No. 10-779

In the Supreme Court of the United States

WILLIAM H. SORRELL, ATTORNEY GENERAL OF VERMONT, ET AL., PETITIONERS

v.

IMS HEALTH INC., ET AL.

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

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONERS

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QUESTION PRESENTED

Prescription drug records contain information that identifies the physicians who have prescribed particular drugs. Pharmacies often sell that information to data-mining companies, which then aggregate and resell the data to pharmaceutical companies for use as a marketing tool. In 2007, the State of Vermont enacted a prescription-confidentiality law, Vt. Stat. Ann. tit. 18, § 4631 (Supp. 2010), aimed at curbing that practice. As relevant here, Section 4631 prohibits certain entities, including pharmacies, from selling records that contain prescriber-identifiable information unless the prescriber consents. Section 4631 similarly prohibits pharmaceutical manufacturers and marketers from using prescriber-identifiable information to market or promote prescription drugs unless the prescriber consents.

The question presented is whether those restrictions violate the Free Speech Clause of the First Amendment.

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INTEREST OF THE UNITED STATES

This case presents the question whether Vermont's restrictions on the use of prescriber-identifiable information violate the First Amendment. The United States has a significant interest in the resolution of that question, because there are a number of federal statutory and regulatory provisions that limit the dissemination or use of information held by highly regulated private entities. See *infra*, Part C.

STATEMENT

1. The dispensing of prescription drugs is heavily regulated by both federal and state laws. Under those laws, pharmacies in Vermont are required to collect and

maintain certain kinds of information about prescription drugs and the physicians who prescribe them.

a. Under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, the Food and Drug Administration (FDA) approves new drugs and determines whether a particular drug may be dispensed only upon a written or oral prescription from a physician. See 21 U.S.C. 353(b)(1). For most prescription drugs, the FDA does not directly regulate what information a prescription from a physician to a pharmacy must contain. But to avoid being misbranded, any drug dispensed to fill a prescription must "bear[] a label containing * * * the name of the prescriber, and, if stated in the prescription, the name of the patient." 21 U.S.C. 353(b)(2); see 21 U.S.C. 352(f) (branding requirements). As a practical matter then, federal law requires that a prescription provide at least the name of the prescribing physician.

For drugs listed under the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, federal law goes further and requires that both prescribing physicians and dispensing pharmacies register with the Drug Enforcement Administration (DEA). See 21 U.S.C. 823; 21 C.F.R. 1301.11(a); *Gonzales* v. *Raich*, 545 U.S. 1, 13-14, 27 (2005). A prescription for a controlled substance must contain, among other things, "the name, address and registration number of the practitioner." 21 C.F.R. 1306.05(a). Such a prescription may be filled only by a registered pharmacy or institutional practitioner (like a hospital). 21 C.F.R. 1306.06. Registered pharmacies must maintain extensive records of their controlled substances and must retain their written and electronic prescriptions. 21 C.F.R. 1304.04(h).

b. The State of Vermont imposes additional requirements on physicians and pharmacies that apply gener-

ally to all prescription drugs. As relevant here, physicians and pharmacies must be licensed by the State to dispense prescription drugs. See Vt. Stat. Ann. tit. 26, § 2041(a) (2006). Vermont also requires that every "[p]rescription drug order" contain the "[f]ull name and street address of the patient" and the "[n]ame, address and telephone number, and, if a controlled substance, * * * [the] DEA registration number of the prescribing practitioner." Vt. Bd. of Pharmacy Admin. Rules § 9.1 (2009) (Pharmacy Rules); see *id.* § 9.20(e)(3). In addition, Vermont requires each pharmacy to maintain "[a] patient record system" that includes a patient's name, street address and telephone number, age or date of birth, and gender. Pharmacy Rules § 9.24(a)-(d). The pharmacy must record the patient's prescription drug orders for the previous three years, including the name and strength of each drug, quantity and date received, prescription number, and name of the prescriber. *Id.* § 9.24(e)(1)-(5).

