No. 10-779

In the
Supreme Court of the United States

WILLIAM H. SORRELL, ET AL.,
PETITIONERS,
v.
IMS HEALTH INC., ET AL.,
RESPONDENTS.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF FOR THE STATES OF ILLINOIS, ALABAMA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, DELAWARE, GEORGIA, HAWAII, IDAHO, INDIANA, IOWA, KENTUCKY, LOUISIANA, MAINE, MARYLAND, MINNESOTA, MISSISSIPPI, MONTANA, NEVADA, NEW HAMPSHIRE, NEW MEXICO, NEW YORK, NORTH CAROLINA, NORTH DAKOTA, OHIO, OKLAHOMA, OREGON, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TENNESSEE, UTAH, WASHINGTON, AND WEST VIRGINIA AND THE DISTRICT OF COLUMBIA AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Whether a law that restricts access to information in nonpublic prescription drug records and affords prescribers the right to consent before their identifying information in prescription drug records is sold or used in marketing runs afoul of the First Amendment.

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INTEREST OF THE *AMICI CURIAE*

States have a critical interest in protecting against the unauthorized use of personal information for marketing purposes. The advent of "data mining" has increased the prevalence of this technique, and States have responded with laws that place reasonable limits on the sale or disclosure of personal data for use in marketing. A decision by this Court invalidating Vermont's Prescription Confidentiality Law would jeopardize these laws, which are vital to States in protecting consumers, the public health, and individual privacy.

But this case is critical to state interests for another, more fundamental, reason. Respondents make clear that they intend to use this case to ask the Court to narrow or abandon the commercial speech doctrine, and the appellate court's decision invites courts to second-guess even well-supported legislative determinations. Abandoning the commercial speech doctrine or revising it as the appellate court did undercuts state efforts "to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons," *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) (internal quotations omitted), and to continue serving as "laboratories for experimentation" with solutions to difficult social and economic problems, *Grutter v. Bollinger*, 539 U.S. 306, 342 (2003) (internal quotations omitted). Affirming the judgment below would subject considered legislative judgments to unprecedented judicial oversight and jeopardize state consumer-protection efforts in arenas far beyond the data-mining restriction at issue here.

STATEMENT

1. Pharmacies are legally required to maintain records of the prescriptions that physicians and other health care providers write. Pet. App. 5a. Pharmacies, in turn, sell these nonpublic records to "data miners," who then sell them to pharmaceutical manufacturers, for use in targeting their direct marketing efforts. Pet. App. 5a-6a. The manufacturers identify frequent prescribers of their drugs and physicians who are brand-loyal or willing to prescribe new medicines, and the manufacturers reward these doctors with gifts and other inducements. Pet. App. 139a. The prescription data also permits manufacturers to place added marketing pressure on physicians who prescribe their brand-name drugs only infrequently or who have been prescribing them less often. Pet. App. 139a. Not surprisingly, many doctors object to the use of their prescribing histories—which exist only because the law requires pharmacies to maintain them—to develop these targeted marketing practices. Pet. App. 134a, 138a.

2. In 2007, Vermont passed a law prohibiting prescriber-identifying data from being sold or used for marketing prescription drugs without the prescriber's consent. See Vt. Stat. Ann. tit. 18, § 4631 (West 2010) (reproduced at Pet. App. 129a-133a). The stated intent of this Prescription Confidentiality Law (the "Act") is to "protect[] the public health," "protect[] the privacy of prescribers and prescribing information," and "ensure [health care] costs are contained." Pet. App. 129a.

3. Vermont's legislature made 31 findings in support of the Act, see 2007 Vt. Acts & Resolves No. 80 (reproduced at Pet. App. 134a-140a), including that the pharmaceutical industry spends more on marketing its products than any other business in the United States: in 2004, for example, drug manufacturers spent $27 billion on marketing (85% directed at doctors). Pet. App. 137a. And when the rise of data miners made physician-specific prescribing histories available, the industry doubled its sales force and upped spending on direct marketing to doctors by more than 275%. *Ibid.* These expensive marketing programs have yielded impressive results: in Vermont alone, spending on drugs and nondurable medical supplies nearly doubled (from $280 to $524 million) between 2000 and 2005, the highest increase in any health care category. Pet. App. 135a. Such results were obtained notwithstanding a variety of new programs in Vermont limiting prescription drug costs to the State's publicly and privately-financed insurance programs. Pet. App. 135a-136a.

Vermont's legislature further found that the success of pharmaceutical marketing "comes at the expense of cost-containment activities and possibly the health of individual patients." Pet. App. 134a. A substantial amount of the exponential increase in drug spending "can be attributed to marketing induced shifts in doctors' prescribing from existing, effective, and lower cost (often generic) therapies to new and more expensive treatments" that have "as yet unknown side-effects." Pet. App. 135a, 136a-137a; see also Pet. App. 135a (serious warnings and safety-related recalls

more likely to occur in first two years that drug is marketed). One example is Vioxx, which was widely prescribed before its removal from the market for inadequately disclosed, potentially lethal side effects. Pet. App. 135a.

Finally, legislators found that pharmaceutical manufacturers' use of prescribing data enhances the effectiveness of direct marketing by "encourag[ing] * * * the quid pro quo nature of relations between pharmaceutical sales representatives and prescribers" and otherwise subjecting doctors to "[a]dded and unwanted pressure." Pet. App. 139a. Vermont doctors have experienced "an undesired increase in the aggressiveness of pharmaceutical sales representatives" (at times in the form of "coerc[ion] and harass[ment]"), prompting the Vermont Medical Society to condemn the use of prescribing data by pharmaceutical representatives as "an intrusion into the way physicians practice medicine." Pet. App. 138a.

Based on these and other findings, the Vermont legislature determined that the Act would "protect prescriber privacy by limiting" the use of prescribing data for marketing "to prescribers who choose to" accept it; "save money for the state, consumers, and businesses by promoting the use of less expensive drugs"; and "protect the public health by * * * promoting drugs with longer safety records." Pet. App. 140a.

4. Before the Act's effective date, it was challenged by three data-mining companies and a trade group representing the pharmaceutical industry (all

respondents here), who asserted that the Act violates their First Amendment rights. After rejecting respondents' claim to strict scrutiny, Pet. App. 82a-84a, the district court upheld the Act under the analytic framework set forth in *Central Hudson Gas & Electricity Corp. v. Public Service Commission*, 447 U.S. 557 (1980), for evaluating the regulation of commercial speech. The district court held that the Act "affects a traditionally regulated area" and accordingly "defer[red] to [the] legislative findings, predictions and judgments" because, after "exercis[ing] independent judgment," the court concluded the legislature's determinations were "reasonable and based on substantial evidence." Pet. App. 86a, 89a. Declining to "substitute its judgment for that of the legislature," Pet. App. 93a, the court upheld the Act as an effective and targeted response to Vermont's important interests in protecting the public against harmful drug prescribing practices and reducing the costs associated with prescription drug spending, Pet. App. 87a-99a.

