC's finding of deceptive advertising was thus correct and easily satisfies the deferential standard of judicial review.

Petitioners and their amici nonetheless try to portray the FTC's decision as the product of "an aggressive policy agenda" to stamp out "accurate, truthful, and carefully qualified" "health benefits" claims that, in POM's words, "are based on the best science that is reasonably available." POM Br. 3, 6. That account might have had traction if (1) POM's ads had contained only generalized "health benefit claims" rather than highly specific disease claims; (2) POM's own RCTs had supported rather than countered their disease claims; (3) POM's ads had been "accurate, truthful, and carefully qualified" rather than disingenuous in their portrayal of POM's research results; and (4) the FTC's decision were the unprecedented and inflexible caricature that petitioners have drawn. But none of these propositions is true, and this is not a close case.

First, the Commission reasonably interpreted the ads in question to convey claims that POM's products combat specific diseases and that clinical tests backed up those disease claims. The very text of these ads refutes POM's suggestion that it was merely making generalized "health" claims. POM explicitly marketed all three of its products—Juice, Liquid, and Pills—for their supposed ability to fight specific diseases, including "atherosclerosis" and "prostate cancer."

Second, these disease claims were deceptive. As all five Commissioners (and the ALJ) reasonably found, POM lacked a solid scientific basis for claiming that its products treated, prevented, or reduced the risk of particular diseases, and POM's ads misrepresented its record of scientific research. For example, POM's ads told consumers through 2010 that consuming POM products would treat atherosclerosis by cutting arterial plaque "up to 30%." But POM's own double-blind RCTs in 2005 and 2006—whose results POM concealed from consumers—showed no significant plaque-reducing benefit. Moreover, the very existence of those double-blind RCTs undermines POM's claim that it should not have been expected to compile scientifically rigorous evidence before making unqualified disease claims. POM in fact performed placebo-controlled trials for both POM Juice and supposedly bioequivalent POM_x Pills. POM understood that scientifically rigorous trials are both feasible and appropriate in this context; that is why it conducted them. The problem for POM was that the *results* of these trials were negative rather than positive.

Third, the Commission reasonably concluded that POM's supposed "qualifications" and "disclaimers" did nothing to cure the deceptive nature of POM's ads. Indeed, in many cases, the supposed qualifications—such as the modifiers "promising," "encouraging," or "hopeful"—served only to intensify POM's deceptively bullish spin on its clinical results. And the formulaic

"disclaimers" POM slapped on some ads were so tiny as to approach the limits of legibility and would have been substantively ineffective even if they had been larger.

Fourth, petitioners badly mischaracterize the Commission's decision as both novel and sweeping; it is neither. As this Court explained in its 1986 *Thompson Medical* decision, which petitioners ignore, the FTC has long deemed advertisers liable for failing to substantiate medical claims with well-controlled clinical trials, even for "safe" products. Indeed, the FTC has imposed, and this Court has upheld, more rigorous substantiation requirements in prior cases than the FTC imposed here.

Petitioners are likewise wrong to contend that the Commission's decision suppresses information useful to consumers about scientific hypotheses that have not yet "been proven to an exacting level of certainty." POM Br. 20. Advertisers may generally inform consumers about an emerging body of science so long as they include clear qualifying language that discloses the limitations of the scientific record and the existence of any contrary evidence. The ads at issue here, however, made no effective disclaimers, disclosed no contrary evidence, and affirmatively distorted the scientific record.

2. Petitioners' First Amendment arguments are likewise misconceived because, as the Supreme Court and this Court have long stressed, deceptive

commercial speech is entitled to no First Amendment protection. Petitioners try to escape that principle and shoehorn the FTC's liability finding into the *Central Hudson* framework by invoking a distinction in the case law between "inherently misleading" and "potentially misleading" commercial speech. But that distinction is relevant only to the constitutionality of prescriptive regulations that prohibit whole categories of information in advertisements or product labels. In that context, if the information can be presented in a way that is *not* deceptive, such as through effective disclaimers or qualifiers, it is said to be only "potentially misleading," and a categorical prohibition on conveying such information is subject to the *Central Hudson* analysis. But that analysis is irrelevant to *ex post* liability findings like this, where a factfinder examines an advertisement that has already been run and concludes that the ad was misleading to many consumers despite whatever disclaimers *were* included. Such an advertisement, like deceptive commercial speech generally, receives no First Amendment protection.

There is also no basis for petitioners' claim that, by holding petitioners liable for running misleading ads, the FTC has somehow "deprive[d] consumers of information." POM Br. 7. As this Court has held, "misleading advertising does not serve, and, in fact, disserves, th[e] interest" of "consumers and society … in the free flow of commercial information," and such advertising thus "may be prohibited entirely." *Brown & Williamson*, 778 F.2d at 43 (internal quotation

marks omitted). Holding advertisers liable for mischaracterizing substantiation evidence gives them appropriate incentives to present their claims in non-misleading ways and thus to convey more, not less, truthful information to the public.

3. Having found petitioners liable for deceiving consumers, the Commission reasonably ordered them to identify positive results from at least two RCTs before making future disease claims (as opposed to general health-benefit claims). As the Commission explained, this "fencing-in" remedy comports with longstanding precedent and is necessary to keep petitioners from perpetuating their long history of distorting the scientific record in their advertising.

4. The Commission reasonably held Mr. Tupper liable for his central role in POM's deceptive advertising scheme. Mr. Tupper misstates the applicable legal standard for individual liability, and, in any event, he would be liable even under the more rigorous standard that he proposes.

5. Mr. Tupper is also wrong to contend that the Administrative Procedure Act required the FTC to conduct notice-and-comment rulemaking on substantiation issues before ruling against petitioners in this adjudicative setting. He has forfeited that claim because no party squarely presented it to the FTC. In any event, it is settled law that agencies may develop policy through either case-by-case

adjudication or rulemaking. Mr. Tupper identifies no plausible basis why a rulemaking should be mandated here.

ARGUMENT

I. THE FTC REASONABLY DETERMINED THAT POM'S ADVERTISEMENTS VIOLATED THE FTC ACT'S PROHIBITION OF FALSE OR DECEPTIVE ADVERTISING.

A. The FTC Reasonably Found That the Subject Ads Claim That POM Products Combat Specific Diseases.

"[I]n interpreting advertisements, the Commission may rely on its own reasoned analysis of the advertisements themselves, without resorting to surveys or consumer testimony," and its conclusions are "due special deference owing to the nature of the inquiry and the Commission's expertise in evaluating deception." *Thompson Med.*, 791 F.2d at 197 (quoting, and approving, FTC's statement of standard of review). Here, no "special deference" is even needed to affirm the FTC's conclusion that most of the ads charged in the complaint made claims that POM products could treat, prevent, or reduce the risk of specified diseases and that scientific evidence backed up those disease claims.

Indeed, it is hard to imagine *what else* these ads could possibly be telling consumers about the specific diseases on which they focus. POM's ads did not merely claim that POM Juice or POM_x Pills were part of a healthy diet or that they were rich in antioxidants. Instead, the ads asserted that POM's products are effective in treating, preventing, or reducing the risk of very specific medical

conditions such as "heart disease," including "atherosclerosis," and "prostate cancer."[7] To drive home the disease-oriented character of these claims, POM often used explicitly medical terminology and imagery. For example, the medical terms included "atherosclerosis" (*see, e.g.*, CX0016, CX0029_0002, CX0169) [JA823, 826, 878]; "coronary heart disease" (CX0169) [JA878]; "ischemia" (CX0180, CX0279, CX0355) [JA880, 893, 976]; "cardiovascular disease" (CX1426 Exh. M) [JA59-61]; "PSA doubling times" (CX1426 Exh. I, CX0180, CX0314_0004, CX0279, CX0280, CX0355) [JA51-55, 880, 902, 893, 895, 976]; and "IMT reduction" (CX0180, CX0279, CX0280) [JA880, 893, 895]. The medical imagery included the caduceus symbol (⚕) and the letter "x" in subscript form ("POM_x"), which POM used to bestow pharmaceutical resonance ("R_x") on POM_x Pills and POM_x Liquid products.[8]

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[7] *See* Op. 7-14, A1-A14 [JA591-598, 638-651]. POM made those disease claims because, as it understood, many of its customers would not otherwise have "put up with the price" of "$4+/bottle [for POM Juice], roughly a 30% premium to our pomegranate competitors," *see* Op. 38 n.31 [JA622], nor would they have paid roughly a dollar for each POM_x Pill, *see* IDF 101 [JA95]. POM finds it "equally plausible to presume that "POM's price [wa]s driven primarily by its production costs" rather than the appeal of POM's disease claims. POM Br. 48. This makes no sense. In a free market, a manufacturer cannot demand that consumers pay higher prices to cover its peculiar "production costs"; it must persuade consumers that its product offers special value to them. That was the point of POM's advertising campaign.

[8] For the caduceus symbol, see, *e.g.*, CX0314_004, CX0372_002, CX0379_002, CX0380_002 [JA902, 914, 910, 918]; *see also* CX0120, CX0122, CX0169 [JA872, 870, 878]. For the "POM_x" notation, see CX1426 Exhs. M & N,

As POM's internal documents confirm, petitioners fully intended that consumers would construe these ads to mean exactly what they said: that POM products would fight the specified diseases. *See* Op. 17 [JA601]. POM intentionally targeted consumers "who are very health-conscious (hypochondriacs)" and who are "seeking a natural cure for current ailments" or who wish to "prevent future ailment[s]," such as older men "who are scared to get prostate cancer." IDF 176-178 [JA104]. For example, the "creative briefs" for certain POM ads emphasized that their "main creative focus is prostate cancer." IDF 1327, 1328 [JA269]. Although such extrinsic evidence of intent is not necessary for a finding of liability, the Commission reasonably concluded that "evidence of [petitioners'] intent to convey claims about disease treatment and prevention supports our reading of [their] ads." Op. 17 [JA601]; *see also* Op. 16 (citing precedent) [JA600].

Petitioners make no serious effort to challenge the Commission's plain-meaning interpretations of these ads. Of the 36 ads that the Commission deemed materially deceptive, it found that all 36 asserted that POM's products treated, prevented, or reduced the risk of specific diseases, and that 34 of the 36 asserted

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CX0120, CX0122, CX0169, CX0180, CX0280, CX0331, CX0328, CX0337, CX0342, CX0350, CX0351 [JA59-64, 872, 870, 878, 880, 895, 924, 957, 959, 961, 970, 972]. *See also* CX0260 [JA882] ("Sometimes, good medicine can taste great. Case in point: POM Wonderful.").

that clinical evidence supported those claims. Op. 41 & Summary Table [JA625, 765-767]. To support that conclusion, the Commission set forth detailed ad-by-ad findings in Appendix A to its opinion [JA638-651].[9] But petitioners ignore Appendix A and its extensive findings; instead, they cherry-pick isolated snippets from a tiny subset of those ads and argue that those snippets did not themselves make disease claims. That failure to confront the Commission's actual findings is fatal to petitioners' ad-interpretation arguments. If a party wishes to challenge an agency's findings of fact, particularly those due "special deference," *Thompson Med.*, 791 F.2d at 197, it must address the factual details of those findings in an effort to carry its heavy burden of showing that they should be overturned. By failing to do so for the overwhelming majority of these ads, petitioners have waived any challenge to the FTC's interpretation of those ads.

Moreover, even if petitioners had identified some basis for challenging the Commission's interpretation of *some* of these ads, that challenge would have no bearing on their liability for deceptive advertising. As petitioners note,

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[9] Appendix A thus refutes petitioner Tupper's argument that, with respect to many ads, the Commission overruled the ALJ on claims interpretation "without any explanation." Tupper Br. 21. Appendix A also refutes petitioners' unelaborated assertion that the FTC's claims interpretation "failed 'to differentiate among 'treatment, prevention, or reduction of risk.'" POM Br. 32; *see*, *e.g.*, Op. A6 [JA643] (upholding ALJ's claims interpretation as to prevention and reduction of risk claims but not as to treatment claims); A13 [JA650] (interpreting ad to contain treatment claims as to prostate cancer and ED but not prevention or reduction-of-risk claims).

Commissioner Ohlhausen and the ALJ disagreed with the Commission majority on how to interpret *some* of the 36 ads at issue. *See* Op. 9 n.9 [JA593] (noting that Commissioner Ohlhausen "agree[d] with the majority of the Commission about the claims conveyed" in "most of the challenged advertisements"). As the Commission explained, however, it would have found liability and issued injunctive relief "even if based only on the smaller number of ads where the ALJ found [petitioners] conveyed the claims." Op. 50 [JA634]. Petitioners thus achieve nothing by focusing, as they do, on the least aggressive statements in a handful of advertisements (POM Br. 24-26) and ignoring the pointedly disease-specific thrust of the great majority of their advertisements.[10]

B. The FTC Reasonably Found That POM's Disease Claims Were Deceptive.

"[I]n general an advertisement is considered deceptive if the advertiser lacks a 'reasonable basis' to support the claims made in it." *Thompson Med.*, 791 F.2d at

[10] Petitioners criticize the Commission for declining to rely on consumer surveys or other "extrinsic evidence" to interpret these ads. POM Br. 5. But even they correctly acknowledge that such reliance is "not required as a matter of law." *Id.* at 30; *see, e.g.*, *Brown & Williamson*, 778 F.2d at 40; *Thompson Med.*, 791 F.2d at 197. In any event, the Commission *did* consider the extrinsic evidence that petitioners offered and reasonably concluded that it cast no doubt on the Commission's facial interpretations. *See* Op. 9, 14-17 [JA593, 598-601]. There is likewise no basis for petitioners' contention that the FTC "required POM to produce extrinsic evidence that its advertisements would not mislead consumers." POM Br. 30. The FTC required no such evidence; it simply construed the plain meaning of POM's ads and rejected POM's attempt to argue that those ads meant something other than what they said.

