ORAL ARGUMENT NOT YET SCHEDULED

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 a Final Order
by the U.S. Federal Trade Commission

BRIEF OF AMICI CURIAE PUBLIC CITIZEN, INC. AND CENTER FOR SCIENCE IN THE PUBLIC INTEREST IN SUPPORT OF RESPONDENT FEDERAL TRADE COMMISSION AND DENIAL OF THE PETITION FOR REVIEW

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CERTIFICATE AS TO PARTIES, RULINGS UNDER REVIEW, RELATED CASES, AND CORPORATE DISCLOSURE STATEMENT

(1) Parties and Amici. All parties, intervenors, and amici appearing in this Court are listed in the Brief for Respondent Federal Trade Commission, with the exception of the Center for Science in the Public Interest, amicus curiae in support of the respondent.

(2) Rulings Under Review. The rulings under review appear in the Brief for Petitioners POM Wonderful LLC, *et al.*

(3) Related Cases. This case has not previously come before this Court or any other court. Counsel is aware of no related cases pending before this Court or any other court within the meaning of D.C. Circuit Rule 28(a)(1)(C).

(4) Corporate Disclosure Statement. Amici curiae Public Citizen, Inc. and the Center for Science in the Public Interest are non-profit organizations that have not issued shares or debt securities to the public and that have no parents, subsidiaries, or affiliates that have issued shares or debt securities to the public. The general purpose of the organizations is to advocate for the public interest on a range of issues, including public health and consumer safety.

/s/ Julie A. Murray
Julie A. Murray

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* *Authorities upon which we chiefly rely are marked with asterisks.*

STATUTES

MISCELLANEOUS

GLOSSARY

CHPA	Amici curiae Consumer Healthcare Products Association and Council for Responsible Nutrition
CSPI	Center for Science in the Public Interest
FTC	Federal Trade Commission
FTCA	Federal Trade Commission Act
RCT	Randomized, controlled trial

INTERESTS OF AMICI CURIAE[1]

Public Citizen, a nonprofit organization with members and supporters nationwide, is devoted to research, advocacy, and education on a wide range of issues, including public-health and consumer-safety issues. Through its nationally recognized Health Research Group, Public Citizen has long advocated reasonable controls on the dissemination of health and disease claims for foods and dietary supplements, promoted research-based, system-wide changes in health care policy, and provided oversight concerning drugs and dietary supplements. Public Citizen also has a substantial interest and expertise in commercial speech doctrine. Its lawyers argued, among other cases, *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976), *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), and *Edenfield v. Fane*, 507 U.S. 761 (1993), and Public Citizen participated as amicus curiae in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), among other pertinent cases.

Center for Science in the Public Interest (CSPI) is a non-profit organization with longstanding interests in the issues presented by this case. Since 1971, CSPI has been a strong advocate for nutrition and health, food safety, and

[1] This brief was not authored in whole or in part by counsel for a party. No person or entity other than Public Citizen, Inc., the Center for Science in the Public Interest, or their counsel made a monetary contribution to the preparation or submission of this brief.

sound science. CSPI works to educate the public, advocate government policies that are consistent with scientific evidence on health and environmental issues, and counter industry's powerful influence on public opinion and public policies. In 1996, the United States Food and Drug Administration awarded CSPI the Commissioner's Special Citation, the highest award given by that agency to outside organizations or individuals who promote public health. As a science-based organization, CSPI has for decades monitored deceptive marketing and labeling claims, including the specific claims by POM that resulted in the FTC action.

All parties have consented to the filing of this brief.

STATUTES AND REGULATIONS

Pertinent statutes are reproduced in the addendum to the Brief of Respondent.

