No. 17-3745

& 17-3791 (CON)

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

FEDERAL TRADE COMMISSION, et al.,
Plaintiffs-Appellants,

v.

QUINCY BIOSCIENCE HOLDING CO., et al.,
Defendants-Appellees.

Appeal from the United States District Court
for the Southern District of New York
No. 1:17-cv-00124-LLS (Hon. Louis L. Stanton)

BRIEF OF AMICI CURIAE PUBLIC CITIZEN, INC., CENTER FOR SCIENCE IN THE PUBLIC INTEREST, AND COLLABORATION FOR RESEARCH INTEGRITY AND TRANSPARENCY IN SUPPORT OF APPELLANTS AND REVERSAL

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CORPORATE DISCLOSURE STATEMENT

Public Citizen, Inc., and Center for Science in the Public Interest are both nonprofit, nonstock corporations. They have no parent corporations, and because they issue no stock, no publicly held corporation owns 10% or more of their stock.

The Collaboration for Research Integrity and Transparency is an organization within Yale University, which is a nonprofit, nonstock corporation, with no parent corporation. It issues no stock, and no publicly held corporation owns 10% or more of its stock.

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INTERESTS OF AMICI CURIAE[1]

Public Citizen, Inc. is a non-profit consumer advocacy organization with members and supporters nationwide. Founded in 1971, Public Citizen has a longstanding interest in 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 has also frequently participated in cases arising from the pharmaceutical and medical device industries' marketing of unsafe drugs and medical devices. In addition to its interest in drug regulation and health issues, Public Citizen has significant interest and expertise in commercial-speech doctrine. Public Citizen has represented parties seeking to invalidate overbroad restraints on commercial speech when those restraints harmed competition and injured consumers, including in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976). Public Citizen has also defended commercial-speech regulations in cases where they were important to protecting the public health or served other

[1] This brief is accompanied by a Motion for Leave to File as required by Federal Rule of Appellate Procedure 29(b). No counsel for any party authored this brief in whole or part. Apart from amici curiae, no person or organization, including parties or parties' counsel, contributed money intended to fund the preparation and submission of this brief.

important state interests, for example as amicus curiae in *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001).

Center for Science in the Public Interest (CSPI) is a national, non-profit organization that advocates for nutrition and health, food safety, and sound science. Since its founding in 1971, CSPI has worked to educate the public and promote government policies that are consistent with scientific evidence on health and the environment. At congressional hearings in 1989, CSPI testified in support of passage of the Nutrition Labeling and Education Act, and subsequently advocated for promulgation of the Food and Drug Administration rules that set forth standards for reliable health claims on foods and dietary supplements. In recent years, CSPI has used litigation under state consumer-protection laws to protect consumers from misleading labeling of food, beverages, and dietary supplements.

The Collaboration for Research Integrity and Transparency (CRIT) is a multidisciplinary initiative of Yale Law School, Yale Medical School, and Yale School of Public Health. CRIT's mission is to promote public health by improving the transparency and integrity of biomedical and clinical data. CRIT's scientists have conducted research showing that data transparency and integrity are crucial to the accurate and informed use of drugs, devices, and biologics. Through litigation and policy work, CRIT focuses on enforcement of statutes and rules governing the accurate reporting of clinical trial results.

Public Citizen, CSPI, and CRIT offer a consumer and public-health perspective on the regulatory and advertising issues presented here, different from that of the parties.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Federal Trade Commission (FTC) and the State of New York brought this action against appellee Quincy Bioscience Holding Co. and related entities and individuals (collectively, Quincy) for making false or misleading statements in product labeling and advertisements for their product Prevagen, in violation of the Federal Trade Commission Act (FTC Act). Prevagen is a dietary supplement that Quincy markets for improved memory. On a motion to dismiss, the district court held that the complaint failed to state a claim under the FTC Act on which relief could be granted because Quincy pointed to subgroup analyses of a larger clinical trial, sponsored and run by Quincy, that showed some improvement in memory. The court's opinion frankly acknowledges that the court did not fully understand the nature of post hoc subgroup analysis or why it is insufficient to substantiate a scientific claim. *See* SA-11 n.4 (D. Ct. Op.). Without addressing the allegations that Quincy also misrepresented the results of the study as a whole, and although the factual dispute over whether the post hoc subgroup analyses substantiate Quincy's memory-improvement claims is central to the question whether Quincy's marketing

