No. 98-235

In the Supreme Court of the United States

OCTOBER TERM, 1998

NUTRITIONAL HEALTH ALLIANCE, ET AL.,
PETITIONERS

v.

DONNA SHALALA, SECRETARY OF
HEALTH AND HUMAN SERVICES, ET AL.

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

BRIEF FOR THE RESPONDENTS IN OPPOSITION

SETH P. WAXMAN
Solicitor General
Counsel of Record
FRANK W. HUNGER
Assistant Attorney General
DOUGLAS N. LETTER
KATHLEEN MORIARTY MUELLER
Attorneys
Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

QUESTIONS PRESENTED

Pursuant to the Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353, 21 U.S.C. 343, the Food and Drug Administration (FDA) has issued regulations that require persons who want to make a health claim in the labeling of a dietary supplement to petition the FDA for authorization to make such a claim. Under the regulations, FDA will grant authorization only when it determines that there is "significant scientific agreement" that a health claim is valid. § 3(r)(3)(B)(i), 104 Stat. 2359, 21 U.S.C. 343(r)(3)(B)(i). Petitioners are a dietary supplement retailer and an association of consumers, producers, and retailers of dietary supplements who have challenged the regulations on First Amendment grounds. The questions presented are:

1. Whether the preauthorization requirement is an unconstitutional prior restraint of commercial speech.

2. Whether petitioners have satisfied standing and ripeness standards for challenging the "significant scientific agreement" standard when they have not alleged that they want to make any particular health claim that has not been authorized by FDA.

3. Whether the "significant scientific agreement" standard violates the First Amendment to the Constitution.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

In the Supreme Court of the United States

OCTOBER TERM, 1998

No. 98-235

NUTRITIONAL HEALTH ALLIANCE, ET AL.,
PETITIONERS

v.

DONNA SHALALA, SECRETARY OF
HEALTH AND HUMAN SERVICES, ET AL.

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

BRIEF FOR THE RESPONDENTS IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-17a) is reported at 144 F.3d 220. The opinion of the district court (Pet. App. 25a-40a) is reported at 953 F. Supp. 526. The order granting summary judgment in part (Pet. App. 20a-24a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on May 15, 1998. The petition for a writ of certiorari was filed on August 5, 1998. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. Under the Nutrition Labeling and Education Act of 1990 (NLEA), Pub. L. No. 101-535, 104 Stat. 2353, 21 U.S.C. 343, a health claim[1] may be made on a food label or labeling only if the Food and Drug Administration (FDA) has determined in a regulation that, "based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), * * * there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence." § 3(r)(3)(B)(i), 104 Stat. 2359, 21 U.S.C. 343(r)(3)(B)(i). NLEA also required FDA to establish, by regulation, a "procedure and standard" for determining the validity of health claims in the labeling of "dietary supplement[s] of vitamins, minerals, herbs, or other similar nutritional substances." § 3(r)(5)(D), 104 Stat. 2360, 21 U.S.C. 343(r)(5)(D).

Pursuant to that mandate, FDA promulgated the regulations at issue here, which apply the same procedure and standard for dietary supplement labeling that Congress established for conventional food labeling. See 21 C.F.R. 101.14, 101.70. The regulations permit a health claim to be made in the labeling of a dietary supplement only if the claim is based on and consistent with an FDA regulation. 21 C.F.R. 101.14(c) and (d). FDA will promulgate a regulation authorizing a health claim

---

[1] A "health claim" is "any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication * * * characterizes the relationship of any substance to a disease or health-related condition." 21 C.F.R. 101.14(a)(1); see also § 3(r)(1)(B), 104 Stat. 2357, 21 U.S.C. 343(r)(1)(B).

when it determines that there is "significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence." 21 C.F.R. 101.14(c).