INTRODUCTION AND SUMMARY OF ARGUMENT

Petitioners POM Wonderful LLC, Roll Global LLC, Stewart Resnick, Lynda Rae Resnick, and Matthew Tupper (collectively, POM) ask this Court to invalidate a Federal Trade Commission (FTC) order that found POM liable for making false or misleading statements in product advertisements, in violation of the Federal Trade Commission Act (FTCA). POM argues in part that the order violates its First Amendment free speech rights. In so doing, it criticizes the FTC for not producing extrinsic evidence of consumer reaction to its advertisements before interpreting the advertising claims and determining that the advertisements were misleading. POM's amici go further by suggesting that the FTC had an obligation to produce such evidence in this case, and perhaps in all cases. POM and its amici also argue that the FTC's order departs from the agency's past practice of using a flexible standard to assess substantiation for health and disease claims and that the FTC's purportedly new approach will hurt consumers by limiting access to important information about developing science.

Public Citizen submits this brief to address two points. First, the FTC is not required to submit extrinsic evidence of consumer deception before finding that advertising claims are misleading and thus subject to proscription. That petitioners raise a First Amendment challenge, as opposed to only a statutory challenge to liability under the FTCA, makes no difference. Both this Court and the Supreme

Court have recognized that extrinsic evidence is not necessary to prove an advertisement's deception for the purpose of First Amendment analysis, even if—as POM wrongly contends—all of POM's advertisements are literally true.

Second, the FTC's order did not break with previous policy used to determine whether, and to what extent, companies must have evidence to substantiate claims they make in advertisements of their products' efficacy. Instead, the FTC followed its longstanding, flexible approach to determine that POM's flawed pilot studies and other supposedly supportive research were insufficient to substantiate the serious disease-related claims that POM made about its products, particularly in light of the scientific evidence in POM's own hands that contradicted its assertions.

The FTC's approach, including its preference for randomized, controlled trials (RCTs) to support disease treatment and prevention claims, is supported by a strong policy rationale. When companies claim that their products treat, prevent, or reduce the risk of disease, consumers cannot independently test those assertions, which are highly material to purchasing decisions. Consumers must instead rely on companies' representations and are particularly vulnerable to fraud and deception, more so than with goods that consumers may evaluate through their own experience. Under these circumstances, a meaningful standard for substantiation is appropriate to ensure that the "stream of commercial information flow[s] cleanly as

well as freely." *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 772 (1976).

BACKGROUND

Sections 5 and 12 of the FTCA prohibit companies from engaging in "false advertis[ing]" and other "unfair or deceptive acts or practices" in the course of advertising their products. 15 U.S.C. §§ 45, 52. In 2013, the FTC held that POM violated the FTCA by repeatedly making false or misleading statements in advertisements for three of its products: POM Wonderful Juice, POM_X Pills, and POM_X Liquid. Specifically, the FTC found that POM made "efficacy claims," that is, claims that the products were effective in treating, preventing, or reducing the risk of heart disease, prostate cancer, and erectile dysfunction. FTC's Final Opinion (hereinafter, Op.) at 9. The agency also concluded that most of the challenged ads made "establishment claims"—that is, claims that appropriate scientific evidence supported the effectiveness of the products. *Id.* at 12. Although the FTC relied in part on extrinsic evidence to support its determination that POM made efficacy claims, *id.* at 11, 17, it did not rely on such evidence in determining that POM made establishment claims. The FTC concluded that extrinsic evidence was unnecessary because the establishment claims were "in fact apparent from the overall, common-sense, net impression of the words and images of the advertisements themselves." *Id.* at 14.

After determining the nature of POM's claims, the FTC considered whether POM had adequate scientific evidence to substantiate them. Without such evidence, the claims, which were material to consumers' purchasing decisions, would be false or misleading under the FTCA. The FTC examined the shortcomings of various studies on which POM relied and noted that some of POM's studies in fact undermined POM's claims. *Id.* at 26-34. The FTC concluded that POM had "insufficient competent and reliable scientific evidence" to substantiate the establishment claims, rendering those claims false. *Id.* at 34. For those few advertisements for which the FTC found an efficacy but not an establishment claim, the FTC considered a series of factors identified in *In re Pfizer Inc.*, 81 F.T.C. 23 (1972) and its progeny—including the amount of evidence that experts in the field would agree is reasonable—and determined that the claims were misleading. Op. at 34-38.