is deceptive, the court dismissed the FTC Act claim for failure to plead a plausible violation. *Id*. at SA-12.

The court's decision was in error. Amici offer this brief to explain consumers' vulnerability to claims made for products, such as dietary supplements, that they cannot independently verify. The brief also explains the significance of post hoc subgroup analyses after a clinical trial and demonstrates that the district court was wrong in concluding that "the complaint fails to show that reliance upon the subgroup data 'is likely to mislead consumers.'" *Id*. at SA-11–12.

Importantly, the FTC applied its longstanding, flexible approach to evaluating substantiation when it alleged that the post hoc subgroup analyses—derived from a study that Quincy conceded otherwise showed no benefit on memory or cognition—is insufficient to substantiate Quincy's claims. The FTC's approach is supported by a strong policy rationale, because consumers cannot independently assess a company's claim that a dietary supplement provides health benefits, yet such claims are central to purchasing decisions. Because consumers necessarily must rely on companies' representations, they are particularly vulnerable to fraud and deception. A meaningful standard for substantiation is therefore vital to ensure that the "stream of commercial information flow[s] cleanly as well as freely." *Va. State Bd. of Pharmacy*, 425 U.S. at 772. And when that standard is not met, the FTC properly can and should take action against a company for violation of the FTC Act.

BACKGROUND

Under the Food, Drug, and Cosmetic Act and the Dietary Supplement Health and Education Act of 1994, supplement manufacturers are restricted from claiming that a supplement can treat, cure, or prevent a disease; such claims generally render the product a "drug." *See* 21 U.S.C. § 321(g)(1). A dietary supplement manufacturer is permitted, however, to make claims about how a product affects the structure or function of the body. *Id*. § 343(r)(6). A claim that a supplement helps to improve memory is generally considered a "structure/function claim" and, if the claim has substantiation, the manufacturer may lawfully make that claim for its product. *See generally* U.S. Gov't Accountability Office (GAO), *Memory Supplements: Clarifying FDA and FTC Roles Could Strengthen Oversight and Enhance Consumer Awareness* (May 2017), https://www.gao.gov/assets/690/684620.pdf. On the other hand, absent substantiation, structure/function claims are deceptive and misleading to consumers and, therefore, in violation of the FTC Act. *See* 15 U.S.C. §§ 45, 52 (prohibiting companies from engaging in "false advertis[ing]" and other "unfair or deceptive acts or practices" in advertising their products).

In this case, the FTC filed a complaint against Quincy for violating the FTC Act by repeatedly making false or misleading statements in advertisements for its product Prevagen. Specifically, the FTC alleged that Quincy made "efficacy claims," that is, claims that the product was effective in reducing memory loss

associated with aging, as well as that the product aids brain functioning and clear thinking. The FTC also alleged that Quincy violated the FTC Act by purporting, falsely, to have proof establishing its claims.

Quincy's claimed substantiation for its memory claims is based wholly on post hoc analyses of subgroups of a single 218-subject study, designed and conducted by Quincy. As the district court noted, the parties agree that, overall, Quincy's study showed no statistically significant improvement in memory for test subjects. SA-10–11 (D. Ct. Op.); JA-37 (Compl. ¶ 28). Quincy therefore conducted more than 30 post hoc analyses of the results, reviewing the data for different subgroups of subjects. Consistent with the study results, Quincy's product showed no memory improvements for the majority of subgroups. Quincy claims, however, the two subgroups of people who had no or very mild memory impairment showed positive results. JA-37 (Compl. ¶¶ 28–29); SA-11 (D. Ct. Op.). On this basis, Quincy broadly advertised Prevagen as "clinically tested," "improves memory," and "tested and shown to improve mild memory problems that occur in aging." JA-22, JA-29 (Compl. ¶ 27 & pp. 9, 16).

