TOMMY G. THOMPSON, SECRETARY OF HEALTH AND HUMAN SERVICES,ET AL., PETITIONERS
v. WESTERN STATES MEDICAL CENTER ET AL.
No. 01-344

SUPREME COURT OF THE UNITED STATES

122 S. Ct. 1497; 152 L. Ed. 2d 563; 2002 U.S. LEXIS 3035; 70U.S.L.W. 4275; 2002 Daily Journal DAR 4627; 15 Fla. L. Weekly Fed. S 217

April 29, 2002, Decided

NOTICE:

[*1]
The LEXIS pagination of this document is subject to change pending release of the final published version.

PRIOR HISTORY: ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT.

CASE SUMMARY

PROCEDURAL POSTURE: Respondent pharmacies brought an action against petitioner government, alleging that the ban on advertising compounded drugs set out in *21 U.S.C.S. § 353a* violated the pharmacies' free speech rights. On application for a writ of certiorari, the government challenged the judgment of the United States Court of Appeals for the Ninth Circuit which upheld the district court's finding that § 353a was unconstitutional.

OVERVIEW: The government contended that, since drugs were compounded for use by individuals for whom commercially available medications were not suitable, the advertising of compounded drugs constituted an attempt to attract a large-scale market. The government thus maintained that prohibiting such advertising would ensure that large-scale manufacturing of compounded drugs would be precluded unless the drugs were subjected to the governmental approval process to protect the public health and safety. The United States Supreme Court held however that the advertising restriction was unconstitutional. Even assuming that the ban directly advanced the government's interest, the government failed to demonstrate that the restrictions on the pharmacies' commercial speech were not more extensive than necessary to serve those interests. There were non-speech-related means to achieve the government's goal, such as regulating large-scale manufacturing, prohibiting wholesale sales, or limiting manufacturing to prescriptions received. Further, § 353a prohibited the pharmacies' beneficial speech such as advising physicians concerning available compounded drugs for special medical needs.

OUTCOME: The circuit court's judgment, affirming the district court's finding that the ban on advertising compounded drugs was unconstitutional, was affirmed.

CORE TERMS: compounded, compounding, advertising, pharmacist, patient, prescription, doctor, pharmacy, commercial speech, new drug, regulation, testing, manufacturing, advertisement, approval process, medication, First Amendment, licensed, advertise, speech-related, effectiveness, ban, untested, ingredient, compound, efficacy, governmental interest, misleading, prescribe, truthful

CORE CONCEPTS -

Governments: Agriculture & Food: Federal Food, Drug & Cosmetic Act
Section 503A of the Food and Drug Administration Modernization Act of 1997, as set out in *21 U.S.C.S. § 353a*, exempts compounded drugs from the Food and Drug Administration's standard drug approval requirements as long as the providers of those drugs abide by several restrictions, including that they refrain from advertising or promoting particular compounded drugs.

Governments: Agriculture & Food: Federal Food, Drug & Cosmetic Act
The Federal Food, Drug, and Cosmetic Act of 1938, *21 U.S.C.S. § 301* et seq., regulates drug manufacturing, marketing, and distribution.

Governments: Agriculture & Food: Federal Food, Drug & Cosmetic Act

See *21 U.S.C.S. § 355*(a).

Governments: Agriculture & Food: Federal Food, Drug & Cosmetic Act
"New drug" is defined by *21 U.S.C.S. § 321*(p) as any drug not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.

Governments: Agriculture & Food: Federal Food, Drug & Cosmetic Act
The Federal Food, Drug, and Cosmetic Act of 1938, *21 U.S.C.S. § 301* et seq., invests the Food and Drug Administration with the power to enforce its requirements. *21 U.S.C.S. § 371*(a).

Governments: Agriculture & Food: Federal Food, Drug & Cosmetic Act
The Food and Drug Administration Modernization Act of 1997, which amends the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), *21 U.S.C.S. § 301* et seq., exempts compounded drugs from the FDCA's "new drug" requirements and other requirements provided the drugs satisfy a number of restrictions, including the following. First, they must be compounded by a licensed pharmacist or physician in response to a valid prescription for an identified individual patient, or, if prepared before the receipt of such a prescription, they must be made only in limited quantities and in response to a history of the licensed pharmacist's or physician's receipt of valid prescription orders for that drug product within an established relationship between the pharmacist, the patient, and the prescriber. *21 U.S.C.S. § 353a*(a). Second, the compounded drug must be made from approved ingredients that meet certain manufacturing and safety standards, *21 U.S.C.S. § 353a*(b)(1)(A)-(B), and the compounded drug may not appear on a Food and Drug Administration list of drug products that have been withdrawn or removed from the market because they were found to be unsafe or ineffective. *21 U.S.C.S. § 353a*(b)(1)(C).

Governments: Agriculture & Food: Federal Food, Drug & Cosmetic Act
The Food and Drug Administration Modernization Act of 1997, which amends the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), *21 U.S.C.S. § 301* et seq., exempts compounded drugs from the FDCA's "new drug" requirements and other requirements provided the drugs satisfy a number of restrictions, including the following. Third, the pharmacist or physician compounding the drug may not compound regularly or in inordinate amounts any drug products that are essentially copies of a commercially available drug product. *21 U.S.C.S. § 353a* (b)(1)(D). Fourth, the drug product must not be identified by the Food and Drug Administration (FDA) as a drug product that presents demonstrable difficulties for compounding in terms of safety or effectiveness. *21 U.S.C.S. § 353a*(b)(3)(A). Fifth, in states that have not entered into a memorandum of understanding with the FDA addressing the distribution of inordinate amounts of compounded drugs in interstate commerce, the pharmacy, pharmacist, or physician compounding the drug may not distribute compounded drugs out of state in quantities exceeding five percent of that entity's total prescription orders. *21 U.S.C.S. § 353a*(b)(3)(B).

Governments: Agriculture & Food: Federal Food, Drug & Cosmetic Act
The Food and Drug Administration Modernization Act of 1997, which amends the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), *21 U.S.C.S. § 301* et seq., exempts compounded drugs from the FDCA's "new drug" requirements and other requirements provided the drugs satisfy a number of restrictions, including the following: the prescription must be unsolicited, *21 U.S.C.S. § 353a*(a), and the pharmacy, licensed pharmacist, or licensed physician compounding the drug may not advertise or promote the compounding of any particular drug, class of drug, or type of drug. *21 U.S.C.S. § 353a*(c). The pharmacy, licensed pharmacist, or licensed physician may, however, advertise and promote the compounding service.

Constitutional Law: Fundamental Freedoms: Freedom of Speech: Commercial Speech
Even a communication that does no more than propose a commercial transaction is entitled to the coverage of the First Amendment.

Constitutional Law: Fundamental Freedoms: Freedom of Speech: Commercial Speech
Although commercial speech is protected by the First Amendment, not all regulation of such speech is unconstitutional. Under the test for determining whether a particular commercial speech regulation is constitutionally permissible, the court asks as a threshold matter whether the commercial speech concerns unlawful activity or is misleading. If so, then the speech is not protected by the First Amendment. If the speech concerns lawful activity and is not misleading, however, the court next asks whether the asserted governmental interest is substantial. If it is, then the court determines whether the regulation directly advances the governmental interest asserted and, finally, whether it is not more extensive than is necessary to serve that interest. Each of these latter three inquiries must be answered in the affirmative for the regulation to be found constitutional.