ARGUMENT

I. The FTC Was Not Required to Produce Extrinsic Evidence of Consumer Reactions Before Determining That POM's Claims Were False or Misleading.

POM and its amici fault the FTC for not producing extrinsic evidence before determining that POM's advertisements conveyed false or misleading disease claims. Although POM recognizes that consumer surveys from the FTC are not required as a matter of law before the agency may determine that a claim is

misleading, it contends that surveys would have helped ground the FTC's "regulatory impulse" in actual deception. POM Br. at 29-30. POM's amici at times take a more extreme position, contending that the FTC *must* use extrinsic evidence to determine the share of consumers who are misled by advertisements before it can determine whether an advertisement is misleading. *See* Consumer Healthcare Products Ass'n, *et al.*, Amicus Br. (CHPA Br.) at 19.

The positions advanced by POM and its amici have no basis in First Amendment precedent. As decisions by the Supreme Court and this Court make clear, the First Amendment does not impose on the FTC a heightened burden to demonstrate by extrinsic evidence that POM made false or misleading disease claims. That principle would remain true even if, as POM wrongly claims, all of its statements were literally true. *See* POM Br. at 23. *But see* FTC Br. at 40 (explaining why POM's claim in this regard is inaccurate).

In *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), for example, the Supreme Court held that an attorney could be disciplined for failing to include in an advertisement of his contingent-fee services a disclaimer that clients might still be liable for litigation costs if they lost their cases. The attorney's advertisement said nothing one way or the other about *costs*, but stated that "if there is no recovery, no *legal fees* are owed by our clients," so it was therefore superficially true. *Id.* at 652 (emphasis added and internal quotation marks

omitted). The Court recognized that "to a layman not aware of the meaning of these terms of art, the advertisement would suggest that employing [the lawyer] would be a no-lose proposition," and that "the possibility of deception" was "self-evident" under these circumstances. *Id.* In upholding as constitutional the attorney's discipline, the Court specifically rejected the contention that a state must "'conduct a survey of the public before it may determine that [an] advertisement ha[s] a tendency to mislead.'" *Id.* at 653 (quoting *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 391-92 (1965)) (internal alterations omitted). *Cf. Peel v. Attorney Registration & Disciplinary Comm'n*, 496 U.S. 91, 102 (1990) (plurality op.) (recognizing, without reference to any requirement of extrinsic evidence, that an advertisement that an attorney obtained a special trial certification could, even if true, "be misleading" if the certification were "issued by an organization that had made no inquiry into [the attorney's] fitness, or by one that issued certificates indiscriminately for a price").

Likewise, this Court's precedent refutes the position of POM and its amici that the FTC should have produced—or was required to produce—extrinsic evidence regarding consumer reactions to POM's claims. In *FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35 (D.C. Cir. 1985), this Court expressly rejected the proposition that the FTC must provide consumer surveys before determining that an advertisement is misleading, even if the advertisement's

statements are "literally true." *Id.* at 41. In that case, a tobacco company claimed that its cigarettes contained only one milligram of tar as measured by the company's own method for such measurements, a statement that was true. However, the cigarettes in fact delivered far more tar than other cigarettes with a one-milligram rating, as measured using a standardized method adopted by the FTC. *Id.* at 42. Before rejecting in large part the company's First Amendment challenge to an injunction barring the company from including the claim in its advertising, this Court upheld the finding that the advertisement was misleading, *id.* at 41, emphasizing "that context may create inherent consumer deception even where an advertisement is facially truthful," *id.* at 42 & n.4 (internal quotation marks omitted). In so doing, the Court rejected the company's claim that consumer survey evidence of the advertisement's deceptive nature was required to impose liability, recognizing that such a contention was at odds with *Zauderer*, 471 U.S. 626 (1985). *Brown & Williamson*, 778 F.2d at 41.

