No. 01-344

In the Supreme Court of the United States

TOMMY G. THOMPSON,
SECRETARY OF HEALTH AND HUMAN SERVICES,
ET AL., PETITIONERS

v.

WESTERN STATES MEDICAL CENTER, ET AL.

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

REPLY BRIEF FOR THE PETITIONERS

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TABLE OF AUTHORITIES

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The Food and Drug Administration Modernization Act of 1997 (FDAMA), 21 U.S.C. 353a (Supp. V 1999), provides a limited exemption from the new drug approval (and certain other) requirements of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, for drugs compounded by pharmacists. This case concerns the constitutionality of FDAMA's limitation of that exemption to pharmacists who do not solicit prescriptions for or advertise particular compounded drugs. 21 U.S.C. 353a(a) and (c) (Supp. V 1999).

The court of appeals erroneously held that the solicitation and advertising limitations on the new statutory exemption are unconstitutional under the First Amend-

ment. See Pet. 16-25. In striking down those limitations, the court of appeals upset the careful balance that Congress established in specifying the point at which potentially harmful drug products should be subject to the FDCA's generally applicable new drug approval requirements. See Pet. 11-16. Those requirements are the linchpin of the Nation's laws regulating the manufacturing and distribution of drugs and thus a central component of Congress's efforts in the FDCA to protect the public health and safety. See generally *United States* v. *Rutherford*, 442 U.S. 544 (1979); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973). The court of appeals' mistaken "exercise of the grave power of annulling an Act of Congress" warrants this Court's review, particularly because it arises in the critical context of protecting public health and safety. *United States* v. *Gainey*, 380 U.S. 63, 65 (1965).

1. Respondents take issue (Br. in Opp. 9) with the contention (Pet. 11, 25) that the decision of the court of appeals warrants review because that court held an Act of Congress unconstitutional. They point to two instances in which (they assert) this Court has denied petitions seeking review of the invalidation of federal statutes. See Br. in Opp. 9 (citing *Children's Legal Found., Inc.* v. *Action for Children's Television (ACT)*, 503 U.S. 913 (1992), and *Nolasco* v. *United States*, 502 U.S. 833 (1991)). In one of those cases, however, the petitioner did not seek review of the appellate court's invalidation of a federal statute; the petitioner sought review only of the court's holding that the trial court was not required to define reasonable doubt. See Pet. at i-ii, *Nolasco* v. *United States*, *supra* (No. 90-8104). In the other case, the respondents opposed certiorari on the ground that the matter had been remanded to the Federal Communications Commission and the court of

appeals' decision was therefore interlocutory, see Br. of Resp. ACT, et al. at 18, *Children's Legal Found., Inc.* v. *ACT*, *supra* (No. 91-833), which is not true of the decision in this case. Thus, neither of the cases cited by respondents provides any basis for this Court to depart from its virtually uniform practice of granting the government's request for review of an appellate decision that holds an Act of Congress unconstitutional. See Robert L. Stern et al., *Supreme Court Practice* 185 (7th ed. 1993).

Moreover, as noted in the petition, this Court's review is particularly warranted here, because the Act of Congress that the court of appeals invalidated is designed to protect the public health and safety from potentially dangerous drugs and to provide adequate and appropriate incentives for those who manufacture and promote new drugs to bear the costs of demonstrating the safety and efficacy of those drugs. See Pet. 12, 15, 19-20, 25. Section 353a embodies a carefully balanced congressional effort to preserve the effectiveness and integrity of the FDCA's new drug approval process, and, at the same time, to ensure the availability of compounded drugs for those individual patients who, for particularized medical reasons, cannot use commercially available products that have already been approved by the FDA. See Pet. 11-16. The new drug approval requirements are at the core of the Nation's laws regulating the manufacturing and distribution of drugs. By unduly limiting Congress's authority to define the scope of those provisions, the decision of the court of appeals impermissibly interferes with important congressional efforts to protect and to promote public health and safety.

2. Respondents attempt to minimize the importance of the court of appeals' decision by disputing (Br. in

Opp. 1) that compounded drugs are "new drugs" subject to the FDCA's pre-market approval requirements. Respondents also take issue (*id.* at 1-2) with the related conclusion that, before enactment of Section 353a, it was illegal to distribute compounded drugs in interstate commerce without complying with those requirements.