Constitutional Law: Fundamental Freedoms: Freedom of Speech: Commercial Speech
The party seeking to uphold a restriction on commercial speech carries the burden of justifying it.

Constitutional Law: Fundamental Freedoms: Freedom of Speech: Scope of Freedom
If the First Amendment means anything, it means that regulating speech must be a last, not first, resort.

Constitutional Law: Fundamental Freedoms: Freedom of Speech: Commercial Speech
Bans against truthful, nonmisleading commercial speech usually rest solely on the offensive assumption that the public will respond irrationally to the truth. The First Amendment directs the courts to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.

SYLLABUS: 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," §[*2] 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, 65 L. Ed. 2d 341, 100 S. Ct. 2343*. 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[*3] governmental interest to be served by the regulation must be substantial, and the regulation must "directly advance" 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[*4] 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 advances" 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] interests." *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, 131 L. Ed. 2d 532, 115 S. Ct. 1585*. Several non-speech-related means of drawing a line between compounding and large-scale manufacturing might be possible [*5]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[*6] 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, 48 L. Ed. 2d 346, 96 S. Ct. 1817.*

(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 clienteles 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[*7] that the prohibition is unconstitutional. Pp. 18-19.

238 F.3d 1090, affirmed.

JUDGES: 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.

OPINIONBY: O'CONNOR

OPINION: JUSTICE O'CONNOR delivered the opinion of the Court.

Section 503A of the Food and Drug Administration Modernization Act of 1997 (FDAMA or Act), 111 Stat. 2328, *21 U.S.C. § 353a*, exempts "compounded drugs" from the Food and Drug Administration's standard drug approval requirements as long as the providers of those drugs abide by several restrictions, including that they refrain from advertising or promoting particular compounded drugs. Respondents, a group of licensed pharmacies that specialize in compounding drugs, sought to enjoin enforcement of the subsections of the Act dealing with advertising and solicitation, arguing that those provisions violate the First Amendment's free speech guarantee. [*8] The District Court agreed with respondents and granted their motion for summary judgment, holding that the provisions do not meet the test for acceptable government regulation of commercial speech set forth in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N. Y., 447 U.S. 557, 566, 65 L. Ed. 2d 341, 100 S. Ct. 2343 (1980)*. The court invalidated the relevant provisions, severing them from the rest of § 503A.

The Court of Appeals for the Ninth Circuit affirmed in part and reversed in part, agreeing that the provisions regarding advertisement and promotion are unconstitutional but finding them not to be severable from the rest of § 503A. Petitioners challenged only the Court of Appeals' constitutional holding in their petition for certiorari, and respondents did not file a cross-petition. We therefore address only the constitutional question, having no occasion to review the Court of Appeals' severability determination. We conclude, as did the courts below, that § 503A's provisions regarding advertisement and promotion amount to unconstitutional restrictions on commercial speech, and we therefore affirm.

I

Drug compounding is a process by which[*9] a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient. Compounding is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product. It is a traditional component of the practice of pharmacy, see J. Thompson, A Practical Guide to Contemporary Pharmacy Practice 11.3 (1998), and is taught as part of the standard curriculum at most pharmacy schools, see American Council on Pharmaceutical Education, Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor

of Pharmacy Degree, Standard 10(a) (adopted June 14, 1997). Many States specifically regulate compounding practices as part of their regulation of pharmacies. See, e.g., Cal. Code Regs. tit. 16, §§ 1716.2, 1751 (2002); Ind. Admin. Code, tit. 856, §§ 1-30-8, 1-30-18, 1-28-8 (2001); N. H. Code Admin. Rules Ann. Pharmacy, pts. PH 404, PH 702.01 (2002); 22 Tex. Admin. Code § 291.36 (2002). Some require all licensed pharmacies to offer compounding services. See, e.g., 49 Pa. Code § 27.18(p)(2) (2002); W. [*10] Va. Code St. Rules, tit. 15, § 19.4 (2002). Pharmacists may provide compounded drugs to patients only upon receipt of a valid prescription from a doctor or other medical practitioner licensed to prescribe medication. See, e.g., Okla. Admin. Code §§ 535:15-10-3, 535:15-10-9(d) (2001); Colorado State Board of Pharmacy Rule 3.02.10 (2001).

The Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), *21 U.S.C. §§ 301*-397, regulates drug manufacturing, marketing, and distribution. Section 505(a) of the FDCA, 52 Stat. 1052, as amended, 76 Stat. 784, provides that "no person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed [with the Food and Drug Administration] . . . is effective with respect to such drug." *21 U.S.C. § 355*(a). "New drug" is defined by § 201(p)(1) of the FDCA, 52 Stat. 1041, as [*11]amended 76 Stat. 781, as "any drug . . . not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." *21 U.S.C. § 321*(p). The FDCA invests the Food and Drug Administration (FDA) with the power to enforce its requirements. § 371(a).

For approximately the first 50 years after the enactment of the FDCA, the FDA generally left regulation of compounding to the States. Pharmacists continued to provide patients with compounded drugs without applying for FDA approval of those drugs. The FDA eventually became concerned, however, that some pharmacists were manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA's new drug requirements. In 1992, in response to this concern, the FDA issued a Compliance Policy Guide, which announced that the "FDA may, in the exercise of its enforcement discretion, initiate federal enforcement actions . . . when the scope[*12] and nature of a pharmacy's activities raises the kinds of concerns normally associated with a manufacturer and . . . results in significant violations of the new drug, adulteration, or misbranding provisions of the Act." Compliance Policy Guide 7132.16 (hereinafter Guide), App. to Pet. for Cert. 76a. The Guide explained that the "FDA recognizes that pharmacists traditionally have extemporaneously compounded and manipulated reasonable quantities of drugs upon receipt of a valid prescription for an individually identified patient from a licensed practitioner," and that such activity was not the subject of the Guide. Id., at 71a. The Guide said, however, "that while retail pharmacies . . . are exempted from certain requirements of the [FDCA], they are not the subject of any general exemption from the new drug, adulteration, or misbranding provisions" of the FDCA. Id., at 72a. It stated that the "FDA believes that an increasing number of establishments with retail pharmacy licenses are engaged in manufacturing, distributing, and promoting unapproved new drugs for human use in a manner that is clearly outside the bounds of traditional pharmacy practice and that constitute violations[*13] of the [FDCA]." Ibid. The Guide expressed concern that drug products "manufactured and distributed in commercial amounts without [the] FDA's prior approval" could harm the public health. Id., at 73a.

