United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued November 10, 2003 Decided January 9, 2004

No. 03-5020

JULIAN M. WHITAKER, ET AL.,
APPELLANTS

v.

TOMMY G. THOMPSON, SECRETARY,
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 99cv03247)

Jonathan W. Emord argued the cause and filed the briefs for appellants.

Anthony L. Young was on the brief for *amicus curiae* American Herbal Products Association in support of appellants.

Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

Howard S. Scher, Attorney, U.S. Department of Justice, argued the cause for appellees. With him on the brief were *Roscoe C. Howard, Jr.*, U.S. Attorney, *Scott R. McIntosh*, Attorney, U.S. Department of Justice, *Alex M. Azar II*, General Counsel, U.S. Department of Health & Human Services, and *Daniel E. Troy*, Chief Counsel.

Before: RANDOLPH and ROBERTS, *Circuit Judges*, and WILLIAMS, *Senior Circuit Judge*.

Opinion for the Court filed by *Senior Circuit Judge* WILLIAMS.

WILLIAMS, *Senior Circuit Judge*: When substances aimed at the treatment or prevention of disease are marketed, their regulation by the Food and Drug Administration ("FDA") commonly turns on the nature of the claims made about the substance. Items to be sold with "drug claims," including foods and dietary supplements, are subject to extensive testing; foods or dietary supplements that merely make "health claims" pass muster far more easily. This case turns primarily on whether the FDA faithfully applied the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, in its analysis of a petition by Dr. Julian Whitaker and others (for simplicity's sake, "Whitaker") to approve their intended marketing of "saw palmetto," an extract from the pulp and seed of the dwarf American palm, *Serenoa repens*, under a label that they argued was a "health claim."

Whitaker proposed a label stating: "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)." Petition, May 25, 1999, p. 18. BPH is a non-cancerous enlargement of the prostate that affects almost half of men over 50. The FDA denied the petition. In explaining the decision, it drew a distinction between claims regarding use of a product to maintain health and to "prevent" disease, on the one hand, and claims that a product could "treat" a disease, on the other. The former could qualify as "health claims," but the latter would always be considered "drug claims." May 26, 2000 FDA Letter ("FDA Letter") at 2, 7–10. As BPH is

classified as a disease despite its comparative ubiquity, and the proposed label indicated an intent to treat it, the FDA decided that saw palmetto could not be marketed under that label without approval as a drug. Whitaker challenged the FDA's decision in district court on statutory and First Amendment grounds. The district court granted the FDA's motion to dismiss, *Whitaker v. Thompson*, 239 F. Supp. 2d 43 (D.D.C. 2003), and Whitaker appealed. We affirm.

* * *

The statutory claim

The FFDCA definition of "drug" includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," 21 U.S.C. § 321(g)(1)(B), which would seem by its plain terms to cover the marketing of a substance intended to mitigate the symptoms associated with BPH. But that apparent simplicity is undermined by language added in 1990 by the Nutrition Labeling and Education Act ("NLEA"), Pub. L. No. 101–535, 104 Stat. 2353, which created a separate procedure authorizing "health claims" for food (or for dietary supplements classified as food). The general purpose of the NLEA appears to have been to allow the dissemination—subject to a regulatory approval process—of certain dietary and health information on food products without requiring that those products be regulated as drugs. Specifically, the NLEA amended the FFDCA to authorize the sale of dietary supplements pursuant to "health claims" that "characterize[ ] the relationship of any nutrient . . . to a disease or health-related condition," *id.* § 343(r)(1)(B), so long as the dietary supplement is "subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary," *id.* § 343(r)(5)(D). Whitaker insists, with some justification, that the label he proposed fits within the plain terms of the "health claim" definition.