This Court's position in *Brown & Williamson* is consistent with other court of appeals decisions addressing First Amendment claims. For example, in *American Academy of Pain Management v. Joseph*, 353 F.3d 1099, 1107-08 (9th Cir. 2004), the court held—without reference to consumer surveys—that where a state law defined "board certification" for doctors to include only certification from a particular organization meeting specified standards, advertisements of "board

certification" from an organization not meeting those standards were misleading and thus not protected speech. Likewise, in *Kraft, Inc. v. FTC*, 970 F.2d 311 (7th Cir. 1992), the court, relying on *Zauderer*, stated that "no first amendment concerns are raised when facially apparent implied claims are found without resort to extrinsic evidence," *id.* at 321, and that the FTC's "common sense and administrative experience" are "sufficient tools to make its findings" with respect to "implied, but conspicuous," claims, *id.* at 320.

In light of these and other cases, this Court should reject the contention that POM's claims were not sufficiently clear to permit the FTC to determine, without production of extrinsic evidence, that the claims were misleading. The advertisements say that POM's products provide specific disease treatment and prevention benefits, and that scientific evidence establishes that those benefits are real. As the FTC's decision carefully documented, POM lacked adequate scientific substantiation for those claimed benefits, and some of POM's own studies even undermined those claims. *See* FTC Br. at 26-34. Thus, as was true in *Zauderer*, there is no need here for complicated inferences about how consumers would understand POM's advertising. If the Court's inferences in *Zauderer*, 471 U.S. at 652-53, did not require support from extrinsic evidence about consumers' understanding of the advertisement at issue there, the FTC's even more straightforward reasoning here does not require it either.

II. The FTC Applied Its Long-Held Substantiation Standards in This Case, and Those Standards Are Appropriate to Protect Consumers' Interest in Accurate Speech About a Product's Effects on Disease.

A. Under the FTCA, an advertiser's claims are deceptive where the advertiser lacks a reasonable basis for making them. *See Thompson Med. Co., Inc. v. FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986); *Daniel Chapter One v. FTC*, 405 Fed. App'x 505, 506 (D.C. Cir. 2010). To determine what type of evidence an advertiser must have to substantiate *efficacy* claims, the FTC considers the *Pfizer* factors, so named after *In re Pfizer*, 81 F.T.C. 23 (1972), the decision that first identified some of those factors. The agency analyzes, among other things, the type of claim, the benefit of a truthful claim, the possible harm of a false claim, and the type of substantiation that experts in the field would require to support the claim. *See, e.g.*, *In the Matter of Thompson Med. Co., Inc.*, 104 F.T.C. 648, 840 (1984). To determine the level of substantiation needed for an *establishment* claim, the FTC does not use the *Pfizer* factors, instead asking only "what evidence would in fact establish such a claim in the relevant scientific community." *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1498 (1st Cir. 1989).

The FTC here concluded that POM's claimed scientific studies did not substantiate POM's establishment or efficacy claims regarding heart disease, prostate cancer, and erectile dysfunction, and that such claims would generally require at least one RCT for substantiation. Op. at 21-38; *see generally* FTC Br. at

48-56. POM's amici attack that determination by contending that the FTC's decision improperly "transform[ed]" its advertising substantiation requirement under *Pfizer*. CHPA Br. at 4; *see also id.* at 27. Specifically, they contend that while the FTC used to "balance[] the benefits of truthful claims against the costs of false ones," it now applies "a rigid rule that requires multiple clinical trials even if the benefits of the claim—if true—overwhelmingly exceed the costs of the claim—if false." *Id.* at 4. The amici further contend that the FTC merely "purport[ed]" to apply the *Pfizer* factors while instead determining—without the benefit of balancing—that the type of claim at issue here required RCTs. *Id.* at 27.

As an initial matter, as noted above, the *Pfizer* factors do not even apply to determine whether an advertisement's *establishment* claim has been substantiated. That is so because when a company claims that its product's ability to treat, cure, or prevent disease is established by scientific evidence, the absence of evidentiary support to satisfy the relevant scientific community of that claim alone makes the claim false or misleading. Here, the FTC found that all but two of the advertisements for which POM was held liable contained establishment claims in addition to efficacy claims.

