No. 03-1610

In the Supreme Court of the United States

JULIAN M. WHITAKER, ET AL., PETITIONERS

v.

TOMMY G. THOMPSON, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

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

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the Food and Drug Administration (FDA) reasonably concluded that a claim that a product will relieve the symptoms of an existing disease is a drug claim, rather than a health claim, subjecting the product to the drug approval requirements of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*

2. Whether FDA's use of petitioners' claim to determine that petitioners' product is subject to the FDCA's drug approval requirements violates the First Amendment.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-10a) is reported at 353 F.3d 947. The opinion of the district court (Pet. App. 11a-30a) is reported at 239 F. Supp. 2d 43.

JURISDICTION

The judgment of the court of appeals was entered on January 9, 2004. A petition for rehearing was denied on March 9, 2004 (Pet. App. 53a). The petition for a writ of certiorari was filed on May 28, 2004. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The Federal Food, Drug, and Cosmetic Act (FDCA or Act), 21 U.S.C. 301 *et seq.*, establishes a comprehensive scheme for the regulation of food and drugs. The FDCA requires the Food and Drug Administration (FDA) to review the safety and effectiveness of any new drug before it is marketed. 21 U.S.C. 321(p), 331(d), 355(a). The FDCA prohibits any person from introducing or delivering for introduction into interstate commerce "any new drug, unless an approval of an application * * * is effective with respect to such drug." 21 U.S.C. 355(a). Distribution of an unapproved new drug violates the FDCA, 21 U.S.C. 355(a), and such drugs may be seized (21 U.S.C. 334(a)) and their distributors enjoined (21 U.S.C. 332(a)) and prosecuted (21 U.S.C. 331(d)).

The touchstone for determining whether a product is subject to the FDCA's drug approval requirements is the FDCA's definition of drug. Under that definition, a "drug" is any "article[] intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 U.S.C. 321(g)(1). The status of an article thus depends on its "intended use." For example, if the intended use of a food is to treat a disease, the food is subject to regulation as a drug.

Under the FDCA, a manufacturer wishing to market a new drug must submit a new drug application (NDA) containing "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use." 21 U.S.C. 355(b)(1)(A). An NDA must contain all information obtained about the drug that is relevant to evaluating its safety and effectiveness. 21 C.F.R. 314.50, 601.2(a). An NDA must also include the "pro-

posed text of the labeling" for the drug, together with "information * * * that support[s] the inclusion of each statement in the labeling." 21 C.F.R. 314.50(c)(2)(i). Labeling must also include adequate directions for use. 21 U.S.C. 352(f)(1). If labeling lacks that information, or is otherwise false or misleading, FDA may refuse to approve the NDA. 21 U.S.C. 355(d); 21 C.F.R. 314.125(b)(6) and (8).

2. A dietary supplement is a product that contains a dietary ingredient, such as a vitamin, mineral, or herb, and that is intended to supplement the diet. 21 U.S.C. 321(ff)(1)(C). The FDCA, as amended by the Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353, and the Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325, authorizes a person to make "health claims" in the labeling of dietary supplements without subjecting the product to the FDCA's drug approval requirements. "[H]ealth claims" are claims that "characterize the relationship of any nutrient * * * to a disease or a health-related condition." 21 U.S.C. 343(r)(1)(B).

Congress has directed the FDA to establish "a procedure and standard, respecting the validity" of health claims for dietary supplements. 21 U.S.C. 343(r)(5)(D). Pursuant to that directive, FDA has adopted the same procedure for dietary supplement health claims as the FDCA establishes for food health claims. 21 C.F.R. 101.70 (mirroring petition procedure set out in 21 U.S.C. 343(r)(4)). If a health claim is not made in accordance with those procedures, the product may be a misbranded drug and an unapproved new drug. It is unlawful under the FDCA to misbrand a drug or to introduce an unapproved new drug into interstate com-

merce. 21 U.S.C. 331(b) and (d), 332, 333, 334, 343, 352(f), 355.

3. In May 1999, petitioners filed a health claim petition with the FDA seeking authorization to include on the label of saw palmetto extract the following claim:

> Consumption of 320 mg daily of Saw Palmetto extract may improve urine flow, reduce nocturia and reduce voiding urgency associated with mild benign prostatic hyperplasia (BPH).