Since the issuance of the regulations, Congress has significantly modified the regulatory scheme for health claims. Section 303(r)(3)(C) of the Food and Drug Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2351 (to be codified at 21 U.S.C. 343(r)(3)(C)), permits a manufacturer to make a health claim that is based on an "authoritative statement" from certain governmental scientific bodies or the National Academy of Sciences, provided that FDA is given 120 days pre-marketing notice. Although that provision applies to conventional foods and not dietary supplements, FDA has stated its intent to publish a proposed rule that applies that provision to dietary supplements. 63 Fed. Reg. 34,084, 34,085 (1998).

In addition, the Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 6(r)(6), 108 Stat. 4329, 21 U.S.C. 343(r)(6), amended the regulatory scheme for dietary supplements to permit three other types of claims to be made without FDA pre-approval: (1) statements that a supplement will have a benefit related to a classical nutrient deficiency disease; (2) statements that describe or characterize a nutrient's role in the structure or function of the body; and (3) statements that describe general well-being from consumption of a dietary supplement. Such claims are permitted if the manufacturer has "substantiation" that the statement is truthful and non-misleading, if the label states that the FDA has not evaluated the claim, and if the FDA was notified within 30 days of the

marketing of the product. § 6(r)(6)(B) and (C), 108 Stat. 4329, 21 U.S.C. 343(r)(6)(B) and (C).

b. Any person may petition FDA to issue a regulation authorizing a health claim in dietary supplement labeling. § 3(r)(4)(A)(i), 104 Stat. 2360, 21 U.S.C. 343(r)(4)(A)(i); 21 C.F.R. 101.70(a). Within 100 days of the receipt of a petition, FDA will either deny the petition or "file" it for more comprehensive review. § 3(r)(4)(A)(i), 104 Stat. 2360, 21 U.S.C. 343(r)(4)(A)(i); 21 C.F.R. 101.70(j)(2). If the petition is "filed," the agency has an additional 90 days to deny the petition or issue a proposed regulation authorizing the health claim. § 3(r)(4)(A)(i), 104 Stat. 2360, 21 U.S.C. 343(r)(4)(A)(i); 21 C.F.R. 101.70(j)(3). Before the present litigation, there was no statutory or regulatory deadline by which FDA was required to publish a final regulation approving or denying the health claim. In response to the district court's initial decision in this case, FDA issued a regulation under which a final rule approving or denying the proposed health claim must be issued within 270 days of the date of publication of the proposed rule. 21 C.F.R. 101.70(j)(4)(i). That deadline may be extended for not more than 180 days for good cause. 21 C.F.R. 101.70(j)(4)(ii).

That regulatory scheme gives FDA at least 460 days and at most 640 days from the time a health claim is submitted before it must publish a final regulation. After FDA issued its regulatory response to the district court's decision in this case, Congress added a requirement that FDA complete its rulemaking within 540 days of the filing of the petition. See Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 302(r)(4)(A)(i), 111 Stat. 2350 (to be codified at 21 U.S.C. 343(r)(4)(A)(i)). FDA amended its regulations to provide that the agency may extend the

regulatory deadline for the final rule only if the publication date of the final rule, as extended, is within the statutory deadline. 21 C.F.R. 101.70(j)(4)(ii).

2. a. Petitioners are an organization of manufacturers, retailers, and consumers of dietary supplements and an individual health food store. Pet. App. 27a. They allege that the preauthorization requirement is an unconstitutional "prior restraint" and that the "significant scientific agreement" standard violates their constitutional right truthfully to inform the public of the relationships between the consumption of dietary supplement products and diseases or health-related conditions. *Id.* at 8a-9a. Petitioners did not allege that they ever filed a petition requesting permission to make a specific health claim in dietary supplement labeling. *Id.* at 10a. Nor did petitioners allege that they wish to make any health claim that is not already authorized by an existing FDA regulation. *Ibid.* The government moved to dismiss the complaint for lack of standing and failure to state a claim, and petitioners moved for summary judgment. *Id.* at 3a.

b. The district court denied in part the government's motion to dismiss and granted in part petitioners' motion for summary judgment. Pet. App. 25a-40a. The court first held that petitioners had standing to challenge the regulations. *Id.* at 31a-32a. The court then analyzed petitioners' claim under the four-part test established in *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557 (1980), for determining whether government regulations of commercial speech are consistent with the First Amendment. Pet. App. 32a-33a.