193. Nearly all of the ads at issue here told consumers that POM's products effectively combat particular diseases and that clinical studies backed up those claims. *See* Op. 41 & Summary Table [JA625, 765-767]. Decades-old precedent thus required POM to possess a level of proof "sufficient to satisfy the relevant scientific community of the claim's truth." *Thompson Med. Co.*, 104 F.T.C. at 821-22 n.59, *aff'd*, *Thompson Med.*, 791 F.2d 189; *see also Removatron Int'l Corp.*, 111 F.T.C. at 297, *aff'd*, *Removatron*, 884 F.2d 1489. The main issues before the Commission, therefore, were whether POM's clinical studies met established standards for experimental rigor and, if so, whether those studies in fact substantiated POM's claims of "a causal relationship" between consumption of its products and "the treatment, prevention, or reduction of risk of the serious diseases at issue in this case," "two of which are potentially fatal." Op. 22, 25 [JA606, 609].[11]

Relying in part on expert medical testimony, the Commission concluded that, to justify these causal claims, POM needed to identify positive and statistically significant results from at least one randomized and well-controlled

[11] Petitioners repeatedly suggest that the Commission addressed substantiation requirements for "general health benefit claims." POM Br. 31. That is wrong. The Commission expressly "decline[d]" to determine "the level of support required for generalized nutritional and health benefit claims," precisely because it did not predicate liability on any such claims. Op. 20 [JA604]. Instead, it considered only POM's support for claims that POM's products treat, prevent, or reduce the risk of specific diseases. *See* Section I.A., *supra.*

(but not necessarily double-blind) clinical trial—*i.e.*, an RCT. Op. 23-24 [JA607-608]. All five Commissioners joined in that conclusion. All five Commissioners likewise concluded that POM failed this standard because some of POM's trials were scientifically unsound and because POM's other trials, while rigorous, produced negative rather than positive results. This Court extends substantial deference to the FTC's "expertise" in "assessing whether advertisements are misleading or deceptive" because they lack adequate substantiation. *Thompson Med.*, 791 F.2d at 193; *see also Colgate-Palmolive*, 380 U.S. at 385. As discussed below, however, such deference is not even necessary to uphold the Commission's finding of deception here because POM's science not only failed to substantiate its ad claims, but actually tended to contradict them.

1. POM's heart disease claims were deceptive.

For the better part of a decade, POM claimed that its products could treat atherosclerosis and otherwise reduce the risk of heart disease. POM touted the dubious results of clinical studies whose blatant shortcomings it never acknowledged, and for years it went on touting those results in its ads even though they had been undermined by an intervening body of contrary scientific evidence. That is a classic case of deceptive advertising.

POM's ads repeatedly told the public 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%." CX0029_0002 [JA826]; *see* Op. 43 [JA627] (citing similar ads). That was medically significant, POM claimed, because "98% of heart attacks are due to atherosclerosis, or too much plaque in the arteries." CX0029_0002 [JA826]. The first problem with this "30%" claim was that the cited clinical study—the Aviram CIMT/BP Study—was unreliable evidence for any unqualified claim of disease benefit, let alone this aggressively numerical claim of clinical substantiation. That 2004 study was tiny, consisting of a sample group of only ten subjects and a control group of nine. This was far too small to permit reliable extrapolations to the population at large. IDF 798, 804 [JA195, 196]. Moreover, the study was neither randomized nor placebo-controlled, and it reported no comparative statistical analysis between the treatment and control groups. IDF 798 [JA195]. Even one of petitioners' experts conceded that the study was "not at all conclusive." IDF 802 [JA196].[12]

[12] In these early years, POM conducted two other non-RCT heart-disease studies, and they were just as unreliable. First, the Aviram ACE/BP study involved only ten subjects and lasted only two weeks; it had no control group at all; and it measured an endpoint that is not a validated surrogate marker of any disease. *See* Op. 28 [JA612]; IDF 780-81 [JA192-193]. Second, the Ornish MP study (which should not be confused with the later Ornish CIMT study discussed below) also measured non-validated surrogate markers; it failed to report the observed data for all subjects; the "placebo" group did not actually receive a placebo treatment; that group differed materially from the active group from the outset of the study; some patients were "unblinded" inappropriately; and the study was terminated prematurely after only three months because of funding problems, even though it was designed for twelve months. *See* IDF 819-845 [JA198-203]. The study's own author acknowledged that the study had "some problems" and

If such inconclusive results had been the only evidence on the subject, POM might have been entitled to cite them in its ads so long as it included "direct and unambiguous" qualifying language "mak[ing] sure consumers underst[oo]d" the limitations and inconclusiveness of the evidence. *2001 Dietary Supplement Guide* at 7 [JA801]. Again, an advertiser may generally cite promising scientific developments, even in the absence of rigorous clinical proof, so long as the ad conveys whatever "qualifying information is necessary to prevent [the] ad from being deceptive." *Id.* at 6 [JA800]. As discussed in Section I.C below, however, POM included no effective qualifiers.

POM, however, was far more deceptive than that. It repeated the same "30%" figure in many of its ads through 2010 even though POM knew from its other studies, completed in 2005 and 2006, that the "30%" claim was a sham. *See* Op. 43 [JA627] (citing, *e.g.*, CX0280, CX0328, CX0331, CX0337).[13]

The first of these was the Ornish CIMT study, completed in 2005. Unlike the Aviram CIMT/BP study, this was a randomized, double-blind, placebo-

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was not "optimal." IDF 819 [JA198]. Peer reviewers agreed: the study was rejected by the American Heart Association and the *Journal of the American Medical Association* before a third journal agreed to publish it without external peer reviews. IDF 816-818 [JA197-198].

[13] In Addenda 2 and 3 to this brief, we have reproduced two such ads: CX0328 [JA957], which ran in the Washington Post Magazine in November 2009, and CX0280 [JA895], which ran nationally and in dozens of cities throughout 2009.

controlled 73-person trial that measured, among other things, carotid intima-media thickness ("CIMT"), a measure of arterial plaque. The study's final report, which POM did not bother to publish, concluded that the treatment group fared no better than the control group in any measurement concerning arterial plaque or, for that matter, in any other measurement relevant to heart disease. IDF 858-859 [JA205]. In other words, this comparatively large and rigorous study found none of the arterial plaque benefits that POM derived from the Aviram CIMT/BP study. *See* IDF 861 [JA205] (noting that Harvard Medical School professor Frank Sacks "described the results of this study as 'convincingly null, showing that pomegranate juice treatment did not improve CIMT or other tested parameters'"). But POM continued to cite the Aviram CIMT/BP study, along with its associated "30%" figure, without mentioning this new negative evidence. Op. 43 [JA627].

The following year, the Davidson CIMT study resolved any lingering doubts about whether it was deceptive for POM to continue running ads that uncritically cited the results of the Aviram CIMT/BP study. This new study, completed in 2006, was an 18-month, 289-person, randomized, double-blinded, and placebo-controlled clinical trial, conducted at two separate sites under an institutionally approved protocol. IDF 872 [JA207]. Both sides' experts acknowledged that the Davidson study was a carefully designed and well-conducted RCT. Like the Ornish CIMT study, the Davidson study was bad news for POM. At the

conclusion of the 18-month period, the treatment group had fared no better than the control group in any measurement relevant to heart disease in general or arterial plaque in particular. IDF 878-883 [JA207-209].

POM nonetheless began looking for ways to spin this negative study to its advantage—if not in its ads themselves, then at least in the final report. First, POM noted that if one arbitrarily stopped looking at the evidence at 12 months rather than 18, the treatment group compared somewhat favorably to the control group in terms of CIMT values, even though "this difference was no longer significant at the end of the treatment period." IDF 878 [JA207-209]. But focusing on 12-month results when the protocol specified an 18-month trial is like flipping a coin 100 times, coming up with 50 heads and 50 tails, and then asserting that the coin is unfair because, after only 60 flips, the number of heads had substantially exceeded the number of tails.[14] Second, even though the treatment group as a whole saw no benefit compared to the control group, "*post hoc* exploratory analyses" prompted by POM suggested that some narrow subgroups defined after the study's conclusion showed some improvement for those subgroups on some measures. *Id*. But it is often possible to gerrymander study

[14] POM has speculated that study participants might have inexplicably stopped drinking the juice with six months left to go in the trial. But Dr. Davidson himself "evaluated the compliance [of participants] with product consumption guidelines" and testified that "compliance diaries showed high levels of compliance." IDF 891 [JA211-212].

results after the fact to give them a positive spin. That is why the scientific community requires study protocols to be identified at the outset: "to prevent a researcher from using positive results and ignoring negative ones, resulting in bias." IDF 610 [JA169].

Moreover, even if one accepted as valid POM's gerrymandering of the Davidson study and focused only on retrospectively defined subgroups at the arbitrarily selected 12-month point, the study *still* "showed, at most, a 5% decrease in arterial plaque" for certain subgroups at that point (and no such benefit for all the other subgroups). Op. 43 [JA627]. Yet POM continued citing the far more aggressive "30%" figure as though the Davidson CIMT study had never been conducted. That is a textbook example of deceptive advertising. *Id.* And the results of those studies refute petitioners' claim that "[t]he actual statements made in each of the POM advertisements are true" even in a literal sense. POM Br. 23; Tupper Br. 23.

The scientific community saw the Davidson study for what it was: a highly rigorous clinical trial that showed none of the heart disease benefits that POM was touting in its ads. One journal rejected the manuscript after "concluding that it was a negative study," IDF 880 [JA209]—*i.e.*, a study that tends to disprove, rather than support, the hypothesis that the study was designed to prove. Another reviewer concluded: "The study needs to be reported as a negative study as it is."

IDF 883 [JA209] (quoting CX1057_0027). In response, Dr. Davidson himself "affirm[ed] that it was a negative study." *Id*. But POM was none too eager to publish on those terms—and it thus "delayed publication of the negative results." Op. 43 [JA627].

In short, POM knew by 2006 that not one but two rigorous clinical trials, both of which it had commissioned, had each produced negative results. POM nonetheless persisted through 2010 in citing the tiny and discredited Aviram CIMT/BP study for the claim that "[p]omegranate juice consumption results in significant reduction in IMT (thickness of arterial plaque) by up to 30% after one year." CX0337_0001 [JA959] (Jan. 2010); *see also* Op. 43 [JA627] (citing similar ads through 2009). The intervening studies, which petitioners did not mention, made that claim profoundly deceptive.

2. POM's prostate cancer claims were deceptive.

As noted, POM's advertising campaign touted the ability of POM products to "save prostates … [m]an by man, gland by gland," citing "$25 million in vigilant medical research" as support. CX0274_0001 [JA891]. In many ads, POM specifically relied on a "recently published pilot study" conducted by associate professor Allan Pantuck of UCLA.[15] POM cited that study to support its claim that

[15] CX0379_0001 [JA909]. Although the Pantuck study involved POM Juice, most of the subject ads that mentioned the study used it to promote POM_x Pills instead. *E.g.*, CX0331_0001 [JA924]; CX1426 Exh. J [JA56]; CX0328_0001

its products dramatically lengthened post-treatment doubling times for PSA (prostate-specific antigen), a protein marker for prostate cancer. In its ads, POM related that "46 men previously treated for prostate cancer" drank "eight ounces of POM Wonderful Pomegranate Juice daily for at least two years" and "experienced significantly slower average PSA doubling times"—indeed, "nearly a four-fold improvement from "15 months" at the beginning of the study to "54 months" at the end. CX0379_0002 [JA910] (reproduced as Addendum 4 to this brief). That effect, POM claimed, is cause for optimism because "the faster PSA levels increase in the blood of men after treatment, the greater their potential for dying of prostate cancer." CX0065_002 [JA867].

This optimistic spin, however, ignored highly material facts. Simply as a logical matter, the clinical results cited by POM could support claims of extended life expectancy for recovering prostate-cancer patients only if two propositions are both true: (1) consumption of POM products (rather than ordinary body processes or some other factor) caused the observed changes in PSA levels, and (2) those changes in fact correlate with greater life expectancy. In fact, POM had no basis for drawing *either* of those conclusions. We address them in reverse order.

[JA957]; CX0337_0001 [JA959]; CX0342_0001 [JA961]; CX0353_0001 [JA974]; CX0348_0001 [JA968]; CX0350_0001 [JA970]; CX0351_0001 [JA972]; CX0355_0001 [JA976].

First, petitioners' own expert confirmed that, in general, "PSA doubling time is not accepted by experts in the field of prostate cancer as a surrogate endpoint for a clinical benefit in chemotherapy trials," IDF 1111 [JA240], and the FDA has therefore not accepted it for that purpose either, IDF 1132 [JA244]. Indeed, PSA doubling times have clinical significance only in very narrow circumstances not presented here: where such doubling times are "very short," on the order of "less than three months," typically just after surgery or radiation. Eastham, Tr. 1262 [JA1233]. But the patients in the Pantuck study had initial PSA doubling periods longer than a year, IDF 1090 [JA238], and further increases in such periods have no accepted clinical significance. Thus, contrary to POM's claim that PSA doubling times correlate closely with the "potential for dying of prostate cancer," CX0065-002 [JA867], the relevant scientific community does not in fact agree that prolonging PSA doubling times will "change[] the natural history of prostate cancer by delaying the development of metastases or death from the disease," IDF 1131 [JA244]. POM nonetheless presented the medical jargon "PSA doubling time" as though changes in that metric would closely correspond to changes in life expectancy. That unqualified assertion was misleading. Op. 31 [JA615].

Second, because it chose to forgo any meaningful control group, POM had no basis for concluding that its products, as opposed to normal body processes or some other factor, caused the observed changes in PSA doubling times. Dr.

Pantuck himself acknowledged that "the greatest limitation" of his study was that it lacked any "blinded control." CX1341_0110 [JA1001]. All of the subjects in the trial had previously undergone radical medical treatments for prostate cancer (such as prostatectomy), and at the beginning of the trial, their average PSA doubling time was already a lengthy 15 months. This meant that they were already "considered to have a far lower risk of clinical progression" than many other recovering prostate-cancer patients. IDF 1090 [JA238]. Thus, even if these men had never consumed POM products, their average PSA doubling time might well have slowed to the same extent anyway. IDF 1087 [JA237]. The POM trial could have controlled, but did *not* control, for that obvious confounding factor. And it therefore did not show that POM products contributed to the reported slowing of PSA doubling times in these recovering patients. Op. 31 [JA615].