2. The prescriber-identifiable data (PI data) that Vermont requires pharmacies to collect and maintain is commercially valuable. Pharmacies sell those PI data to data-mining companies like respondents IMS Health Inc.; Verispan, LLC; and Source Healthcare Analytics, Inc., which remove some patient-identifiable information and aggregate the PI data to reveal individual physician prescribing practices. Data-mining companies then sell the PI data, primarily to pharmaceutical researchers and manufacturers like those represented by respondent Pharmaceutical Research and Manufacturers of America (PhRMA). Pet. App. 5a. Some federal governmental agencies, including the DEA and FDA, purchase more general types of aggregated prescription data for important public health or law enforcement purposes,

but this Office has been informed that, at least at present, those agencies generally do not purchase PI data.

Pharmaceutical manufacturers find the use of PI data valuable, because it allows them to target their marketing efforts for brand-name prescription drugs at individual physicians—often through personal visits known as "detailing." Pet. App. 5a-6a. Pharmaceutical sales representatives visit directly with physicians; provide details regarding the use, side effects, and risks of particular drugs; and distribute medical literature, free drug samples, and various small gifts. *Id.* at 71a. These practices are big business: pharmaceutical manufacturers spend nearly $8 billion each year on marketing efforts directed at doctors. *Ibid.* PI data allow manufacturers to allocate those resources more efficiently, for example, by targeting physicians who are prescribing a generic alternative to a brand-name drug.

3. a. In June 2007, Vermont adopted the prescription-confidentiality law at issue in this case, Vt. Stat. Ann. tit. 18, § 4631 (Supp. 2010). As part of that law, Vermont described three separate interests in preventing the sale and commercial use of PI data: (1) "protecting the public health of Vermonters," (2) "protecting the privacy of prescribers and prescribing information," and (3) "ensur[ing] costs are contained in the private health care sector, as well as for state purchasers of prescription drugs." *Id.* § 4631(a).

As amended in March 2008, Section 4631(d) advances the State's interests by placing two key restrictions on the sale or commercial use of PI data:

> A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity shall not sell, license, or exchange for value regulated records containing

> prescriber-identifiable information, nor permit the use of regulated records containing prescriber-identifiable information for marketing or promoting a prescription drug, unless the prescriber consents as provided in subsection (c) of this section. Pharmaceutical manufacturers and pharmaceutical marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents as provided in subsection (c) of this section.

The first restriction is thus on pharmacies and other entities with access to PI data: they may not sell records containing PI data, nor permit the use of such records for marketing prescription drugs, absent prescriber consent. The second restriction is on pharmaceutical manufacturers and marketers who obtain PI data: they may not use PI data to promote prescription drugs, absent prescriber consent.

Section 4631(e) establishes certain exceptions to the restrictions on the sale or use of PI data. For instance, those restrictions do not apply to

> the sale, license, exchange for value, or use, of regulated records for the limited purposes of pharmacy reimbursement; prescription drug formulary compliance; patient care management; utilization review by a health care professional, the patient's health insurer, or the agent of either; or health care research.

Vt. Stat. Ann. tit. 18, § 4631(e)(1). Accordingly, Section 4631 does not restrict the purchase or use of PI data by physicians in managing patient care; by researchers in conducting health care studies; or by insurance companies in monitoring compliance with their formularies, *i.e.*, their lists of prescription drugs covered by particu-

lar drug benefit plans. The statute also permits the "transmission of prescription information to a Vermont or federal law enforcement officer," *id.* § 4631(e)(6), or "as otherwise provided by law," *id.* § 4631(e)(5). Finally, the statute does not restrict the sale or use of "patient and prescriber data for marketing or promoting if the data do not identify a prescriber" and "could [not] be used to identify a prescriber." *Id.* § 4631(e)(7).