Thus, although the consequences of classification as a "drug claim" or a "health claim" are quite substantial, Congress has given definitions that at least partially overlap. And it has given little guidance as to how the FDA should sort out

claims that seem to fit both definitions. On the one hand, as the FDA points out, the statutory definition of "dietary supplement" plainly contemplates that dietary supplements may fall under the § 321(g) definition of "drugs": it says that a dietary supplement shall be deemed to be a "food" "[e]xcept for purposes of [§ 321(g)]," which defines "drugs" and "counterfeit drugs." 21 U.S.C. § 321(ff). On the other hand, the last sentence of § 321(g)(1), which defines drugs, explicitly states that a "dietary supplement for which a [health claim under § 343(r)] is made . . . is not a drug . . . solely because the label or the labeling contains such a statement." *Id.* § 321(g)(1). This is the statutory provision most directly relevant to the relationship between health claims and drug claims, but there are at least three ways it might be read, all of them problematic.

First, the last sentence of § 321(g)(1) might mean that a § 343(r) health claim cannot *by itself* establish that a product is "intended" to cure, mitigate, prevent, or treat disease, but such a statement may be used in conjunction with other evidence to establish such intent. Under this view, a health claim would be relevant but not sufficient to establish that a product is a drug. Though this construction provides a grammatically plausible reading of "solely," it is not pressed by any of the parties; in practice it might not make sense, as a product's label may often be the only readily available evidence of the product's intended use.

Second, the sentence in question might mean that a product for which a "drug claim" is made under § 321(g)(1) is not automatically exempt from drug regulation just because the product label *also* makes a separate health claim under § 343(r). This view, urged by amicus American Herbal Products Association, founders on the broad definition of health claims advanced by Whitaker. Such claims appear coextensive with—or perhaps even broader than—§ 321(g) drug claims. The amicus's own brief demonstrates the problem. The amicus seeks to illustrate its reading of the "solely" language, saying that it means only that "use of an authorized health claim on the label of a dietary supplement (*e.g.*, folate reduces the risk of neural tube defects) does not give a

manufacturer blanket immunity to include other claims for the product that would otherwise be classified as drug claims (*e.g.*, folate cures cancer)." But if § 343(r) covers anything that characterizes the "relationship" between a nutrient and a disease, then "folate cures cancer" is just as much a health claim as "folate reduces the risk of neural tube defects." Amicus's interpretation of "solely" is sensible only if there are "drug claims" for foods or dietary supplements that are not also "health claims," but Whitaker's broad interpretation of health claims, and indeed the literal wording of § 343(r)(1)(B) itself, foreclose that possibility.

Finally, the "solely" language in § 321(g) might mean that while a claim that would qualify as a health claim *may* be considered a drug claim, such a claim is not *necessarily* a drug claim. Under this reading, in other words, the statute allows *some* health claims to be exempted from the drug claim definition; but as this class is not defined, it implicitly leaves the choice to the FDA. This interpretation, urged by the FDA, is plausible, but it too is problematic. The statute on its face supplies no guiding principle for determining which health claims should be exempt, and nowhere else evinces an intent to give the FDA unfettered discretion to make so drastic a choice.

Because we are reviewing an agency's interpretation of the statute it is entrusted to administer, and the agency reached its interpretation after a relatively formal process with public notice and comment, cf. *United States v. Mead Corp.*, 533 U.S. 218, 230–31 (2001) (expressing assumption that Congress "contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure"), we review under the familiar framework established by *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). We first ask whether, applying the "traditional tools of statutory construction," *id.* at 843 n.9, we can discern "the unambiguously expressed intent of Congress," *id.* at 843. If the statute is ambiguous, then we defer to the agency's interpretation so long as it is reasonable. *Id.* at 843–45.

As the discussion above suggests, we see no basis for finding any "unambiguously expressed intent of Congress." We thus turn to the FDA's rationale for classifying certain types of health claims as drug claims in order to decide whether the FDA's approach is reasonable in light of the statute's structure, history, and purposes.