In fact, compounded drugs *are* "new drugs" because they are "not generally recognized * * * as safe and effective for use under the conditions prescribed." 21 U.S.C. 321(p). A drug's safety and effectiveness must be demonstrated by controlled clinical trials conducted by qualified experts. See *Hynson, Westcott & Dunning*, 412 U.S. at 630; *Weinberger* v. *Bentex Pharm.*, 412 U.S. 645, 652 (1973). Neither the clinical impressions of practicing physicians nor the fact that a number of physicians throughout the country prescribe a product establishes that it is generally recognized as safe and effective. See *Hynson, Westcott & Dunning*, 412 U.S. at 630; *United States* v. *Sene X Eleemosynary Corp.*, 479 F. Supp. 970, 977 (S.D. Fla. 1979), aff'd, [1982-1983 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,207 (11th Cir. Jan. 12 1983).

Therefore, before enactment of Section 353a, several courts of appeals had determined that compounded drugs are "new drugs," which are subject to the FDCA's pre-market approval requirements. See *Professionals & Patients for Customized Care* v. *Shalala*, 56 F.3d 592, 593 n.3 (5th Cir. 1995); *United States* v. *Algon Chem. Inc.*, 879 F.2d 1154, 1158 (3d Cir. 1989); *United States* v. *9/1 Kg. Containers*, 854 F.2d 173, 179 (7th Cir. 1998); 21 U.S.C. 355(a). Distribution of compounded drugs in interstate commerce without the approval of the FDA was thus illegal before enactment of Section 353a. See 21 U.S.C. 331(d), 355(a). Section 353a

establishes an exemption from FDA approval for compounded drugs but subjects that exemption to reasonable conditions, including that particular compounded drugs not be advertised and promoted in the manner that characterizes the manufacture and distribution of new drugs.*

3. Respondents also contend (Br. in Opp. 4-5) that certiorari is not warranted because, in their view, the government seeks review of only "the misapplication of a properly stated rule of law." Sup. Ct. R. 10. That mischaracterizes the government's position. Review is sought to correct a mistaken exercise of the greatest power possessed by the federal courts—the power to

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* As discussed in the petition (at 14-15, 18-19), Section 353a "bring[s] the legal status of compounding in line with FDA's longstanding enforcement policy," 143 Cong. Rec. S9839 (daily ed. Sept. 24, 1997) (Sen. Kennedy), pursuant to which the FDA did not enforce the FDCA's new drug approval requirements against pharmacies engaged in traditional compounding on an individualized basis in response to the medical needs of particular patients. See Pet. App. 71a; *Professionals & Patients*, 56 F.3d at 593 n.3. The FDA did take action, however, when compounding was outside the scope of normal pharmacy practice and compounded drugs were mass-produced and distributed in a manner tantamount to the manufacture of unapproved new drugs. Pet. App. 73a-74a. Among the factors that the FDA considered in determining whether a pharmacy was manufacturing drugs rather than engaging in traditional compounding was whether the pharmacy was "[s]oliciting business (e.g. promoting, advertising, or using sales persons) to compound specific drug products, product classes, or therapeutic classes of drug products." *Id.* at 76a. Thus, contrary to respondents' contention (Br. in Opp. 2), there were "restrictions on the advertising and promotion of compounded drugs by pharmacists" before enactment of Section 353a. As respondents acknowledge, "there was no constitutional challenge" to those restrictions (*id.* at 3), and there are no judicial decisions that call into question their constitutionality.

declare an Act of Congress unconstitutional—in the critical context of important laws promoting the public health and safety.

Respondents are also incorrect in suggesting (Br. in Opp. 5) that an erroneous application of the test for determining the constitutionality of restrictions on commercial speech set out in *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557 (1980), is the kind of "misapplication of a properly stated rule of law" for which certiorari is rarely granted. On the contrary, this Court has repeatedly granted certiorari to review application of the general *Central Hudson* test to particular statutory contexts, especially where the constitutionality of an Act of Congress is at issue. See, *e.g.*, *Lorillard Tobacco Co.* v. *Reilly*, 121 S. Ct. 2404 (2001); *Greater New Orleans Broad. Ass'n* v. *United States*, 527 U.S. 173 (1999); *44 Liquormart, Inc.* v. *Rhode Island*, 517 U.S. 484 (1996); *Rubin* v. *Coors*, 514 U.S. 476 (1995); *United States* v. *Edge Broad. Co.*, 509 U.S. 418 (1993).

