No. 10-125

In the Supreme Court of the United States

NATIONAL UROLOGICAL GROUP, INC., ET AL.,
PETITIONERS

v.

FEDERAL TRADE COMMISSION

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the judgment below, which imposed liability on petitioners under the Federal Trade Commission Act for disseminating advertisements that the district court determined to be false and misleading, violated petitioners' First Amendment right to engage in commercial speech.

2. Whether the Federal Trade Commission's standard for determining whether a dietary supplement advertisement has sufficient substantiation is unconstitutionally vague.

3. Whether the judgment below conflicts with the Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325.

4. Whether the district court correctly determined that there were no disputed issues of material fact.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

Cases—Continued: Page

Constitution, statutes, regulation and rule:

Miscellaneous:

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-2a) is not published in the *Federal Reporter* but is reprinted in 356 Fed. Appx. 358. The opinion of the district court (Pet. App. 3a-86a) is reported at 645 F. Supp. 2d 1167.

JURISDICTION

The judgment of the court of appeals was entered on December 15, 2009. A petition for rehearing was denied on April 26, 2010 (Pet. App. 87a-88a). The petition for a writ of certiorari was filed on July 23, 2010. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Petitioners are two closely held companies (National Urological Group, Inc. and Hi-Tech Pharmaceuticals, Inc.), officers of those companies (Jared Wheat, Thomasz Holda, and Stephen Smith), and a medical doctor affiliated with them (Terrill Mark Wright). Pet. App. 4a. Along with a now-dissolved company, petitioners have collectively been responsible for the production, marketing, and sale of the weight-loss supplements Thermalene and Lipodrene, and the erectile-performance supplement Spontane-ES. *Id.* at 4a & n.1, 79a.

Petitioners produced advertisements for these supplements that touted their efficacy and safety, frequently by reference to scientific and clinical studies. Pet. App. 34a-56a. The advertisements claimed, for example, that "Thermalean's scientifically proven formula" had yielded a "42% reduction in body fat" in "independent university-sponsored trials"; that Lipodrene is "[c]linically PROVEN to be SAFE AND EFFECTIVE"; and that "in preliminary testing, Spontane-ES's active components have been shown to be effective in nearly 90% of all men who have taken it." *Id.* at 44a, 53a, 55a (citations omitted). The advertisements also indicated that petitioners themselves were actively engaged in product testing. See, *e.g.*, *id.* at 63a (quoting advertisement's claim that one of the corporate petitioner's "professional staff and Medical Board" had "aligned with one of the nation's largest manufacturing facilities to begin Phase I testing of Lipodrene").

In fact, however, petitioners had never conducted, nor were they aware of, any clinical or scientific studies conducted on any of these supplements. Pet. App. 59a. Petitioners instead relied solely on studies that had

tested individual ingredients of their products, but without testing the efficacy or safety of those ingredients in the particular dosages and combinations that petitioners were marketing. *Id.* at 58a & n.21. Petitioners themselves, moreover, maintained no medical or scientific facilities for product testing. *Id.* at 64a.

2. a. Respondent Federal Trade Commission (FTC or Commission) is "empowered and directed" by the Federal Trade Commission Act "to prevent * * * unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. 45(a)(2). The statutory definition of "unfair or deceptive act or practice" includes the dissemination of "any false advertisement * * * for the purpose of inducing, or which is likely to induce, * * * the purchase in or having an effect upon commerce, of food, drugs, devices, services, or cosmetics." 15 U.S.C. 52. The Commission can establish a violation of these provisions by showing that a defendant has made a material representation that is likely to mislead reasonable consumers. See, *e.g.*, *FTC* v. *Cyberspace.com LLC*, 453 F.3d 1196, 1199 (9th Cir. 2006); *FTC* v. *Bay Area Bus. Council, Inc.*, 423 F.3d 627, 635 (7th Cir. 2005); *FTC* v. *Tashman*, 318 F.3d 1273, 1277 (11th Cir. 2003).