Indeed, Dr. Pantuck himself conceded in his published report that well-known clinical experience—specifically, a placebo-controlled study involving the use of a different drug (rosiglitazone) after radical medical treatment—confirms the importance of using a proper control group in this context. *See* IDF 1060-1063 [JA234]. In the rosiglitazone study, 38% of the recovering prostate-cancer patients who used the drug saw an increase in PSA doubling times. At first blush, that might sound like a significant result. But a similar percentage of subjects receiving a placebo (40%) also saw an increase in *their* PSA doubling times. That outcome

not only illustrates why control groups are essential in this context, but also confirms that PSA doubling times can lengthen all by themselves in the average recovering prostate cancer patient. *Id.* In the Pantuck study, too, there is no reason to believe that the treatment group would have fared any better than a placebo-control group if the study had included one. Op. 31 [JA615]. But POM's ads misleadingly cited the PSA statistics as though they meant that consumers would live longer if they used POM's products.

Finally, POM's own studies suggest, if anything, that consumption of POM's products might well have no effect on PSA doubling times. In addition to the Pantuck study, POM conducted a second trial—the Carducci study—that also addressed the effects of POM_x Pills on recovering prostate-cancer patients. Here, too, POM dispensed with any placebo control group ("too costly"), IDF 1069 [JA235], and the Carducci study thus suffered from the same methodological flaws as the Pantuck study. The Carducci study did, however, assess whether subjects taking three times the dosage of POM_x Pills showed any better PSA results than subjects taking a single dose. IDF 1069-70 [JA235-236]. The answer was no: PSA results did not vary with POM_x dosage. IDF 1075 [JA236]. That outcome comports with the hypothesis that POM_x Pills have no effect on PSA levels at all, no matter what the dosage. Again, readers of POM's ads knew none of this; they saw only superficially promising medical statistics.

3. POM's ED claims were deceptive.

Although the FTC's decision focused mostly on POM's heart-disease and prostate-cancer claims, a few of the subject advertisements also claimed that POM products had been clinically shown to treat erectile dysfunction. For example, one ad cited a published study for the proposition that clinical trial subjects who consumed POM products "reported a 50% greater likelihood of improved erections as compared to placebo." CX0355_0001 [JA976]; *see also* CX0351_0001 [JA972], CX0128_0002 [JA876].

That claim was misleading because it, too, misrepresented material facts; if anything, the cited study suggested that POM products did *not* treat ED. The study in question ("Forest/Padma-Nathan") was a placebo-controlled (and double-blinded) analysis of the effects of POM Juice on 53 men with mild-to-moderate ED. It used two metrics to measure patient's perceptions of efficacy: a "Global Assessment Questionnaire" (GAQ) and the "International Index of Erectile Function" (IIEF). Experts in the field consider the IIEF, but *not* the GAQ, a validated measure for assessing erectile function. IDF 1190, 1196 [JA251, 252].

The results fell short of statistical significance under both metrics. Op. 33 [JA617]. Moreover, although the results came close to statistical significance under the *non*-validated metric (the GAQ), they were, in the words of petitioners' own expert, "nowhere near approaching statistical significance" under the

validated metric (the IIEF). IDF 1226 [JA255]. As a result, when the study was presented for publication, a peer reviewer concluded that the cited trial was in fact "a negative study, not a positive study, and should be presented that way," and a separate published review likewise concluded that the study had negative results. Op. 33 [JA617]; IDF 1231-1232 [JA256].

In its ads, POM ignored all of these problems with its science and simply touted a "50% greater likelihood of improved erections." POM also ignores these same problems in its appellate brief. POM instead lampoons the FTC's opinion, suggesting that it categorically "prevent[s] advertisers from making any claim about [study] results" that fall one percentage point short of what experts in the field consider statistical significance (94% rather than 95%). POM Br. 20-21. That is not remotely what the opinion concludes. Instead, it finds that POM's ads were misleading because they overtly misrepresented the results of POM's scientific research. To avoid deceiving consumers, POM would have needed, at a minimum, to qualify its "50%" 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.

* * *

In sum, for each of the three diseases at issue, POM cherry-picked the evidence, selectively trumpeting superficially positive results even though, on balance, the larger scientific record it had compiled was negative. And petitioners could hardly be more wrong when they contend throughout their briefs that they "carefully qualified" their disease claims. POM Br. 3; Tupper Br. 22. As discussed in Section I.C below, POM's supposed "qualifications" were ineffective at best and, in some cases, merely exacerbated the deceptive character of POM's ads.

4. Petitioners' attacks on the FTC's substantiation analysis are immaterial and untenable.

As part of its substantiation analysis, the FTC considered what "'level of proof'" would be "'sufficient to satisfy the relevant scientific community'" that POM's ineffectively qualified disease claims were true. Op. 21 [JA605] (quoting *Thompson Med. Co.*, 104 F.T.C. at 821-22 n.59, *aff'd*, *Thompson Med.*, 791 F.2d 189).[16] Relying in large part on case-specific expert testimony, the FTC unanimously concluded that "the relevant scientific community" would require positive, statistically significant results from at least one RCT. Op. 2, 21-34 [JA586, 605-618]. That decision followed prior FTC findings over several decades

[16] Under longstanding precedent, this is the sole inquiry for the establishment claims that appeared in 34 out of 36 ads that the FTC cited as a basis for liability. For the remaining two ads, this inquiry is one of several *Pfizer* factors that the FTC considers for efficacy claims. *See* Op. 38 [JA622]; pp. 6-7, 17 and notes 2, 5, *supra.*

that experts in the relevant scientific communities would expect RCTs as substantiation for a broad range of medical claims, even where the product in question poses no health risk. *See*, *e.g.*, *Thompson Med.*, 791 F.2d at 194-196 (upholding two-RCT requirement for topical analgesic); *Removatron*, 884 F.2d at 1498 (upholding one-RCT requirement for hair-removal product).

Petitioners argue that the FTC erred in applying that familiar standard to their products. That argument is untenable. To begin with, the Commission's choice of substantiation standards is virtually irrelevant to the ultimate question of petitioners' liability. Although the Commission concluded that POM was required to have at least one RCT that supported (rather than countered) its claims, POM would have been liable for deceptive advertising even under a less demanding standard. Indeed, the ALJ *did* adopt a less demanding standard—requiring clinical research but *not* necessarily an RCT—and he nonetheless concluded that petitioners had misled consumers and violated the FTC Act. *See* pp. 16-17 and note 5, *supra.* That is no surprise. As discussed in the previous section, this is not a case where an advertiser's claims may or may not be true, where the evidence is positive but incomplete, and where the only question is whether an advertiser has enough reliable science to substantiate simple efficacy claims. Instead, the most reliable science in POM's possession tended to discredit rather than support its claims, and POM affirmatively distorted the scientific record. *E.g.*, Op. 43

[JA627]. POM's ads were thus deceptive under any standard of competent science.

In any event, the evidentiary record in this case amply supported the Commission's choice of substantiation standards for the disease claims at issue in this case, and it was certainly sufficient to satisfy the "substantial evidence" test on review.[17] For example, the Commission reasonably relied on the testimony of Professor Meir Stampfer of Harvard Medical School and the Harvard School of Public Health, who confirmed that "most scientists in the field of clinical trials, epidemiology, and the prevention of cardiovascular disease and prostate cancer would agree" that positive results from RCTs are required for the heart disease and prostate cancer claims at issue in this case. "[T]his is what we teach in medical schools and schools of public health" and "write about in journals," he testified, because it is the "common practice." Tr. 718 [JA1215].[18] Indeed, some of petitioners' own experts also testified to the same effect. For example, despite

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[17] As discussed in Section I.C below, POM's disease claims were not effectively qualified. The level of substantiation required for a disease claim that *is* effectively qualified might well be lower.

[18] *See id*. at 706-07 [JA1213-1214]; CX1293_009 [JA1104] (Stampfer Expert Report) (same); *see also* CX1291_010-011 [JA1048-1049] (Expert Report of Harvard Medical Professor Frank Sacks) (same for heart disease claims); CX1287_012 [JA1024] (Expert Report of Dr. James Eastham, Chief of Urology at Sloan-Kettering) (same for prostate cancer claims); CX1289_008, 012 [JA1085, 1089] (Expert Report of Professor Arnold Melman) (same for erectile dysfunction claims).

petitioner Tupper's contrary suggestion (Br. 48 n.10), Dr. Burnett quite clearly agreed that experts in the field "would require two to three human randomized, controlled trials to conclude that a product treats erectile dysfunction." Tr. 2264 [JA1271]. Likewise, petitioners' expert Irwin Goldstein confirmed that his published articles express the view that RCTs "are considered the criterion standard for determining causality." Tr. 2612-15 [JA1287].[19]

The Commission also reasonably concluded that POM's contrary expert testimony focused on inapposite issues. First, POM's experts had taken their cues from POM's counsel, who—then as now—interpreted POM's advertising claims as more akin to general health benefit claims than to disease claims. POM's experts thus tended to focus their testimony on how much substantiation is needed for "general nutritional and health benefit claims" instead of "the level of substantiation necessary for the specific disease treatment and prevention claims at

[19] Amicus Consumer Healthcare Products Association mistakenly suggests (Br. 9) that the FTC's decision somehow overruled past FTC guidance that, in appropriate cases, "epidemiological evidence alone may suffice to substantiate efficacy claims." But that guidance remains valid, and there is no conflict between it and this decision. *See 2001 Dietary Supplement Guide* at 11 [JA805] (noting that an appropriately qualified claim based on epidemiological evidence would be permitted where "[a] clinical intervention trial would be very difficult and costly to conduct," "experts in the field generally consider epidemiological evidence to be adequate" and there is no "stronger body of contrary evidence"). POM did not proffer any epidemiological evidence to substantiate its claims; it relied instead on the same human clinical research that POM's advertisements themselves touted. The Commission likewise said nothing about the value of epidemiological evidence in cases where it is actually offered.

issue in this case." Op. 20 [JA604]. As the Commission explained, however, "such evidence does not address the issue before us"—the substantiation needed for POM's actual claims of disease benefit. *Id.*

Second, like POM's counsel, POM's experts also focused on whether it is feasible to conduct double-blind trials involving familiar "foods." *See*, *e.g.*, Ornish, Tr. 2328 [JA1278]; *see also* Miller, Tr. 2212 [JA1267]. Their testimony was misdirected for that reason as well. Two out of the three products at issue here (POM_x Pills and Liquid) were not conventional "foods" at all, but straightforward dietary supplements. As the Commission observed, such products are obviously amenable to double-blind RCTs. Op. 24 [JA608].[20] Moreover, POM *repeatedly subjected POM Juice itself to double-blind RCTs*. For example, the Davidson and Ornish CIMT studies, discussed in Section I.B.1, were both double-blind, placebo-controlled inquiries into the effects of POM Juice on atherosclerosis. *See also* Section I.B.3, *supra* (discussing double-blind, placebo-controlled Forest/Padma-Nathan study). Those studies confirm that POM Juice—unlike, say, broccoli or other whole food products—can be tested with placebo controls. Again, the main

[20] As noted, POM in fact conducted a clinical trial of POM_x Pills to analyze their effects on prostate-cancer patients. *See* p. 45, *supra* (Carducci study). But POM concluded that using a placebo control group for that study would be "too costly" and chose instead to conduct a double-blind assessment only of whether three times the dosage of POM_x Pills showed any better results than the normal dose. IDF 1069-70 [JA235-236]. The answer was no. IDF 1075 [JA236].

problem with those double-blind POM Juice studies was not that they lacked experimental rigor, but that they produced negative results at odds with POM's advertising campaign.[21] In short, whatever might have been the views of petitioners' experts on the need for RCTs to substantiate general "health claims" for everyday "foods," those views had little bearing on the actual facts of this case.

In any event, the Commission's choice among competing substantiation standards was supported by substantial evidence and fell well within the Commission's "special expertise in determining what sort of substantiation is necessary to assure that advertising is not deceptive." *Thompson Med.*, 791 F.2d at 196. As the First Circuit has held in analogous circumstances, that choice should be upheld even where, unlike here, an advertiser's "suggested alternative conclusions" regarding the appropriate substantiation standard are "equally or even more reasonable and persuasive." *Removatron Int'l Corp.*, 884 F.2d at 1496

[21] POM similarly argues that uncertain patent protection for food-derived products will deter the investment necessary for rigorous clinical testing. *See* POM Br. 15-16. That argument is inapposite and meritless. First, any concerns about patent protection did not in fact deter POM either from investing tens of millions of dollars in its quest for medical proof, *e.g.*, CX0274_0001 [JA891], or from touting the patent eligibility of its products, *e.g.*, CX1426_039 [JA52]. Second, the FTC made clear that the evidentiary standards in this context are flexible and claim-specific and do not necessarily require compliance with "the FDA standard of proof for drugs." Op. 25 [JA609]. Third, "[a]llowing firms to continue [unsubstantiated] advertising because to stop would hurt the firm's economic interests is obviously not part of the calculus of interests Congress intended the FTC to consider." *Thompson Med.*, 791 F.2d at 196.

(quoting *Montgomery Ward & Co., Inc. v. FTC*, 691 F.2d 1322, 1327 (9th Cir. 1982)); *accord Arkansas v. Oklahoma*, 503 U.S. at 113 (reviewing court "should accept [an] agency's factual findings if those findings are supported by substantial evidence on the record as a whole," whether or not a challenger can "identify[] alternative findings that could be supported by substantial evidence") (emphasis omitted); *see also Florida Gas Transmission*, 604 F.3d at 645 (substantial-evidence standard "requires more than a scintilla, but … less than a preponderance of the evidence") (internal quotation marks omitted).