ARGUMENT

I. Consumers are particularly vulnerable to claims that a dietary supplement has health benefits.

"Memory supplements—dietary supplements claiming to improve memory—are a growing market, with sales estimated at $643 million in 2015, almost double

2006 sales." GAO, *Memory Supplements*, *supra*, at 1. The Food and Drug Administration "and FTC share oversight of memory supplement marketing—labeling and advertising claims—but generally do not approve claims before products are marketed." *Id*. With respect to supplements, the FTC's authority is limited to enforcing the FTC Act's prohibitions against deceptive advertising.

The FTC's role in enforcing the FTC Act against claims that a dietary supplement has health benefits is vitally important to consumers, who are unable to assess the veracity of such claims on their own. Consumers may be desperate to find a cure or treatment for a disease or health-related condition when conventional treatment is unavailable or 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. Yet the science behind the products' promised benefits is out of reach for most consumers. To assess Quincy's claims, for example, a consumer would need to have a access to the study results and protocols, as well as a sophisticated understanding of the type of evidence on which Quincy relied and the extent to which scientific and medical "facts" touted in the advertisements—such as Prevagen's purported ability to "cross[] the blood brain barrier and the gastrointestinal barrier," JA-26 (Compl. ¶ 27)—are (or are not) relevant to showing whether Prevagen has the claimed effect on memory and cognition.

Not surprisingly, "surveys and experts indicate that consumers are not well-informed about the safety and efficacy of dietary supplements and have difficulty interpreting labels on these products." GAO, *Dietary Supplements: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding* 30 (2009), https://www.gao.gov/new.items/d09250.pdf. "Without a clear understanding of the safety, efficacy, and labeling of dietary supplements, consumers may be exposed to greater health risks associated with the uninformed use of these products," *id.*, and may be more likely to spend money unwittingly on products of no value.

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 dietary supplements, 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 (1984), https://www.ftc.gov/system/files/documents/public_statements/410531/831014deceptionstmt.pdf.

In these circumstances, a meaningful substantiation requirement—especially for claims about health—is appropriate and needed to protect consumers from

deception. *See* FTC, *Dietary Supplements: An Advertising Guide for the Industry* (2001), https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry (stating that the FTC "will closely scrutinize the scientific support" for 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").

II. Because the FTC alleged facts demonstrating that Quincy's claims lack substantiation, it stated a claim that the ads are deceptive, in violation of the FTC Act.

A. The FTC's substantiation standard is well-established.

In challenging Quincy's advertising of Prevagen, the FTC seeks to enforce its long-established substantiation standard, which has been acknowledged and approved by this Court and others. *See FTC v. Verify Int'l, Ltd.*, 443 F.3d 48, 63 (2d Cir. 2006); *Bristol-Myers Co. v. FTC*, 738 F.2d 554, 560 (2d Cir. 1984); *see also POM Wonderful, LLC v. FTC*, 777 F.3d 478, 490 (D.C. Cir. 2015). As the Supreme Court has recognized, the FTC "is often in a better position than are courts to determine when a practice is 'deceptive' within the meaning of the [FTC] Act." *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 385 (1965), *quoted in POM Wonderful*, 777 F.3d at 490. That "admonition is especially true with respect to allegedly deceptive

advertising since the finding of [an FTC Act] violation in this field rests so heavily on inference and pragmatic judgment." *Id.*