The court concluded that the government had three substantial interests at issue in this case: "preventing the spread of unsubstantiated health claims on labels so

that consumers may not be deceived and follow unsound health practices; ensuring the reliability of scientific information disseminated in connection with the sale of dietary supplements; and protecting consumers from being induced to purchase products by misleading information on labels." Pet. App. 33a-34a. The court also determined that the NLEA and FDA's regulations "directly and materially advance [those] substantial interests." *Id.* at 34a. The court concluded, however, that, in light of the absence of any deadline for the final authorization of a proposed health claim, the regulations were more extensive than necessary to accomplish the government's substantial interests. *Id.* at 35a-39a. The court directed FDA to "establish and submit to the Court for approval, a reasonable time limit for the promulgation of a final rule for a health claim on dietary supplement labels." *Id.* at 39a.

c. In response to the district court's decision, FDA promulgated the regulation previously noted that requires publication of a final rule authorizing or declining to authorize the proposed health claim within 270 days of the date of publication of the proposed rule, unless the agency extends the deadline for good cause. See 21 C.F.R. 101.70(j)(4); 62 Fed. Reg. 28,230 (1997). The district court upheld that regulation, Pet. App. 18a-19a, finding that the "270 days, 75 to invite public comment and roughly six months to allow the agency to assess whatever it receives[,] is not unreasonable," *id.* at 18a.

3. The court of appeals affirmed in part and vacated in part. Pet. App. 1a-17a. The court first held that petitioners' challenge to the "significant scientific agreement" is not ripe for review, because petitioners had not specified any particular health claim that they wish to make. *Id.* at 9a-14a. Agreeing with the Tenth Circuit's reasoning in *National Council for Improved*

Health v. *Shalala*, 122 F.3d 878, 883 n.7 (1997), the court concluded that "without a specific proposed health claim to review, on evidence of record before the FDA," a court "cannot determine whether the 'significant scientific agreement' requirement actually bars any truthful, non-misleading speech." Pet. App. 11a.

The court next held that petitioners' claim that the FDA authorization process constitutes an unconstitutional prior restraint is ripe for review, because it "involves a purely legal question that is eminently fit for judicial review." Pet. App. 14a. Even if FDA eventually authorizes petitioners' desired health claims, the court added, petitioners would be "subject to the allegedly unconstitutional FDA preclearance procedure." *Ibid.*

On the merits, the court rejected petitioners' claim that the regulations impose an unconstitutional prior restraint of commercial speech. Applying circuit precedent, the court held that there must be "procedural safeguards" for a prior restraint on commercial speech that ensure that the restraint is "not more extensive than necessary to serve [the asserted governmental] interest." Pet. App. 15a, 16a (quoting *Central Hudson*, 447 U.S. at 566). Applying that standard, the court concluded that "given the need to protect consumers before any harm occurs," a "540-day prior restraint is sufficiently narrowly tailored." *Ibid.* The court explained that a 540-day period "grants a limited, but reasonable, time within which the FDA can evaluate the evidence in support of labeling claims." *Ibid.* The court also noted that the regulatory scheme places "sufficiently definite" constraints on FDA's authority to deny a proposed health claim, since FDA is required to approve such a claim if it satisfies the "significant scientific agreement" standard. *Ibid.*

The court of appeals declined to consider whether it would be constitutional for FDA to take more than 540 days to evaluate the validity of a proposed health claim. The court held that a challenge to possible extensions to the 540-day review process is not ripe because petitioners have not requested FDA review of any proposed health claim. Pet. App. 17a n.17.