Finally, petitioners are wrong to contend that the Commission's RCT determination "depart[s] from … prior precedent." Tupper Br. 13; *see also* POM Br. 8, 10, 55. To the contrary, decades of FTC precedent imposed RCT requirements in similar circumstances and with judicial approval. In *Thompson Medical*, for example, this Court affirmed an FTC order holding a topical-analgesic manufacturer liable for lacking adequate substantiation for its pain-relief claims. In that 1986 decision, the Court noted approvingly that "[t]he FTC has usually required two well-controlled clinical tests" to substantiate generalized establishment claims—*i.e.*, messages that "scientific tests" support a product's asserted medical benefits. 791 F.2d at 194. That observation has special significance for this case, in which 34 of the 36 ads forming the basis for liability contain establishment claims in addition to efficacy claims. *See* p. 17, *supra.* The

Thompson Medical Court further found that the FTC had acted reasonably in extending that two-RCT requirement even to the advertiser's basic efficacy claims, deferring to the Commission's "special expertise in determining what sort of substantiation is necessary to assure that advertising is not deceptive." 791 F.2d at 196.[22]

The Commission's substantiation findings here comport with—and indeed are more modest than—those upheld in *Thompson Medical*. Unlike petitioners, the advertiser in *Thompson Medical* made no claims that its topical cream could help treat or prevent life-threatening diseases; it simply offered pain relief. And the Commission here did not even go as far as it had gone in *Thompson Medical* because it explicitly held open the possibility that, for liability purposes, POM could have met the substantiation requirement even for its establishment claims with only one well-controlled study rather than two. Op. 3 [JA587]. Moreover,

[22] In the liability portion of its *Thompson Medical* decision, the FTC found that, at the time the ads were run, the manufacturer needed but lacked positive results from "two well-controlled clinical tests" to justify both its establishment claims and its efficacy claims. 104 F.T.C. at 820-21 (establishment claims); *id.* at 825-26 (efficacy claims). In the remedial portion, the FTC enjoined the manufacturer from making various claims in the future unless it first met the same substantiation standard used for liability—"two well-controlled clinical tests." *Id.* at 831-32. This Court upheld the entirety of the FTC's decision, as to both liability and remedy. *See*, *e.g.*, 791 F.2d at 194 ("the Commission has properly employed the framework established by its precedents in concluding that there was no reasonable basis shown here and in requiring two clinical studies"); *id.* at 197 ("We cannot find fault in the Commission's conclusions or in the remedial measures it imposed. Indeed, in all respects, we find the FTC Order and Opinion clear and logical.").

although the product at issue in *Thompson Medical* was an over-the-counter pain-relief cream rather than a dietary supplement, it was no less "safe" than POM's products here. *See Thompson Med. Co.*, 104 F.T.C. at 663, 703, 791 n.14.[23]

The Commission has also applied the same substantiation analysis to medical claims for food-derived products that it has applied to medical claims for other types of products. For example, the Commission observed in 2001 that even three clinical trials would be inadequate to substantiate a claim that a hypothetical "compound extracted from fruit" could help prevent blood clots if each trial was inadequately controlled or insufficiently probative. *2001 Dietary Supplement Guide* at 13 [JA807]. And just three years ago, this Court summarily upheld an FTC order against a manufacturer of herbal and animal-derived supplements that had advertised disease benefits without adequate substantiation. *Daniel Chapter One*, 405 Fed. Appx. at 506. Notably, petitioners cite neither *Thompson Medical* nor *Daniel Chapter One* in either of their two full-length briefs.[24]

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[23] In recent cases involving medical claims for a variety of "safe" products, federal district courts sitting as factfinders have likewise found that, to avoid deceiving consumers, advertisers must generally base such claims on RCTs. *See, e.g., FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 303 (D. Mass. 2008) (herbal dietary supplements), *aff'd*, 624 F.3d 1 (1st Cir. 2010); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 938-48 (N.D. Ill. 2006) (pain-relief device), *aff'd*, 512 F.3d 858 (7th Cir. 2008).

[24] Petitioners misconstrue various FTC materials as evidence that the decision below departs from precedent. First, petitioners assume that the phrase "competent and reliable scientific evidence," as it appears in prior FTC opinions, denotes a

C. POM's Disclaimers Did Not Cure Its Deceptive Messages.

As discussed, POM's disease claims were deceptive because they lacked adequate substantiation and distorted the scientific record. Petitioners nonetheless insist that they "carefully qualified" all their disease claims, POM Br. 3; Tupper Br. 22, and "describe[d] the supporting science in highly qualified language" as well, POM Br. 29. That is simply false, and in any event petitioners cannot overcome the deference the Commission is due when determining whether supposed disclaimers effectively neutralize otherwise deceptive messages that appear within an advertising message. *See*, *e.g.*, *Brown & Williamson*, 778 F.2d at 40 n.1, 42-43 (deferring to district court's finding that disclaimers were too inconspicuous and indicating that a similar FTC finding would have been entitled

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discrete level of substantiation less rigorous than an RCT standard. *E.g.*, Tupper Br. 11-12. That is incorrect: the phrase is generic and denotes whatever level of substantiation is warranted by the record in each case. *See*, *e.g.*, Op. 45 [JA629] (citing authorities). Second, the 2009 FTC staff speeches cited by petitioners did not address the substantiation showings needed to avoid *liability*. Instead, the speeches concerned how specific the Commission should be in its *remedial orders* about the substantiation requirements imposed as fencing-in relief on parties already deemed liable for deceptive advertising. *See*, *e.g.*, David Vladeck, *Priorities for Dietary Supplement Advertising Enforcement*, at 11-12 (Oct. 22, 2009) [JA930-941] (cited in Tupper Br. at 13). The speeches proposed that future remedial orders should explicitly confirm that, in certain cases, "competent and reliable scientific evidence" means RCTs. But they never suggested that the FTC should alter how it determines what constitutes such evidence for liability purposes.

to even greater deference); *see generally* pp. 9-10, *supra* (describing principles concerning disclaimers).

First, the FTC reasonably concluded that consumers would impute no particular significance to certain adjectives that petitioners describe as "qualifiers." For example, one ad described the results of POM's clinical research this way:

> We've been working with a number of top scientists, including a Nobel Laureate, for 6 years now and our seven published, peer-reviewed papers reveal heartening results. … [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%.

CX0029_0002 [JA826]. Another ad stressed that "[a] recently published pilot study" showed that "[a]fter drinking eight ounces of POM Wonderful 100% Pomegranate Juice daily for at least two years," 46 men previously treated for prostate cancer "experienced significantly slower average PSA doubling times." CX0379_0002 [JA910]. In each case, the supposed qualifier is the word "pilot." The Commission reasonably agreed with a testifying expert who "opined that the typical consumer would likely have little understanding of what 'initial' or 'pilot' means, particularly in the context of [a study] being referred to as having been published in a major journal." Op. 14 [JA598] (some internal quotation marks omitted).

Worse, petitioners' supposed "qualifiers" often succeeded only in magnifying rather than reducing the deceptively optimistic message of POM's

disease claims. As the Commission found, the use of qualifiers such as "promising," "encouraging," or "hopeful" does nothing to "alter the net impression that clinical studies prove [POM's] claims"; if anything, those qualifiers "provide a positive spin on the studies rather than a substantive disclaimer." *See* Op. 13 [JA597]; *see also* Op. A2-A3 [JA639-640] (discussing ineffectiveness of various POM disclaimers); *cf. 2001 Dietary Supplement Guide* at 7 [JA801] ("[v]ague qualifying terms—for example, that the product 'may' have the claimed benefit or 'helps' achieve the claimed benefit—are unlikely to be adequate"). Also, "in many instances, ads describing study results using such qualifying language include[d] other elements that also contribute[d] to the net impression that the claims at issue are clinically proven, such as … statements relating to the overall amount of money spent on 'medical' research, ranging from $20 million to over $30 million, depending on the relevant time period." Op. 14 [JA598]. The Commission's findings on these points are correct and, in any event, certainly not unreasonable.

POM is wrong to assert that, under the logic of this FTC decision, advertisers may now say "nothing … about the weight of the existence of evidence" until "a causal link has … been proven to an exacting level of certainty." POM Br. 13, 20.[25] As before, advertisers remain free to inform consumers about

[25] Petitioners note that practicing physicians sometimes recommend that their patients undergo certain medical procedures whose efficacy has not yet been established through RCTs. Pom Br. 21-22; Tupper Br. at 43 n.8, 51. But

"an emerging body of science" supporting a product claim if they include clear qualifying language "mak[ing] sure consumers understand both the extent of scientific support and the existence of any significant contrary evidence," so long as the claim is not "contrary to a stronger body of evidence." *2001 Dietary Supplement Guide* at 7 [JA801]. Indeed, the FTC explained that if POM "had made disclaimers such as those described in *Pearson*, … the Commission would have considered the representations in the ads in light of such statements." Op. 44 [JA628]. But POM made no such disclosures for the ads in question, and "[w]ithout such disclaimers, [those] ads are deceptive and misleading." *Id.* Moreover, for a number of ads, such disclosures would have been ineffective anyway insofar as POM's disease claims were "contrary to a stronger body of evidence," *2001 Dietary Supplement Guide* at 7 [JA801], such as the Davidson CMIT study, *see* Section I.B, *supra.*

Finally, petitioners rely in vain on a stock FDA-related disclaimer that POM buried in the small print of some of its ads. *See* POM Br. 37. That disclaimer appeared, for example, in a five-page advertising insert that, in highly medical and

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responsible physicians do exactly what POM did not do: they give each patient a *forthright and appropriately qualified* account of the likelihood that a particular procedure will yield results. Unlike an advertiser, a physician also serves as a learned and unbiased intermediary for each patient, using a full understanding of the relevant science to make reasoned decisions about that patient's individual needs.

quantitative terms, cited clinical studies as support for claims that POM_x Pills were effective in treating "atherosclerosis" and prolonging "PSA doubling time" (and thus life expectancy) for prostate-cancer patients. CX1426_0038-42 [JA51-55]. On a single page of that advertising insert, a keen-eyed reader might have noticed the following footnote in tiny font: "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." CX1426_0041 [JA54]; *see also* Addenda 2-4. POM derived that boilerplate from a provision of federal law regulating how dietary supplement manufacturers must present labeling claims about, *inter alia*, a supplement's effects on the structure or function of the body ("structure/function claims") or on general well-being. *See* 21 U.S.C. § 343(r)(6)(C).

This barely legible disclaimer did nothing to cure the deceptive message in this or similar ads. The whole point of the ad was to tell consumers that, according to clinical studies, POM_x Pills help fight "atherosclerosis" and "prostate cancer." CX 1426_0041-42 [JA54-55]. Those claims were prominent and deceptive, and POM could not cure that deception simply by tacking on obliquely contrary boilerplate in fine print. As this Court has held, a "fine-print legend[s]" cannot "eliminat[e] the deception" arising from "more visibl[e]" claims in the same ad. *Brown & Williamson*, 778 F.2d at 42-43.

The FTC has similarly explained:

> To ensure that disclosures are effective, marketers should use *clear language, avoid small type, place any qualifying information close to the claim being qualified, and avoid making inconsistent statements or distracting elements that could undercut or contradict the disclosure*. Because consumers are likely to be confused by ads that include inconsistent or contradictory information, disclosures need to be both direct and unambiguous to be effective.

2001 Dietary Supplement Guide at 7 [JA801] (emphasis added). POM's tiny boilerplate violated nearly every one of these principles. POM used "small type" that consumers could barely read. POM did not place its boilerplate "close to" any particular "claim being qualified" within this five-page insert. It did not explain in "direct and unambiguous terms" how the boilerplate "qualified" any such claim. And the ad's disease claims "undercut" and "contradict[ed]" the boilerplate for those few readers who read it in the first place. "A statement that studies prove a product cures a certain disease, followed by a disclaimer that … the product actually does not cure the disease, leaves an overall impression of nonsense, not clarity." *Direct Mktg. Concepts*, 624 F.3d at 12 n.9.[26]

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[26] Indeed, this FDA-oriented disclaimer violates even the statutory provision from which it arises. The Federal Food, Drug, and Cosmetic Act requires the use of the disclaimer to accompany, *inter alia*, structure/function claims (and claims of general well-being) in labeling for dietary supplements. The same provision expressly prohibits manufacturers that use the disclaimer from "claim[ing] to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." 21 U.S.C. § 343(r)(6). Again, the whole point of this and similar ads was to claim that POM_x Pills did "treat" or "mitigate" both prostate cancer and atherosclerosis and help "prevent" heart disease. In fact, the FDA sent POM a warning letter in

II. PETITIONERS' FIRST AMENDMENT CHALLENGE TO THE FTC'S LIABILITY FINDINGS ASSUMES AWAY THE MISLEADING CHARACTER OF THEIR ADVERTISEMENTS.

As discussed, the FTC reasonably concluded after formal adjudication that the advertisements underlying petitioners' liability were materially false or misleading and thus violated the FTC Act. That conclusion is a complete answer to petitioners' First Amendment challenge to the FTC's liability findings.

"For commercial speech to come within [the First Amendment], it at least must concern lawful activity and *not be misleading*." *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of NY*, 447 U.S. 557, 566 (1980) (emphasis added).[27] Thus, as this Court reaffirmed three years ago, "[d]eceptive commercial speech," including any inadequately substantiated disease claim, "is entitled to no protection under the First Amendment." *Daniel Chapter One*, 405 Fed. Appx. at

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2010 concluding that "your POM Wonderful 100% Pomegranate Juice product is promoted for conditions that cause the product to be a drug" under the Food, Drug, and Cosmetic Act because "it is intended for use in the cure, mitigation, treatment, or prevention of disease." CX0344_0001 [JA963].

[27] *Accord Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 638 (1985) ("The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading."); *In re R.M.J.*, 455 U.S. 191, 203 (1982) ("Misleading advertising may be prohibited entirely."); *Bates v. State Bar of Arizona*, 433 U.S. 350, 383 (1977) ("Advertising that is false, deceptive, or misleading of course is subject to restraint.").

506 (upholding liability finding for dietary supplement manufacturers who made unsubstantiated disease claims).[28]

This category of unprotected misleading speech includes not only "actually false" statements, as petitioners suggest (POM Br. 24), but also statements that may be literally accurate but are nonetheless misleading. The First Amendment poses "no obstacle" to the prohibition even of commercial speech that "is not provably false, or even wholly false, but only deceptive and misleading," because the government should ensure that "the stream of commercial information flow[s] cleanly as well as freely." *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771-72 (1976).

As this Court has explained, that principle promotes the very First Amendment values that justify extending some constitutional protection to *non*-misleading commercial speech in the first place:

> Both consumers and society have a strong interest "in the free flow of commercial information," *see Virginia State Board* [425 U.S. at 763], and it is this interest in ensuring the flow of that information essential to "the proper allocation of resources" and the regulation of our economy that the first amendment vindicates in extending its scope to

[28] Petitioners have not disputed—either before the FTC or on appeal—that the advertisements in question are "commercial speech" for First Amendment purposes. *See generally Pittsburgh Press Co. v. Human Relations Comm'n*, 413 U.S. 376, 385 (1973). Petitioners and Complaint Counsel did dispute below whether certain media appearances should be classified as commercial speech, but the FTC declined to predicate liability on those appearances. Op. 46-47 [JA630-631].