To establish that an advertisement is deceptive under the FTC Act, the FTC first must show that "consumers acting reasonably under the circumstances" would interpret the advertisement to convey a particular claim. *FTC v. LeadClick Media, LLC*, 838 F.3d 158, 168 (2d Cir. 2016); *Verify Int'l, Ltd.*, 443 F.3d at 63. That is, looking to "the overall net impression" of the ad, the FTC must show that "at least a significant minority of reasonable consumers would likely interpret the ad to assert the claim." *POM Wonderful*, 777 F.3d at 490 (internal quotation marks and citations omitted). Second, if the advertisement makes a claim, the FTC must demonstrate that the claim is false, misleading, or unsubstantiated. *LeadClick Media*, 838 F.3d at 168; *POM Wonderful*, 777 F.3d at 490. Finally, if consumers would reasonably interpret an ad to make a claim and that claim is false, misleading, or unsubstantiated under the applicable standard, the FTC must show that the claim is material to consumers' purchasing decisions. *POM Wonderful*, 777 F.3d at 490 (citing cases); *LeadClick Media*, 838 F.3d at 168.

Here, Quincy does not dispute this standard, and it does not dispute that its claims of improved memory and cognition are material to consumers' purchasing decision. SA-10 (D. Ct. Op.). The only question is whether the FTC has adequately pleaded the second step—that is, whether the factual allegations in the FTC's

complaint would, if proven, be sufficient as a matter of law to establish that Quincy's memory claims are likely to mislead consumers.

B. Quincy's post hoc subgroup analyses do not meet the FTC's longstanding standard.

Under the FTC Act, an advertiser's claims are deceptive where the advertiser lacks a reasonable basis for making them. *See POM Wonderful*, 777 F.3d at 490; *Thompson Med. Co., Inc. v. FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986); *Bristol-Myers Co.*, 738 F.2d at 560. As the FTC asks of any industry making health-related claims, it "typically requires claims about the efficacy or safety of dietary supplements to be supported with 'competent and reliable scientific evidence.'" FTC, *Dietary Supplements*, *supra*. And FTC cases have defined such evidence as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *Id.*; *see also POM Wonderful*, 777 F.3d at 490–91 (citing cases). Moreover, when an advertisement suggests that the product's effectiveness has been scientifically established—for example, by referencing clinical trials or studies—the "advertiser must possess the specific substantiation claimed." *Id.* at 491 (citing *Bristol-Myers Co.*, 102 F.T.C. 21, 321 (1983), *aff'd*, 738 F.2d 554 (2d Cir. 1984)); *see Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1498 (1st Cir. 1989).

1. Here, the advertisements both claim efficacy regarding improved memory and cognitive function and claim specific substantiation. JA-22–36 (Compl. ¶ 27). As the FTC, Quincy, and the district court all agreed, both types of claims are based on one in-house study, referred to as the Madison Study, that "on the whole" did not substantiate the claims. SA-10–11 (D. Ct. Op.). And the FTC alleged that Quincy misrepresented the results of the study *as a whole*. *See* JA-38 (Compl. ¶ 30) (alleging that Quincy's labels and ads included a chart "indicat[ing] that a 'doubleblinded, placebo controlled study' showed dramatic improvement in recall tasks when, in fact, the results for the specific task referenced in the chart showed no statistically significant improvement in subjects taking Prevagen compared to subjects taking a placebo"); *e.g.*, JA-25 (Compl. ¶ 27) (quoting Quincy ad stating "218 adults over 40 years old participated in the three month study. Prevagen significantly improved learning and word recall."). Because the district court dismissed the case without addressing those allegations, the decision below should be reversed.