In light of these considerations, the Guide announced that it was FDA policy to permit pharmacists to compound drugs after receipt of a valid prescription for an individual patient or to compound drugs in "very limited quantities" before receipt of a valid prescription if they could document a history of receiving valid prescriptions "generated solely within an established professional practitioner-patient-pharmacy relationship" and if they maintained the prescription on file as required by state law. Id., at 73a-75a. Compounding in such circumstances was permitted as long as the pharmacy's activities did not raise "the kinds of concerns normally associated with a manufacturer." Id., at 76a. The Guide listed nine examples of activities that the FDA believed raised such concerns and that would therefore be considered by the agency in determining whether to bring an enforcement action. These activities included: "soliciting business (e.g., promoting, advertising, [*14]or using salespersons) to compound specific drug products, product classes, or therapeutic classes of drug products"; "compounding, regularly, or in inordinate amounts, drug products that are commercially available . . . and that are essentially generic copies of commercially available, FDA-approved drug products"; using commercial scale manufacturing or testing equipment to compound drugs; offering compounded drugs at wholesale; and "distributing inordinate amounts of compounded products out of state." Id., at 76a to 77a. The Guide further warned that pharmacies could not dispense drugs to third parties for resale to individual patients without losing their status as retail entities. Id., at 75a.

Congress turned portions of this policy into law when it enacted the FDAMA in 1997. The FDAMA, which amends the FDCA, exempts compounded drugs from the

FDCA's "new drug" requirements and other requirements provided the drugs satisfy a number of restrictions. First, they must be compounded by a licensed pharmacist or physician in response to a valid prescription for an identified individual [*15]patient, or, if prepared before the receipt of such a prescription, they must be made only in "limited quantities" and in response to a history of the licensed pharmacist's or physician's receipt of valid prescription orders for that drug product within an established relationship between the pharmacist, the patient, and the prescriber. *21 U.S.C. § 353a*(a). Second, the compounded drug must be made from approved ingredients that meet certain manufacturing and safety standards, §§ 353a(b)(1)(A)-(B), and the compounded drug may not appear on an FDA list of drug products that have been withdrawn or removed from the market because they were found to be unsafe or ineffective. § 353a(b)(1)(C). Third, the pharmacist or physician compounding the drug may not "compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product." § 353a(b)(1)(D). Fourth, the drug product must not be identified by the FDA as a drug product that presents demonstrable difficulties for compounding in terms [*16]of safety or effectiveness. § 353a(b)(3)(A). Fifth, in States that have not entered into a "memorandum of understanding" with the FDA addressing the distribution of "inordinate amounts" of compounded drugs in interstate commerce, the pharmacy, pharmacist, or physician compounding the drug may not distribute compounded drugs out of State in quantities exceeding five percent of that entity's total prescription orders. § 353a(b)(3)(B). Finally, and most relevant for this litigation, the prescription must be "unsolicited," § 353a(a), and the pharmacy, licensed pharmacist, or licensed physician compounding the drug may "not advertise or promote the compounding of any particular drug, class of drug, or type of drug." § 353a(c). The pharmacy, licensed pharmacist, or licensed physician may, however, "advertise and promote the compounding service." Ibid.

Respondents are a group of licensed pharmacies that specialize in drug compounding. They have prepared promotional materials that they distribute by mail and at medical conferences to inform patients and physicians of the use and effectiveness[*17] of specific compounded drugs. Fearing that they would be prosecuted under the FDAMA if they continued to distribute those materials, respondents filed a complaint in the United States District Court for the District of Nevada, arguing that the Act's requirement that they refrain from advertising and promoting their products if they wish to continue compounding violates the Free Speech Clause of the First Amendment. Specifically, they challenged the requirement that prescriptions for compounded drugs be "unsolicited," *21 U.S.C. § 353a*(a), and the requirement that pharmacists "not advertise or promote the compounding of any particular drug, class of drug, or type of drug," § 353a(c). The District Court granted summary judgment to respondents, finding that the FDAMA's speech-related provisions constitute unconstitutional restrictions on commercial speech under *Central Hudson, 447 U.S. at 566,* and that their enforcement should therefore be enjoined. *Western States Medical Center v. Shalala, 69 F. Supp. 2d 1288 (Nev. 1999)*. The District Court, however, found those provisions to be severable from the rest of § 503A of the[*18] FDAMA, *21 U.S.C. § 353a,* and so left the Act's other compounding requirements intact.

The Government appealed both the holding that the speech-related provisions were unconstitutional and the holding that those provisions were severable from the rest of § 503A. The Court of Appeals for the Ninth Circuit affirmed in part and reversed in part. *Western States Medical Center v. Shalala, 238 F.3d 1090 (2001)*. The Court of Appeals agreed that the FDAMA's advertisement and solicitation restrictions fail Central Hudson's test for permissible regulation of commercial speech, finding that the Government had not demonstrated that the speech restrictions would directly advance its interests or that alternatives less restrictive of speech were unavailable. The Court of Appeals disagreed, however, that the speech-related restrictions were severable from the rest of § 503A, *21 U.S.C. § 353a*, explaining that the FDAMA's legislative history demonstrated that Congress intended to exempt compounding from the FDCA's requirements only in return for a prohibition on promotion of specific compounded drugs. Accordingly, the Court[*19] of Appeals invalidated § 503A in its entirety.

We granted certiorari, *534 U.S. 992 (2001)*, to consider whether the FDAMA's prohibitions on soliciting prescriptions for, and advertising, compounded drugs violate the First Amendment. Because neither party petitioned for certiorari on the severability issue, we have no occasion to review that portion of the Court of Appeals decision. Likewise, the provisions of the FDAMA outside § 503A, which are unrelated to drug compounding, are not an issue here and so remain unaffected.

II

The parties agree that the advertising and soliciting prohibited by the FDAMA constitute commercial speech.

In *Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 48 L. Ed. 2d 346, 96 S. Ct. 1817 (1976)*, the first case in which we

explicitly held that commercial speech receives First Amendment protection, we explained the reasons for this protection: "It is a matter of public interest that [economic] decisions, in the aggregate, be intelligent and well-informed. To this end, the free flow of commercial information is indispensable." *Id., at 765*. Indeed, we recognized that[*20] a "particular consumer's interest in the free flow of commercial information . . . may be as keen, if not keener by far, than his interest in the day's most urgent political debate." *Id., at 763*. We have further emphasized:

"The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented. Thus, even a communication that does no more than propose a commercial transaction is entitled to the coverage of the First Amendment." *Edenfield v. Fane, 507 U.S. 761, 767, 123 L. Ed. 2d 543, 113 S. Ct. 1792 (1993)*.

Although commercial speech is protected by the First Amendment, not all regulation of such speech is unconstitutional. See *Virginia Bd. of Pharmacy, supra, at 770*. In *Central Hudson, supra,* [*21] we articulated a test for determining whether a particular commercial speech regulation is constitutionally permissible. Under that test we ask as a threshold matter whether the commercial speech concerns unlawful activity or is misleading. If so, then the speech is not protected by the First Amendment. If the speech concerns lawful activity and is not misleading, however, we next ask "whether the asserted governmental interest is substantial." *Id., at 566*. If it is, then we "determine whether the regulation directly advances the governmental interest asserted," and, finally, "whether it is not more extensive than is necessary to serve that interest." Ibid. Each of these latter three inquiries must be answered in the affirmative for the regulation to be found constitutional.