Because the statute only restricts the sale or use of PI data without a prescriber's consent, Section 4631(c) requires state authorities "[to] establish a prescriber data-sharing program to allow a prescriber to give consent." Vt. Stat. Ann. tit. 18, § 4631(c)(1). As part of that program, state officials must "solicit the prescriber's consent on licensing applications or renewal forms." *Ibid.* When a physician completes his initial licensing application, and every two years thereafter when he completes a renewal form, he may consent to use of his identifying information for promotional purposes. See, *e.g.*, Vermont Department of Health, Physician Licensure Application, http://healthvermont.gov/hc/med_board/documents/MDInitial2.10.11/pdf (last visited Feb. 28, 2011).

b. The Vermont General Assembly made 31 legislative findings in support of Section 4631. See 2007 Vt. Acts & Resolves No. 80, § 1. Those findings generally track Vermont's three stated interests: public health, prescriber privacy, and cost containment. First, the Assembly found that "[n]ewer drugs on the market do not necessarily provide additional benefits over older drugs, but do add * * * as yet unknown side-effects." *Id.* § 1(7). The Assembly further found that "[m]arketing which results in prescribers using the newest drugs will also result in prescribing drugs that are more likely

to be subject to * * * withdrawal from the market because of the serious public health concerns." *Id.* § 1(8).

Second, the Assembly found that physicians "have a reasonable expectation that the information in [a] prescription, including their own identity and that of the patient, will not be used for purposes" other than filling that prescription. 2007 Vt. Acts & Resolves No. 80, § 1(29). The Assembly also found that the trading of PI data "can result in harassing sales behaviors by pharmaceutical sales representatives toward doctors." *Id.* § 1(28). The Assembly observed that "[t]he Vermont Medical Society, an organization representing two-thirds of Vermont doctors, unanimously passed a resolution stating 'the use of physician prescription information by sales representatives is an intrusion into the way physicians practice medicine.'" *Id.* § 1(20).

Third, the Assembly found that spending on prescription drugs in Vermont had ballooned, from $280 million in 2000 to approximately $524 million in 2005. 2007 Vt. Acts & Resolves No. 80, § 1(9). "Nearly one-third of the five-fold increase in U.S. spending on drugs," the Assembly further found, "can be attributed to marketing induced shifts in doctors' prescribing [practices]." *Id.* § 1(14). Because detailing is generally "confined to high-margin, high-profit drugs," the Assembly concluded that "the work of pharmaceutical sales representatives drives drug use toward the most expensive products" and in turn "contributes to the strain on health care budgets for individuals as well as health care programs." *Id.* § 1(15) (internal quotation marks omitted); see *id.* § 1(31).

4. Vermont adopted its statute shortly after New Hamshire had enacted a similar statute in June 2006 and shortly before Maine enacted a similar statute in June

2007. New Hampshire's statute provides that records containing PI data "shall not be licensed, transferred, used, or sold" for "any commercial purpose" by various entities, including pharmacies, insurance companies, and retailers. N.H. Rev. Stat. Ann. § 318:47-f (LexisNexis Supp. 2010). Like the Vermont statute, the New Hampshire statute permits the use of PI data for purposes such as "formulary compliance," "care management," or "health care research." *Ibid.* The New Hampshire statute does not, however, provide that PI data may be used for commercial purposes with the prescriber's consent.

The Maine statute provides that any "pharmacy or prescription drug information intermediary may not license, use, sell, transfer or exchange for value, for any marketing purpose, prescription drug information that identifies a prescriber who has filed for confidentiality protection." Me. Rev. Stat. Ann. tit. 22, § 1711-E (Supp. 2010). Like the Vermont statute, the Maine statute prohibits the sale or use of PI data for "marketing purpose[s]," rather than all commercial purposes. The Maine statute establishes an "opt-in" program that bars the dissemination of prescribing information only with respect to physicians who have filed for confidentiality protection. *Id.* § 1711-E(2-A); Pet. App. 9a.