Respondents mistakenly rely on what they assert is settled law that "absolute prohibitions upon truthful commercial speech, such as those that exist in this case, are unconstitutional." Br. in Opp. 5. As an initial matter, Section 353a does not impose an absolute prohibition upon speech. Rather, it provides a limited exemption for pharmaceutical compounding from the FDCA's otherwise generally applicable provisions governing the distribution of "new drugs" in interstate commerce, good manufacturing practices, and adequate directions for use. See 21 U.S.C. 353a(a) (Supp. V 1999). That exemption is subject to certain conditions, which include that the prescription for the compounded product must be "unsolicited," 21 U.S.C. 353a(a) (Supp. V 1999), and that the compounder may "not advertise or

promote the compounding of any particular drug, class of drug, or type of drug" (21 U.S.C. 353a(c) (Supp. V 1999)). Pharmacies remain free, however, to solicit prescriptions for and to advertise particular compounded products provided that they (like others who manufacture new drugs and introduce them into interstate commerce) comply with the FDCA's new drug approval and related requirements.

Furthermore, this Court has never held that prohibitions upon truthful commercial speech are per se unconstitutional, or even that they are subject to strict scrutiny. Rather, the Court has analyzed such prohibitions under the four-part *Central Hudson* test. See *Lorillard*, 121 S. Ct. at 2421 (rejecting petitioners' request that the Court apply strict scrutiny rather than *Central Hudson*). Although the Court has found restrictions on commercial speech to be unconstitutional in some cases, it has not invariably reached that conclusion, as even respondents acknowledge. See Br. in Opp. 7-8 (citing *Lorillard*, 121 S. Ct. at 2429; *Florida Bar* v. *Went For It, Inc.*, 515 U.S. 618 (1995); *United States* v. *Edge Broad. Co.*, 509 U.S. 418 (1993); *Ohralik* v. *Ohio State Bar Ass'n*, 436 U.S. 447 (1978)).

4. In order to determine whether a limitation on commercial speech is permissible under the First Amendment, a court must carefully apply the general principles set forth in *Central Hudson* and this Court's other commercial speech cases to the particular limitation that is challenged. As explained in the petition, the court of appeals misapplied those principles in striking down Section 353a.

In particular, the court of appeals erroneously failed to credit as substantial the government's interest in preserving the integrity of the drug approval process by preventing the widespread distribution of drugs that

have not been proven safe and effective, on the one hand, and permitting the compounding of drugs in limited circumstances to address the particularized medical needs of individual patients, on the other. See Pet. 16-19. The court of appeals concluded (and respondents continue to contend (Br. in Opp. 4, 7, 8)) that the government presented insufficient evidence to demonstrate that the widespread distribution of drugs that have not been proven safe and effective poses substantial health risks. But that is a fundamental premise of the FDCA, the validity of which this Court itself has acknowledged. See *Rutherford*, 442 U.S. at 556-557; *Hynson, Westcott & Dunning*, 412 U.S. at 619, 622. The court of appeals had no basis to insist that the government introduce evidence in court to establish the manifest importance of that central purpose of the FDCA. See Pet. 17-18; see also *Lorillard*, 121 S. Ct. at 2422 (explaining that restrictions on commercial speech may be justified "based solely on history, consensus, and 'simple common sense'").

Because of its failure to credit the government's substantial interest in preserving both the integrity of the drug approval process and the availability of compounding on an individualized basis in response to particular medical needs, the court of appeals also erroneously concluded that limiting the compounding exemption to pharmacies that do not promote particular compounded products does not directly and materially advance the government's interests and is not narrowly tailored. See Pet. 19-25. In fact, Congress properly concluded that advertising and promotion of a particular compounded drug to the public reasonably identifies the point at which the interest in preserving the integrity of the drug approval requirements outweighs the interest in protecting the availability of

traditional pharmaceutical compounding in response to the special medical needs of identified individuals. That determination reflects the judgment by Congress that advertising and promotion of particular drugs are characteristics of manufacturing, as distinguished from traditional pharmacy compounding in response to particularized medical needs. See Pet 14-15. It also reflects the FDA's prior enforcement experience (see Pet. 4-5), and conforms to the FDCA's premise that those who promote and seek to profit from an expanded market for new drugs should be required and encouraged to bear the cost of proving that those drugs are safe and effective before they are widely disseminated in interstate commerce. See Pet. 12, 15-16. The court of appeals incorrectly rejected those reasonable congressional determinations and improperly invalidated as unconstitutional an Act of Congress designed to promote the public health and safety. That decision warrants this Court's review.

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For the reasons stated above and in the petition for a writ of certiorari, the petition should be granted.

Respectfully submitted.

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Solicitor General

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