Neither party has challenged the appropriateness of applying the Central Hudson framework to the speech-related provisions at issue here. Although several Members of the Court have expressed doubts about the Central Hudson analysis and whether it should apply in particular cases, see, e.g., *Greater New Orleans Broadcasting Assn., Inc. v. United States, 527 U.S. 173, 197, 144 L. Ed. 2d 161, 119 S. Ct. 1923 (1999)*[*22] (THOMAS, J., concurring in judgment); 44 *Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 501, 510-514, 134 L. Ed. 2d 711, 116 S. Ct. 1495 (1996)* (opinion of STEVENS, J., joined by KENNEDY, and GINSBURG, JJ.); *id., at 517* (SCALIA, J., concurring in part and concurring in judgment); *id., at 518* (THOMAS, J., concurring in part and concurring in judgment), there is no need in this case to break new ground. "'Central Hudson, as applied in our more recent commercial speech cases, provides an adequate basis for decision.'" *Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 554-555, 150 L. Ed. 2d 532, 121 S. Ct. 2404 (2001)* (quoting Greater New Orleans, supra, at 184).

III

The Government does not attempt to defend the FDAMA's speech-related provisions under the first prong of the Central Hudson test; i.e., it does not argue that the prohibited advertisements would be about unlawful activity or would be misleading. Instead, the Government argues that the FDAMA satisfies the remaining three prongs of the Central Hudson test.

The Government asserts that three substantial interests underlie[*23] the FDAMA. The first is an interest in "preserving the effectiveness and integrity of the FDCA's new drug approval process and the protection of the public health that it provides." Brief for Petitioners 19. The second is an interest in "preserving the availability of compounded drugs for those individual patients who, for particularized medical reasons, cannot use commercially available products that have been approved by the FDA." Id., at 19-20. Finally, the Government argues that "achieving the proper balance between those two independently compelling but competing interests is itself a substantial governmental interest." Id., at 20.

Explaining these interests, the Government argues that the FDCA's new drug approval requirements are critical to the public health and safety. It claims that the FDA's experience with drug regulation demonstrates that proof of the safety and effectiveness of a new drug needs to be established by rigorous, scientifically valid clinical studies because impressions of individual doctors, who cannot themselves compile sufficient safety data, cannot be relied upon. The Government also argues that a premarket approval process, under which manufacturers[*24] are required to put their proposed drugs through tests of safety and effectiveness in order to obtain FDA approval to market the drugs, is the best way to guarantee drug safety and effectiveness.

While it praises the FDCA's new drug approval process, the Government also acknowledges that "because obtaining FDA approval for a new drug is a costly process, requiring FDA approval of all drug products compounded by pharmacies for the particular needs of an individual patient would, as a practical matter, eliminate the practice of compounding, and thereby eliminate availability of compounded drugs for

those patients who have no alternative treatment." Id., at 26. The Government argues that eliminating the practice of compounding drugs for individual patients would be undesirable because compounding is sometimes critical to the care of patients with drug allergies, patients who cannot tolerate particular drug delivery systems, and patients requiring special drug dosages.

Preserving the effectiveness and integrity of the FDCA's new drug approval process is clearly an important governmental interest, and the Government has every reason to want as many drugs as possible to be subject[*25] to that approval process. The Government also has an important interest, however, in permitting the continuation of the practice of compounding so that patients with particular needs may obtain medications suited to those needs. And it would not make sense to require compounded drugs created to meet the unique needs of individual patients to undergo the testing required for the new drug approval process. Pharmacists do not make enough money from small-scale compounding to make safety and efficacy testing of their compounded drugs economically feasible, so requiring such testing would force pharmacists to stop providing compounded drugs. Given this, the Government needs to be able to draw a line between small-scale compounding and large-scale drug manufacturing. That line must distinguish compounded drugs produced on such a small scale that they could not undergo safety and efficacy testing from drugs produced and sold on a large enough scale that they could undergo such testing and therefore must do so.

The Government argues that the FDAMA's speech-related provisions provide just such a line, i.e., that, in the terms of Central Hudson, they "directly advance the governmental[*26] interests asserted." *447 U.S. at 566*. Those provisions use advertising as the trigger for requiring FDA approval -- essentially, 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. If they advertise their compounded drugs, however, FDA approval is required. The Government explains that traditional (or, in its view, desirable) compounding responds to a physician's prescription and an individual patient's particular medical situation, and that "advertising the particular products created in the provision of [such] service (as opposed to advertising the compounding service itself) is not necessary to . . . this type of responsive and customized service." Brief for Petitioners 34. The Government argues that advertising particular products is useful in a broad market but is not useful when particular products are designed in response to an individual's "often unique needs." Ibid. The Government contends that, because of this, advertising is not typically associated with compounding for particular individuals. In contrast it is typically associated, [*27] the Government claims, with large-scale production of a drug for a substantial market. The Government argues that advertising, therefore, is "a fair proxy for actual or intended large-scale manufacturing," and that Congress' decision to limit the FDAMA's compounding exemption to pharmacies that do not engage in promotional activity was "rationally calculated" to avoid creating "'a loophole that would allow unregulated drug manufacturing to occur under the guise of pharmacy compounding.'" Id., at 35 (quoting 143 Cong. Rec. S9839 (Sept. 24, 1997) (statement of Sen. Kennedy)).

The Government seems to believe that without advertising it would not be possible to market a drug on a large enough scale to make safety and efficacy testing economically feasible. The Government thus believes that conditioning an exemption from the FDA approval process on refraining from advertising is an ideal way to permit compounding and yet also guarantee that compounding is not conducted on such a scale as to undermine the FDA approval process. Assuming it is true that drugs cannot be marketed on a large scale without advertising, the FDAMA's prohibition on advertising compounded drugs might indeed "directly [*28]advance" the Government's interests. *Central Hudson, 447 U.S. at 566*. Even assuming that it does, however, the Government has failed to demonstrate that the speech restrictions are "not more extensive than is necessary to serve [those] interests." Ibid. In previous cases addressing this final prong of the Central Hudson test, we have made clear that if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so. In *Rubin v. Coors Brewing Co., 514 U.S. 476, 131 L. Ed. 2d 532, 115 S. Ct. 1585 (1995)*, for example, we found a law prohibiting beer labels from displaying alcohol content to be unconstitutional in part because of the availability of alternatives "such as directly limiting the alcohol content of beers, prohibiting marketing efforts emphasizing high alcohol strength . . .,or limiting the labeling ban only to malt liquors." *Id., at 490-491*. The fact that "all of [these alternatives] could advance the Government's asserted interest in a manner less intrusive to . . . First Amendment rights," indicated that the law was "more[*29] extensive than necessary." *Id., at 491*. See also 44 *Liquormart, Inc. v. Rhode Island, 517 U.S. at 507* (plurality opinion) (striking down a prohibition on advertising the price of alcoholic beverages in part because "alternative forms of regulation that would not involve any restriction on speech would be more likely to achieve the State's goal of promoting temperance").

