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 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 Guide to Food and Drug Law and Regulation, 95–102 (K. Piña & 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 pro-

mote 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 (1980). It concedes that the statutory provision tries to "[p]reserv[e] the effectiveness and integrity of the . . . new drug 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 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 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 . . . prevent[ing] *small-scale* manufacturing under the guise of compounding") (emphasis 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 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 "[c]ompounding" as involving a pre-

scription "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 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 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 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 anti-

histamine manufacturers spent $313 million on advertising in 1998 and accounted for 90% of prescription drug antihistamine market); 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 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 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 in significantly 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 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 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 "ca[p] 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 "[t]he 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 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 to say that the Government "fear[s]" 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 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 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 (1996) ("[T]he 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 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 (2001) (flexibility necessary if FDA is to "pursu[e] difficult (and often competing) objectives"). See also *Illinois Bd. of Elections* v. *Socialist Workers Party,* 440 U. S. 173, 188–189 (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 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 possble").

Regardless, we here consider a facial attack on the statute. The respondents here focus their 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.