ARGUMENT

1. Petitioners contend (Pet. 14-21) that the FDA regulation requiring FDA preauthorization of any health claim made on the label of a dietary supplement constitutes an unconstitutional prior restraint on commercial speech. That contention is without merit and does not warrant review.

a. As an initial matter, petitioners failed to establish Article III standing to challenge the preauthorization requirement. To establish Article III standing, petitioners were required to show that the preauthorization requirement caused them an "injury in fact" that is "concrete and particularized" and "actual or imminent." *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 560 (1992). Petitioner failed to make that showing. As the court of appeals noted, petitioners have not alleged that they want to make any particular health claim that is not currently permitted by FDA regulations. Nor have petitioners alleged that the FDA has denied them permission to make any particular claim. Pet. App. 10a. Petitioners therefore lack Article III standing to challenge the preauthorization requirement.

b. In any event, petitioners' contention that the preauthorization review requirement is an unconstitutional prior restraint is without merit. As an initial matter, the prior restraint doctrine does not appear to play any distinct role in commercial speech cases, and there is no

reason why this sort of preauthorization process for the commercial labeling of products with respect to health claims should be subjected to a different First Amendment standard than other means of regulating commerical speech concerning such products. That view is supported by this Court's recognition that commercial speech is more hardy and resilient than other speech. "Since advertising is the *sine qua non* of commercial profits, there is little likelihood of its being chilled by proper regulation and forgone entirely." *Virginia State Bd. of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 772 n.24 (1976). Consistent with that recognition, the Court has expressed approval of prior review requirements in commercial speech cases. *Shapero* v. *Kentucky Bar Ass'n*, 486 U.S. 466, 476 (1988) (lawyer may be required to file solicitation letter with State in advance, to give it "ample opportunity to supervise mailings and penalize actual abuses"); *Central Hudson*, 447 U.S. at 571 n.13 (State may require "a system of previewing advertising campaigns").

Even assuming that the prior restraint doctrine has some independent application to commercial speech cases, however, it could not serve to invalidate the preauthorization review procedures at issue here. Given "the need to protect consumers before any harm occurs," Pet. App. 16a, there is an obvious governmental interest in some kind of preauthorization requirement. Moreover, as the court of appeals in this case concluded, the preauthorization requirement at issue here has adequate procedural safeguards to prevent the two principal dangers of prior restraints—unreasonable delay in the dissemination of protected speech and unbridled governmental discretion to suppress speech. *Ibid.* The 540-day statutory review period "grants a limited, but reasonable, time within

which the FDA can evaluate the evidence in support of labeling claims." *Ibid.* That is particularly true in light of the complexity of the issues involved and the serious public health consequences that could result from mistaken approvals. And the "significant scientific agreement" standard for evaluating proposed health claims is "sufficiently definite to constrain the FDA within reasonable bounds." *Ibid.* Thus, even assuming that the prior restraint doctrine has some independent application to commercial speech, the regulatory scheme at issue here satisfies that doctrine as it has been applied outside the commercial speech context. See *Central Hudson*, 447 U.S. at 571 n.13 (in areas outside of commercial speech, "prescreening arrangement can pass constitutional muster if it includes adequate procedural safeguards").[2]

Petitioners contend (Pet. 18-21) that the court of appeals' prior restraint analysis was incomplete because it did not assess the merits of the "significant scientific agreement" standard under the *Central Hudson* four-part test. The court of appeals did not engage in that analysis, however, because it had already con-

---

[2] Two courts of appeals have upheld prior restraints that, like the FDA regulations at issue here, protect the public from deceptive, misleading, or overreaching commercial speech. See *Kleiner* v. *First Nat'l Bank*, 751 F.2d 1193, 1206-1207 (11th Cir. 1985) (in class action against a bank, the district court properly imposed a prior restraint on the bank's communications with customers to protect potential class members from coercion); *United States Postal Serv.* v. *Athena Prods., Ltd.*, 654 F.2d 362 (5th Cir. 1981) (affirming preliminary injunction permitting the Postal Service to detain incoming mail for up to 120 days to determine whether the recipient was using the mail to obtain money through false pretenses), cert. denied, 456 U.S. 915 (1982). None of the cases cited by petitioners (Pet. 15-16) suggests that such a prior restraint would be unconstitutional.