Several non-speech-related means of drawing a line between compounding and large-scale manufacturing might be possible here. First, it seems that the Government could use the very factors the FDA relied on to distinguish compounding from manufacturing in its 1992 Compliance Policy Guide. For example, the Government could ban the use of "commercial scale manufacturing or testing equipment for compounding drug products." Compliance Policy Guide, App. to Pet. for Cert. 76a. It could prohibit pharmacists from compounding more drugs in anticipation of receiving prescriptions than in response to prescriptions already received. See ibid. It could prohibit pharmacists from "offering compounded drugs at wholesale to other state licensed persons or commercial entities for resale." [*30] Id., at 77a. Alternately, it could limit the amount of compounded drugs, either by volume or by numbers of prescriptions, that a given pharmacist or pharmacy sells out of State. See ibid. Another possibility not suggested by the Compliance Policy Guide would be capping the amount of any particular compounded drug, either by drug volume, number of prescriptions, gross revenue, or profit that a pharmacist or pharmacy may make or sell in a given period of time. It might even be sufficient to rely solely on the non-speech-related provisions of the FDAMA, such as the requirement that compounding only be conducted in response to a prescription or a history of receiving a prescription, *21 U.S.C. § 353a*(a), and the limitation on the percentage of a pharmacy's total sales that out-of-state sales of compounded drugs may represent, § 353a(b)(3)(B).

The Government has not offered any reason why these 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. Indeed, there is no hint that the Government even considered these or any other alternatives. Nowhere[*31] in the legislative history of the FDAMA or petitioners' briefs is there any explanation of why the Government believed forbidding advertising was a necessary as opposed to merely convenient means of achieving its interests. Yet "it is well established that 'the party seeking to uphold a restriction on commercial speech carries the burden of justifying it.'" *Edenfield v. Fane, 507 U.S. at 770* (quoting *Bolger v. Youngs Drug Products Corp., 463 U.S. 60, 71, n. 20, 77 L. Ed. 2d 469, 103 S. Ct. 2875 (1983))*. The Government simply has not provided sufficient justification here. If the First Amendment means anything, it means that regulating speech must be a last -- not first -- resort. Yet here it seems to have been the first strategy the Government thought to try.

The dissent describes another governmental interest -- an interest in prohibiting the sale of compounded drugs to "patients who may not clearly need them," post, at 2 (opinion of BREYER, J. [*32]) -- and argues that "Congress could . . . conclude that the advertising restrictions 'directly advance'" that interest, post, at 8. Nowhere in its briefs, however, does the Government argue that this interest motivated the advertising ban. Although, for the reasons given by the dissent, Congress conceivably could have enacted the advertising ban to advance this interest, we have generally only sustained statutes on the basis of hypothesized justifications when reviewing statutes merely to determine whether they are rational. See L. Tribe, American Constitutional Law 1444-1446 (2d ed. 1988) (describing the "rational basis" or "conceivable basis" test); see also, e.g., *Minnesota v. Clover Leaf Creamery Co., 449 U.S. 456, 466, 66 L. Ed. 2d 659, 101 S. Ct. 715 (1981)* (sustaining a milk packaging regulation under the "rational basis" test because "the Minnesota Legislature could rationally have decided that [the regulation] might foster greater use of environmentally desirable alternatives" (emphasis deleted)). The Central Hudson test is significantly stricter than the rational basis test, however, requiring the Government not only to identify specifically[*33] "a substantial interest to be achieved by [the] restriction on commercial speech," *447 U.S. at 564*, but also to prove that the regulation "directly advances" that interest and is "not more extensive than is necessary to serve that interest," *id., at 566*. The Government has not met any of these requirements with regard to the interest the dissent describes.

Even if the Government had argued 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. Aside from the fact that this concern rests on the questionable assumption that doctors would prescribe unnecessary medications (an assumption the dissent is willing to make based on one magazine article and one survey, post at 7, neither of which was relied upon by the Government), this concern amounts to a fear that people would make bad decisions if given truthful information about compounded drugs. See supra, at 10 (explaining that the Government does not claim the advertisements[*34] forbidden by the FDAMA would be false or misleading). We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information. In Virginia Bd. of Pharmacy, the State feared that if people received price advertising from pharmacists, they would "choose the low-cost, low-quality service and drive the 'professional' pharmacist out of business" and would "destroy the pharmacist-customer

relationship" by going from one pharmacist to another. We found these fears insufficient to justify a ban on such advertising. *425 U.S. at 769*. We explained:

"There is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them . . . . But the choice among these alternative approaches is not ours to make or the Virginia General Assembly's. It is precisely[*35] this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us. Virginia is free to require whatever professional standards it wishes of its pharmacists; it may subsidize them or protect them from competition in other ways. But it may not do so by keeping the public in ignorance of the entirely lawful terms that competing pharmacists are offering." *Id., at 770* (citation omitted).

See also 44 *Liquormart, Inc. v. Rhode Island, 517 U.S. at 503* ("Bans against truthful, nonmisleading commercial speech . . . usually rest solely on the offensive assumption that the public will respond 'irrationally' to the truth. The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good" (citation omitted)).

Even if the Government had asserted an interest in preventing people who do not need compounded drugs from obtaining those drugs, the statute does not directly[*36] advance that interest. The dissent claims that the Government "must exclude from the area of permitted drug sales . . . those compounded drugs sought by patients who may not clearly need them." Post, at 2. Yet the statute does not directly forbid such sales. It instead restricts advertising, of course not just to those who do not need compounded drugs, but also to individuals who do need compounded drugs and their doctors. Although the advertising ban may reduce the demand for compounded drugs from those who do not need the drugs, it does nothing to prevent such individuals from obtaining compounded drugs other than requiring prescriptions. But if it is appropriate for the statute to rely on doctors to refrain from prescribing compounded drugs to patients who do not need them, it is not clear why it would not also be appropriate to rely on doctors to refrain from prescribing compounded drugs to patients who do not need them in a world where advertising was permitted.

The dissent may also be suggesting that the Government has an interest in banning the advertising of compounded drugs because patients who see such advertisements will be confused about the drugs' risks. See post[*37] , at 11 ("[the Government] fears the systematic effect . . . of advertisements that will not fully explain the complicated risks at issue"). This argument is precluded, however, by the fact that the Government does not argue that the advertisements are misleading. Even if the Government did argue that it had an interest in preventing misleading advertisements, this interest could be satisfied by the far less restrictive alternative of requiring each compounded drug to be labeled with a warning that the drug had not undergone FDA testing and that its risks were unknown.

If the Government's failure to justify its decision to regulate speech were not enough to convince us 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 affect pharmacists other than those interested in producing drugs on a large scale. It would prevent pharmacists with no interest in mass-producing medications, but who serve clienteles with special medical needs, from telling the doctors treating those clients about the alternative drugs available through compounding. For example, a[*38] 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. Forbidding advertising of particular compounded drugs would also prohibit a pharmacist from posting a notice informing customers that if their children refuse to take medications because of the taste, the pharmacist could change the flavor, and giving examples of medications where flavoring is possible. 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 our belief that the prohibition is unconstitutional.

Accordingly, we affirm the Court of Appeals' judgment that the speech-related provisions of FDAMA § 503A are unconstitutional.

So ordered.

CONCURBY: THOMAS

CONCUR: JUSTICE THOMAS, concurring.