Pet. App. 2a. Petitioners requested that the FDA "approve the claim * * * with such disclaimer or disclaimers as the agency reasonably deems necessary to avoid a potentially misleading connotation." *Ibid.*

After 90 days passed without FDA issuing a decision, the petition was deemed denied by operation of law. Pet. App. 16a. Petitioners then filed suit in federal district court, arguing that denial of their petition violated the FDCA, the Administrative Procedure Act, and the First Amendment. *Id.* at 16a, 19a, 28a. The district court stayed proceedings while the FDA reconsidered its decision. *Id.* 16a. After holding a public hearing and receiving public comment, the FDA issued an explanation of its decision to deny the petition. *Ibid*; see *id.* at 33a-50a. The FDA drew a distinction between a claim that a product helps reduce the risk of a disease (risk reduction claim), and a claim that a product treats, cures, or relieves the symptoms an existing disease (disease treatment claim). *Id.* at 2a. The FDA concluded that while a claim that a dietary supplement may reduce the risk of a chronic disease can qualify as a "health claim" under 21 U.S.C. 342(r), a claim that a dietary supplement may treat a disease cannot. Pet. App. 2a, 36a-43a. A person wishing to make a disease treatment claim for a dietary supplement must there-

fore satisfy the FDCA's drug approval requirements. *Id.* at 36a-43a.

The district court rejected petitioners' challenge to the FDA's decision. Pet. App. 11a-30a. It held that the FDA reasonably concluded that Section 342(r) authorizes risk-reduction claims, but not disease treatment claims. *Id.* at 19a-28a. The court further held that the FDA's refusal to approve petitioners' treatment claim as a permissible health claim under Section 342(r) did not violate the First Amendment. *Id.* at 28a-29a.

4. The court of appeals affirmed. Pet. App. 1a-10a. Applying the framework set forth in *Chevron U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the court first held that Congress had not unambiguously expressed its intent on the question whether a disease treatment claim can be a health claim, or whether all disease treatment claims subject a product to the FDCA's drug approval requirements. The court explained that the statutory definitions of "drug claim" and "health claim" overlap and that the FDCA provides "little guidance as to how the FDA should sort out claims that seem to fit both definitions." Pet. App. 3a. The court then held that the FDA's interpretation is reasonable and therefore entitled to deference. *Id.* at 5a-8a. The court explained that the FDA had acted reasonably in basing its interpretation on the following considerations: (1) a number of statements in the legislative history indicate that the purpose of the health claim provision was to promote long-term health maintenance and prevention of disease, while no statement contemplated treatment of disease with a dietary supplement; (2) Congress mandated research into ten possible health claims, all of which involve reduction of the risk of a chronic disease, rather than treatment; (3) the health claims provision was

enacted against the backdrop of the FDA's long-standing application of drug regulation to food and dietary supplements for which treatment claims are made; (4) interpreting health claims to encompass treatment claims could undermine the protections of the drug approval system. *Id.* at 6a-7a. The court rejected petitioners' reliance on the principle that a statute should be interpreted to avoid raising constitutional questions, on the ground that petitioners had not raised a sufficiently serious constitutional objection to require the court "to abandon or qualify *Chevron* deference." *Id.* at 9a.

The court of appeals also rejected petitioners' constitutional claim on the merits. Pet. App. 9a-10a. The court explained that under *Wisconsin* v. *Mitchell*, 508 U.S. 476 (1993), "it is constitutionally permissible for the FDA to use speech, in the form of labeling, to infer intent for purposes of determining that [petitioners'] proposed sale of saw palmetto extract would constitute the forbidden sale of an unapproved drug." Pet. App. 10a.

ARGUMENT

The decision of the court of appeals is correct. It does not conflict with any decision of this Court or any other court of appeals. Further review is therefore not warranted.

1. Petitioners contend (Pet. 17-20) that the court of appeals erred in deferring to the FDA's conclusion that a claim that a product can treat a disease subjects the product to the FDCA's drug approval requirements. That contention lacks merit. Because the FDA's interpretation is reasonable, the court of appeals correctly sustained it under *Chevron*.

Under the FDCA, a product is subject to drug approval requirements when it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. 321(g)(1)(B). On the other hand, a person can make a "health claim" that "characterizes the relationship of any nutrient * * * to a disease or a health-related condition" under less stringent requirements. 21 U.S.C. 343(r)(1)(B). As the court of appeals concluded, the FDCA does not definitively resolve the interaction between those two provisions.

Petitioners contend that Section 343(r)(1)(B) creates a total carve out from the FDCA's drug approval scheme, permitting a person to make both risk-reduction claims and disease treatment claims for a dietary supplement without subjecting the product to the FDCA's drug approval requirements. Even when viewed in isolation, the provision does not have such a sweeping effect. It does not refer specifically to the treatment of existing diseases. Nor does it specify the kind of "relationship" between nutrients and diseases that Congress had in mind when it enacted the provision.