In separate cases, data-mining companies challenged the New Hampshire and Maine statutes on First Amendment grounds. The companies argued that those statutes were restrictions on commercial speech that could not survive intermediate scrutiny under this Court's decision in *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557 (1980) (*Central Hudson*). The district courts held that the statutes were unconstitutional, see *IMS Health Inc.* v. *Ayotte*, 490 F. Supp. 2d 163 (D.N.H. 2007); *IMS Health*

Corp. v. *Rowe*, 532 F. Supp. 2d 153 (D. Me. 2007), but in both cases the First Circuit reversed and upheld the statutes' constitutionality, see *IMS Health Inc.* v. *Ayotte*, 550 F.3d 42 (2008); *IMS Health Inc.* v. *Mills*, 616 F.3d 7 (2010).

5. In this case, respondents sought declaratory and injunctive relief to bar enforcement of the Vermont statute. After a five-day bench trial, the district court held that Section 4631 is constitutional. Pet. App. 68a-118a. As relevant here, the court concluded that the exchange of PI data is protected commercial speech and thus that Section 4631 is subject to intermediate scrutiny under *Central Hudson*. *Id.* at 79a-84a. Applying that standard, the court held that Vermont has substantial state interests in cost containment and public health, but not prescriber privacy. *Id.* at 87a-88a. The court further held that Section 4631 directly advances those interests because "a shift in prescribing practices from new drugs to generic [drugs] would result in a significant cost savings to the State" and "the unrestricted use of PI data in marketing contribute[s] to overprescription of new drugs." *Id.* at 92a, 95a. Finally, the court found that "[t]he law is in reasonable proportion to the State's interests," because it "is a targeted response to the harm of overprescription caused by detailers' use of PI data." *Id.* at 99a.

6. a. A divided panel of the court of appeals reversed. Pet. App. 1a-34a. Like the district court, the panel majority subjected Section 4631 to intermediate scrutiny and held that Vermont has substantial interests in cost containment and public health. *Id.* at 17a-24a. The panel majority concluded, however, that Section 4631 does not directly advance those interests because it does not restrict "the prescribing practices of doctors"

or "the marketing practices of detailers." *Id.* at 25a. Rather, the panel majority reasoned that the statute attempts to curtail detailing by restricting the information available to detailers, a route "too indirect to survive intermediate scrutiny." *Id.* at 28a. The panel majority also concluded that Vermont has "more direct, less speech-restrictive means available" to achieve its interests, such as "mandat[ing] the use of generic drugs as a first course of treatment" or "target[ing] new brand-name drugs particularly when there are alternatives available." *Id.* at 30a-31a.

b. Judge Livingston dissented. Pet. App. 35a-67a. In her view, Section 4631's limitation on the sale of PI data by pharmacies is "a permissible restriction on access to information." *Id.* at 43a; see *id.* at 39a-43a. Judge Livingston questioned whether, in contrast to pharmacies, respondents have cognizable First Amendment interests at stake. *Id.* at 43a-50a. But assuming that they do, she would have upheld the statute under intermediate scrutiny because all three interests advanced by Vermont are substantial, *id.* at 51a-53a; the statute directly advances those interests by "reduc[ing] the pressure on doctors to prescribe more expensive, less proven drugs" and by "restrict[ing] the flow of otherwise private information about doctors' prescribing habits," *id.* at 59a; and the statute places "exceedingly limited burdens on commercial speech," *id.* at 62a.

SUMMARY OF ARGUMENT

A. Section 4631 restricts the sale or commercial use of PI data without prescriber consent. Pharmacies in Vermont have access to PI data as part of a comprehensive system of federal and state regulation. Vermont's statute therefore does not run afoul of the Free Speech

Clause, because there is no First Amendment right to obtain information that is in private possession solely as a result of such governmental regulation. At most, however, Section 4631 is subject to intermediate scrutiny as a restriction on commercial speech, because respondents sell and use PI data as part of commercial transactions. Respondents' various arguments for strict scrutiny lack merit.

B. Applying intermediate scrutiny, Section 4631 is a permissible restriction on commercial speech because it directly and reasonably advances Vermont's substantial interests in lowering health care costs and safeguarding prescriber privacy. The record in this case shows that limiting the dissemination and use of PI data lowers spending on prescription drugs without producing offsetting harms to the public health. Although Vermont and other States have tried more direct alternatives, those measures simply have not proven effective in containing the health care costs caused by the pharmaceutical industry's detailing practices. Section 4631 is also tailored to protect physicians' interests in ensuring that their prescribing practices remain confidential and that they are able to avoid unwanted commercial solicitation.