5. Although the appellate court agreed that the *Central Hudson* standard (rather than strict scrutiny) applied, Pet. App. 17a-20a, the court held that the Act failed *Central Hudson*'s intermediate scrutiny test. The appellate court faulted the Act for being "too indirect" because it did not "directly restrict" either the prescribing practices of doctors or the marketing practices of pharmaceutical manufacturers. Pet. App. 25a, 28a. The court also concluded that Vermont has "more direct, less speech-restrictive means available" to achieve its stated goals. Pet. App. 30a. Specifically, the court speculated that Vermont might have engaged in a

"counter-speech program," "mandate[d] the use of generic drugs," or limited the Act's scope to new brand-name drugs or drugs with a generic equivalent. Pet. App. 29a-31a.

6. This Court granted certiorari on January 7, 2011.

SUMMARY OF ARGUMENT

Many state laws restrict the unauthorized use of personal information for commercial purposes. These laws are essential in States' efforts to protect the public from abusive selling practices, and these and other exercises of States' traditional police power depend on the existence and proper application of the commercial speech doctrine. Accordingly, respondents' invitation to dismantle the doctrine, and its misapplication by the appellate court, strike directly at States' ability to regulate for the public good.

Petitioners ably explain that the Act does not regulate First Amendment protected speech at all. See Pet. Br. 22-33. *Amici* States share this view. Assuming respondents' conduct enjoys First Amendment protection, however, it is subject to intermediate scrutiny under the commercial speech doctrine, not the strict scrutiny that respondents demand. The intermediate scrutiny traditionally afforded commercial speech strikes the proper balance between First Amendment rights and States' traditional power to regulate for the protection of the public health and welfare.

Properly applied, the commercial speech doctrine affords meaningful deference to legislative judgments. In this pre-enforcement challenge, therefore, the appellate court should have deferred to the Vermont legislature's determination—supported by studies and medical testimony—that restrictions on the use of doctors' prescribing histories in drug marketing would be in the public interest. Nor was Vermont required to adopt the less restrictive means of achieving these aims that the appellate court hypothesized, particularly given that the Act leaves ample channels for communication between drug manufacturers and physicians.

ARGUMENT

In their filings below and in opposing the certiorari petition in this Court, respondents have announced their intent to use this case to roll back the commercial speech doctrine, urging the Court to forego application of that doctrine altogether in this case or, alternately, to weaken a tenet of that doctrine—namely, its usual deference to legislative judgments. *Amici* States submit this brief to defend their sovereign prerogative to regulate for the public health and safety by enforcing reasonable limitations on commercial speech.

I. A HOST OF STATE LAWS NATIONWIDE PROTECT CONSUMERS FROM THE SALE OR DISCLOSURE OF PERSONAL INFORMATION FOR MARKETING PURPOSES.

The unauthorized sale or disclosure of personal information for marketing purposes is "a practice rife with possibilities for overreaching, invasion of privacy,

the exercise of undue influence, and outright fraud." *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 641 (1985). States, like the federal government, have enacted a number of laws to limit the negative effects of these practices.

A. Many States Have Or Are Considering Reasonable Restrictions On The Use Of Prescribing Data In Pharmaceutical Marketing.

Amici States share Vermont's concern about the social harms associated with the disclosure and use of nonpublic prescribing records for marketing purposes. New Hampshire and Maine have laws that, like the Act, limit the marketing use of prescribing data. See N.H. Rev. Stat. Ann. § 318:47-f (West 2010); Me. Rev. Stat. Ann. tit. 22, § 1711-E (West 2010).[1] And legislatures in Arizona, California, Connecticut, Florida, Georgia, Hawaii, Illinois, Iowa, Kansas, Maryland, Massachusetts, Minnesota, Missouri, Montana, Nevada, New Jersey, New York, North Carolina, Oklahoma, Oregon, Rhode Island, Texas, Virginia, Washington, West Virginia, and the District of Columbia have

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[1] Even if the Court affirms the judgment below, such a ruling will not necessarily resolve the constitutionality of Maine's law. In Maine, doctors may "opt out" of the use of their prescribing data for marketing prescription drugs to them. See *IMS Health Inc. v. Mills*, 616 F.3d 7, 12, 16-17, 21-22 (1st Cir. 2010). Vermont's law, which permits the marketing use of prescribing data only if a doctor consents to its use, adopts a somewhat "broader approach" to prescriber confidentiality, as the court of appeals noted below. Pet. App. 27a-28a n.4.

considered or are considering such restrictions.[2] Many States undoubtedly are awaiting resolution of the constitutional challenge presented by this case before taking further legislative action. A decision invalidating Vermont's law would undermine these nationwide efforts to protect prescriber privacy, patient health, and the public fisc.

B. Affirming The Judgment Below Would Jeopardize The Many State And Federal Laws Protecting Personal Information From Unauthorized Sale Or Disclosure.

More broadly, a decision striking down the Act

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[2] See S.B. 1234, 49th Leg., 2d Reg. Sess. (Ariz. 2010); Assem. B. 2112, 2009-10 Reg. Sess. (Cal. 2010); S.B. 1046, Gen. Assem. Jan. Sess. 2009 (Conn. 2009); B17-364, 2007 Council (D.C. 2007); S.B. 1402, 111th Reg. Sess. (Fla. 2009); H.B. 820, 115th Gen. Assem., 2009-2010 Reg. Sess. (Ga. 2009); S.B. 449, 25th Leg., Reg. Sess. (Haw. 2009); H.B. 1459, 95th Gen. Assem., 1st Reg. Sess. (Ill. 2007); H. File 622, 83rd Gen. Assem., 2009 Sess. (Iowa 2009); S.B. 229, Sess. of 2007 (Kan. 2007); S.B. 1040, 427th Sess. (Md. 2010); S.B. 17, 186th Gen. Court, 2009 Reg. Sess. (Mass. 2009); S. File 1044, 86th Legis. Sess. (Minn. 2009); H.B. 794, 95th Gen. Assem., 1st Reg. Sess. (Mo. 2009); H.B. 394, 61st Leg., 2009 Reg. Sess. (Mont. 2009); S.B. 231, 72d Reg. Sess. (Nev. 2007); Assem. B. 3764, 213th Leg., 2d Ann. Sess. (N.J. 2009); S.B. 4111, 231st Legis. Sess. (N.Y. 2009); S.B. 159, 2007-2008 Sess. (N.C. 2007); S.B. 379, 52d Leg., 1st Reg. Sess. (Okla. 2009); H.B. 2680, 75th Legis. Assem., 2009 Reg. Sess. (Or. 2009); H.B. 5093, 2009 Legis. Sess. (R.I. 2009); S.B. 1620, 77th Leg., Reg. Sess. (Tex. 2007); H.B. 2452, 2009 Reg. Sess. (Va. 2009); H.B. 1850, 60th Leg., 2007 Reg. Sess. (Wash. 2007); S.B. 434, 2007 Sess. (W. Va. 2007).

would threaten myriad laws protecting individuals from the unauthorized disclosure and use of their personal information. State and federal laws restrict the further dissemination of medical, financial, and other personal information that individuals routinely disclose as a cost of doing business in modern society. But if the Court were to embrace respondents' view that regulation of commercial speech is subject to strict, rather than intermediate, scrutiny or that, even under intermediate scrutiny, considered legislative determinations are entitled to scant deference, then this would threaten States' ability to protect the privacy, security, and well-being of their citizens.