> commercial speech. *Id.* at 765. Yet, *"[f]alse, deceptive, or misleading advertising" does not serve, and, in fact, disserves, that interest*, and thus the subcategory of commercial speech consisting of false and deceptive advertising "remains subject to restraint." *In re R.M.J.*, 455 U.S. 191, 200 (1982). In fact, *"[m]isleading advertising may be prohibited entirely." Id.* at 203.

Brown & Williamson, 778 F.2d at 43 (emphasis added). That holding refutes petitioners' claim that effective enforcement of deceptive-advertising law "deprive[s] consumers of information." POM Br. 7. Indeed, effective enforcement gives advertisers sound incentives to present their claims in non-misleading ways and thus to convey more rather than less useful information to the public.

As this Court has also held, 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. *Brown & Williamson*, 778 F.2d at 40 n.1; *accord Colgate-Palmolive*, 380 U.S. at 385; *Kraft*, 970 F.2d at 316-318. Petitioners' First Amendment challenge to the FTC's liability findings is thus pure makeweight.

Petitioners try to escape this First Amendment precedent by arguing that their advertisements were only "*potentially* misleading" rather than "*actually* misleading" and are thus subject to the three-part *Central Hudson* analysis. POM Br. 2. But the FTC found that petitioners' ads were indeed actually misleading because, among other things, they distorted the scientific record. Op. 41-42 [JA625-626]. Petitioners argue that this characterization is wrong because, they

say, a given product claim is only potentially rather than inherently misleading "'if the information also may be presented in a way that is not deceptive,'" such as through the use of "corrective disclaimers." POM Br. 33-34 (quoting *R.M.J.*, 455 U.S. at 203). But that distinction between "potentially" and "inherently" misleading speech is simply inapposite in this context, where concrete ads have already been run, where they are the subject of individual scrutiny, and where they are either misleading or not, depending on what specific claims they conveyed to consumers and whatever specific disclaimers they may have contained.

In particular, courts use the category of "potentially misleading" commercial speech when assessing the constitutionality of *ex ante* speech regulations that prospectively ban all messages conveying specified information even if the information can be conveyed in ways that are not misleading. In that context, if "the information … may be presented in a way that is not deceptive," such as through effective "disclaimers or explanation," it is characterized as only "potentially misleading," and an "absolute prohibition" on conveying such information in any and all forms is subject to constitutional challenge under *Central Hudson*. *R.M.J.*, 455 U.S. at 203.

Pearson v. Shalala, on which petitioners heavily rely, illustrates this point. The plaintiffs there challenged an FDA regulation that prospectively barred them from making certain types of health claims on their product labels whether or not

the claims could be adequately qualified to avoid misleading consumers. 164 F.3d at 651. This Court thus addressed whether, under the First Amendment, the FDA could prohibit the future use of such claims in any and all forms by "unequivocally reject[ing] the notion of requiring disclaimers to cure 'misleading' health claims." *Id.* at 655. The Court concluded that FDA's regulation raised constitutional concerns because the information to be conveyed was only "potentially misleading"—*i.e.*, it was possible to imagine disclaimers that could "correct for deceptiveness." *Id.* at 660. The Court held that such disclaimers, where available, are "constitutionally preferable to outright suppression." *Id.* at 657.[29]

These principles have no logical application here. The FTC is *not* prophylactically banning defined types of future commercial messages regardless of how they are worded and whether or not they are combined with effective disclaimers. Instead, the FTC is judging actual ads, in light of any disclaimers they contained, to determine whether they have in fact misled consumers. In that enforcement context, a given ad either includes effective disclaimers or it does not, and it is either misleading or it is not. *See Kraft*, 970 F.2d at 317 (a "prophylactic regulation … completely prohibiting an entire category of potentially misleading

[29] The court added, however, that the FDA could deem a claim "incurable by a disclaimer and ban it outright" where "evidence in support of the claim is qualitatively weaker than evidence against the claim—for example, where the claim rests on only one or two old studies." 164 F.3d at 659 & n.10 (emphasis omitted).

commercial speech" is constitutionally distinct from "an individualized FTC cease and desist order, prohibiting a particular set of deceptive ads"). Here, the FTC concluded that petitioner's actual advertisements made materially misleading claims that lacked effective disclaimers and contained "many omissions of material facts … that consumers cannot verify independently." Op. 43 [JA627]; *see* Section I.B, *supra*. Such claims are not "potentially misleading"; they are *actually* misleading, and that is the end of the First Amendment inquiry.

Although petitioners repeatedly suggest otherwise, courts do *not* use the term "potentially misleading" to describe real-life ads that mislead many but not all consumers. Every case that petitioners cite on this point (*see* Pom Br. 23-38) uses the term "potentially misleading" in the same way that *Pearson* uses it: to describe types of information that are banned by *ex ante* regulations no matter how they appear but that can be conveyed in a form that does not mislead consumers.[30]

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[30] *See Ibanez v. Florida Dep't of Bus. and Prof. Reg.*, 512 U.S. 136, 144-47 (1994) (invalidating state regulations restricting truthful advertising of accounting designations where there was no evidence that any consumer could be misled by them); *Peel v. Attorney Registration and Disciplinary Comm'n of Ill.*, 496 U.S. 91, 101, 106 (1990) (plurality op.) (invalidating professional conduct rules prohibiting attorneys from truthfully advertising "specialist" certifications where there was "no contention that any potential client or person was actually misled" and a "complete absence of any evidence of deception"); *Zauderer*, 471 U.S. at 649 (invalidating "broad prophylactic rules" prohibiting broad categories of truthful attorney advertising where there was no basis for inferring consumer deception); *R.M.J.*, 455 U.S. at 203 (invalidating professional conduct rules restricting attorney advertising that amounted to "an absolute prohibition on certain types of potentially misleading information, *e.g.*, a listing of areas of practice," even though

Petitioners cite no decision that extended any First Amendment protection to particular commercial advertisements that had already been disseminated and were in fact misleading.

Moreover, longstanding precedent affirmatively forecloses petitioners' argument that the category of constitutionally protected "potentially misleading" speech includes speech that is actually misleading to many but not all consumers. As this Court has explained, "advertisements reasonably capable of being interpreted in a misleading way are unlawful even though other, non-misleading interpretations may also be possible." *Thompson Med.*, 791 F.2d at 197 (quoting and affirming FTC position). Accordingly, the Commission has held for decades that "[a]n ad is misleading if at least a significant minority of reasonable consumers are likely to take away the misleading claim." *In re Telebrands Corp*., 140 F.T.C. 278, 291 (2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006); *1984 Deception*

"the information also may be presented in a way that is not deceptive"); *see also Central Hudson*, 447 U.S. at 558 (utility regulation "completely ban[ning]" any promotional advertising); *Friedman v. Rogers*, 440 U.S. 1, 3 (1979) (state statute prohibiting practice of optometry under trade name); *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 449 (1978) (professional conduct rule prohibiting attorneys' in-person solicitation of clients); *Bates*, 433 U.S. at 353 (professional conduct rule prohibiting any attorney advertising); *Brown & Williamson*, 778 F.2d at 36 (affirming tobacco company's liability for deceptive advertising, and *upholding* remedy of banning advertising of cigarette tar content outside a prescribed range); *Alliance for Natural Health U.S. v. Sebelius*, 786 F. Supp. 2d 1, 15 (D.D.C. 2011) (same FDA regulation as in *Pearson*).

Statement, 103 F.T.C. at 177 n.20; *see also Nat'l Comm'n on Egg Nutrition v. FTC*, 570 F.2d 157, 161 n.4 (7th Cir. 1977).[31] If petitioners' contrary position were correct, any advertiser who intentionally misled many consumers within its target audience could trigger First Amendment protection by subtly conveying to savvier consumers that the advertiser's product claims are not to be taken at face value. That is not the law.

In any event, even if petitioners were correct that the First Amendment protects advertisers who are careful to mislead fewer than all viewers, that principle would not actually help petitioners themselves because *their* ads could have been expected to mislead virtually any viewer. *See* Section I.B, *supra*. For example, even the savviest readers of POM's "30%" arterial plaque claim would have been unaware that the cited figure was based on a minuscule and flawed study and was contradicted by POM's larger and more rigorous clinical trials. In short, POM could not be more wrong in suggesting that any consumer could

[31] Although the Commission recited that standard here and found that POM's ads conveyed given messages "to *at least* a significant minority of reasonable consumers," *e.g.*, Op. at 12 [JA596] (emphasis added), it did *not* find that *only* a significant minority would take away those messages. Indeed, POM's advertising campaign conveyed quite unambiguous assertions about, for example, the findings of certain clinical studies relevant to specific diseases. *See*, *e.g.*, Section I.A, *supra.* It is thus unclear why amici CHPA et al. view this case as a vehicle for attacking the "significant minority" standard (Br. 13-19); the standard played no evident role in the Commission's decision.

"accurately read [such] advertisements as straightforward and qualified summaries of existing science." POM Br. 24.

Finally, petitioners' efforts to portray deceptive-advertising enforcement as "viewpoint discrimination" (POM Br. 8) are misconceived because they ignore the basic distinction between public debate and misleading product marketing. *See Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 65-68 (1983). *Outside* the commercial-speech context, people are generally free to make whatever claims they wish without government intervention. For example, the First Amendment protects the ability of people in general to argue that homeopathy, acupuncture, or shark-cartilage extract is effective in treating cancer. A law prohibiting such arguments would very likely be invalidated as viewpoint discrimination. But the government may prohibit commercial actors from inducing consumers to buy shark-cartilage extract from them by deceptively promising that such extract is effective at fighting cancer. *See Daniel Chapter One, supra*; *see also Bolger*, 463 U.S. at 65-68. Of course, POM or any other commercial speaker subject to an FTC enforcement action "is free to voice its disagreement with the FTC in every medium" *except* misleading commercial speech. *Brown & Williamson*, 778 F.2d at 45.[32]

[32] Petitioners contend that if this Court accepts their argument that the *Central Hudson* analysis applies to the FTC's liability findings, the Court "need not remand the case because the Commission did not even attempt to argue that its

III. THE COMMISSION'S FENCING-IN REMEDY COMPLIES WITH THE FIRST AMENDMENT AND IS JUSTIFIED ON THIS RECORD.

Having found that petitioners violated the FTC Act, the FTC adopted a remedial order with appropriate fencing-in relief specific to petitioners. In the future, petitioners "must have at least two RCTs before making any representation regarding a product's effectiveness in the diagnosis, treatment, or prevention of any *disease*." Op. 51 [JA635] (emphasis added). Petitioners may continue to make general *health*-related claims so long as they satisfy generally applicable substantiation requirements. Op. 52 [JA636]; Order 2-3 [JA579-580]. The Commission determined that this two-RCT substantiation requirement was necessary to ensure that petitioners do not continue their long track record of distorting scientific evidence when portraying the disease benefits of their products.

Petitioners complain that, rather than holding them accountable for running misleading ads that lacked any effective disclaimers, the Commission should have merely "direct[ed] them to correct or strengthen those disclaimers," POM Br. 37, or "simply have required that [their] representations be 'non-misleading,' " *id.* at

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Order could withstand First Amendment scrutiny" under that analysis. POM Br. 6. This makes no sense. If this Court were to impose *Central Hudson*-style rules in this context, it should remand to the Commission for an application of those rules in the first instance. *See*, *e.g.*, *Pearson*, 164 F.3d at 659-60.

55.[33] But the Commission's choice of remedies in false-advertising cases has never been confined to orders merely directing wrongdoers to stop violating the law. "Having been caught violating the [FTC] Act, respondents 'must expect some fencing in.'" *Colgate-Palmolive*, 380 U.S. at 395 (quoting *FTC v. National Lead Co.*, 352 U.S. 419, 431 (1957)). Specifically, the Commission may issue injunctions containing "provisions … that are broader than the conduct that is declared unlawful." *Telebrands Corp. v. FTC*, 457 F.3d 354, 357 n.5 (4th Cir. 2006). The Commission need not restrict its orders to the "narrow lane" of a wrongdoer's past violations, but may effectively "close all roads to the prohibited goal." *FTC v. Ruberoid Co*., 343 U.S. 470, 473 (1952). In deceptive-advertising cases in particular, the Commission may impose substantiation requirements that are reasonably related to preventing unlawful conduct even though those requirements may exceed what would be required of companies that have *not* been found liable for deceptive advertising. *See*, *e.g.*, *Removatron Int'l Corp.*, 884 F.2d at 1499.

Petitioners simply ignore that precedent when they argue that the FTC may impose substantiation requirements no more rigorous than it could require anyway

[33] Insofar as it relates to claim qualifications, this argument is not only wrong, but misdirected. If petitioners run future ads with effectively *qualified* disease claims, they would be subject only to Part III of the FTC's remedial order, which does not require RCT substantiation and, in that respect, treats petitioners the same as any other commercial advertiser. *See* Order 2-3 [JA579-580].

had it never found petitioners liable for their longstanding pattern of deceiving consumers about substantiation issues. *See* POM Br. 53. The cases petitioners cite for that perverse position (*see id.*) are inapposite because they all addressed prescriptive regulations addressed to the public at large, not fencing-in remedies against adjudicated wrongdoers who are potential recidivists.

Insofar as these fencing-in remedies are viewed as prophylactic measures, they—unlike the underlying liability findings—may be subject to analysis under *Central Hudson*. *See Novartis Corp. v. FTC*, 223 F.3d 783, 789 (D.C. Cir. 2000); *cf. R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1213 (D.C. Cir. 2012) (adopting even more lenient standard for "cases in which disclosure requirements are 'reasonably related to the State's interest in preventing deception of consumers'"); *Spirit Airlines, Inc. v. U.S. Dep't of Transp.*, 687 F.3d 403, 412-14 (D.C. Cir. 2012) (same). Restrictions on commercial speech meet that test if (1) "the asserted governmental interest is substantial"; (2) "the regulation directly advances the governmental interest asserted"; and (3) "it is not more extensive than is necessary to serve that interest." 447 U.S. at 566. In the commercial speech context, the government need not employ the least restrictive means of advancing its interest; rather, the restriction must "fit" the interest served—"a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is in proportion to the interest served." *Board of*

Trustees of State Univ. of New York v. Fox, 492 U.S. 469, 480 (1989) (internal quotation marks and citations omitted). "Within those bounds," it is for "governmental decisionmakers to judge what manner of regulation may best be employed." *Id*.