C. There are a number of federal statutory and regulatory provisions that regulate the dissemination or use of information by private parties for various reasons, including to protect individual privacy or to deter unwanted commercial solicitation. Regardless of whether Section 4631 survives constitutional scrutiny, those federal provisions should not be affected, because they are even more narrowly tailored to the clearly substantial federal interests at stake.

ARGUMENT

VERMONT'S PRESCRIPTION-CONFIDENTIALITY LAW DOES NOT VIOLATE THE FIRST AMENDMENT'S FREE SPEECH CLAUSE

A. Section 4631 Is Subject At Most To Intermediate Scrutiny As A Restriction On Commercial Speech

1. There is no First Amendment right to obtain information that is in private possession pursuant to a comprehensive system of governmental regulation

a. Vermont's prescription-confidentiality statute restricts the sale or commercial use of PI data without prescriber consent in two ways. First, Section 4631 restricts the dissemination of PI data by entities with access to that information. The statute provides that "[a] health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity shall not sell, license, or exchange for value regulated records containing prescriber-identifiable information." Vt. Stat. Ann. tit. 18, § 4631(d). Even if those entities do not sell records containing PI data, they may not "permit the use of regulated records containing prescriber-identifiable information for marketing or promoting a prescription drug." *Ibid.* Section 4631 thus prevents various entities that have access to PI data from selling or otherwise permitting commercial use of the data, absent prescriber consent.[1]

The statute takes account of the fact that pharmaceutical companies may obtain PI data for purposes other

[1] The court of appeals stated that Section 4631 "only imposes restrictions on the sale * * * of [PI] data for marketing or promoting a prescription drug." Pet. App. 22a. On its face, however, Section 4631 restricts the sale of PI data without limitation and separately restricts the use of PI data for marketing or promoting a prescription drug.

than marketing prescription drugs, such as conducting clinical trials or safety recalls. See Vt. Stat. Ann. tit. 18, § 4631(e)(4). Section 4631(d) therefore provides that, to the extent "[p]harmaceutical manufacturers and pharmaceutical marketers" do obtain PI data, "[they] shall not use prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents." By its terms, however, the Vermont statute does not directly regulate other downstream purchasers or users, including data-miners. See Pet. Br. 11.[2]

b. Pharmacies in Vermont have access to prescription information through their participation under a comprehensive system of federal and state regulation. The FDCA requires a prescription for drugs that are "not safe for use except under the supervision of a practitioner licensed by law" or that are "limited by an approved [new drug] application" to such supervised use. 21 U.S.C. 353(b)(1)(A)-(B). Under the FDCA, a pharmacy may not dispense a prescription drug without a prescription from a licensed physician. See 21 U.S.C. 353(b)(1)(i)-(ii). Because any drug dispensed to fill a prescription must bear a label containing the prescriber's name, see 21 U.S.C. 353(b)(2), a pharmacy may not fill a prescription under federal law unless the prescribing physician identifies himself—information that the physician and the patient would not otherwise be required to provide to the pharmacy.

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[2] The court of appeals asserted that Section 4631 "prohibits data miners from selling or transmitting PI data * * * if that PI data will later be used for marketing purposes." Pet. App. 20a. But the court did not square that assertion with the statutory language, which places limitations only on data-miners' potential suppliers (*e.g.*, pharmacies) and primary customers (pharmaceutical manufacturers and marketers).