Under the FTC's longstanding interpretation of the Act, as set forth in its policy statements and adjudicatory decisions, an advertisement is misleading not only if it makes claims that are provably untrue, but also if it makes claims that the advertiser "lack[s] a reasonable basis" to support. Pet. App. 4a; see, *e.g.*, *FTC* v. *Pantron I Corp.*, 33 F.3d 1088, 1096 n.22 (9th Cir. 1994), cert. denied, 514 U.S. 1083 (1995); *Thompson Med. Co., Inc.* v. *FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987); *FTC Policy Statement on Deception* n.5 (Oct. 14, 1983), http://www.ftc.gov/

bcp/policystmt/ad-decept.htm. With respect to health-related claims, the Commission has required that an advertising claim be supported by "competent and reliable scientific evidence." FTC, *Dietary Supplements: An Advertising Guide for Industry* 9 (2001), http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.pdf (*Dietary Supplements Guide*); see, *e.g.*, *Removatron Int'l Corp.* v. *FTC*, 884 F.2d 1489, 1498 (1st Cir. 1989).

b. In 2004, the Commission filed suit against petitioners in federal district court, alleging that many of their advertising claims about their dietary supplements were false and/or lacked a reasonable basis in scientific evidence. Pet. App. 6a-7a, 34a-35a, 49a, 53a-54a, 62a-63a. The FTC sought an injunction against future violations and repayment of nearly $16 million in revenue petitioners had earned from selling the supplements. *Id.* at 71a, 79a; see 15 U.S.C. 53(b). Following cross-motions for summary judgment, the district court granted judgment in favor of the Commission. Pet. App. 85a-86a.

The district court rejected petitioners' First Amendment challenge to the Commission's standards for determining whether an advertisement is false or deceptive. Pet. App. 21a-22a. Petitioners argued that those standards constituted an impermissible restriction on commercial speech under the test set forth in *Central Hudson Gas & Elec. Corp.* v. *Public Serv. Comm'n*, 447 U.S. 557 (1980). The district court observed, however, that the *Central Hudson* test applies only to constitutionally protected speech, and that false speech is not constitutionally protected. Pet. App. 21a-22a. The court therefore rejected petitioner's argument—"that the Court must use the *Central Hudson* test * * * to determine

whether or not speech is protected"—as a "confusing" and "illogical" exercise in "circular logic." *Id.* at 22a.

The district court also rejected petitioners' constitutional vagueness challenge to the Commission's requirement that advertising claims about dietary supplements be supported by "competent and reliable scientific evidence." Pet. App. 23a-25a. That phrase was not impermissibly vague, the district court held, because it had been defined by the Commission to mean "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.* at 24a (quoting *Dietary Supplements Guide* 9). The court explained that, although the application of that "context specific" rule will necessarily vary depending on how experts would evaluate a particular type of advertising claim, "the standard by which these issues of fact are resolved is clear." *Id.* at 23a-24a.

Turning to the merits of the case, the district court determined, applying the traditional summary judgment standards, Pet. App. 12a-13a, that all but one of the advertising claims identified in the Commission's complaint violated the Act. *Id.* at 61a-62a, 65a. The court concluded that petitioners had not merely made claims about the efficacy, safety, and testing of various ingredients of their dietary supplements, but had made claims about the efficacy, safety, and testing of their dietary supplements as a whole. *Id.* at 41a ("The unambiguous intent and meaning of the advertisement is that Thermalean—not its 'proprietary components'—causes rapid and substantial weight loss."); see *id.* at 43a, 47a n.17, 55a n.19. It found no dispute of material fact that those

claims were material to consumers in deciding whether to purchase the supplements. *Id.* at 60a-61a, 64a-65a. And it found no dispute of material fact that the claims were false, unsubstantiated, or both. *Id.* at 57a-60a, 64a-65a. In making that latter determination, the district court relied on petitioners' concession that the supplements had not been scientifically tested (as various advertisements claimed that they had) and the Commission's unrebutted expert evidence that, in the absence of such testing, petitioners lacked a reasonable basis for making various claims about the supplements' efficacy and safety. *Id.* at 58a-59a.

3. The court of appeals affirmed the district court's "well-reasoned decision" in an unpublished per curiam opinion. Pet. App. 2a.

ARGUMENT

The district court correctly granted summary judgment based on the uncontroverted evidence presented by the Commission. The Eleventh Circuit's decision affirming that judgment does not conflict with any decision of this Court or any other court of appeals. Further review is not warranted.