In practice, this test is undemanding when, as in this case, a speech restriction applies only to parties who have already been found liable for deceptive advertising. *See Novartis*, 223 F.3d at 789. As the Fourth Circuit has explained, the FTC has "broad discretion" in fashioning effective remedies for violations of the FTC Act, and "courts will interfere with the remedy selected by the FTC 'only where there is no reasonable relation between the remedy and the violation.'" *Telebrands*, 457 F.3d at 358 (quoting *Atlantic Ref. Co. v. FTC*, 381 U.S. 357, 377 (1965)); *accord Chrysler Corp. v. FTC*, 561 F.2d 357, 364 (D.C. Cir. 1977).

That standard is easily met here. First, "there is no question that [the government's] interest in ensuring the accuracy of commercial information in the marketplace is substantial." *Edenfield v. Fane*, 507 U.S. 761, 769 (1993); *accord Spirit Airlines*, 687 F.3d at 415; *Novartis*, 223 F.3d at 789; *Pearson*, 164 F.3d at 656; *Brown & Williamson*, 778 F.2d at 43. Second, the Order directly advances this interest by enjoining petitioners from making the very type of false or deceptive disease claims that their challenged advertisements have conveyed. *See* Order 2-3 [JA579-580].

Third, the Order's scope is narrowly tailored to serve the government's interest in preventing recidivism by these petitioners. The Commission unanimously found that petitioners "demonstrated [a] propensity to misrepresent to their advantage the strength and outcomes of scientific research … about serious diseases." Op. 51 [JA635]. Moreover, they "made serious yet unsupported claims about three diseases, some of which can be life-threatening," and they were entirely aware of "the inconsistency between the results of some of their later studies and the results of earlier studies to which [they] refer in their ads." Op. 49 [JA633]. This is thus *not* a case where an advertiser made good-faith qualified claims of disease benefits that fell just short of the necessary level of scientific support. *Cf.* POM Br. 55. Instead, over half a dozen years, petitioners distorted the scientific record concerning potentially fatal diseases, all as part of a "deliberate and consistent course of conduct" that was "no mere isolated incident or mistake." Op. 51 [JA635]; *see generally* Section I.B, *supra*.

The Commission thus acted reasonably when, for purposes of designing an appropriate remedy, it unanimously "agree[d] with the ALJ's conclusion that [petitioners'] actions were serious and deliberate." Op. 49 [JA633]; *see* ID 312-13 [JA391-392].[34] The Commission likewise acted reasonably when it required that

[34] Petitioners' record of deception would justify the Commission's remedies even if POM were correct that "egregious or deliberate conduct is necessary to justify broad fencing-in orders." POM Br. 55. In any event, that is not the

these highly culpable petitioners justify any future disease claims with two RCTs rather than one. That remedy comports with FTC precedent, imposes belt-and-suspenders safeguards against the risk that petitioners will again misrepresent clinical results, and is grounded in expert testimony that replication of clinical results helps confirm the veracity of scientific claims. Op. 51 [JA635]; *see also Thompson Med.*, 791 F.2d at 195-96 (upholding two-RCT remedial order). *See generally Colgate-Palmolive*, 380 U.S. at 392 (extending deference to FTC's expertise in "determining the type of [remedial] order that is necessary to cope with the unfair practices found").

Finally, the Commission also acted reasonably in extending its fencing-in remedy to the products manufactured by petitioner Roll Global LLC as well as POM Wonderful on the ground that petitioners' collective propensity for distorting science "would be transferable to [their] other products." Op. 50 [JA634] (citing *Colgate-Palmolive Co.*, 380 U.S. at 394-95; *Telebrands*, 457 F.3d at 361-62; *Kraft*, 970 F.2d at 326-27; *American Home Prods. Corp. v. FTC*, 695 F.2d 681, 704-10 (3d Cir. 1982)). Both POM and Roll are wholly owned by petitioners Stewart and

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standard. *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385 (9th Cir. 1982), which POM cites for this point, adopts no such standard; the court merely agreed with the FTC that the advertiser's conduct in that case had, in fact, been "flagrant and egregious." *Id.* at 396. Under longstanding precedent, the relevant legal question is simply the "'seriousness and deliberateness of the violation.'" Op. 49 [JA633] (quoting *In re Stouffer Foods Corp.*, 118 F.T.C. 746, 811 (1994)).

Lynda Resnick (through a revocable trust), and the two companies extensively share marketing resources. Indeed, POM used Roll's in-house marketing agency for the advertising campaign at issue here. IDF 138 [JA100]. As both the ALJ and the Commission recognized, both companies "could use similar marketing techniques to make disease claims about other food products, including the other food products [petitioners] currently sell," such as FIJI Water and Wonderful Pistachios. Op. 50-51 [JA634-635].

Petitioners claim that the FTC should not have "bann[ed] Roll from saying anything about the *health benefits* of its other products" unless Roll first meets the two-RCT requirement set forth in the remedial order. POM Br. 56 (emphasis added). But the FTC imposed no such ban. It made clear that the two-RCT requirement "applies only to claims for disease prevention, risk reduction, and treatment." Op. 52 [JA636]. And it stressed that "future representations relating to efficacy or health benefits of covered products that fall short of disease claims are covered by Part III of the Order." *Id.* That section does *not* prescribe a two-RCT standard for generalized health-benefit claims and, indeed, subjects petitioners to the same substantiation requirements as any other advertiser of health benefits for food products. *Id.*

IV. THE COMMISSION REASONABLY FOUND MR. TUPPER LIABLE.

To impose non-monetary injunctive relief against an individual, the FTC must show either that "the individual participated directly in the business entity's deceptive acts or practices" or that he "had the authority to control such acts or practices." *FTC v. Freecom Commc'ns, Inc.*, 401 F.3d 1192, 1204 (10th Cir. 2005). This is a disjunctive test: "[e]ither participation or control suffices." *QT*, 512 F.3d at 864; *see also Direct Mktg. Concepts*, 624 F.3d at 12; *FTC v. Publ'g Clearing House, Inc.*, 104 F.3d 1168, 1170 (9th Cir. 1997); *FTC v. Amy Travel Serv. Inc.*, 875 F.2d 564, 573 (7th Cir. 1989). Here, the Commission found that petitioner Matthew Tupper—POM's COO and ultimately its President during the relevant period—was liable because he "*both* participated directly in *and* had the authority to control the acts or practices at issue." Op. 52 [JA636] (emphasis added); *see also* IDF 36-53 [JA89-90].

Mr. Tupper does not deny that he "participated directly in" the relevant advertising practices, but he does deny that he "had the authority to control" them. As he acknowledges (Br. 31), that argument could help him only if this Court were to reject the position of every other court that has addressed the issue and convert the disjunctive "participate or authority to control" standard into a conjunctive "participate *and* authority to control" standard. But that position has been rejected because it would perversely enable the individuals most directly responsible for

any fraud to escape liability simply by claiming that they were just following orders from a more senior corporate official, even if that official was involved only in giving general direction and providing formal sign-off.

In any event, even if petitioners' conjunctive standard were the law, and even if wrongdoers could thus invoke a "just-following-orders" defense to fraud, Mr. Tupper would *still* be subject to liability here because he could not plausibly invoke such a defense himself. As the FTC found, Mr. Tupper:

- "managed the day-to-day affairs of POM, including its marketing team, … and had the authority to determine which advertisements should run";
- "had the authority to hire and fire … the head of POM's marketing department";
- "implement[ed] POM's direction with regard to health benefit advertising and the use of science in connection with the advertising";
- "was heavily involved in the direction of POM's medical research";
- "participated in meetings reviewing advertising concepts and content, and reviewed, edited, and in some cases had the final say on advertising concepts and advertising copy"; and
- "provid[ed] specific medical language for use in advertisements [and] draft[ed] magazine cover wraps found by the ALJ (and here by the Commission) to have made the claims alleged by Complaint Counsel."

Op. 53 [JA637]. Given these findings, which Mr. Tupper does not contest, it is difficult to imagine a clearer case of "control."

Finally, Mr. Tupper contends that "providing individual liability requires a showing of knowledge." Br. 34. That is simply incorrect. A showing of

knowledge is necessary only when the FTC seeks equitable *monetary* relief against an individual, not when it imposes, as here, a mere cease-and-desist order. *See*, *e.g.*, *FTC v. World Travel Vacation Brokers, Inc.*, 861 F.2d 1020, 1029 (7th Cir. 1988); *Amy Travel*, 875 F.2d at 573. Mr. Tupper's claims of good faith (Br. 33-37) are irrelevant for that reason alone. In any event, he does not deny that he "was heavily involved in the direction of POM's medical research," "implement[ed] POM's direction with regard to health benefit advertising and the use of science in connection with the advertising," personally oversaw "specific medical language for use in advertisements," and "reviewed, edited, and in some cases had the final say" on advertising copy. Op. 52 [JA636]. Given those uncontested facts, it is difficult to credit his claims that he did not know, for example, that it was misleading for POM to run ads extolling the supposed ability of POM products to reduce arterial plaque by "up to 30%" years after the Davidson and Ornish CMIT studies showed no such effect. *See* Section I.B.1, *supra.*

V. PETITIONER TUPPER'S ARGUMENT THAT THE FTC VIOLATED THE APA BY ACTING THROUGH ADJUDICATION RATHER THAN RULEMAKING IS BOTH WAIVED AND MERITLESS.

Petitioner Tupper argues that the Commission violated the Administrative Procedure Act because it did not "initiate a rulemaking or issue new policy guidance" before finding petitioners liable for making inadequately qualified disease claims even though they lacked even a single RCT to substantiate those

claims. Tupper Br. 52-56. That argument is not properly before the Court and lacks merit in any event.

First, Mr. Tupper has waived this APA claim because neither he nor any other petitioner presented it to the FTC, which is why the FTC did not address it. Petitioners *did* argue below that predicating liability on an RCT standard would violate "the constitutional guarantee that liberty cannot be deprived without due process of the law." POM *et al*. Answ. Br. at 24 [JA554]. The FTC properly rejected that claim, Op. 45-46 [JA629-630], and Mr. Tupper does not seek to revive it. Instead, he argues that, whatever the constitutional standard might be, the FTC violated the APA by adopting what he calls a "legislative rule" through adjudication rather than notice-and-comment rulemaking. Tupper Br. 52. Before the FTC, however, petitioners did not present this APA claim; at most, they presented APA precedents in passing to bolster their due process claim.[35]

[35] In particular, petitioners argued that the FTC would "compound[] the due process problem" if it adopted an RCT standard "through adjudication," and they asserted that those precedents "reinforce[d] due process values." POM *et al*. Answ. Br. at 27-28 [JA557-558]. But that passage did not clearly make any standalone APA claim, and it appeared only in a single paragraph within a five-page section entitled "Penalizing Respondents For Failure To Meet An RCT Substantiation Requirement Would Violate Respondents' Right To Due Process Of The Law." *Id.* at 24 [JA554]. Moreover, that due process section appeared within the context of a 44-page brief that was one of five briefs filed collectively by petitioners on appeal from the ALJ's order.

This Court has "repeatedly held" that an agency "'need not sift pleadings and documents to identify' arguments that are not 'stated with clarity' by a petitioner." *New England Pub. Commc'ns Council, Inc. v. FCC*, 334 F.3d 69, 79 (D.C. Cir. 2003) (quoting *Bartholdi Cable Co., Inc. v. FCC*, 114 F.3d 274, 279 (D.C. Cir. 1997)) (some internal quotation marks omitted). Here, the Commission could not have been expected to view petitioners' passing recitation of APA precedents as a standalone APA claim rather than as mere support for their constitutional due process claim. In short, petitioners did not effectively "flag[] the relevant issues" (*id.*) even though they could have done so, and they have therefore waived this claim for purposes of judicial review. *See CSX Transp., Inc. v. Surface Transp. Bd.*, 584 F.3d 1076, 1079 (D.C. Cir. 2009) (under "the well-established doctrine of issue waiver," courts may disregard "arguments not raised before the agency where the party had notice of the issue").

In any event, petitioners' APA argument is without merit. Under the *Bell Aerospace* doctrine, "[a]gencies often have a choice of proceeding by adjudication rather than rulemaking," *Central Texas Tel. Co-op, Inc. v. FCC*, 402 F.3d 205, 210 (D.C. Cir. 2005), and that choice "'lies in the first instance within the [agency's] discretion.'" *Cassell v. FCC*, 154 F.3d 478, 486 (D.C. Cir. 1998) (quoting *NLRB*

v. Bell Aerospace Co., 416 U.S. 267, 294 (1974)).[36] Indeed, some agencies, such as the National Labor Relations Board, develop doctrine almost entirely through adjudication. *See Bell Aerospace*, *supra.* Here, just as common-law courts properly flesh out tort and property-law principles through case-specific precedents, the FTC may properly develop false-advertising doctrine through case-by-case adjudication rather than notice-and-comment rulemaking.

Mr. Tupper notes that courts have required agencies to conduct notice-and-comment rulemaking to implement new policy in particular contexts, but the cases he cites for this argument (Br. 52-55) are inapposite. Those cases merely required the agencies in question to follow APA rulemaking procedures when they issued informal or supposedly nonbinding policy guidance that in fact made substantive changes in the agencies' existing regulations. *See*, *e.g.*, *Appalachian Power Co. v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000). Those decisions do not remotely suggest that agencies somehow trigger APA rulemaking obligations whenever they decide legal issues in the course of a highly structured adjudication such as this. That proposition would turn the rule of *Bell Aerospace* on its head, and it would have

[36] *See also Warner-Lambert Co. v. FTC*, 562 F.2d 749, 759 n.45 (D.C. Cir. 1977) (rejecting argument that the Commission, in ordering corrective advertising, should have proceeded by rulemaking rather than adjudication); *National Petroleum Refiners Ass'n v. FTC*, 482 F.2d 672, 679 (D.C. Cir. 1973) (reaffirming, while upholding the Commission's authority for substantive rulemaking, "the primacy of adjudication in the development of agency policy").

especially perverse effects for the development of false-advertising law. As this Court itself suggested in *Pearson*, "adjudication … would seem a more natural fit" than rulemaking for precisely the type of "individualized determination" at issue here: whether a claim is sufficiently substantiated. 164 F.3d at 652 (noting that Congress nonetheless mandated rulemaking in the FDA labeling context); *see also SEC v. Chenery Corp.*, 332 U.S. 194, 202-03 (1947) (identifying various circumstances in which adjudication is preferable to rulemaking).