cluded that petitioners' challenge to the "significant scientific agreement" standard is not ripe for review. Pet. App. 9a-14a. Having concluded that petitioners' challenge to that standard is not ripe, the court of appeals correctly declined to assess the merits of that standard as part of its inquiry into whether the preauthorization review constitutes an unconstitutional prior restraint.

2. Petitioners next contend (Pet. 22-26) that the court of appeals erred in holding that their challenge to the "significant scientific agreement" standard is not ripe. That contention is without merit and does not warrant review.

As we have noted, petitioners' complaint did not allege that they wished to make any particular health claim. Nor have they ever sought FDA authorization to make a particular claim. Pet. App. 10a. In those circumstances, petitioners' constitutional challenge to the "significant scientific agreement" standard is entirely abstract and hypothetical. See *United Public Workers* v. *Mitchell*, 330 U.S. 75, 90-91 (1947) (federal employees lacked standing to bring a First Amendment challenge to restrictions on political activity where the Court could "only speculate as to the kinds of political activity the appellants desire to engage in or as to the contents of their proposed public statements or the circumstances of their publication").

Moreover, the central premise of petitioners' constitutional challenge to the "significant scientific agreement" standard is that it bars the dissemination of truthful, non-misleading information. As the court of appeals concluded, that contention cannot be intelligently evaluated in the absence of a concrete FDA decision barring a particular labeling claim. As the court explained (Pet. App. 11a), "without a specific

proposed health claim to review, on evidence of record before the FDA, we cannot determine whether the 'significant scientific agreement' requirement actually bars any truthful, non-misleading speech." The court of appeals therefore correctly concluded that petitioners' challenge to the "significant scientific agreement" standard is not ripe for review. See *Renne* v. *Geary*, 501 U.S. 312, 321-322 (1991) (First Amendment challenge to election regulations not ripe where the factual record was not sufficient to present the constitutional issues in a "clean-cut and concrete form").

The reasoning of the court below tracks the reasoning of the Tenth Circuit in *National Council for Improved Health* v. *Shalala*, *supra*. In that case, the Tenth Circuit rejected on standing grounds a First Amendment challenge to the same statute and regulations at issue in this case. The court explained:

> [A] critical issue in evaluating the constitutionality of commercial speech is whether the speech at issue is truthful or misleading. Without knowing what claims plaintiffs seek to disseminate, this court cannot assess whether such claims are truthful and not misleading. Therefore, an analysis of this issue would rest on mere speculation.

122 F.3d at 883 n.7 (citation omitted).

Thus, the only two appellate courts that have addressed the issue have both concluded that the constitutionality of the "significant scientific agreement" standard should be resolved in the context of a specific claim that has been rejected by the FDA. Review of that issue is not warranted.

b. Petitioners also contend (Pet. 25-26) that the court of appeals erred in declining to review on ripeness grounds their claim that the 540-day deadline is inade-

quate because FDA may act beyond the 540-day period as long as it provides to Congress the reasons for the delay. As this Court recently reiterated, however, "[a] claim is not ripe for adjudication if it rests upon 'contingent future events that may not occur as anticipated, or indeed may not occur at all.'" *Texas* v. *United States*, 118 S. Ct. 1257, 1259 (1998) (quoting *Thomas* v. *Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 581 (1985)). Since petitioners have not asked FDA to evaluate a proposed health claim, it is impossible to determine whether FDA would act on some hypothetical claim beyond the 540-day limit, much less what FDA's reason for needing more time might be. The court of appeals therefore correctly concluded (Pet. App. 17a n.17) that any question about the constitutionality of a possible extension of the 540-day review period is not ripe for review.