1. Petitioners contend (Pet. 9-14) that the district court's decision violates their First Amendment right to engage in commercial speech. That contention lacks merit. The district court determined that petitioners' advertisements were false and misleading. Pet. App. 57a-60a, 64a-65a. False and misleading commercial speech does not receive First Amendment protection. See *Zauderer* v. *Ohio Office of Disciplinary Counsel*, 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 mislead-

ing."); see also, *e.g.*, *Thompson* v. *Western States Med. Ctr.*, 535 U.S. 357, 367 (2002); *Virginia State Bd. of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771-772 (1976).

Contrary to petitioners' assertion (Pet. 10-11), the district court's determination that petitioners' advertisements were false and misleading does not conflict with the D.C. Circuit's decision in *Pearson* v. *Shalala*, 164 F.3d 650 (1999). That case concerned a regulation under which the Food and Drug Administration (FDA) would allow health claims to appear on a dietary supplement's label only if there were "significant scientific agreement" that the claims were true. *Id.* at 652 (quoting 21 C.F.R. 101.14(c)). The FDA had applied the regulation to ban certain health claims for which the marketers had "supporting evidence," on the ground that the supporting evidence was "inconclusive for one reason or another and thus failed to give rise to 'significant scientific agreement.'" *Id.* at 653. The court held that this regulatory approach violated the First Amendment: the health claims were protected by the First Amendment because they were only "potentially misleading," rather than "inherently misleading," (*id.* at 655); and the agency had not considered whether this problem could be cured through the less-restrictive means of adding disclaimers (*id.* at 656-657).

This case, in contrast to *Pearson*, involves marketing claims that were *actually* misleading, not just potentially misleading. See *Pearson*, 164 F.3d at 655 (recognizing that if marketing claims "could be thought inherently misleading, that would be the end of the inquiry," because the claims would not be protected speech). Unlike in *Pearson*, the district court here determined that petitioners' advertisements were "false" because, for

example, they "assert[ed] that a clinical test was performed on the products" when petitioners "admitted that the products have not been clinically tested." Pet. App. 59a; see *id.* at 60a, 64a. Also unlike in *Pearson*, the district court here determined that petitioners had made claims that they had no "reasonable basis" to believe were true, because they were unsupported by any "competent and reliable scientific evidence." *Id.* at 57a-58a; cf. *Pearson*, 164 F.3d at 653 (noting that there was "supporting evidence" for the label claims at issue). Petitioners identify no decision holding that either of these forms of speech is protected under the First Amendment.[*]

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[*] Petitioners attempt to rebut the district court's conclusion that their speech was false and misleading by asserting that the FTC "conceded in discovery that 'it did not contend that any individual statement in the advertisement was not 100% accurate.'" Pet. 8-9; see *id.* at 13. That language is taken out of context from the Commission's responses to petitioners' interrogatories. A fuller quotation demonstrates that the Commission was not admitting that petitioners' speech was truthful, but was instead making clear that its complaint was based on each advertisement viewed as a whole, rather than on isolated statements therein. 1:04-CV-3294 Docket entry No. 168-1, Exh. M at 10, 22, 30 (N.D. Ga. Aug. 24, 2007) ("[T]he Commission's allegations against [petitioner National Urological Group, Inc.] are based upon claims derived from the overall net impression that is created by the interaction of various elements in the challenged advertising * * *. Regarding how and/or why the [Commission] contends that the advertising claim departs from 100% accuracy, it is not the Commission's contention that any individual statement contained in the challenged advertisement * * * is not 100% accurate. The Commission charges [petitioners] with making claims that are false and/or unsubstantiated."); see *id.* at 7, 15, 27 ("[I]t is neither the Commission's burden nor a necessary element of the Commission's proof in this litigation to demonstrate that any individual statement * * * contained in the challenged advertisement * * * is false or misleading.").

2. Petitioners also contend (Pet. 14-16) that the Commission's "competent and reliable scientific evidence" standard is unconstitutionally vague. As a threshold matter, that contention bears only upon the district court's conclusion that certain claims were unsubstantiated (because petitioners lacked a reasonable basis for making them), and not upon its separate conclusion that many of these same claims (and others) were provably false. See Pet. App. 34a-35a, 49a, 53a-54a, 62a-63a. It therefore would not provide a basis for petitioners to avoid liability.