Finally, Mr. Tupper's argument for mandating a rulemaking approach also depends on the flawed premise that the FTC effected major changes in its substantiation standards in 2009. That premise is factually incorrect for the reasons discussed above. *See* p. 56 and note 24, *supra*.

CONCLUSION

The petition for review should be denied.

/s/ Jonathan Nuechterlein

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March 25, 2014

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7) and this Court's Circuit Rule 32(a), I hereby certify that the foregoing Brief of Respondent Federal Trade Commission complies with the type-volume limitations of this Court's Order of January 8, 2014, because it contains 20,684 words, excluding the parts of the brief exempted by the Federal Rules of Appeallate Procedure and this Court's Circuit Rules.

March 25, 2014 /s/ Imad Abyad
Imad D. Abyad

CERTIFICATE OF SERVICE

I hereby certify that on March 25, 2014, I filed the foregoing Brief of Respondent Federal Trade Commission, using this Court's CM/ECF system (in addition to the eight (8) paper copies filed pursuant to this Court's Circuit Rule 31(b)). All counsel of record in this case are registered CM/ECF users and will be served by this Court's CM/ECF system, pursuant to Circuit Rule 25(c).

/s/ Imad Abyad
Imad D. Abyad

ADDENDA

TABLE OF CONTENTS

ADDENDUM

1

STATUTES AND REGULATIONS

15 U.S.C. § 45. Unfair methods of competition unlawful; prevention by Commission

(a) Declaration of unlawfulness; power to prohibit unfair practices; inapplicability to foreign trade

(1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.

(2) The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations, except banks, savings and loan institutions described in section 57a (f)(3) of this title, Federal credit unions described in section 57a (f)(4) of this title, common carriers subject to the Acts to regulate commerce, air carriers and foreign air carriers subject to part A of subtitle VII of title 49, and persons, partnerships, or corporations insofar as they are subject to the Packers and Stockyards Act, 1921, as amended [7 U.S.C. 181 et seq.], except as provided in section 406(b) of said Act [7 U.S.C. 227 (b)], from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

(3) This subsection shall not apply to unfair methods of competition involving commerce with foreign nations (other than import commerce) unless—

(A) such methods of competition have a direct, substantial, and reasonably foreseeable effect—

(i) on commerce which is not commerce with foreign nations, or on import commerce with foreign nations; or

(ii) on export commerce with foreign nations, of a person engaged in such commerce in the United States; and

(B) such effect gives rise to a claim under the provisions of this subsection, other than this paragraph.

If this subsection applies to such methods of competition only because of the operation of subparagraph (A)(ii), this subsection shall apply to such conduct only for injury to export business in the United States.

(4) (A) For purposes of subsection (a), the term "unfair or deceptive acts or practices" includes such acts or practices involving foreign commerce that—

(i) cause or are likely to cause reasonably foreseeable injury within the United States; or

(ii) involve material conduct occurring within the United States.

(B) All remedies available to the Commission with respect to unfair and deceptive acts or practices shall be available for acts and practices described in this paragraph, including restitution to domestic or foreign victims.

* * *

15 U.S.C. § 52. Dissemination of false advertisements

(a) Unlawfulness

It shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement—

(1) By United States mails, or in or having an effect upon commerce, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food, drugs, devices, services, or cosmetics; or

(2) By any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce, of food, drugs, devices, services, or cosmetics.

(b) Unfair or deceptive act or practice

The dissemination or the causing to be disseminated of any false advertisement within the provisions of subsection (a) of this section shall be an unfair or deceptive act or practice in or affecting commerce within the meaning of section 45 of this title.

* * *

15 U.S.C. § 55. Additional definitions

For the purposes of sections 52 to 54 of this title—

(a) False advertisement

(1) The term "false advertisement" means an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among

other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual. No advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied in each instance by truthful disclosure of, the formula showing quantitatively each ingredient of such drug.

* * *

ADDENDUM

2

VMS ID: 090312940
RUN DATE: 03/12/2009

LIVE LONG ENOUGH TO WATCH YOUR 401(K) RECOVER.

The Antioxidant Superpill.™

Antioxidants are a necessity. Not a luxury.

Emerging science suggests that antioxidants are critically important to maintaining good health because they protect you from free radicals, which can damage your body. Taking one POMx pill a day will help protect you from free radicals and keep you at your healthy best. Even when you're going through the worst.

Recession-proof your health with POMx.

POMx – an ultra-potent antioxidant extract made from the same pomegranates as POM Wonderful® 100% Pomegranate Juice – is the most potent natural antioxidant supplement available. Each 1000mg POMx pill has the antioxidant power of a full glass of POM Wonderful 100% Pomegranate Juice.

The antioxidant power of our 8oz juice.

$25 million in medical research. A sound investment.

POMx is made from the only pomegranates backed by $25 million in medical research at the world's leading universities. Not only has this research documented the unique and superior antioxidant power of pomegranates, it has revealed promising results for prostate and cardiovascular health.

Hope for the future. Yours.

Our POMx pills are made from the same pomegranates we use to make our POM Wonderful 100% Pomegranate Juice, on which each of the following medical studies was conducted.

An initial UCLA study on our juice found hopeful results for prostate health, reporting "statistically significant prolongation of PSA doubling times," according to Dr. Allen J. Pantuck in *Clinical Cancer Research*, '06.[1,2,3]

Two additional preliminary studies on our juice showed promising results for heart health. "Stress-induced ischemia (restricted blood flow to the heart) decreased in the pomegranate group," Dr. Dean Ornish reported in the *American Journal of Cardiology*, '05.[1,2,4]

"Pomegranate juice consumption resulted in significant reduction in IMT[5] (thickness of arterial plaque) by up to 30% after one year," said Dr. Michael Aviram in *Clinical Nutrition*, '04.[1,2,5,6]

Try POMx Monthly FREE for ONE MONTH.
We'll even pay for the shipping.*

Order Now: 888-766-7455 or pompills.com/n3
Use discount code: N330

*SIGN UP FOR POMx MONTHLY, AND WE'LL SEND YOUR FIRST BOTTLE FREE. AFTER THAT, YOU'LL CONTINUE TO RECEIVE MONTHLY SHIPMENTS FOR $29.95 WITH COMPLIMENTARY SHIPPING. Offer expires 5/30/09 and applies only to the purchase price for the first bottle of POMx Monthly. Following months will be $29.95 per bottle. One discount per customer. Cannot be combined with other offers. No substitutions, transfer rights or cash equivalents. We reserve the right to discontinue this promotion, change product price or shipping charge at any time. Valid only at pompills.com or 1-888-766-7455. Not valid on POMx Trial or other POM products.

POM WONDERFUL®

[1]pompills.com/research [2]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. [3]46 men with rising PSA after surgery or radiotherapy drank 8oz 100% pomegranate juice daily for two years. [4]45 patients with coronary heart disease and myocardial ischemia drank 8oz 100% pomegranate juice daily for three months. [5]Study measured intima-media thickness (IMT). [6]19 patients aged 65-75 years with severe atherosclerosis drank 8oz 100% pomegranate juice daily for one year.

VMS-0000293

CX0280_0001

Product POM X
Media: Print
Ad Title: Live Long Enough to Watch...
VMS Ad ID: 090312940
Date Range:

Run Date	Market	Rank	Media Vehicle	Media Type	Unit	Cost
08/01/2009	NATIONAL	0	Advocate	Magazine	Full Page	$964
11/01/2009	NATIONAL	0	Men's Health Magazine	Magazine	Full Page	$142,240
06/01/2009	NATIONAL	0	Men's Health Magazine	Magazine	Full Page	$127,060
10/25/2009	Albany GA	147	Albany Herald	Magazine	4 X 10	$2,073
07/17/2009	Albuquerque/Santa Fe	46	Albuquerque Journal	Local Newspaper	5 X 11.5	$7,020
03/22/2009	Albuquerque/Santa Fe	46	Albuquerque Journal	Local Newspaper	5 X 10.5	$6,410
07/19/2009	Alexandria LA	178	Alexandria Town Talk	Local Newspaper	3.75 X 11.5	$1,743
07/19/2009	Amarillo	131	Amarillo Globe-News	Local Newspaper	5 X 10.5	$2,697
03/22/2009	Austin	44	Austin American-Statesman	Local Newspaper	5 X 10.5	$11,011
03/22/2009	Bakersfield	125	Bakersfield Californian	Magazine	5 X 10.5	$3,824
05/27/2009	Boston	7	Quincy Patriot Ledger	Local Newspaper	4 X 10	$2,109
03/22/2009	Buffalo	51	Buffalo News	Local Newspaper	5 X 10.5	$12,662
08/02/2009	Cedar Rapids/Waterloo/Dubuque	88	Dubuque Telegraph-Herald	Local Newspaper	5 X 10	$1,681
05/11/2009	Cedar Rapids/Waterloo/Dubuque	88	Dubuque Telegraph-Herald	Local Newspaper	5 X 11	$1,849
05/15/2009	Chicago	3	Addison Press	Local Newspaper	4.5 X 11.5	$490
07/12/2009	Cincinnati	33	Cincinnati Enquirer	Local Newspaper	4.166667 X 11	$17,174
05/08/2009	Colorado Springs/Pueblo	92	Colorado Springs Gazette	Local Newspaper	5 X 10	$4,899
07/12/2009	Columbus OH	34	Columbus Dispatch	Local Newspaper	5 X 11	$12,185
03/22/2009	Dallas/Ft. Worth	5	Dallas Morning News	Local Newspaper	5 X 11.5	$38,820

07/12/2009	Detroit	11	Detroit News & Free Press Weekend	Local Newspaper	4 X 9.5	$21,073
07/19/2009	El Paso	97	El Paso Times	Local Newspaper	5 X 10.5	$6,241
10/25/2009	Fort Myers/Naples	65	Ft. Myers News-Press	Local Newspaper	4 X 9.5	$3,980
07/12/2009	Fort Myers/Naples	65	Ft. Myers News-Press	Local Newspaper	4 X 10	$4,322
03/22/2009	Fresno/Visalia	55	Fresno Bee	Local Newspaper	4.166667 X 10.5	$10,316
10/25/2009	Greenville/Spartanburg	36	Greenville News	Local Newspaper	4 X 10	$5,635
07/12/2009	Greenville/Spartanburg	36	Greenville News-Piedmont Compan	Local Newspaper	5 X 9.5	$6,904
03/22/2009	Houston	10	Houston Chronicle	Local Newspaper	5 X 11.5	$34,312
10/25/2009	Jacksonville/Brunswick	49	Jacksonville Florida Times Union	Local Newspaper	4 X 9.5	$7,948
07/12/2009	Jacksonville/Brunswick	49	Jacksonville Florida Times Union	Local Newspaper	4.5 X 9.5	$9,282
07/11/2009	Lafayette IN	188	Lafayette Journal and Courie	Local Newspaper	5 X 10	$2,394
07/19/2009	Los Angeles	2	La Opinior	Local Newspaper	5 X 9.5	$3,889
03/22/2009	Los Angeles	2	Los Angeles Times	Local Newspaper	5 X 10.5	$40,098
03/22/2009	Los Angeles	2	Riverside Press Enterprise	Local Newspaper	5 X 10.5	$7,262
08/09/2009	Los Angeles	2	San Bernardino Sur	Local Newspaper	4 X 9.5	$2,341
07/19/2009	Louisville	50	Louisville Courier-Journa	Local Newspaper	5 X 9.5	$13,150
07/12/2009	Milwaukee	35	Milwaukee Journal Sentine	Local Newspaper	4.5 X 8.5	$11,866
05/12/2009	Milwaukee	35	Milwaukee Journal Sentine	Local Newspaper	5 X 10	$15,511
08/02/2009	Minneapolis/St. Paul	15	Minneapolis Star Tribune	Local Newspaper	5 X 10.5	$14,982
07/26/2009	Minneapolis/St. Paul	15	St. Cloud Times	Local Newspaper	4 X 9	$1,895
07/12/2009	Mobile/Pensacola	60	Pensacola News Journa	Local Newspaper	5 X 10	$8,035
07/19/2009	Nashville	29	Nashville Tennessean	Local Newspaper	5 X 10.5	$16,531
03/22/2009	New York	1	Bergen Record	Local Newspaper	5 X 10.5	$11,638
07/26/2009	New York	1	Long Island Newsday	Local Newspaper	4.5 X 9.5	$25,375
07/26/2009	New York	1	New York Daily News	Local Newspaper	4 X 9.5	$25,834
03/15/2009	New York	1	New York Times	Local Newspaper	4.5 X 11.5	$60,014
10/25/2009	Panama City	156	Panama City News-Herald	Magazine	4 X 9.5	$1,647

07/12/2009	Panama City	156	Panama City News-Herald	Magazine	4.5 X 11.5	$2,480
07/26/2009	Philadelphia	4	Camden Courier-Post	Local Newspaper	4 X 9.5	$5,795
07/19/2009	Phoenix	12	Phoenix Arizona Republic	Local Newspaper	5 X 10	$21,310
03/22/2009	Portland OR	22	Portland Oregonian	Local Newspaper	4.5 X 11.5	$12,934
07/26/2009	Rochester NY	81	Rochester Democrat & Chronicle	Local Newspaper	4.5 X 9.5	$16,635
03/22/2009	Sacramento/Stockton/Modesto	20	Sacramento Bee	Local Newspaper	5 X 10.5	$14,080
03/22/2009	Salt Lake City	32	Salt Lake Tribune	Local Newspaper	5 X 10	$11,332
03/22/2009	San Antonio	37	San Antonio Express News	Local Newspaper	5 X 11.5	$17,079
03/22/2009	San Diego	28	San Diego Union-Tribune	Local Newspaper	5 X 10.5	$21,465
03/22/2009	San Francisco/Oakland	6	San Francisco Chronicle	Local Newspaper	5 X 10.5	$28,211
08/01/2009	San Francisco/Oakland	6	San Jose Mercury News	Local Newspaper	5 X 10	$26,001
08/09/2009	Santa Barbara/Santa Maria	122	Santa Barbara News Press	Local Newspaper	5 X 9.5	$2,337
03/22/2009	Seattle/Tacoma	13	Tacoma News Tribune	Local Newspaper	5 X 11	$7,594
07/19/2009	Shreveport/Texarkana	83	Shreveport Times	Local Newspaper	4.5 X 11.5	$6,477
08/02/2009	Sioux City	149	Sioux City Journa	Magazine	5 X 10	$2,404
05/13/2009	Sioux City	149	Sioux City Journa	Magazine	5 X 11	$2,644
08/02/2009	Sioux Falls/Mitchel	112	Sioux Falls Argus Leade	Magazine	5 X 10	$3,038
08/02/2009	Springfield MO	74	Springfield News-Leade	Local Newspaper	5 X 10.5	$4,891
10/25/2009	Tallahassee/Thomasville	105	Tallahassee Democra	Magazine	4 X 9.5	$3,445
07/12/2009	Tallahassee/Thomasville	105	Tallahassee Democra	Magazine	4.5 X 11.5	$4,841
07/19/2009	Tucson	67	Tucson Arizona Daily Sta	Local Newspaper	4 X 9.5	$4,159
03/22/2009	Tucson	67	Tucson Arizona Daily Sta	Local Newspaper	5 X 11	$6,020
03/22/2009	Waco/Temple/Bryan	89	Waco Tribune-Herald	Local Newspaper	5 X 10.5	$3,964
03/22/2009	Yakima	126	Yakima Herald-Republic	Magazine	5 X 11	$1,941
	Total 70 Occurrence(s)					$1,000,463

ADDENDUM

3

YOUR NEW HEALTH CARE PLAN.