3. Petitioners also argue (Pet. 26-28) that certiorari should be granted to determine the constitutionality of the "significant scientific agreement" standard. Because the court of appeals correctly concluded that that issue is not ripe for review, however, it did not resolve that issue on the merits. That question therefore is not properly presented here.

In any event, the "significant scientific agreement" standard is constitutional. It is well-established that the government may ban not only commercial speech that is "provably false," but also commercial speech that is "deceptive or misleading." *Virginia State Bd. of Pharmacy*, 425 U.S. at 771-772. Of particular relevance here, experience has shown that there is a substantial potential for health claims on dietary supplements to be deceptive and misleading in practice. Prior to the enactment of the NLEA, "unfounded health claims [were] being made in the marketplace." H. R. Rep. No.

538, 101st Cong., 2d Sess. 9 (1990). Morever, health claims address matters of great importance to the public (such as ways to reduce cancer risk) and, when made on labels, are likely to exert substantial influence on purchasers at the point of sale. See 59 Fed. Reg. 395, 421 (1994) (incorporating by reference FDA's earlier analysis published in 58 Fed. Reg. 2478, 2524-2528 (1993)). Health claims also purport to contain or convey scientific information and are based on studies that the average consumer would have difficulty interpreting or verifying, and consumers may rely on health claims because they believe that the claims are regulated by the government, whether they are or not. Thus, to protect consumers from being misled, the government may prohibit health claims that are not supported by "significant scientific agreement." Cf. *Ohralik* v. *Ohio State Bar Ass'n*, 436 U.S. 447, 464 (1979) (upholding ban on attorney's in-person solicitation of clients where experience supported State's percepton of potential for harm); *Friedman* v. *Rogers*, 440 U.S. 1, 13-15 (1979) (upholding ban on practice of optometry under trade name where "possibilities for deception" were numerous and legislature had evidence of deceptive practices).

The significant potential for health claims on labeling both to be deceptive or misleading and to have particular influence on consumers—coupled with the heightened governmental interest in protecting public health and safety—are sufficient in themselves to sustain the regulatory scheme adopted by Congress and FDA.[3] In

[3] This Court made clear in *Central Hudson* itself that "[t]he government may ban forms of communication more likely to deceive the public than to inform it." 447 U.S. at 563. In addition, we argued below that the "significant scientific agreement" standard is constitutional because it imposes only an incidental restriction on speech as part of a comprehensive regulatory scheme. See

any event, the most the government would have to show to sustain the constitutionality of the "significant scientific agreement" standard is that it satisfies the second, third and fourth prongs of the *Central Hudson* inquiry, *i.e.*, that it is designed to serve substantial governmental interests, that it directly advances those interests, and that it is no more extensive than necessary to serve those interests. See *Central Hudson*, 447 U.S. at 566. The "significant scientific agreement" standard easily satisfies each of those prongs.

Petitioners assert (Pet. 28) that the government's interest at issue here is the impermissible one of preventing consumers from making their own decisions on the basis of truthful and non-misleading information. That assertion mischaracterizes the government's interest. As the district court explained (Pet. App. 33a-34a), the "significant scientific agreement" standard is designed to serve three substantial governmental interests:

> preventing the spread of unsubstantiated health claims on labels so that consumers may not be deceived and follow unsound health practices; ensuring the reliability of scientific information disseminated in connection with the sale of dietary supplements; and protecting consumers from being induced to purchase products by misleading information on labels.

Allied Tube & Conduit Corp. v. *Indian Head, Inc.*, 486 U.S. 492, 507-509 (1988) (antitrust); *NLRB* v. *Retail Store Employees Union, Local 101*, 447 U.S. 607, 616 (1980) (labor). Because the "significant scientific agreement" standard readily satisfies the more stringent *Central Hudson* test, we do not address that alternative argument in detail here.