2. Quincy's position that its claims have a reasonable basis and are supported by scientific evidence falls back on its post hoc subgroup analyses: Quincy argued below that the subgroup analyses necessarily satisfied the FTC's substantiation standard because the analysis was part of a randomized controlled clinical study. *But see* JA-37 (Compl. ¶ 29) ("This [post hoc subgroup] methodology greatly increases the probability that some statistically significant differences would occur by chance

alone."). Quincy emphasized below that a randomized, controlled clinical trial is the "gold standard" type of study and suggested that the FTC's position here was an alteration of its long-standing view on substantiation. But Quincy misses a key point: The question here is not whether the Madison study as a whole, had it substantiated the claims, would qualify as "competent and reliable scientific evidence," because, again, the parties agree that the study "as a whole" does not substantiate Quincy's claims. *See* SA-10–11 (D. Ct. Op.). The question—with respect to the ads that address the subgroups, as opposed to misrepresentations about the study results as a whole—is whether the post hoc subgroup analyses from that study qualify. Because the experts in the field of medical research would not generally accept Quincy's post hoc subgroup analyses as yielding scientifically sound and reliable results, the FTC has adequately alleged that the analyses do not substantiate the claims and properly stated a claim on which relief can be granted.

Subgroup analysis refers to an evaluation of study results in a subgroup of the subjects defined by certain baseline characteristics. *See* Rui Wang, et al., *Statistics in Medicine – Reporting of Subgroup Analyses in Clinical Trials*, 357 New Eng. J. of Med. 2189 (2007). Subgroup analyses are post hoc when the subgroup levels and "the hypotheses being tested are not specified before any examination of the data." *Id*. at 2190. Post hoc subgroup analyses have long been viewed with skepticism by research scientists and statisticians. *See*, *e.g*., Andrew Oxman, et al., *A Consumer's*

Guide to Subgroup Analyses, 116 Annals of Internal Medicine 78, 83 (1992) (stating that "there are those who ignore scientific principles in the subgroup analyses they undertake and report, go on fishing expeditions, and indulge in data-dredging exercises" and that subgroup analyses showing small, marginally significant interactions generated by post hoc exploration of a single dataset "should be viewed with great skepticism").

As the FDA has cautioned, "[a]lthough post hoc analyses of trials that fail on their prospectively specified endpoints may be useful for generating hypotheses for future testing, they do not yield definitive results. The results of such analyses can be biased because the choice of analyses can be influenced by a desire for success." FDA, *Multiple Endpoints in Clinical Trials*, Guidance for Industry, Draft Guidance at 8 (Jan. 2017).[2] In fact, "[s]ubgroup analyses have historically misinformed as much as they have informed." *Id.*; *see also* Joshua Wallach, et al., *Evaluation of Evidence of Statistical Support and Corroboration of Subgroup Claims in Randomized Clinical Trials*, 177 J. Am. Med. Ass'n Internal Med. 554, 559 (2017) ("Our results support the notion that individual subgroup analyses are often spurious

[2] Available at https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm536750.pdf. The FDA Guidance also describes the problem of "multiplicity," explaining that "[w]hen a trial is designed so that more than one study endpoint or comparison (of treatment to control) could lead to a conclusion that effectiveness was established, testing each endpoint separately … will overstate the statistical significance." *Id.* at 6. In other words, multiplicity increases the error rate.

and should be considered hypothesis generating."); Wang, 357 New Eng. J. of Med. at 2190 (stating that "post hoc subgroup analyses are subject to inflated false positive rates"). For these reasons, although post hoc subgroup analyses may be useful for generating hypotheses to explore in future studies, reliance on such analyses to draw conclusions about patient health is widely rejected by experts. As the FDA has succinctly stated, "post hoc analyses by themselves cannot establish effectiveness." FDA, *Multiple Endpoints*, *supra*, at 8.

Quincy's post hoc subgroup analyses display the primary flaws noted by the FDA and many experts in medical research: Quincy did not prespecify its subgroup hypotheses, and it undertook a large number of subgroup analyses. *See* Xin Sun, et al., *Credibility of claims of subgroup effects in randomized controlled trials: systematic review*, 344 BMJ 1, 2 (2012). In this situation, experts find that "many inferences from subgroup analyses have proved spurious." *Id.*

The district court rejected the FTC's position that post hoc subgroup analyses are inadequate substantiation because, it said, the FTC had not explained "the nature of" the increased risk of false positives and increased probability of results obtained by chance alone. SA-11 (Dist. Ct. Op.). The FDA and expert literature answer these questions. At the motion to dismiss stage, where the allegations in the complaint should be accepted as true, the court erred in rejecting the FTC's allegation that these

risks exist and that the claims therefore failed to meet the FTC's longstanding test for substantiation.