I concur because I agree with the Court's application of the test set forth in *Central Hudson Gas & Elec. Corp. v.*

Public Serv. Comm'n. of N. Y., 447 U.S. 557, 65 L. Ed. 2d 341, 100 S. Ct. 2343 (1980).[*39] I continue, however, to adhere to my view that cases such as this should not be analyzed under the Central Hudson test. "I do not believe that such a test should be applied to a restriction of 'commercial' speech, at least when, as here, the asserted interest is one that is to be achieved through keeping would-be recipients of the speech in the dark." 44 *Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 523, 134 L. Ed. 2d 711, 116 S. Ct. 1495 (1996)* (opinion concurring in part and concurring in judgment).

DISSENTBY: BREYER

DISSENT: JUSTICE BREYER, with whom THE CHIEF JUSTICE, JUSTICE STEVENS, and JUSTICE GINSBURG join, dissenting.

Federal law requires strict safety and efficacy testing of all "new" prescription "drugs." *21 U.S.C. § 355*. See *21 CFR § 310.3(h)* (2002) (defining "new drug" broadly). This testing process requires for every "new drug" a preclinical investigation and three separate clinical tests, including small, controlled studies of healthy and diseased humans as well as scientific double-blind studies designed to identify any possible health risk or side effect associated with the new drug. Practical[*40] Guide to Food and Drug Law and Regulation, 95-102 (K. Pina & W. Pines eds. 1998). The objective of this elaborate and time-consuming regulatory regime is to identify those health risks -- both large and small -- that a doctor or pharmacist might not otherwise notice.

At the same time, the law exempts from its testing requirements prescription drugs produced through "compounding," -- a process "by which a pharmacist or doctor combines, mixes or alters ingredients to create a medication tailored to the needs of an individual patient." Ante, at 2. The exemption is available, however, only if the pharmacist meets certain specified conditions, including the condition that the pharmacist not "advertise or promote the compounding of any particular drug." *21 U.S.C. § 353a*(c) (emphasis added).

The Court holds that this condition restricts "commercial speech" in violation of the First Amendment. See *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N. Y., 447 U.S. 557, 564, 65 L. Ed. 2d 341, 100 S. Ct. 2343 (1980)*. It concedes that the statutory provision tries to "preserv[e] the effectiveness and integrity of the . . . new drug[*41] approval process," ante, at 11, and it assumes without deciding that the statute might "'directly advance"' that interest, ante, at 13. It nonetheless finds the statute unconstitutional because it could advance that interest in other, less restrictive ways. Ante, at 14-15, 17. I disagree with this conclusion, and I believe that the Court seriously undervalues the importance of the Government's interest in protecting the health and safety of the American public.

I

In my view, the advertising restriction "directly advances" the statute's important safety objective. That objective, as the Court concedes, is to confine the sale of untested, compounded, drugs to where they are medically needed. But to do so the statute must exclude from the area of permitted drug sales both (1) those drugs that traditional drug manufacturers might supply after testing-- typically drugs capable of being produced in large amounts, and (2) those compounded drugs sought by patients who may not clearly need them -- including compounded drugs produced in small amounts.

The majority's discussion focuses upon the first exclusionary need, but it virtually ignores the second. It describes the[*42] statute's objective simply as drawing a "line" that will "distinguish compounded drugs produced on such a small scale that they could not undergo safety and efficacy testing from drugs produced and sold on a large enough scale that they could undergo such testing and therefore must do so." Ante, at 11-12 (emphasis added). This description overlooks the need for a second line -- a line that will distinguish (1) sales of compounded drugs to those who clearly need them from (2) sales of compounded drugs to those for whom a specially tailored but untested drug is a convenience but not a medical necessity. That is to say, the statute, in seeking to confine distribution of untested tailored drugs, must look both at the amount supplied (to help decide whether ordinary manufacturers might provide a tested alternative) and at the nature of demand (to help separate genuine need from simple convenience). Cf. 143 Cong. Rec. S9840 (Sept. 24, 1997) (remarks of Sen. Kennedy) (understanding that "some of the conditions are intended to ensure that the volume of compounding does not approach that ordinarily associated with drug manufacturing" while others are "intended to ensure that the compounded[*43] drugs that qualify for the exemption have appropriate assurances of quality and safety since [they] would not be subject to the more comprehensive regulatory requirements that apply to manufactured drug products").

This second intermediate objective is logically related to Congress' primary end -- the minimizing of safety risks. The statute's basic exemption from testing requirements inherently creates risks simply by placing untested drugs in the hands of the consumer. Where an individual has a specific medical need for a specially tailored drug those risks are likely offset. But where an

untested drug is a convenience, not a necessity, that offset is unlikely to be present.

That presumably is why neither the Food and Drug Administration (FDA) nor Congress anywhere suggests that all that matters is the total amount of a particular drug's sales. That is why the statute's history suggests that the amount supplied is not the whole story. See S. Rep. No. 105-43, p. 67 (1997) (statute seeks to assure "continued availability of compounded drug products as a component of individualized therapy, . . . while . . . preventing small-scale manufacturing under the guise of compounding") (emphasis[*44] added); accord, H. R. Conf. Rep. No. 105-399, p. 94 (1997). That is why the statute itself, as well as the FDA policy that the statute reflects, lists several distinguishing factors, of which advertising is one. See FDA Compliance Policy Guide 7132.16, reprinted in App. to Pet. for Cert. at 71a-77a (hereinafter Compliance Policy Guide). And that is likely why, when faced with the possibility of severing the advertising restriction from the rest of the statute, the Government argued that the "other conditions in section 353a alone are inadequate to achieve Congress's desired balance among competing interests." See Brief for Appellants in No. 99-17424 (CA9), p. 57. See also id., at 55. (to nullify advertising restrictions would undermine '"finely tuned balance"' achieved by requiring that "pharmacies refrain from promoting and soliciting prescriptions for particular compounded drug products until they have been proven safe and effective").

Ensuring that the risks associated with compounded drug prescriptions are offset by the benefits is also why public health authorities, testifying in Congress, insisted that the doctor's prescription represent an individualized determination of[*45] need. See, e.g., FDA Reform Legislation: Hearings before the Subcommittee on Health and the Environment of the House Committee on Commerce, 104th Cong., 2d Sess., p. 120 (1996) (Statement of Mary K. Pendergast, Deputy Commissioner of the FDA and Senior Advisor to the Commissioner) (Allowing traditional compounding is "good medicine" because "an individual physician" was making "an individualized determination for a patient") (hereinafter FDA Reform Legislation). See also National Association of Boards of Pharmacy, Model State Pharmacy Act and Rules, Art I, § 1.05(e) (1996) (NABP Model Act) (defining "compounding" as involving a prescription "based on the Practitioner/patient/Pharmacist relationship in the course of professional practice").

