

## Syllabus

*NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued.*

*The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader.*

*See United States v. Detroit Timber & Lumber Co., [200 U.S. 321](#), 337.*

### SUPREME COURT OF THE UNITED STATES

THOMPSON, SECRETARY OF HEALTH AND HUMAN SERVICES, et al. v. WESTERN STATES MEDICAL CENTER et al.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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No. 01—344. Argued February 26, 2002—Decided April 29, 2002

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Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to an individual patient's needs. The Food and Drug Administration Modernization Act of 1997 (FDAMA) exempts "compounded drugs" from the Food and Drug Administration's (FDA) standard drug approval requirements under the Federal Food, Drug, and Cosmetic Act (FDCA), so long as the providers of the compounded drugs abide by several restrictions, including that the prescription be "unsolicited," [21 U.S.C. § 353a\(a\)](#), and that the providers "not advertise or promote the compounding of any particular drug, class of drug, or type of drug," §353a(c). Respondents, a group of licensed pharmacies that specialize in compounding drugs, sought to enjoin enforcement of the advertising and solicitation provisions, arguing that they violate the [First Amendment](#)'s free speech guarantee. The District Court agreed and granted respondents summary judgment, holding that the provisions constitute unconstitutional restrictions on commercial speech under *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N. Y.*, [447 U.S. 557](#), 566. Affirming in relevant part, the Ninth Circuit held that the restrictions in question fail *Central Hudson's* test because the Government had not demonstrated that the restrictions would directly advance its interests or that alternatives less restrictive of speech were unavailable.

*Held:* The FDAMA's prohibitions on soliciting prescriptions for, and advertising, compounded drugs amount to unconstitutional restrictions on commercial speech. Pp. 8–19.

(a) For a commercial speech regulation to be constitutionally permissible under the *Central Hudson* test, the speech in question must concern lawful

activity and not be misleading, the asserted governmental interest to be served by the regulation must be substantial, and the regulation must “directly advanc[e]” the governmental interest and “not [be] more extensive than is necessary to serve that interest,” 447 U.S., at 566. Pp. 8–9.

(b) The Government asserts that three substantial interests underlie the FDAMA: (1) preserving the effectiveness and integrity of the FDCA’s new drug approval process and the protection of the public health it provides; (2) preserving the availability of compounded drugs for patients who, for particularized medical reasons, cannot use commercially available products approved by the FDA; and (3) achieving the proper balance between those two competing interests. Preserving the new drug approval process is clearly an important governmental interest, as is permitting the continuation of the practice of compounding so that patients with particular needs may obtain medications suited to those needs. Because pharmacists do not make enough money from small-scale compounding to make safety and efficacy testing of their compounded drugs economically feasible, however, it would not make sense to require compounded drugs created to meet the unique needs of individual patients to undergo the entire new drug approval process. The Government therefore needs to be able to draw a line between small-scale compounding and large-scale drug manufacturing. The Government argues that the FDAMA’s speech-related provisions provide just such a line: As long as pharmacists do not advertise particular compounded drugs, they may sell compounded drugs without first undergoing safety and efficacy testing and obtaining FDA approval. However, even assuming that the FDAMA’s prohibition on advertising compounded drugs “directly advance[s]” the Government’s asserted interests, the Government has failed to demonstrate that the speech restrictions are “not more extensive than is necessary to serve [those] interest[s].” *Central Hudson, supra*, at 566. If the Government can achieve its interests in a manner that does not restrict commercial speech, or that restricts less speech, the Government must do so. *E.g., Rubin v. Coors Brewing Co.*, 514 U.S. 476, 490–491. Several non-speech-related means of drawing a line between compounding and large-scale manufacturing might be possible here. For example, the Government could ban the use of commercial scale manufacturing or testing equipment in compounding drug products, prohibit pharmacists from compounding more drugs in anticipation of receiving prescriptions than in response to prescriptions already received, or prohibit them from offering compounded drugs at wholesale to other state licensed persons or commercial entities for resale. The Government has not offered any reason why such possibilities, alone or in combination, would be insufficient to prevent compounding from occurring on such a scale as to undermine the new drug approval process. Pp. 10–15.

(c) Even if the Government had argued (as does the dissent) that the FDAMA’s speech-related restrictions were motivated by a fear that advertising compounded drugs would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway, that fear would fail to justify the restrictions. This concern rests on the questionable assumption that doctors would prescribe unnecessary medications and amounts to a fear that people would make bad decisions if given truthful information, a notion that the Court rejected as a

justification for an advertising ban in, *e.g.*, *Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, [425 U.S. 748](#), 770. Pp. 15–18.

(d) If the Government's failure to justify its decision to regulate speech were not enough to convince the Court that the FDAMA's advertising provisions were unconstitutional, the amount of beneficial speech prohibited by the FDAMA would be. Forbidding the advertisement of compounded drugs would prevent pharmacists with no interest in mass-producing medications, but who serve clientele with special medical needs, from telling the doctors treating those clients about the alternative drugs available through compounding. For example, a pharmacist serving a children's hospital where many patients are unable to swallow pills would be prevented from telling the children's doctors about a new development in compounding that allowed a drug that was previously available only in pill form to be administered another way. The fact that the FDAMA would prohibit such seemingly useful speech even though doing so does not appear to directly further any asserted governmental objective confirms that the prohibition is unconstitutional. Pp. 18–19.

238 F.3d 1090, affirmed.

*O'Connor, J., delivered the opinion of the Court, in which Scalia, Kennedy, Souter, and Thomas, JJ., joined. Thomas, J., filed a concurring opinion. Breyer, J., filed a dissenting opinion, in which Rehnquist, C. J., and Stevens and Ginsburg, JJ., joined.*