1. State and federal laws prohibit the unauthorized sale or disclosure of information contained in medical records. For example, federal law bars health care providers and other "covered entities" from selling electronic health records or protected health information without the patient's consent. 42 U.S.C. § 17935(d). And federal law penalizes—with as much as ten years' imprisonment and $250,000 in fines—the intentional sale, transfer, or use of individually identifiable health information "for commercial advantage" or "personal gain." 42 U.S.C. § 1320d-6.

States separately restrict the unnecessary disclosure of medical information, including for commercial uses. For example, Illinois prohibits physicians, health care providers, health services corporations, and insurance companies from disclosing "the nature or details of services provided to patients" without their consent. 410 Ill. Comp. Stat. 50/3(d) (2008). And although there are exceptions to this prohibition, marketing use is not

among them. See *ibid.* Many States have similar statutory protections for medical privacy.[3]

A number of States place further restrictions on the disclosure of specific classes of medical information—such as mental health records,[4] genetic data,[5] and information that an individual is infected with a communicable disease,[6] including a sexually

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[3] See, *e.g.*, Ariz. Rev. Stat. Ann. §§ 12-2292 & 12-2294 (West 2011); Cal. Civ. Code §§ 56.10 & 1798.91 (West 2011); Colo. Rev. Stat. Ann. § 18-4-412 (West 2011); Conn. Gen. Stat. Ann. § 38a-988a(a) (West 2010); Fla. Stat. Ann. § 456.057 (West 2010); Ind. Code Ann. § 16-39-5-3 (West 2010); Mass. Gen. Laws Ann. ch. 111, § 70E (West 2010); Minn. Stat. Ann. § 144.651 (West 2010); Mont. Code Ann. § 50-16-530 (West 2010); N.H. Rev. Stat. Ann. § 332-I:1 (West 2010); R.I. Gen. Laws. Ann. § 5-37.3-4 (West 2010); Tenn. Code Ann. § 10-7-504 (West 2011); Tex. Health & Safety Code Ann. § 161.022 (West 2011) (records of those participating in medical studies); Va. Code Ann. § 32.1-127.1:03 (West 2011); Wash. Rev. Code Ann. § 70.02.020 (West 2011); Wis. Stat. Ann. § 146.82 (West 2011); Wyo. Stat. Ann. § 35-2-609 (West 2011).

[4] See, *e.g.*, Alaska Stat. Ann. § 47.30.845(2) (West 2011); D.C. Code § 7-1202.07 (West 2011); 740 Ill. Comp. Stat. 110/3 (2008); N.J. Stat. Ann. § 30:4-24.3 (West 2010) (referring to records of noncorrectional institutions); N.M. Stat. Ann. § 43-1-19 (West 2010).

[5] See, *e.g.*, Minn. Stat. Ann. § 13.386 (West 2010).

[6] See, *e.g.*, Ariz. Rev. Stat. Ann. § 36-664(A) (West 2011); Ind. Code Ann. § 16-41-8-1 (West 2010); Mich. Comp. Laws Ann. § 333.5131 (West 2011); Utah Code Ann. § 26-6-27 (West 2010).

transmitted disease.[7] Similarly, federal law requires States receiving grants for AIDS prevention to ensure the confidentiality of HIV-related records. See 42 U.S.C. § 300ff-61. And nearly every State independently protects these records.[8]

2. A related body of law protects consumer credit and financial information. A federal statute prohibits banks and other financial institutions from disclosing "nonpublic personal information to a nonaffiliated third party," unless the consumer first may opt out of such disclosure. 15 U.S.C. § 6802(b). Many States similarly

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[7] See, *e.g.*, Ala. Code § 22-11A-22 (West 2011); Del. Code Ann. tit. 16, § 711 (West 2011); Wash. Rev. Code Ann. § 70.24.105 (West 2011).

[8] See, *e.g.*, Ala. Code § 22-11A-54 (West 2011); Ark. Code Ann. § 20-15-904 (West 2011); Del. Code Ann. tit. 16, § 1203 (West 2011); Fla. Stat. Ann. § 381.004 (West 2010); Haw. Rev. Stat. Ann. § 325-101 (West 2010); 410 Ill. Comp. Stat. 305/1-9 (2008); Iowa Code Ann. § 141A.9 (West 2010); Kan. Stat. Ann. § 65-6002 (West 2010); Ky. Rev. Stat. Ann. § 214.181 (West 2010); La. Rev. Stat. Ann. § 40:1300.14 (West 2011); Me. Rev. Stat. Ann. tit. 5, § 19203 (West 2010); Mass. Gen. Laws Ann. ch. 111, § 70F (West 2010); Mich. Comp. Laws Ann. § 333.5131 (West 2011); Mont. Code Ann. § 50-16-1009 (West 2010); N.H. Rev. Stat. Ann. § 141-F:8 (West 2010); N.J. Stat. Ann. § 26:5C-7 (West 2010); N.M. Stat. Ann. § 24-2B-6 (West 2010); N.Y. Pub. Health Law § 2782 (West 2011); N.C. Gen. Stat. Ann. § 130A-143 (West 2010); Ohio Rev. Code Ann. § 3701.243 (West 2010); Or. Rev. Stat. Ann. § 433.075 (West 2011); 35 Pa. Cons. Stat. Ann. § 7607 (West 2011); Va. Code Ann. § 32.1-36.1 (West 2011); W. Va. Code Ann. § 16-3C-3 (West 2011); Wis. Stat. Ann. § 252.15 (West 2011).

prohibit financial institutions from selling or disclosing customer financial information without consent.[9]

Federal law also requires credit reporting agencies to adopt "reasonable procedures" to ensure the "confidentiality * * * and proper utilization" of consumer information. 15 U.S.C. § 1681. Several States have followed suit,[10] and States also prohibit credit card issuers, see Cal. Civ. Code § 1748.12 (West 2011), credit card registration services, see N.Y. Gen. Bus. Law § 521-c (West 2011), and insurers, see Cal. Ins. Code § 791.13 (West 2011); Conn. Gen. Stat. Ann. § 38a-988(11) (West 2010); Ga. Code Ann. § 33-39-14(11) (West 2011); 215 Ill. Comp. Stat. 5/1014(K) (2008), from disclosing personal information for marketing purposes without first allowing consumers to opt out.