Those interests are plainly substantial. See *44 Liquormart, Inc.* v. *Rhode Island*, 517 U.S. 484, 501 (1996) (plurality opinion) (protecting consumers from "misleading, deceptive, or aggressive sales practices" is a substantial reason for the government to regulate commercial speech).

Petitioners also err in contending (Pet. 28) that the government failed to satisfy the third prong of the *Central Hudson* inquiry because it failed to introduce empirical evidence that the challenged standard directly and materially advances the government's important interests. FDA reached the commonsense judgment that requiring health claims in dietary supplement labeling to be scientifically valid will prevent consumer fraud and protect the public health, thereby directly advancing the government's interests. 59 Fed. Reg. 395, 423 (1994). Such commonsense judgments are sufficient to satisfy the third prong of *Central Hudson*. See *Metromedia, Inc.* v. *City of San Diego*, 453 U.S. 490, 509 (1981) (accepting the "commonsense judgment[]" of the legislature that a restriction on billboards advanced the government's interest in traffic safety); see also *United States* v. *Edge Broad. Co.*, 509 U.S. 418, 427-429 (1993) (upholding Congress's commonsense judgment that prohibition on lottery advertising directly served governmental interest); cf. *Burson* v. *Freeman*, 504 U.S. 191, 211 (1992) (upholding restrictions under strict scrutiny standard based on history, consensus, and "simple common sense").

Finally, petitioners contend (Pet. 28) that the "significant scientific agreement" standard is more restrictive than necessary "given the availability of the regulatory alternatives." In the rulemaking process, however, FDA considered less stringent standards for evaluating dietary supplement health claims, but ultimately con-

cluded that none would satisfy the NLEA's goal of ensuring that health claims in labeling are scientifically valid and understandable. 59 Fed. Reg. at 404-405. In fact, "rather than bringing the use of claims on dietary supplements under control, [the suggested alternatives] would ratify the state of affairs that caused Congress to act." *Id.* at 405. No evidence was submitted showing that "consumers would be able to understand gradations of scientific reliability of claims on food labeling," nor was it clear that consumers could distinguish between preliminary and established claims. *Ibid.* It is also significant that the regulations at issue here apply only to health claims that are made on a product's label or labeling. Petitioners may therefore publish health claims that are not supported by "significant scientific agreement" in books, magazines, or scientific journals, as long as those publications are not used as labeling. In light of the record before it and the tailored scope of the restriction, FDA reasonably determined that the "significant scientific agreement" standard is no more extensive than necessary to accomplish the government's important interests.

In the end, petitioners suggest (Pet. 29-30) that commercial speech restrictions should be subjected to strict scrutiny and that *Central Hudson* should be reconsidered. This Court's precedents both before and after *Central Hudson*, however, recognize that the First Amendment does not prevent the government from regulating false, misleading, or deceptive commercial speech. For that reason, regulations that protect consumers from misleading commercial claims, like the FDA labeling regulation at issue in this case, are not subject to the same strict scrutiny that attends regulation of non-commercial speech. See, e.g., *Virginia State Bd. of Pharmacy*, 425 U.S. at 771-772 & n. 24 (the First

Amendment places "no obstacle" to the government's dealing effectively with the problem of speech that is false, deceptive, or misleading, and the "commonsense differences" between commercial and non-commercial speech "suggest that a different degree of protection is necessary"); *44 Liquormart*, 517 U.S. at 501 (plurality opinion) ("When a State regulates commercial messages to protect consumers from misleading, deceptive, or aggressive sales practices, * * * the purpose of its regulation is consistent with the reasons for according constitutional protection to commercial speech and therefore justifies less than strict review."). Petitioners offer no basis for reconsidering that well-established understanding of the government's power to regulate misleading commercial speech.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

SETH P. WAXMAN
Solicitor General
FRANK W. HUNGER
Assistant Attorney General
DOUGLAS N. LETTER
KATHLEEN MORIARTY MUELLER
Attorneys

NOVEMBER 1998