Moreover, even when considering the efficacy claims, the FTC did not pay mere lip service to the *Pfizer* factors. It expressly recognized that, under its own precedent, it must "weigh" those factors to determine "the appropriate level of

substantiation the advertiser is required to have for objective advertising claims." Op. at 34. And it discussed each factor in turn, *see id.* at 35-38, recognizing, for example, that one consequence of a false claim is that "[c]onsumers pay a higher price for POM products at least in part because of [the products'] ostensible health benefits," *id.* at 38. The FTC also considered the costs associated with conducting RCTs, but pointed out that such costs were not prohibitive and that POM had in fact conducted "several clinical trials designed as RCTs." *Id.* at 37. The results of those RCTs simply did not support POM's claims. *Id.*

B. POM's amici contend that the FTC's substantiation standards—and the requirement of one or more RCTs here—will cut off public access to important, health-related information because companies may find it difficult to conduct RCTs and because other types of scientific evidence may suggest promising benefits from foods and supplements. CHPA Br. at 19-27. The FTC has adequately explained that challenges in devising and funding RCTs are not relevant here because POM *did* conduct RCTs and those trials contradicted some of POM's claims. *See* FTC Br. at 52. Furthermore, as the FTC has explained, FTC Br. at 72-73 n.33, under the agency's longstanding substantiation regime, companies may advertise the possible benefits of their products based on developing science, so long as those advertisements are appropriately qualified. *Cf. Pearson v. Shalala*, 164 F.3d 650, 659-60 (D.C. Cir. 1999) (holding that the Food

and Drug Administration could not adopt a prophylactic rule requiring preapproval of certain health claims for dietary supplements where effective disclaimers could cure the likelihood of consumer confusion). Here, however, POM's claims were not meaningfully qualified. As the FTC's decision explained, consumers will generally have little understanding of what "initial" results or "pilot" studies are, Op. at 14, and other supposed qualifiers on which POM relied—such as those describing POM's research as "promising" or "hopeful"—actually put a "positive spin" on POM's findings, *id.* at 13.

A strong policy rationale supports requiring RCTs as substantiation for the kinds of unqualified establishment and efficacy claims with respect to disease treatment and prevention that POM made for its products. First, claims that a food or supplement has disease-related benefits can be persuasive to consumers—that is why companies make them. Consumers may be desperate to find a cure or treatment for their disease when conventional treatment has not worked; others may be looking for a lower-cost alternative to medical treatment, or a more "natural" option, and thus turn to food products or dietary supplements. At the same time, the science behind the products' promised benefits is out of reach for most consumers. To assess POM's claims, one would have needed to have a sophisticated sense of the types of scientific evidence on which POM relied and the extent to which "facts" that POM highlighted in its advertisements—such as its

products' claimed ability to lengthen "doubling times" for prostate-specific antigen—were (or, more to the point, were not) relevant to measuring treatment or recurrence of disease. *See* Op. at 31.

The promise of a benefit that is difficult or even impossible for laymen to evaluate is a common one in the marketing of what economists call "credence goods." A credence good is one whose qualities are "known only through the benefits promised by the product's manufacturer . . . at the time of purchase." *Lee v. Carter-Reed Co., LLC*, 4 A.3d 561, 579 (N.J. 2010). Credence goods are thus unlike "search goods," such as clothing, which consumers can evaluate before making a purchase, and "experience goods," which consumers can assess through use. *See* Ariel Katz, *Pharmaceutical Lemons: Innovation and Regulation in the Drug Industry*, 14 Mich. Telecomm. Tech. L. Rev. 1, 13 (2007).