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[9] See, *e.g.*, Ala. Code § 5-5A-43 (West 2011); Cal. Fin. Code § 4052.5 (West 2011); Conn. Gen. Stat. Ann. § 36a-42 (West 2010); 205 Ill. Comp. Stat. 5/48.1 (2008); La. Rev. Stat. Ann. §§ 6:333 & 9:3571 (West 2011); Md. Code Ann., Fin. Inst. § 1-302 (West 2010); Mass. Gen. Laws Ann. ch. 167B, § 16 (West 2010); N.H. Rev. Stat. Ann. §§ 359-C:1 through C:7 (West 2010); N.J. Stat. Ann. § 17:16K-3 (West 2010); N.C. Gen. Stat. Ann. § 53B-3 (West 2010); N.D. Cent. Code Ann. § 6-08.1-03 (West 2011); Tenn. Code Ann. § 45-10-104 (West 2011); Vt. Stat. Ann. tit. 8, § 10203 (West 2010).

[10] See, *e.g.,* Me. Rev. Stat. Ann. tit. 10, §§ 1311-A & 1321 (West 2010); Mass. Gen. Laws Ann. ch. 93, §§ 51 & 51A (West 2010); N.M. Stat. Ann. § 56-3-8 (West 2010); N.Y. Gen. Bus. Law § 380-b (McKinney 2010); Wash. Rev. Code Ann. § 19.182.020 (West 2011).

3. Myriad state and federal laws protect the confidentiality of consumer information in other contexts. For example, federal law prohibits the unauthorized disclosure of personal information by members of the video rental and sale industry, see 18 U.S.C. § 2710(b), the cable industry, see 47 U.S.C. § 551, and the electronic communications industry, see 18 U.S.C. § 2702(c). States have similar non-disclosure laws for home entertainment sale and rental services,[11] and for cable and other communications companies.[12] Many of these laws specifically prohibit the collection and dissemination of customer viewing habits and other marketing data. Finally, federal law limits disclosure of education records and personal information contained therein by educational institutions receiving federal

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[11] See, *e.g.*, Cal. Civ. Code § 1799.3 (West 2011); Conn. Gen. Stat. Ann.§ 53-450 (West 2010); Del. Code Ann. tit. 11, § 925 (West 2011); Iowa Code Ann. § 727.11 (West 2010); La. Rev. Stat. Ann. § 37:1748 (West 2011); Md. Code Ann., Crim. Law § 3-907 (West 2010); Mich. Comp. Laws Ann. §§ 445.1712 & 445.1713 (West 2011); N.Y. Gen. Bus. Law §§ 673 & 674 (West 2011); R.I. Gen. Laws. Ann. § 11-18-32 (West 2010).

[12] See, *e.g.*, Cal. Penal Code § 637.5 (West 2011); Conn. Gen. Stat. Ann. § 53-422 (West 2010); D.C. Code § 34-1260.02 (West 2011); 720 Ill. Comp. Stat. 110/3 (2008); N.J. Stat. Ann. § 48:5A-57 (West 2010); Wis. Stat. Ann. § 134.43 (West 2011); see also N.J. Stat. Ann. § 48:3-85(b)(1) (West 2010) (applying to utility companies generally).

funds. See 20 U.S.C. § 1232g(b). And state laws similarly protect the confidentiality of student records.[13]

4. A decision affirming the Second Circuit's judgment in this case would jeopardize each of these laws. The court below did not address this eventuality, and respondents' effort to distinguish the Act from other state and federal laws, see IMS Health Br. in Opp. 17-18, provides no answer. First, respondents' assertion that the Act, unlike the above-cited laws, does not foster confidentiality is wrong. Respondents ignore (as did the appellate court, in suggesting that the Act "does not ban * * * widespread publication to the general public," Pet. App. 22a) that the Act must be viewed in conjunction with the many laws that restrict access to, and use of, prescription records. See Pet. Br. 5-6, 36-37 (detailing restrictions). And respondents forget that Vermont doctors had no problem with the disclosure of their

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[13] See, *e.g.*, Cal. Educ. Code § 49073 (West 2011); Colo. Rev. Stat. Ann. § 24-72-204 (West 2011); Del. Code Ann. tit. 14, § 4111 (West 2011); Fla. Stat. Ann. § 1003.25 (West 2010); 105 Ill. Comp. Stat. 10/6 (2008); 110 Ill. Comp. Stat. 305/30 (2008); 110 Ill. Comp. Stat. 805/3-60 (2008); Iowa Code Ann. § 22.7 (West 2010); Md. Code Ann., State Gov't § 1-616 (West 2010); Minn. Stat. Ann. § 13.32 (West 2010); Miss. Code Ann. § 37-15-3 (West 2010); N.J. Stat. Ann. § 18A:36-19 (West 2010); Ohio Rev. Code Ann. § 3319.321 (West 2010); Okla. Stat. Ann. tit. 70, § 6-115 (West 2011); Or. Rev. Stat. Ann. §§ 326.587 & 326.589 (West 2011); Tenn. Code Ann. § 10-7-504 (West 2011); Tex. Gov't Code Ann. § 552.114 (West 2011); Vt. Stat. Ann. tit. 1, § 317 (West 2010); Va. Code Ann. § 23-276.8 (West 2011); Wash. Rev. Code Ann. § 42.56.230 (West 2011); Wis. Stat. Ann. § 118.125 (West 2011).

prescribing data for regulatory and administrative purposes—they objected only to the data's use for marketing.

Second, just like the Act, the foregoing laws are replete with exceptions. *Cf.* IMS Health Br. in Opp. 17 (asserting that, unlike Act, other non-disclosure laws "make the prohibition on disclosure the rule, not the exception"). Illinois' medical privacy law, for example, authorizes disclosure to parties "directly involved with providing treatment to the patient"; "processing the payment for that treatment"; "responsible for peer review, utilization review and quality assurance"; and as "authorized or required by law." 410 Ill. Comp. Stat. 50/3(d) (2008). And Illinois' financial confidentiality law allows disclosure to a custodial bank's employees and agents; federal and state regulatory authorities; the Internal Revenue Service and state taxing authorities; fellow financial institutions and commercial enterprises, "directly or through a consumer reporting agency"; law enforcement authorities; and others. 205 Ill. Comp. Stat. 5/48.1 (2008). Health care providers, financial institutions, insurance companies, communications providers, schools, and others must engage in ordinary, everyday uses of personal information. And just like the Act, the non-disclosure requirements to which these entities are subject provide exemptions for these uses. Respondents ignore that their position (and the reversal of decades of First Amendment jurisprudence) would threaten a broad coalition of other laws protecting personal information from unauthorized disclosure.

