SUPREME COURT OF THE UNITED STATES

No. 01–344

TOMMY G. THOMPSON, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL., PETITIONERS *v.* WESTERN STATES MEDICAL CENTER ET AL.

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

[April 29, 2002]

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. 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 (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 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. 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 "[n]o 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). "[N]ew drug" is defined by §201(p)(1) of the FDCA, 52 Stat. 1041, as amended 76 Stat. 781, as "[a]ny 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 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 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: "[s]oliciting business (*e.g.*, promoting, advertising, or using salespersons) to compound specific drug products, product classes, or therapeutic classes of drug products"; "[c]ompounding, 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 "[d]istributing 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 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 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 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 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 re-

turn for a prohibition on promotion of specific compounded drugs. Accordingly, the Court 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 (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 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 (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,* 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 (1999) (THOMAS, J., concurring in judgment*); 44 Liquormart, Inc.* v. *Rhode Island*, 517 U. S. 484, 501, 510–514 (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 (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 the FDAMA. The first is an interest in "preserv[ing] 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 "preserv[ing] 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 "[a]chieving 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 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 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 advanc[e] the governmental interest[s] 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 "[a]dvertising 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 need[s]." *Ibid.* The Government contends that, because of this, advertising is not typically associated with compounding for particular individuals. In contrast it is typically associated, 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 advanc[e]" 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] interest[s]." *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 (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 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 "[o]ffering compounded drugs at wholesale to other state licensed persons or commercial entities for resale." *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 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 "[i]t 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 (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.)—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 (1981) (sustaining a milk pack-

aging 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 "a substantial interest to be achieved by [the] restrictio[n] 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 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 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 ("[B]ans 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 advance that interest. The dissent claims that the Gov-

ernment "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*, 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 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.