The FDA gave several reasons for classifying claims regarding cure, mitigation, or treatment of an existing disease ("treatment claims") as drug claims and for exempting only health claims that concern reducing the risk of contracting a disease ("prevention claims"). First, the agency reasoned that the legislative history of the NLEA demonstrated an understanding that the health claim provision was intended for claims of prevention rather than ones of treatment. The agency noted statements in the legislative history indicating that the purpose of the health claims provision was to promote long-term health maintenance and prevention of disease, but found nothing suggesting that legislators enacting this provision contemplated treatment of a person's existing disease with dietary supplements. See FDA Letter at 5–6, citing 136 Cong. Rec. H5843 (statement of Rep. Moakley); 136 Cong. Rec. H12,954 (statement of Rep. Moakley); 136 Cong. Rec. H5843 (statement of Rep. Madigan); 136 Cong. Rec. S16,609 (statement of Sen. Metzenbaum); 136 Cong. Rec. S16,610–11 (statement of Sen. Hatch). Indeed, all the specific examples of "health claims" mentioned in the NLEA's legislative history involved prevention rather than treatment. See *id.* at 5, citing H.R. Rep. No. 101–538 at 8, 20, reprinted in 1990 U.S.C.C.A.N. at 3337, 3350; 136 Cong. Rec. H5841 (statement of intent of changes since bill was reported out of committee); 136 Cong. Rec. H12,953 (statement of House floor managers); 136 Cong. Rec. H5841 (statement of Rep. Waxman); 136 Cong. Rec. H12,954 (statement of Rep. Madigan); 136 Cong. Rec. S16,609 (statement of Sen. Mitchell).

Second, the FDA looked to research mandated by Congress when it adopted the NLEA. At that time Congress instructed the FDA, in adopting regulations to implement § 343(r), to investigate ten specific possible health claims, all of which

involved prevention—"reduction of the risk of a chronic disease"—rather than treatment. FDA Letter at 5, citing Pub. L. No. 101–535, § 3(b)(1)(A)(vi),(x), 104 Stat. 2353, 2361 (1990) (see 21 U.S.C. § 343 note).

Third, the FDA noted that the health claims provision was enacted against a backdrop of longstanding application of drug regulation to foods and dietary supplements that made treatment claims—an assertion Whitaker does not dispute. The agency inferred that Congress meant the "solely" sentence of § 321(g)(1) to preserve this practice. FDA Letter at 6.

Finally, the FDA invoked policy concerns to support a distinction between treatment and prevention claims. It argued that, because the health of diseased populations is particularly vulnerable, greater regulation may be justified for products intended for their consumption. Moreover, it argued that treatment claims for symptoms of a disease might lull people with those symptoms into a "false sense of security," leading them to delay a visit to a doctor that might result, for example, in a diagnosis of prostate cancer rather than BPH. *Id.* at 9. Finally, in a statement looking only at possible benefits of its classification decision (and not any of the possible drawbacks), the FDA said that if products could escape regulation as drugs by qualifying as "dietary supplements" that make treatment claims, the protections of the drug approval system could be undermined and incentives to research a substance's health effects would be diminished. *Id.* at 10.

None of these is a knock-down argument, and we doubt that any of them would be sufficient to overcome a strong textual or structural inference in favor of a different interpretation. Certainly there is nothing in the two statutory definitions that would obviously equate claims of "treatment" with drug claims and of "prevention" with health claims. But given our finding that the statute is ambiguous on the critical question of how to classify a claim that meets the statutory definitions both of a drug claim *and* of a health claim, the

legislative history and statutory context invoked by FDA are enough to render its interpretation reasonable.

Whitaker also attacks the FDA's distinction between prevention and treatment claims as arbitrary and capricious. First, he argues that there is no sharp distinction between "prevention" and "treatment"; the two categories may often overlap. They may, of course, but that does not render the distinction either unworkable or irrational. The existence of dawn and dusk, as has often been said, doesn't make it absurd to distinguish between day and night. Second, Whitaker claims that the FDA failed to explain adequately how it could square its decision not to allow Whitaker's claim that saw palmetto extract alleviates symptoms of BPH with the agency's prior approval of a "health claim" that low-fat diets lower cholesterol. See 21 C.F.R. § 101.75(e)(3). But here the FDA plausibly explains that the reference to the lower cholesterol consequences of low-fat diets merely clarifies the mechanism by which heart disease is prevented; the FDA did not authorize a claim that a low-fat diet could treat hypercholesterolemia. So the cholesterol example doesn't show an irrationality in the FDA's attempted distinction.