And that, in part, is why federal and state authorities have long permitted pharmacists to advertise the fact that they compound drugs, while forbidding the advertisement of individual compounds. See Compliance Policy Guide 76a; Good Compounding Practices Applicable to State Licensed Pharmacies, NABP Model Act App. C.2, subpart A, (forbidding pharmacists to "solicit business (e.g., promote, advertise, or use salespersons) to compound specific drug[*46] products"). The definitions of drug manufacturing and compounding used by the NABP and at least 13 States reflect similar distinctions. NABP Model Act, Art. I, §§ 105(e), (t), and (u) (defining drug manufacturing to "include the promotion and marketing of such drugs or devices" but excluding any reference to promotion or marketing from the definition of drug compounding); Alaska Stat. § 08.80.480(3) and (15) (2000) (same); La. Rev. Stat. Ann. § 37:1164(5) and (25) (West 2000) (same); Miss. Code Ann. §§ 73-21-73(c) and (s) (Lexis 1973-2000) (same); Mont. Code Ann. §§ 37-7-101(7) (1997) (same); N. H. Rev. Stat. Ann. §§ 318-1(III) and (VIII) (Supp. 2001) (same); N. M. Stat. Ann. § 61-11-2(C) and (Q) (2001) (same); Ohio Rev. Code Ann. § 3715.01 (14) (West Supp. 2002) (same); Okla. Stat., Tit 59, § 353.1(20) and (26) (Supp. 2002) (same); S. C. Code Ann. §§ 40-43-30(7) and (29) (2001); Tenn. Code Ann. §§ 63-10-404(4) and (18) (1997)(same); Tex. Occ. Code Ann. §§ 551.003(9) and (23) (2002 Pamphlet) (same); W. Va. Code Ann. §§ 30-5-1b(c) and (o) (1966-1998) (same).

These policies and statutory provisions reflect the view that individualized consideration is more likely present, and[*47] convenience alone is more likely absent, when demand for a compounding prescription originates with a doctor, not an advertisement. The restrictions try to assure that demand is generated doctor-to-patient-to-pharmacist, not pharmacist-to-advertisement-to-patient-to-doctor. And they do so in order to diminish the likelihood that those who do not genuinely need untested compounded drugs will not receive them.

There is considerable evidence that the relevant means -- the advertising restrictions -- directly advance this statutory objective. No one denies that the FDA's complex testing system for new drugs -- a system that typically relies upon double-blind, or other scientific studies -- is more likely to find, and to assess, small safety risks than are physicians or pharmacists relying upon impressions and anecdotes. See supra, at 1.

Nor can anyone deny that compounded drugs carry with them special risks. After all, compounding is not necessarily a matter of changing a drug's flavor, cf. ante, at 17, but rather it is a matter of combining different ingredients in new, untested ways, say, adding a pain medication to an antihistamine to counteract allergies or increasing the ratio[*48] of approved ingredients in a salve to help the body absorb it at a faster rate. And the

risks associated with the untested combination of ingredients or the quicker absorption rate or the working conditions necessary to change an old drug into its new form can, for some patients, mean infection, serious side effects, or even death. See, e.g., J. Thompson, Practical Guide to Contemporary Pharmacy Practice 11.5 (1998) (hereinafter Contemporary Pharmacy Practice). Cf. *21 CFR § 310.3(h)(1)* (2002) (considering a drug to be "new" and subject to the approval process if the "substance which composes such drug" is new); § 310.3(h)(3) (considering a drug to be "new" and subject to the approval process if approved ingredients are combined in new proportions).

There is considerable evidence that consumer oriented advertising will create strong consumer-driven demand for a particular drug. See, e.g., National Institute for Health Care Management, Factors Affecting the Growth of Prescription Drug Expenditures iii (July 9, 1999) (three antihistamine manufacturers spent $313 million on advertising in 1998 and accounted for 90% of prescription drug antihistamine market); [*49] Kritz, Ask Your Doctor About . . . Which of the Many Advertised Allergy Drugs Are Right for You? Washington Post, June 6, 2000, Health, p. 9 (The manufacturer of the world's top selling allergy drug, the eighth best-selling drug in the United States, spent almost $140 million in 1999 on advertising); 1999 Prevention Magazine 10 (spending on direct-to-consumer advertising of prescription medicine increased from $965.2 million in 1997 to $1.33 billion in 1998).

And there is strong evidence that doctors will often respond affirmatively to a patient's request for a specific drug that the patient has seen advertised. See id., at 32 (84% of consumers polled report that doctors accommodate their request for a specific drug); Henry J. Kaiser Family Foundation, Understanding the Effects of Direct-to-Consumer Prescription Drug Advertising 3 (Nov. 2001) (A Foundation survey found that more than one in eight Americans had asked for --and received -- a specific prescription from their doctor in response to an advertisement).

In these circumstances, Congress could reasonably conclude that doctors will respond affirmatively to a patient's request for a compounded drug even if the doctor would[*50] not normally prescribe it. When a parent learns that a child's pill can be administered in liquid form, when a patient learns that a compounded skin cream has an enhanced penetration rate, or when an allergy sufferer learns that a compounded antiinflammatory/allergy medication can alleviate a sinus headache without the sedative effects of antihistamines, that parent or patient may well ask for the desired prescription. And the doctor may well write the prescription even in the absence of special need -- at least if any risk likely to arise from lack of testing is so small that only scientific testing, not anecdote or experience, would reveal it. It is consequently not surprising that 71% of the active members of the American Academy of Family Physicians "believe that direct-to-consumer advertising pressures physicians into prescribing drugs that they would not ordinarily prescribe." Rosenthal, Berndt, Donohue, Frank, & Epstein, Promotion of Prescription Drugs to Consumers, *346 New Eng. J. Med. 498-505 (2002)* (citing Lipsky, The Opinions and Experiences of Family Physicians Regarding Direct-To-Consumer Advertising, 45 J. Fam. Pract. 495-499 (1997)).

Of course, the added[*51] risks in any such individual case may be small. But those individual risks added together can significantly affect the public health. At least, the FDA and Congress could reasonably reach that conclusion. And that fact, along with the absence of any significant evidence that the advertising restrictions have prevented doctors from learning about, or obtaining, compounded drugs, means that the FDA and Congress could also conclude that the advertising restrictions "directly advance" the statute's safety goal. They help to assure that demand for an untested compounded drug originates with the doctor, responding to an individual's special medical needs; they thereby help to restrict the untested drug's distribution to those most likely to need it; and they thereby advance the statute's safety goals. There is no reason for this Court, as a matter of constitutional law, to reach a different conclusion.

II

I do not believe that Congress could have achieved its safety objectives insignificantly less restrictive ways. Consider the several alternatives the Court suggests. First, it says that "the Government could ban the use of 'commercial scale manufacturing or testing equipment in compounding[*52] drug products.'" Ante, at 14. This alternative simply restricts compounding to drugs produced in small batches. It would neither limit the total quantity of compounded drugs produced, nor help in any way to assure the kind of individualized doctor-patient need determination that the statute's advertising restriction are designed to help achieve.

Second, the Court says that the Government "could prohibit pharmacists from compounding more drugs in anticipation of receiving prescriptions than in response to prescriptions already received." Ibid. This alternative, while addressing the issue of quantity, does virtually nothing to promote the second, need-related statutory objective.

Third, the Court says the Government "could prohibit pharmacists from 'offering compounded drugs at wholesale to other state licensed persons or commercial entities for resale." Ibid. This alternative is open to the same objection.