More important, as this Court has said specifically with respect to the FDCA, it is "a fundamental canon of statutory construction that the words of a statute must be read in context and with a view to their place in the overall statutory scheme." *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). Petitioners' interpretation is at odds with other provisions of the FDCA. The FDCA defines a "dietary supplement" as a food "*[e]xcept for purposes of [the definition of 'drug' in § 321]*." 21 U.S.C. 321(ff) (emphasis added). And the FDCA drug definition states that a food or dietary supplement "is not a drug *solely* because the label or the labeling contains * * * a [health-related]

claim." 21 U.S.C. 321(g)(1)(B) (emphasis added). Those provisions both presuppose that a dietary supplement is sometimes subject to the drug approval requirements. Yet, under petitioners' interpretation, a person could claim that a dietary supplement has all the characteristics of a drug, without ever triggering the FDCA's drug approval protections.

While both the dietary supplement and drug definitions establish that the exemption for dietary supplements is only partial, they do not define the extent of that partial exemption. As it was entitled to do under *Chevron*, the FDA reasonably filled that gap. Several considerations support the reasonableness of the FDA's approach.

First, Congress directed the FDA to consider whether ten specific "nutrient-disease" relationships qualify as "health claims" under the Act. See Pub. L. No. 101-535, § 3(b)(1)(A)(vi) and (x), 104 Stat. 2361. Those relationships all involve the reduction of the risk of a chronic disease; none involves the treatment of a disease. 55 Fed. Reg. 5192 (1990) (col. 1). Those examples show that, in enacting Section 343(r)(1)(B), Congress was focused on the role nutrition may play in reducing the risk of contracting a disease in the future, not on the treatment of existing diseases.

Second, the FDCA distinguishes between medical foods and other foods. Medical foods are intended to treat an existing disease. See 21 U.S.C. 360ee(b)(3). In the NLEA, Congress permitted health-related claims for foods, see 21 U.S.C. 343(r)(1)(B), but it excluded medical foods from the health claim provisions. See 21 U.S.C. 343(r)(5)(A). That exclusion shows that, in the case of food, a health-related claim encompasses a risk reduction claim, but not a disease treatment claim. Because dietary supplements are also foods, the FDA

reasonably concluded that the same distinction should inform the health claims that can be made for dietary supplements.

Third, the legislative history reflects an understanding that a health claim for a dietary supplement encompasses only the relationship between a nutrient and the reduction of the risk of contracting a disease. As the court of appeals explained, all of the "health claims" mentioned in the legislative history involve such claims. See Pet. App. 6a. (citing statements). Thus, as the court of appeals held, the FDA reasonably concluded that the health claims authorized by Section 343(r)(1)(B) encompass risk reduction claims, but not disease treatment claims. A person who wants to make a disease treatment claim for a dietary supplement must satisfy the FDCA's drug approval requirements.

Petitioners contend (Pet. 14-16) that the court of appeals should have applied the principle of constitutional avoidance, rather than *Chevron* deference, to resolve the ambiguity in the scope of Section 343(r)(1)(B). But the principle of constitutional avoidance applies only when an interpretation of a statute would raise a "grave and doubtful" constitutional question. *Rust* v. *Sullivan*, 500 U.S. 173, 191 (1991). Because the FDA's interpretation does not raise a grave and doubtful constitutional question, see pp. 9-10, *infra*, the court of appeals correctly applied *Chevron* deference, rather than the principle of constitutional avoidance, to resolve the ambiguity in Section 343(r)(1)(B).

2. Petitioners contend (Pet 11-14) that the FDA's interpretation of the FDCA violates the First Amendment because it fails to satisfy the standards established in *Central Hudson Gas & Electric Corp* v. *Public Service Commission*, 447 U.S. 557 (1980), for regulation of commercial speech. Petitioners, however, have not

challenged the FDCA's drug approval requirements, and it is those requirements that bar petitioners from making disease treatment claims about their product without first establishing through testing that their product is safe and effective. Petitioners' failure to challenge the drug approval requirements is understandable. Those requirements directly further the compelling governmental purpose of ensuring that commercial information about products marketed as drugs is scientifically substantiated, truthful, and nonmisleading.

The FDA used petitioners' proposed claim to determine that petitioners wished to make a drug claim, rather than a health claim, and that petitioners therefore must satisfy the drug approval requirements, rather than the requirements for health claims. But that aspect of the FDA's decision does not raise a substantial First Amendment issue. Under *Wisconsin* v. *Mitchell*, 508 U.S. 476 (1993), the First Amendment does not bar the government from making evidentiary use of a person's speech, and that is precisely what the FDA did here. It simply used petitioners' proposed claim as evidence that they wanted to market a product intended for use in the treatment of a disease, something that can be done under the FDCA only after the drug approval requirements have been satisfied. The First Amendment does not bar the FDA from taking petitioners at their word and categorizing their product accordingly. As the court of appeals explained, "it is constitutionally permissible for the FDA to use speech, in the form of labeling, to infer intent for purposes of determining that [petitioners'] proposed sale of saw palmetto extract would constitute the forbidden sale of an unapproved drug." Pet. App. 10a.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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