3. A meaningful substantiation standard for claims like those made by Quincy is particularly appropriate in light of the evolving nature of the science of health and disease. Claims based on preliminary evidence often later turn out to be inaccurate, as results from randomized controlled trials replace those from small-scale or preliminary studies lacking in rigor. For example, the D.C. Circuit noted in *POM Wonderful* that, there, although some smaller preliminary studies suggested positive results, the findings were not borne out by three larger, well-controlled studies that the company later sponsored. 777 F.3d at 485. The National Academies of Science's Institute of Medicine found a similar dynamic in a study examining evidence that had been thought to support nutrient-disease relationships. That study compared findings in a 1989 report to those in a series of reports from the late 1990s through 2001. *See* Institute of Medicine, *Evolution of Evidence for Selected Nutrient and Disease Relationships* 2 (2002), https://www.nap.edu/catalog/10379/evolution-of-evidence-for-selected-nutrient-and-disease-relationships. 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.

The FTC's allegation that the post hoc subgroup analyses do not substantiate Quincy's claims reflects a standard that protects consumers from inaccurate claims regarding a product's established ability to improve health and mental performance. *See* JA-37 (Compl. ¶ 29) ("[T]he few positive findings on isolated tasks for small subgroups of the study population do not provide reliable evidence of a treatment effect."). Moreover, by policing claims such as those made here, the FTC creates incentives for the development of more accurate consumer information, not just from Quincy, but from other dietary supplement manufacturers. This incentive is important, because the multi-billion dollar supplement industry, *see* GAO, *Memory Supplements*, *supra*, at 7 (estimating total sales of memory supplements in 2015 at $643 million); GAO, *Dietary Supplements*, *supra*, at 9 (reporting that total sales of dietary supplements in 2007 were about $23.7 billion), is subject to lax regulation and is rife with prohibited health and disease claims. *See* Office of Inspector General, Dep't of Health and Human Servs., *Dietary Supplements: Structure/Function Claims Fail to Meet Federal Requirements* i (Oct. 2012), https://oig.hhs.gov/oei/reports/oei-01-11-00210.pdf (finding that, in a sample of 127 dietary supplements, 20 percent included prohibited disease claims on their labels). Even permissible claims—those that describe the product's effect on the structure or function of the body, without purporting to say that the product treats, prevents, mitigates, or cures a disease or health-related condition—often lack adequate (or any) substantiation.

See id. at 11–12. Yet "[t]rust in the medical research enterprise—and the regulatory system that oversees this enterprise—is conditional on the belief that medical products and practices have more than the mere possibility of efficacy behind them." Spencer Hey & Aaron Kesselheim, *An Uninformative Truth: The Logic of Amarin's Off-Label Promotion*, PLOS Medicine 4 (Mar. 15, 2016). Balancing the competing interests, the FTC's substantiation requirements accommodate companies' interest in relying on developing science, while protecting consumers from companies that peddle falsehoods and misleading claims.

CONCLUSION

For the foregoing reasons and the reasons stated in the brief of appellants, the district court's decision should be reversed.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The brief complies with Fed. R. App. P. 32(a)(5)and (6); it was prepared in a proportionally spaced typeface using Microsoft Word 2010 in 14-point Times New Roman. This brief contains 4,290 words, excluding the portions exempted by Fed. R. App. P. 32(a)(7)(B)(iii), if applicable.

/s/
Allison M. Zieve

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Second Circuit on March 6, 2018, by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/
Allison M. Zieve