(NO TOWN HALL MEETING REQUIRED.)

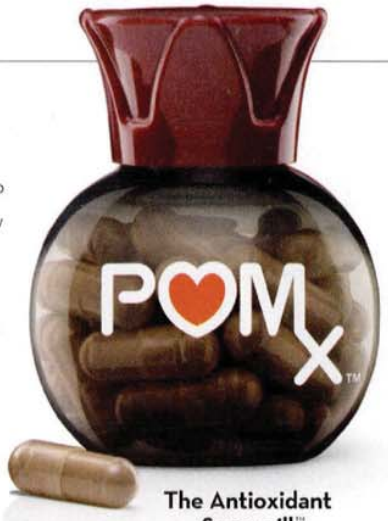
Antioxidant Health Insurance.

Emerging science suggests that antioxidants are critically important to maintaining good health because they protect you from free radicals, which can damage your body. Taking one POMx pill a day will help protect you from free radicals and keep you at your healthy best. Better yet, it's a health plan that's open to everyone.

The antioxidant power of our 8oz juice.

All-natural. Non-political.

POMx is an all-natural, ultra-potent antioxidant extract. Containing a full spectrum of pomegranate polyphenols, POMx is so concentrated that a single capsule has the antioxidant power of a full glass of POM Wonderful® 100% Pomegranate Juice.



The Antioxidant Superpill.™

$32 million in medical research. Zero deductible.

POMx is made from the only pomegranates backed by $32 million in medical research at the world's leading universities. Not only has this research documented the unique and superior antioxidant power of pomegranates, it has revealed promising results for prostate and cardiovascular health.

A health care plan for a healthy future.

Our POMx pills are made from the same pomegranates we use to make our POM Wonderful 100% Pomegranate Juice, on which each of the following medical studies was conducted.

An initial UCLA study on our juice found hopeful results for prostate health, reporting "statistically significant prolongation of PSA doubling times," according to Dr. Allen J. Pantuck in *Clinical Cancer Research*, '06.[1,2,3]

Two additional preliminary studies on our juice showed promising results for heart health. "Stress-induced ischemia (restricted blood flow to the heart) decreased in the pomegranate group," Dr. Dean Ornish reported in the *American Journal of Cardiology*, '05.[1,2,4]

"Pomegranate juice consumption resulted in significant reduction in IMT[5] (thickness of arterial plaque) by up to 30% after one year," said Dr. Michael Aviram, in *Clinical Nutrition*, '04.[1,2,5,6]

Try POMx Monthly FREE for ONE MONTH.
We'll even pay for the shipping.*

Order Now: 888-766-7455 or pompills.com/wp
Use discount code: WP30

*SIGN UP FOR POMx MONTHLY, AND WE'LL SEND YOUR FIRST BOTTLE FREE. AFTER THAT, YOU'LL CONTINUE TO RECEIVE MONTHLY SHIPMENTS FOR $29.95 WITH COMPLIMENTARY SHIPPING. Offer expires 4/30/10 and applies only to the purchase price for the first bottle of POMx Monthly. Following months will be $29.95 per bottle. One discount per customer. Cannot be combined with other offers. No substitutions, transfer rights or cash equivalents. We reserve the right to discontinue this promotion, change product price or shipping charge at any time. Valid only at pompills.com or 1-888-766-7455. Not valid on POMx Trial or other POM products.

POM WONDERFUL®

[1]pompills.com/research [2]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. [3]46 men with rising PSA after surgery or radiotherapy drank 8oz 100% pomegranate juice daily for two years. [4]45 patients with coronary heart disease and myocardial ischemia drank 8oz 100% pomegranate juice daily for three months. [5]Study measured intima-media thickness (IMT).[6]19 patients aged 65-75 years with severe atherosclerosis drank 8oz 100% pomegranate juice daily for one year.

Product POM X
Media: Print
Ad Title: Your new health care plan.
VMS Ad ID: 091107449
Date Range:

Run Date	Market	Rank	Media Vehicle	Media Type	Unit	Cost
11/08/2009	Washington DC	9	Washington Post	Local Newspaper	3.5 X 10	$25,626
	Total 1 Occurrence(s)					$25,626

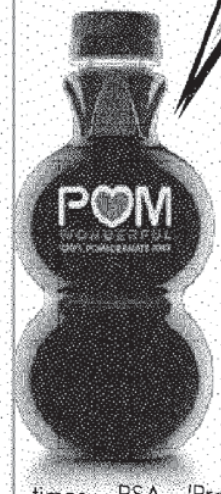
ADDENDUM

4

JOB NO.: PJ2005	TRIM: 7.875"x10.5"	COLOR: 4/C PROCESS	DATE IN: 7-22-09
PROJECT: TimeWrap Oct09	LIVE: 7.125" x 9.75"	LIVE, TRIM, BLEED (DO NOT PRINT)	DATE OUT: 8-20-09
SCALE: 1 : 1	BLEED: 8.375" x 11"	PRINTOUT SIZE: 100%	PROOF ROUND: F2

POM WONDERFUL

HOLY HEALTH!
$32 million in medical research.



A recently published pilot study* involving POM Wonderful 100% Pomegranate Juice followed 46 men previously treated for prostate cancer either with surgery or radiation.

After drinking eight ounces of POM Wonderful 100% Pomegranate Juice daily for at least two years, these men experienced significantly slower average PSA doubling times. PSA (Prostate-Specific Antigen) is a biomarker that indicates the presence of prostate cancer. PSA doubling time is a measure of how long it takes for PSA levels to double. A longer doubling time may indicate slower progression of the disease.

At the beginning of the study, PSA levels doubled on average every 15 months. By the end of the study, doubling time had slowed to 54 months – nearly a four-fold improvement. *"This is a big increase. I was surprised when I saw such an improvement in PSA numbers," said Dr. Allan Pantuck, lead author of the UCLA Study.*

One important note: All of the patients drank the same POM Wonderful 100% Pomegranate Juice which is available in your supermarket produce section.

Prostate cancer is the most commonly diagnosed cancer in men in the United States. After lung cancer, it's the second leading cause of cancer death in men. However, emerging science suggests that diet and lifestyle may be able to significantly improve prostate health.

The Research Continues Results from this study were so promising that many of the original patients continued to drink pomegranate juice daily, and their PSA doubling times remained suppressed. Three more clinical studies are now underway to further investigate the effects of POM on prostate health.

Learn why POM Wonderful is the only pomegranate juice you can trust. *(See inside back cover of this wrap.)*

pomwonderful.com

POM WONDERFUL

* Pantuck et al., Phase II study of pomegranate juice for men with rising prostate specific antigen following surgery or radiation for prostate cancer, *Clinical Cancer Research* (2006)
Visit pomwonderful.com/health/research to review this and other published studies.

POM WONDERFUL

KA-POM!

100% Authentic

POM is the only brand guaranteed to contain 100% real pomegranate juice. We wish other brands were as honest. In fact, according to recent independent tests, nine out of ten so-called "pomegranate" juices were found to have added sugar, colorants and other low-grade fruit juices.

Tree to Bottle

POM is the only brand that controls its juice from tree to bottle, batch to batch, year to year. We only grow "Wonderful" variety pomegranates, renowned for their superior antioxidants and delicious taste. And every 16oz bottle contains the juice of five whole pomegranates.

The Antioxidant Superpower®

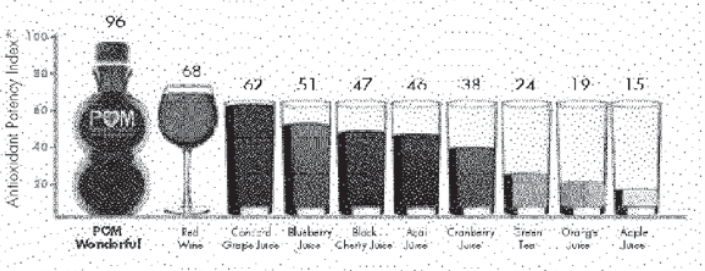
With uniquely high levels of powerful antioxidants, POM Wonderful 100% Pomegranate Juice has demonstrated superior ability to neutralize harmful free radicals and to inhibit excess inflammation.

Backed by Science

Only POM products are backed by $32 million in medical research conducted at the world's leading universities, primarily in the areas of cardiovascular, prostate and erectile function.

More Antioxidants

Sip for sip, POM Wonderful 100% Pomegranate Juice has more polyphenol antioxidants than red wine, green tea and other juices.



POM WONDERFUL® **pomwonderful.com**

*Index combines results from four leading antioxidant tests (ORAC, DPPH, FRAP, TEAC). N. Seeram, et al., Comparison of Antioxidant Potency of Commonly Consumed Polyphenol-Rich Beverages in the United States, Journal of Agricultural and Food Chemistry (2008). Study found at pomwonderful.com/compare.

PJ2005_TimeWrapOct09_F2.indd 3 8/20/09 3:47:28 PM

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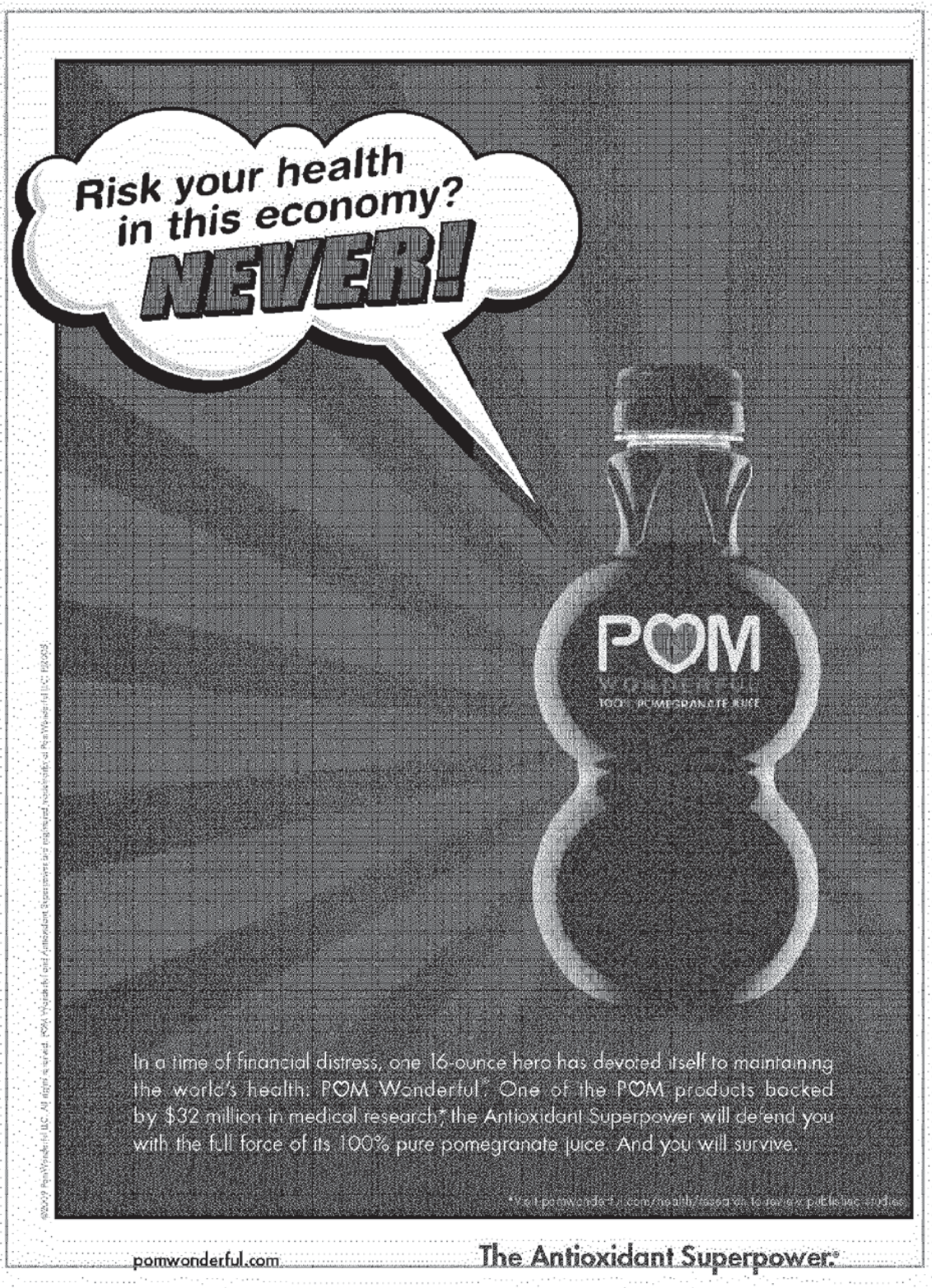
PROJECT: TimeWrap Oct09	LIVE: 7.125" x 9.75"	LIVE, TRIM, BLEED (DO NOT PRINT)	DATE OUT: 8-20-09
SCALE: 1 : 1	BLEED: 8.375" x 11"	PRINTOUT SIZE: 100%	PROOF ROUND: F2



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