II. At Most, The Act Regulates Commercial Speech Subject To Intermediate Scrutiny.

Assuming the Act even regulates speech protected by the First Amendment, but see Pet. Br. 22-33, the Court should decline respondents' invitation to "revisit the * * * question whether commercial speech should remain subject to lessened First Amendment protection," IMS Health Br. in Opp. 12 n.1. Restrictions on commercial speech generally do not suppress individual self-expression or undermine the functioning of the political process, and subjecting these restrictions to intermediate, rather than strict, scrutiny is also "consistent with both federalism concerns and the historic primacy of state regulation in matters of health and safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). Nor is there any reason to carve out an exception to the commercial speech doctrine for the Act, which falls within the doctrine's core and exemplifies the need for intermediate scrutiny to preserve States' historical police powers.

A. The Court Should Not Use This Case To Weaken Or Dismantle The Commercial Speech Doctrine.

1. The commercial speech doctrine is well founded, both because commercial speech often advances relatively fewer social interests and because its regulation is a matter of traditional state power, making the doctrine an essential part of the deference to state law that federalism demands.

To be sure, commercial speech at times "'performs an indispensable role in the allocation of resources in a free enterprise system.'" *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 421 n.17 (1993) (quoting *Bates v. State Bar*, 433 U.S. 350, 364 (1977)). But because other commercial messages disserve rather than "serve individual and societal interests in assuring informed and reliable decisionmaking," *Bates*, 433 U.S. at 364, the Court has recognized "commonsense differences" between speech on "subject[s] cultural, philosophical, or political" and "speech that does no more than propose a commercial transaction," *Va. State Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 761, 771 (1976) (internal quotations omitted). Worse, unfettered commercial discourse may threaten the "'commercial harms'" associated with "misleading, deceptive, or aggressive sales practices." *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 501, 502 (1996) (plurality op.) (quoting *Discovery Network*, 507 U.S. at 426). Accordingly, commercial speech has long enjoyed "a lesser protection." *Central Hudson*, 447 U.S. at 563; accord *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 553 (2001).

Unlike noncommercial speech, moreover, commercial speech "'occurs in an area traditionally subject to government regulation.'" *Lorillard Tobacco*, 533 U.S. at 554 (quoting *Central Hudson*, 447 U.S. at 562); see also *44 Liquormart*, 517 U.S. at 499 (plurality op.) ("the State's power to regulate commercial transactions justifies its concomitant power to regulate commercial speech that is linked inextricably to those transactions") (internal quotations omitted). By

according commercial speech less exacting scrutiny than noncommercial speech, the Court thus affords proper deference to the States' role in regulating for the public health and welfare. See generally *Gonzales*, 546 U.S. at 270 ("the structure and limitations of federalism * * * allow the States 'great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons'") (quoting *Medtronic*, 518 U.S. at 475). In this way, the commercial speech doctrine also brings First Amendment protections in line with the Court's deferential approach to due process review of economic legislation. *Cf. United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 347 (2007) (declining "invitations to rigorously scrutinize economic legislation passed under the auspices of the police power" as efforts to "reclaim th[e] ground for judicial supremacy" rejected after *Lochner v. New York*, 198 U.S. 45 (1905)).

Nor is there cause for concern that the commercial speech doctrine insufficiently protects First Amendment rights. The doctrine ensures that "the force of the Amendment's guarantee with respect to" noncommercial speech will not be "dilut[ed], simply by a leveling process." *Florida Bar v. Went for It, Inc.*, 515 U.S. 618, 623 (1995) (internal quotations omitted); *Bd. of Trs. of State Univ. v. Fox*, 492 U.S. 469, 481 (1989) (same). And the doctrine provides for rigorous judicial oversight of commercial speech restrictions. Beyond requiring the State to identify a "substantial" government interest to be achieved by a restriction of truthful commercial speech, the *Central Hudson* test

demands a showing that the "restriction directly and materially advanc[es] the asserted government interest" and that there is "a reasonable fit between the legislature's ends and the means chosen to accomplish those ends." *Lorillard Tobacco*, 533 U.S. at 554, 555, 556 (internal quotations and citations omitted). This approach strikes the appropriate balance between First Amendment rights and States' traditional police power, crucial to our federalist system, to protect the public welfare.

2. This case presents no reason to abandon the commercial speech doctrine. On the contrary, the case exemplifies the need for it. If the unauthorized sale and use of prescribing data for marketing purposes is protected speech at all, but see Pet. Br. 22-33, these activities fall squarely within what the Court has "described as 'core' commercial speech." *Discovery Network*, 507 U.S. at 423. The Act regulates an "aggressive sales practice[] " that has "the potential to exert 'undue influence over consumers,'" *44 Liquormart*, 517 U.S. at 498 (plurality op.) (quoting *Bates*, 433 U.S. at 366)), and is "rife with possibilities for overreaching [and] invasion of privacy," *Zauderer*, 471 U.S. at 641; see also *Edenfield v. Fane*, 507 U.S. 761, 769, 774 (1993) (approving government regulation of commercial messages that are "inherently conducive to overrreaching and other forms of misconduct" or "pressed with such frequency or vehemence as to intimidate, vex, or harass the recipient") (internal quotations omitted). As the Vermont legislature found, the use of prescribing data in marketing encourages "the quid pro quo nature of relations between"

pharmaceutical companies and doctors, subjects doctors to "added and unwanted pressure," and "is an intrusion into the way physicians practice medicine." Pet. App. 138a, 139a.

Accordingly, the Act squarely implicates the very reason for permitting broader regulation of commercial speech, namely, "preventing commercial harms." *Discovery Network*, 507 U.S. at 426. And the law does not "prevent[]the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information." *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 374 (2002). Doctors already know their prescribing histories, and, in any event, the Act permits any doctor to authorize the marketing use of this information if the doctor believes such use will be appropriate and beneficial. And physicians' prescribing options are not limited. If a doctor decides that a brand-name drug better meets the patient's needs, the doctor may prescribe it. In short, while the Court has expressed "skeptic[ism]" of regulations that "seek to keep people in the dark for what the government perceives to be their own good," *44 Liquormart*, 517 U.S. at 503, the Act is not such a regulation.

3. Nor, finally, is there any merit to respondents' claim that pharmaceutical manufacturers' commercial messages are entitled to added protection—that is, an exception to the commercial speech doctrine allowing for strict scrutiny—because these messages may include references to public issues. See IMS Health Br. in Opp. 12 n.1 (arguing for strict scrutiny because respondents' "commercial message is inextricably intertwined with

otherwise fully protected speech") (internal quotations omitted); PHRMA Br. in Opp. 14-15 (same). This is no more than a thinly disguised invitation to cast aside the commercial speech doctrine entirely, for "[m]any, if not most, products may be tied to public concerns." *Central Hudson*, 447 U.S. at 563 n.5. Applying strict scrutiny to "any advertising that links a product to current public debate," *ibid.*, would allow "advertisers to immunize false or misleading product information from government regulation simply by including references to public issues,'" *Discovery Network*, 507 U.S. at 426 n.21 (quoting *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 68 (1983)), an approach this Court has already rejected, see *Central Hudson*, 447 U.S. at 563 n.5 (because petitioners "enjoy the full panoply of First Amendment protections for their direct comments on public issues," "[t]here is no reason for providing similar constitutional protection when such statements are made only in the context of commercial transactions"). Nothing prevents respondents from speaking "direct[ly] * * * on public issues," *ibid.*, in this case by giving prescribers "information regarding drug safety and treatments for medical conditions," PHRMA Br. in Opp. 15.