When purchasing credence goods or services (such as over-the-counter drugs, many medical services, and car repairs), a consumer must take representations about a product's quality "on faith." Richard A. Posner, *An Economic Approach to the Law of Evidence*, 51 Stan. L. Rev. 1477, 1489 (1999) (internal quotation marks omitted). "Because consumers cannot accurately rate the products for themselves, advertising, and the expectations [that] it engenders, becomes a significantly more influential source of consumer beliefs than it would otherwise be." *Am. Home Prods. Corp. v. FTC*, 695 F.2d 681, 698 (3d Cir. 1983);

see also Uwe Dulleck & Rudolf Kerschbamer, *On Doctors, Mechanics, and Computer Specialists: The Economics of Credence Goods*, 44 J. Econ. Lit. 5, 5-6 (2006) (recognizing that sellers of credence goods can easily exploit the informational asymmetry that exists between sellers and the buyers of their products).

Consumers are, unsurprisingly, "more vulnerable to fraud or deception" when purchasing credence goods or services than when entering the market for search goods. Dan L. Burk & Brett H. McDonnell, *Trademarks and the Boundaries of the Firm*, 51 Wm. & Mary L. Rev. 345, 378 (2009). They cannot rely on those "market incentives [that] place strong constraints on the likelihood of deception," applicable when "consumers can easily evaluate [a] product or service." FTC, Policy Statement on Deception, *appended to Cliffdale Assocs., Inc.*, 103 F.T.C. 110, 174 (1984), *available at* http://www.ftc.gov/ftc-policy-statement-on-deception. In these circumstances, a meaningful substantiation requirement—especially for disease claims—is appropriate. *See* FTC, *Dietary Supplements: An Advertising Guide for the Industry* 21 (2001) (stating that the agency "will closely scrutinize the scientific support" for disease claims made by dietary supplement manufacturers, "particularly where the claim could lead consumers to forego other treatments that have been validated by scientific evidence, or to self-medicate for potentially serious conditions without medical supervision").

Second, a meaningful substantiation standard for disease claims like those POM made is appropriate in light of the evolving nature of the science of health and disease. Claims based on preliminary evidence may later turn out to be inaccurate, as results from RCTs replace those from pilot and other preliminary studies lacking in rigor. The evolution of POM's own research demonstrates this dynamic: Some of POM's findings based on small, nonrandomized studies were not borne out by a "much larger, well-designed, well-controlled study" that POM later sponsored. Op. at 43. One study by the Institute of Medicine found a similar dynamic after examining evidence that supported nutrient-disease relationships. That study compared findings in a 1989 report to those in a series of reports from the late 1990s through 2001. Institute of Medicine, Evolution of Evidence for Selected Nutrient and Disease Relationships 2 (2002). It found that two of the relationships considered "promising" in 1989 were considered far more "uncertain" by 2002 and that one relationship considered "uncertain" in 1989 had later been disproved entirely. *Id.* at 4.

By finding that POM's unqualified disease claims were unsubstantiated in the absence of RCTs, the FTC applied a standard that protects consumers from inaccurate claims regarding a product's established ability to treat, prevent, or cure disease. If POM chooses to add *effective* qualifications to future disease claims unsupported by RCTs—which the FTC's order permits, *see* FTC Br. at 72-73

n.33—consumers will at least be able to understand that those claims are open to revision as science develops and that the claims are not in fact supported by a high degree of scientific evidence. Moreover, by policing the disease claims made here, the FTC's order creates incentives for the development of more accurate consumer information, not just from POM, but from its current or future competitors. In this way, the FTC's order accommodates companies' interest in relying on developing science while protecting consumers from companies that peddle in falsehoods and misleadingly bullish claims.

CONCLUSION

For the foregoing reasons, this Court should deny the petition for review of the FTC's order.

Dated: February 14, 2014

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-face and volume limitations set forth in Federal Rule of Appellate Procedure 32(a)(7)(B) as follows: The type face is fourteen-point Times New Roman font, and the word count is 3,988.

/s/ Julie A. Murray
Julie A. Murray

CERTIFICATE OF SERVICE

I certify that on February 14, 2014, I caused the foregoing to be filed with the Clerk of the Court through the Court's ECF system, which will serve notice of the filing on all filers registered in this case.

/s/ Julie A. Murray
Julie A. Murray