Fourth, the Court says the Government "could limit the amount of compounded drugs, either by volume or by numbers of prescriptions, that a given pharmacist or pharmacy sells out of State." Ibid. This alternative, applying only to out-of-state sales, would not significantly restrict[*53] sales, either in respect to amounts or in respect to patient need. In fact, it could prevent compounded drugs from reaching out-of-state patients who genuinely need them.

Fifth, the Court says that the Government could "cap the amount of any particular compounded drug, either by drug volume, number of prescriptions, gross revenue, or profit." Ibid. This alternative, like the others, ignores the patient-need problem, while simultaneously threatening to prevent compounded drugs from reaching those who genuinely need them, say, a patient whose prescription represents one beyond the arbitrarily imposed quantitative limit.

Sixth, the Court says that the Government could rely upon "non-speech-related provisions of the FDAMA, such as the requirement that compounding only be conducted in response to a prescription." Ibid. This alternative also ignores the patient-need problem and was specifically rejected by the Government in the Court of Appeals for the Ninth Circuit. See supra, at 4.

The Court adds that "the Government has not offered any reason why these possibilities, alone or in combination, would be insufficient." Ante, at 14. The Government's failure to do so may reflect the[*54] fact that only the Court, not any of the respondents, has here suggested that these "alternatives," alone or in combination, would prove sufficient. In fact, the FDA's Compliance Policy Guide, from which the Court draws its first four alternatives, specifically warned that these alternatives alone were insufficient to successfully distinguish traditional compounding from unacceptable manufacturing. See Compliance Policy Guide 77a.

III

The Court responds to the claim that advertising compounded drugs causes people to obtain drugs that do not promote their health, by finding it implausible given the need for a prescription and by suggesting that it is not relevant. The First Amendment, it says, does not permit the Government to control the content of advertising, where doing so flows from "fear" that "people would make bad decisions if given truthful information about compounded drugs." Ante, at 15. This response, however, does not fully explain the Government's regulatory rationale; it fails to take account of considerations that make the claim more than plausible (if properly stated); and it is inconsistent with this Court's interpretation of the Constitution.

It is an oversimplification[*55] to say that the Government "fears" that doctors or patients "would make bad decisions if given truthful information." Ante, at 15. Rather, the Government fears the safety consequences of multiple compound-drug prescription decisions initiated not by doctors but by pharmacist-to-patient advertising. Those consequences flow from the adverse cumulative effects of multiple individual decisions each of which may seem perfectly reasonable considered on its own. The Government fears that, taken together, these apparently rational individual decisions will undermine the safety testing system, thereby producing overall a net balance of harm. See, e.g., FDA Reform Legislation 121 (Statement of David A. Kessler, Commissioner of the FDA) (voicing concerns about "quality controls" and the integrity of the drug-testing system). Consequently, the Government leaves pharmacists free to explain through advertisements what compounding is, to advertise that they engage in compounding, and to advise patients to discuss the matter with their physicians. And it forbids advertising the specific drug in question, not because it fears the "information" the advertisement provides, but because it fears the systematic[*56] effect, insofar as advertisements solicit business, of advertisements that will not fully explain the complicated risks at issue. And this latter fear is more than plausible. See Part I, supra.

I do not deny that the statute restricts the circulation of some truthful information. It prevents a pharmacist from including in an advertisement the information that "this pharmacy will compound Drug X." Nonetheless, this Court has not previously held that commercial advertising restrictions automatically violate the First Amendment. Rather, the Court has applied a more flexible test. It has examined the restriction's proportionality, the relation between restriction and objective, the fit between ends and means. In doing so, the Court has asked whether the regulation of commercial speech "directly advances" a "substantial" governmental objective and whether it is "more extensive than is necessary" to achieve those ends. See *Central Hudson, 447 U.S. at 566*. It has done so because it has concluded that, from a constitutional perspective, commercial speech does not warrant application of the Court's strictest speech-protective tests. And it has reached this conclusion in[*57] part because restrictions on commercial speech do not often repress individual self-expression; they rarely interfere with the functioning

of democratic political processes; and they often reflect a democratically determined governmental decision to regulate a commercial venture in order to protect, for example, the consumer, the public health, individual safety, or the environment. See, e.g., 44 *Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 499, 134 L. Ed. 2d 711, 116 S. Ct. 1495 (1996)* ("The State's power to regulate commercial transactions justifies its concomitant power to regulate commercial speech that is 'linked inextricably' to those transactions"); L. Tribe, American Constitutional Law § 12-15, p. 903 (2d ed. 1988) ("commercial speech doctrine" seeks to accommodate "the right to speak and hear expression about goods and services" with "the right of government to regulate the sales of such goods and services") (emphasis in original).

I have explained why I believe the statute satisfies this more flexible test. See Parts I and II, supra. The Court, in my view, gives insufficient weight to the Government's regulatory rationale, and too readily assumes the [*58]existence of practical alternatives. It thereby applies the commercial speech doctrine too strictly. Cf. *Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349, 148 L. Ed. 2d 854, 121 S. Ct. 1012 (2001)* (flexibility necessary if FDA is to "pursue difficult (and often competing) objectives"). See also *Illinois Bd. of Elections v. Socialist Workers Party, 440 U.S. 173, 188-189, 59 L. Ed. 2d 230, 99 S. Ct. 983 (1979)* (Blackmun, J., concurring) (warning against overly demanding search for less restrictive alternatives).

In my view, the Constitution demands a more lenient application, an application that reflects the need for distinctions among contexts, forms of regulation, and forms of speech, and which, in particular, clearly distinguishes between "commercial speech" and other forms of speech demanding stricter constitutional protection. Otherwise, an overly rigid "commercial speech" doctrine will transform what ought to be a legislative or regulatory decision about the best way to protect the health and safety of the American public into a constitutional decision prohibiting the legislature from enacting necessary protections. As history in respect[*59] to the Due Process Clause shows, any such transformation would involve a tragic constitutional misunderstanding. See *id., at 189* (Blackmun, J., concurring).

IV

Finally, the majority would hold the statute unconstitutional because it prohibits pharmacists from advertising compounded drugs to doctors. Ante, at 17, 18. Doctors, however, obtain information about individual drugs through many other channels. And there is no indication that restrictions on commercial advertising have had any negative effect on the flow of this information. See e.g., Contemporary Pharmacy Practice 11.4 (compounded drug information "available" and "widely disseminated" through books, journals, monographs, and vendors). Nor, with one exception, have doctors or groups of doctors complained that the statute will interfere with that flow of information in the future. But see Brief for Juilian M. Whitaker, M. D. et al. as Amicus Curiae 1 (alleging, without evidentiary support, that the regulations prevent doctors from knowing how to get "competitively priced compounded drugs as efficiently as possible").

Regardless, we here consider a facial attack on the statute. The respondents here focus their[*60] attack almost entirely upon consumer-directed advertising. They have not fully addressed separate questions involving the effect of advertising restrictions on information received by physicians. I would consequently leave these questions in abeyance. Considering the statute only insofar as it applies to advertising directed at consumers, I would hold it constitutional.

For these reasons, I dissent.