B. States Rely On The Commercial Speech Doctrine To Regulate For The Public Health And Welfare.

A decision by this Court to jettison the commercial speech doctrine (or severely limit it, as respondents alternately urge) would not only require invalidation of the Act (and call into question its counterparts in other States) but also substantially undermine the States'

ability to protect the public health and welfare by regulating abusive sales practices.

The following example demonstrates the dangers of respondents' rule. Federal laws have long prohibited manufacturers from marketing their drugs and medical devices for off-label (*i.e.*, non-FDA approved) uses. See *United States v. Caputo*, 517 F.3d 935, 937-938 (7th Cir. 2008) (Easterbrook, *J.*); *United States v. Caronia*, 576 F. Supp. 2d 385, 393 (E.D.N.Y. 2008). While off-label uses may be appropriate under certain circumstances (and thus doctors may prescribe or use approved products for any purpose), such uses can have adverse public health and safety effects. The federal government and the States accordingly have played an active role in enforcing the prohibition against off-label promotion.

For example, Pfizer recently pled guilty to a federal felony charge and agreed to pay $2.3 billion, plus $60 million to 34 States to settle state-law charges, following allegations that it had marketed its drug Bextra for off-label uses.[14] The FDA had approved Bextra, which was subsequently shown to increase the risk of heart attacks and strokes, for very narrow indications:

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[14] See "Pharmacia & Upjohn Company Inc. Pleads Guilty To Fraudulent Marketing Of Bextra," U.S. Dep't of Justice Press Release dated Sept. 15, 2009 (available at http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Sept2009/PharmaciaPlea.html); "Madigan, 33 AGs Reach $60 Million Settlement With Pfizer," Ill. Att'y Gen'l Press Release dated October 22, 2008 (available at http://www.illinoisattorneygeneral.gov/pressroom/2008_10/20081022.html).

chronic arthritis and acute menstrual pain.[15] But Pfizer allegedly trained its sales force to market the drug to doctors for acute general pain, including surgical pain—uses the FDA had expressly rejected based on safety concerns.[16] Similarly, Eli Lilly agreed to pay $1.415 billion to the federal government and $62 million to 33 States to settle charges of off-label promotion of its drug Zyprexa.[17] Although Zyprexa was approved for treatment of schizophrenia and certain bipolar disorders in adults, Eli Lilly allegedly trained its sales representatives to encourage doctors to prescribe the drug (which is associated with weight gain, obesity, hyperglycemia, diabetes, and cardiovascular complications) for pediatric use, for treatment of dementia in elderly patients, and for symptoms of anxiety and low-level depression.[18]

The prohibition against promoting off-label uses has been upheld as an effective and well-targeted means of

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[15] See *ibid*.

[16] See *ibid*.

[17] See "Pharmaceutical Company Eli Lilly To Pay Record $1.415 Billion For Off-Label Drug Marketing," U.S. Dept. of Justice Press Release dated Jan. 15, 2009 (available at http://www.justice.gov/usao/pae/News/Pr/2009/jan/lillyrelease.pdf); "Madigan Reaches Landmark $62 Million Settlement With Eli Lilly," Ill. Att'y Gen'l Press Release dated October 7, 2008 (available at http://www.illinoisattorneygeneral. gov/pressroom 2008_10/20081007.html).

[18] See *ibid*.

compelling manufacturers to subject off-label uses to the FDA's evaluation process, while leaving doctors with considerable freedom to treat their patients with the broad range of drugs and medical devices available. See *Caronia*, 576 F. Supp. 2d at 398-402; *United States v. Caputo*, 288 F. Supp. 2d 912, 920-922 (N.D. Ill. 2003), aff'd in part and vacated in part on other grounds by 517 F.3d 935 (7th Cir. 2008). These decisions make clear, however, that the federal regime may not be sufficiently "narrowly tailored" to satisfy strict scrutiny. In *Caronia*, for example, the district court noted that "non-regulatory alternatives for Congress to incentivize manufacturers to seek FDA approval for new uses" have been "suggested" but sustained the law because, unlike strict scrutiny, "*Central Hudson* does not require the government to choose the 'least restrictive means.'" 576 F. Supp. 2d at 402 n.12.

A decision rendering the federal regime unenforceable would have effects detrimental to the public health and safety. It might induce the FDA to "withhold[] any approval of drugs or medical devices that have questionable additional uses," to the detriment of companies with no desire to promote off-label uses, as well as "[c]onsumers who could benefit from such drugs or devices." *Caputo*, 517 F.3d at 939-940. "[A] court should hesitate before extending an ahistorical reading of the Constitution in a way that injures the very audience that is supposed to benefit from free speech." *Ibid.* Yet that is exactly the rule that respondents seek in asking this Court to roll back or abandon the commercial speech doctrine.

III. THE ACT SATISFIES INTERMEDIATE SCRUTINY.

Thus, the Act is properly judged against the *Central Hudson* test, which requires a State to demonstrate that its regulation of truthful commercial speech serves a "substantial" government interest, "directly and materially advances that interest," and "is not more extensive than necessary to serve" the interest. *Supra* pp. 19-20. Although the court of appeals recognized as much, and correctly acknowledged that Vermont has substantial interests in protecting the public health and containing health care costs, Pet. App. 24a, the court misapplied the *Central Hudson* factors in a way that gave short shrift to Vermont's considered legislative determinations.

A. In Commercial Speech Cases, States' Considered Legislative Judgments Are Entitled To Deference So That States May Perform Their Role As "Laboratories."

In passing the Act, Vermont offered a new solution to a developing problem. Like many States, Vermont faces concerns about spiraling prescription drug costs, adverse health effects associated with the over-prescription of brand-name drugs, and invasions of medical privacy. By addressing these problems through a limited restriction on the sale and use of prescribing data, Vermont (like States that have passed or are considering similar laws, see *supra* pp. 8-9 & n.2) performed its role as a "'laborator[y] for experimentation'" in an arena "'where the best solution is far from clear.'" *Grutter*, 539 U.S. at 342 (quoting

United States v. Lopez, 514 U.S. 549, 581 (1995) (Kennedy, *J.*, concurring)); see also *Garcia v. San Antonio Metro. Trans. Auth.*, 469 U.S. 528, 546 (1985) ("'The science of government . . . is the science of experiment.'") (quoting *Anderson v. Dunn*, 6 Wheat 204, 226 (1821) (omission in original)).