Finally, Whitaker urges us to adopt his reading of the statute on the ground that this will enable us to avoid the "grave and doubtful constitutional questions" that the FDA's understanding would entail. *United States ex rel. Attorney General v. Del. & Hudson Co.*, 213 U.S. 366, 408 (1909). It is true that the canon of constitutional avoidance can trump *Chevron*. See *Edward J. DeBartolo Corp. v. Florida Gulf Coast Bldg. & Const. Trades Council*, 485 U.S. 568, 575 (1988); *Chamber of Commerce of the United States v. Federal Election Comm'n*, 69 F.3d 600, 604–05 (D.C. Cir. 1995). But if the avoidance canon were extravagantly applied it would tend, in effect, to expand unnecessarily the scope of constitutional prohibitions. Thus in practice the canon's application requires a comparatively high likelihood of unconstitutionality, or at least some exceptional intricacy of constitutional doctrine. Compare, e.g., *Rust v. Sullivan*, 500 U.S. 173, 191 (1991) (finding the constitutional question not so "grave and doubtful" as to justify avoidance doctrine); *Republican Nat.*

Committee v. Federal Election Comm'n, 76 F.3d 400, 409 (D.C. Cir. 1996) (same), with *Chamber of Commerce*, 69 F.3d at 604–05 (applying avoidance doctrine because agency's interpretation would "preclude[ ] appellants from communicating on political subjects with thousands of persons, heretofore regarded by the Commission as members"). As the discussion below should make clear, here we do not find Whitaker's First Amendment objection so powerful as to require us to abandon or qualify *Chevron* deference.

The constitutional claim

Whitaker argues that the FDA's refusal to allow marketing of saw palmetto extract under the proposed label, which he describes as a true and non-misleading statement about its salutary effects on BPH symptoms, violates the First Amendment's limits on restrictions of commercial speech. Under *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), commercial speech enjoys First Amendment protection only if it concerns a lawful activity and is not misleading. If the speech in question passes those screens, the government may impose restrictions that advance a "substantial" government interest and are no "more extensive than is necessary to serve that interest." *Id.* at 566.

The district court upheld the FDA's decision under the first step of *Central Hudson*. "Because the FDA determined that the saw palmetto claim was a drug claim for disease treatment, it concluded that the claim was an *unlawful* health claim. . . ." *Whitaker v. Thompson*, 239 F. Supp. 2d at 54. Accordingly, the proposed label constituted speech about unlawful activities. *Id.*

So worded, the analysis appears, as Whitaker points out, completely circular. Because sale pursuant to the claim was "unlawful" under the statute, the speech related to an unlawful activity and enjoyed no First Amendment protection.

But one may recharacterize the analysis in a way that avoids the circularity. Assuming that the government may condition the sale of drugs on passage through the elaborate

testing that the statute requires (an assumption that Whitaker doesn't question), the key step is the FFDCA principle that classification of a substance as a "drug" turns on the nature of the claims advanced on its behalf.

That principle, in turn, rests on the idea that claims about a product by its manufacturer and vendors, including product labeling, serve as evidence of the sellers' intent that consumers will purchase and use the product for a particular purpose—and, therefore, as evidence whether the product is or is not a drug. See, e.g., *Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980). The question is whether this use of speech to infer intent, which in turn renders an otherwise permissible act unlawful, is constitutionally valid. In fact, the First Amendment allows "the evidentiary use of speech to establish the elements of a crime or to prove motive or intent." *Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993) (upholding use of speech to determine that defendant selected battery victim because of his race, for purposes of statutory sentence enhancement). Thus it is constitutionally permissible for the FDA to use speech, in the form of labeling, to infer intent for purposes of determining that Whitaker's proposed sale of saw palmetto extract would constitute the forbidden sale of an unapproved drug.

* * *

The judgment of the district court dismissing plaintiffs' claim is

Affirmed.