In any event, the district court correctly rejected petitioners' vagueness argument. As the district court recognized, and as petitioners acknowledge, the Commission has provided published guidance on how its standard applies in cases like this. Pet. App. 23a-24a; Pet. 15; see, *e.g.*, *Dietary Supplements Guide* 9-18 (explaining how the standard is "defined in [Commission] cases" and describing application of the standard, including 15 examples). Petitioners' generalized complaint that this guidance is insufficient (Pet. 15), which declines even to quote the guidance or to address it with any degree of specificity, provides no reason to disturb the district court's conclusion. Petitioners' assertion that they "cannot be expected to review the [Commission's] vague standard and have any confidence as to whether the [Commission] would consider their substantiation for their advertising claims adequate" (*ibid.*) rings hollow in a circumstance where they did not do *any* scientific testing on the dietary supplements to support their advertising claims.

Petitioners are mistaken in suggesting (Pet. 14-15) that the court in *Pearson* reached a conflicting result. That decision held (in addition to its First Amendment

holding) that the Administrative Procedure Act required the FDA to "explain what it mean[t]" by requiring claims in dietary supplement labels to be supported by "significant scientific agreement." 164 F.3d at 661. Even assuming that the court would have reached that same conclusion as a constitutional matter, see *id.* at 660 ("[c]onsideration of [the] constitutional claim seems unnecessary"), it would not dictate the outcome here. The Commission's standard here ("competent and reliable scientific evidence") shares only a single word in common with the standard addressed in *Pearson* ("significant scientific agreement"), and there is no reason to believe that the vagueness analysis would be the same. Moreover, the Commission's extensive guidance provides exactly what the court found lacking in *Pearson*: an explanation of what the agency "means by" its standard. *Id.* at 661.

3. Petitioners additionally contend (Pet. 16-20) that the district court's decision "eviscerates" the Dietary Supplement Health and Education Act of 1994 (DSHEA), Pub. L. No. 103-417, 108 Stat. 4325. That contention appeared for the first time in their appellate petition for rehearing, and it was not addressed by either the district court or the court of appeals. See Pet. for Reh'g En Banc 3, 9-11. This Court does not ordinarily consider issues that were neither pressed nor passed on below, see, *e.g.*, *Zobrest* v. *Catalina Foothills Sch. Dist.*, 509 U.S. 1, 8 (1993), and there is no reason for it to do so here.

In any event, petitioners' argument is without merit. *Inter alia*, the argument rests on the premise that petitioners' advertisements comply with DSHEA's requirement that "the manufacturer of [a] dietary supplement ha[ve] substantiation that" a statement made about the

supplement "is truthful and not misleading." DSHEA § 6, 108 Stat. 4329 (21 U.S.C. 343(r)(6)(B)); see Pet. 16-17. The district court concluded, however, that petitioners had made claims that were not truthful and not substantiated. Pet. App. 57a-60a, 64a-65a.

4. Petitioners finally contend that the district court erred by granting the Commission's motion for summary judgment because there were material facts in dispute. Pet. 21-24. That fact-bound contention does not warrant this Court's review.

The district court correctly applied the well-settled legal standard to the parties' cross-motions for summary judgment. Pet. App. 12a-13a. It considered the evidence and the arguments at length before granting the Commission's motion on the ground that no reasonable jury could find for petitioners. *Id.* at 25a-86a; Fed. R. Civ. P. 56(c)(2). The court determined that petitioners had admitted critical facts (*e.g.*, Pet. App. 59a), failed to rebut evidence presented by the Commission (*e.g.*, *id.* at 58a), and neglected to comply with local rules concerning summary judgment motions (*e.g.*, *id.* at 60a).

Petitioners do not demonstrate that the outcome would have been different in another circuit. Contrary to petitioners' assertion (Pet. 22), the D.C. Circuit does not require the Commission to present consumer survey evidence in order to prove that an advertisement is deceptive. See *FTC* v. *Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 40 (1985) ("[W]e do not accept appellant's contention that consumer survey evidence must, as a matter of law, be presented to support a finding that an advertisement has a tendency to deceive and violates section 5 of the FTC Act.") (cited at Pet. 22). Further review is accordingly unwarranted.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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