"It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, *J.*, dissenting); accord, *e.g.*, *Oregon v. Ice*, 129 S. Ct. 711, 718-719 (2009). But States may perform their role as laboratories only if given "'great latitude under their police powers,'" *Gonzales*, 546 U.S. at 270 (quoting *Medtronic*, 518 U.S. at 475) (internal punctuation omitted), and left free to engage in regulation "that their citizens choose for the common weal, no matter how unorthodox or unnecessary anyone else—including the judiciary—deems state involvement to be," *Garcia*, 469 U.S. at 546. Properly applied, therefore, the commercial speech doctrine "recognize[s] some room for the exercise of legislative judgment." *44 Liquormart*, 517 U.S. at 508 (plurality op.) (citing *Metromedia, Inc. v. San Diego*, 453 U.S. 490, 507-508 (1981)); accord *United States v. Edge Broad. Co.*, 509 U.S. 418, 434 (1993) ("Within the bounds of the general protection provided by the Constitution to commercial speech, we allow room for legislative judgments."); *Fox*, 492 U.S. at 480 ("leav[ing] it to governmental decisionmakers to judge what manner of regulation may best be employed").

As the next two sections show, the appellate court violated these principles. It adopted a cramped version of the *Central Hudson* test that affords little deference to Vermont's legislative rationale and invites courts to hypothesize their own alternatives to a State's chosen method of redressing public harms. The appellate court did so, moreover, in the context of a pre-enforcement challenge, requiring Vermont to prove the impossible—that a law that had yet to take effect would produce the real-world results that legislators predicted. In this way, the court transformed what ought to be a legislative decision about the best way to protect the public health and safety into a constitutional decision prohibiting legislatures from enacting necessary protections.

B. The Appellate Court Failed To Defer To The Legislature's Well-Supported Judgment That The Act Would "Directly Advance" Its Identified Goals.

1. The "directly advances" *Central Hudson* prong requires a State to "'demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.'" *Lorillard Tobacco*, 533 U.S. at 555 (quoting *Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173, 188 (1999)). Although "'mere speculation or conjecture'" is insufficient, *ibid.* (same), the State need not present "'empirical evidence * * * accompanied by a surfeit of background information'" that its regulation is an effective means of addressing the identified problem, *ibid.* (quoting *Florida Bar*, 515 U.S. at 628). Instead,

recognizing the deference due to considered legislative judgments, States may "justify speech restrictions by reference to studies and anecdotes pertaining to different locales altogether, or even * * * solely on history, consensus, and 'simple common sense.'" *Ibid.* (same); accord *44 Liquormart*, 517 U.S. at 505 (plurality op.) (deferring to "common sense" legislative judgments); *Edge*, 509 U.S. at 428 (same).

2. The Act easily satisfies this standard. It is "simple common sense" that "product advertising stimulates demand for products, while suppressed advertising may have the opposite effect." *Lorillard Tobacco*, 533 U.S. at 557 (internal quotations omitted); accord *Greater New Orleans*, 527 U.S. at 189; *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995); *Edge*, 509 U.S. at 434; *Central Hudson*, 447 U.S. at 568-569. And it follows that a brand-name drug manufacturer would not spend up to $20 million each year to purchase prescribing data from data vendors, Tr. 95, 108, 208, much less defend their ability to do so in court, unless that data gave manufacturers' sales efforts a substantial boost. See *Central Hudson*, 447 U.S. at 569 (petitioner "would not contest the advertising ban unless it believed that promotion would increase its sales"). This alone should have been enough to satisfy *Central Hudson*'s "directly advance" requirement.

But the Vermont legislature relied on far more than "common sense." It found that pharmaceutical manufacturers induce doctors to prescribe expensive, unnecessary, and sometimes dangerous drugs; use of prescribing data amplifies the success of these practices and subjects doctors to "added and unwanted pressure,"

as well as increased "aggressiveness," "coerc[ion], and harass[ment]"; and, finally, marketing use of prescribing data "is an intrusion into the way physicians practice medicine." Pet. App. 134a-139a. The legislature supported its determinations with medical testimony and studies. Pet. App. 137a-138a (citing testimony of Dr. Jerry Avorn, report of Vermont Attorney General, resolution of Vermont Medical Society, and studies reproduced in the New England Journal of Medicine and the Journal of General Internal Medicine); *cf. Thompson*, 535 U.S. at 374 (rejecting *unsupported* "assumption that doctors would prescribe unnecessary medications"). Indeed, the legislative record, which is several thousand pages long, reflects that multiple legislative committees spent months (over the course of 41 separate committee hearings) amassing and reviewing written submissions and oral testimony from a broad range of interested public and private parties, including respondents. See Doc. 413 (Defs. Proposed Findings of Fact) 2-4. Although proper deference to the legislature's considered determinations should make reliance on this legislative record unnecessary, the record provides ample, additional support for the legislature's conclusions. See Doc. 414 (Defs. Annotated Legislative Findings).

3. In short, Vermont's legislature did not defend its judgments with a "series of conclusory statements." *Edenfield*, 507 U.S. at 771; see also *ibid.* (State did not satisfy its burden where it presented "no studies" or "anecdotal evidence"). Yet the appellate court's analysis does not even mention Vermont's amply supported legislative determinations, much less give

them the deference they deserve. See *supra* pp. 26-27. This failure is particularly egregious because respondents filed suit before the Act took effect. As one of the earliest States to regulate the use of prescribing data in pharmaceutical marketing, it asks the impossible to require Vermont to present evidence demonstrating that its legislature's educated predictions are correct. See *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 665 (1994) (giving "substantial deference" to government's "predictive judgments" because "[s]ound policymaking often requires legislatures to forecast future events and to anticipate the likelihood of these events based on deductions and inferences for which complete empirical support may be unavailable"); accord *Turner Broad. Sys., Inc. v. FCC*, 520 U.S. 180, 195-196 (1997).

The appellate court found that the Act's means of accomplishing the State's aims are "too indirect," Pet. App. 28a; see also Pet. App. 25a (Vermont could have "directly restrict[ed] the prescribing practices of doctors" or "marketing practices of detailers."), but *Central Hudson* requires far more deference than this to legislative determinations. See *Lorillard Tobacco*, 533 U.S. at 561 (evidence that limited youth exposure to smoking advertising is linked to decrease in underage smoking tends to demonstrate that advertising regulation directly advances state interest in decreasing minors' use of smoking products); *Central Hudson*, 447 U.S. at 569 (law prohibiting advertising of electricity directly advances state interest in energy conservation). And the court's suggestion that the Act does not "directly" restrict sales representatives' activities is

incorrect in any event; the Act squarely precludes the specific practice that doctors opposed, namely, the unauthorized use of prescribing data as a marketing tool. As for the view that Vermont should have regulated physicians' prescribing practices directly, its legislature reasonably determined to pursue its goals by a means less likely to intrude on the way physicians practice medicine. Vermont, like many States,[19] already regulates prescribing practices to some extent, through mandatory generic substitution, preferred drug lists, and other cost control programs. Pet. App. 135a-136a. The legislature's decision to pursue its goals without imposing further constraints on physician prescribing was entitled to deference.

Finally, the court condemned the Act for "seek[ing] to alter the marketplace of ideas by taking out some truthful information that the state thinks could be used too effectively." Pet. App. 26a. But this misconceives the Act's operation, which, as explained, keeps no physician "in the dark" about his or her prescribing data: physicians know their own prescribing histories and, if they do not, the Act authorizes them to consent

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[19] See Nat'l Conf. of State Legis., Health Cost Containment & Efficiencies, NCSL Briefs for State Legislators, *Use of Generic Prescription Drugs and Brand-Name Discounts* (June 2010), available at http://www.ncsl.org/portals/1/documents/health/GENERICS-2010.pdf; Nat'l Conf. of State Legis., Health Cost Containment & Efficiencies, NCSL Briefs for State Legislators, *Prescription Drug Agreements and Volume Purchasing* (June 2010), available at http://www.ncsl.org/portals/1/documents/health/NEGOTIATED-2010.pdf.

to disclosure and use of the data for marketing. See *supra* p. 21.

C. The Appellate Court Failed To Defer To The Legislature's Reasonable Determination Regarding The Means-End Fit Of the Act.

1. *Central Hudson*'s final requirement is "a reasonable fit between the means and ends of the regulatory scheme." *Lorillard Tobacco*, 533 U.S. at 561. Thus, a regulation may be more extensive than necessary to serve the State's interests as long as it is not unreasonably so. See *id.* at 556 ("'the least restrictive means' is not the standard"). And the Court "ha[s] been loath to second-guess the Government's judgment to that effect." *Fox*, 492 U.S. at 479.[20]

To be sure, a State may not be able to show a "reasonable fit" between its legitimate interests and the chosen regulation "if there are numerous and obvious less-burdensome alternatives" available. *Discovery Network*, 507 U.S. at 417 n.13. Thus, "the challenged regulation should indicate that its proponent carefully

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[20] The Court stated in *Thompson* 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." 535 U.S. at 371. Because the Court did not purport to overrule its prior rejection of the "least restrictive means" test, however (indeed, the problem in *Thompson* was that there was "no hint" the government had considered alternatives, *id.* at 373), we do not read *Thompson* to abandon the "reasonable fit" standard, which gives appropriate deference to the State's historic primacy in matters of public health and safety.

calculated the costs and benefits associated with the burden on speech imposed by its prohibition." *Id.* at 417. But "almost all of the restrictions disallowed under *Central Hudson*'s fourth prong have been *substantially* excessive, disregarding far less restrictive and more precise means." *Fox*, 492 U.S. at 479 (internal quotations omitted) (emphasis added).

Moreover, "reasonable fit" is a sliding scale. Complete bans on truthful commercial speech receive the most rigorous scrutiny. See *44 Liquormart*, 517 U.S. at 500 (plurality op.). States have leeway, however, when enacting less burdensome restrictions. See *id.* at 501 (plurality op.) ("complete speech bans * * * are particularly dangerous because they all but foreclose alternative means of disseminating certain information," justifying "more careful[]" review than other restrictions); compare *Bates*, 433 U.S. at 383 (invalidating "blanket" prohibition against attorney advertising), with *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 449 (1978) (upholding ban on in-person solicitation by attorneys). States also have greater freedom to regulate speech related solely to "the individual interest of the speaker and its specific business audience," because such speech involves matters of limited (if any) public concern. *Dun & Bradstreet, Inc. v. Greenmoss Bldrs., Inc.*, 472 U.S. 749, 762 (1985).

2. Here, the Vermont legislature "carefully calculated the costs and benefits associated with" the Act's speech restrictions. On the costs side, Vermont did not completely ban direct marketing to doctors, or even all marketing use of prescribing data. Vermont

merely prohibited a particular aspect of the practice (unauthorized use of data) that physicians had identified as objectionable, Pet. App. 138a, and left respondents with "ample channels" for communicating their commercial messages, *Lorillard Tobacco*, 533 U.S. at 569. Nor did Vermont interfere with respondents' "interest in conveying truthful information about their products." *Id.* at 564.

As for benefits, Vermont's legislature not only carefully considered alternate methods of accomplishing its goals, but it actually adopted many of them. See Pet. App. 135a (legislative finding that "Vermont has been a leader in prescription drug cost-containment"). None of these measures, however, including many suggested by the court of appeals, successfully impeded the explosion in brand-name prescriptions. On this legislative record, the appellate court should have held that Vermont established a "reasonable fit" between its identified goals and the Act.

3. In holding otherwise, the court gave mere lip service to the dictates of *Central Hudson*'s fourth prong, see Pet. App. 31a (acknowledging "that *Central Hudson* does not require the state to use the least restrictive means available"), but failed to apply the test faithfully. The court's view that the Act is over-inclusive (because it is not targeted to drugs with "problem[s]" or "a generic alternative," Pet. App. 30a) is a canard. The Act seeks to prevent the over-prescription of drugs whose efficacy is not yet known; accordingly, it asks the impossible of Vermont to limit the Act's scope to drugs with an equally effective but less costly generic equivalent, as Judge Livingston recognized. Pet. App.

62a (Livingston, *J.*, dissenting). Nor is the appellate court correct that "more direct, less speech-restrictive means" are available. Pet. App. 30a-31a (suggesting "counter-speech" and mandatory generic prescribing). Vermont requires both generic substitution and counter-detailing. But its legislature also concluded that (1) government educational outreach could not compete with the more than $8 billion ($10 million in Vermont alone) that manufacturers spend each year trying to influence the prescribing practices of doctors, Pet. App. 71a, 137a; and (2) patients would not be well served by the more restrictive alternative of preventing doctors from prescribing brand-name drugs. The appellate court should have deferred to these reasonable legislative determinations.

More fundamentally, however, the appellate court held Vermont to a "least restrictive means" test that has no place under *Central Hudson*. This failure to defer to the legislature's considered judgments regarding the available means of regulation is particularly egregious where, as here, the legislature did not enact a "blanket ban" on all commercial speech but instead a limited prohibition on the unauthorized use of doctors' prescribing data for marketing purposes.

* * *

In sum, proper application of the *Central Hudson* test leaves "some room for the exercise of legislative judgment." *44 Liquormart*, 517 U.S. at 508 (plurality op.). This is particularly true where, as here, a State has engaged in a novel approach to solving a problem that all recognize as substantial. Without this

deference, which the appellate court here failed to afford, States will lose their ability to serve as "laboratories for experimentation" that is a hallmark of our federalist system.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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