Vermont has gone even further. It requires all physicians and pharmacies to be licensed by the State in order to dispense prescription drugs. See Vt. Stat. Ann. tit. 26, § 2041(a). Under state law, every "[p]rescription drug order" must contain the "[f]ull name and street address of the patient" and the "[n]ame, address and telephone number, and, if a controlled substance, * * * [the] DEA registration number of the prescribing practitioner." Pharmacy Rules § 9.1. Vermont also requires each pharmacy to maintain "[a] patient record system" that keeps track of a patient's name, street address and telephone number, age or date of birth, and gender. *Id.* § 9.24(a)-(d). The pharmacy also must record the patient's prescription drug orders for the previous three years, including the name and strength of each drug, the quantity and date received, the prescription number, and the name of the prescriber. *Id.* § 9.24(e)(1)-(5). Vermont thus requires that pharmacies collect and maintain certain information, including patients' drug histories and their prescribing physicians.

c. Because PI data are generated pursuant to a comprehensive system of federal and state regulation, and because pharmacies have access to PI data as a result of their participation in that comprehensive system, Vermont has wide latitude to regulate the manner in which PI data will be disseminated and used by private parties.

If the information were in the State's possession, it could deny access without any constitutional difficulty. In *Los Angeles Police Department* v. *United Reporting Publishing Corp.*, 528 U.S. 32 (1999) (*United Reporting*), this Court rejected a facial challenge to a California statute limiting access to the addresses of individuals arrested by state and local law enforcement. *Id.* at 34. The Court reasoned that the statute was "not an

abridgment of anyone's right to engage in speech, be it commercial or otherwise," but was "simply a law regulating access to information in the hands of the police department." *Id.* at 40. The Court therefore upheld the statute without any First Amendment inquiry into the substantiality of California's asserted interests or the means-ends fit between those interests and the statute. To be sure, the information here is in private hands rather than the government's possession, but it came into those hands as a result of the pharmacies' participation in a "closed regulatory system" for the safe dispensing of prescription drugs. *Gonzales* v. *Raich*, 545 U.S. 1, 13 (2005). In these circumstances at least, it should not matter whether federal and state law require the information to reside with the government itself or with a set of highly regulated private entities.

As Judge Livingston pointed out in dissent below, the result in *United Reporting* should be no different if instead of using its own officers "to process and house its arrestees," the Los Angeles Police Department relied on "private prison or security contractors." Pet. App. 41a. Those private entities would have access to arrestees' identifying information solely by virtue of state regulation or contract, and the State could employ the same regulatory or contractual means to restrict dissemination of that information without abridging any free speech right. See *Houchins* v. *KQED, Inc.*, 438 U.S. 1, 15-16 (1978) (plurality opinion) (The First Amendment does not generally "mandate[] a right of access to government information or sources of information within the government's control."); see *id.* at 16 (Stewart, J., concurring in the judgment) ("The First and Fourteenth Amendments do not guarantee the public a right of access to information generated or con-

trolled by the government."). Thus, just as there is no First Amendment right of access to information that is in the government's possession, an entity has no general First Amendment right to obtain information—for private commercial purposes—concerning other private parties that came into a pharmacy's possession by virtue of its participation in a comprehensive and closed system for the safe dispensing of prescription drugs.[3]

2. In any event, Section 4631 is subject to no more than intermediate scrutiny as a restriction on commercial speech

a. Even assuming, however, that some level of First Amendment scrutiny is appropriate, the fact that PI data come into a pharmacy's possession pursuant to a comprehensive system of federal and state regulation significantly affects the constitutional analysis and means that, at most, Vermont's statute is subject to some form of intermediate scrutiny. This Court faced a similar question in *Seattle Times Co.* v. *Rhinehart*, 467 U.S. 20 (1984), in which civil litigants claimed a First Amendment right to disseminate, in advance of trial, information gained through the pretrial discovery process. The Court held against an unqualified right in that

[3] The result might be different in the case of a restriction that imposed certain selective limitations on access to information in private possession as a result of government regulation. Contrast *United Reporting*, 528 U.S. at 42 (Scalia, J., concurring) (allowing that selective access may create "a restriction upon speech rather than upon access to government information"), with *id.* at 43-44 (Ginsburg, J., concurring) (suggesting that selective access is permissible when it does not "discriminate[] on the basis of viewpoint or some other proscribed criterion"). But as Judge Livingston noted in dissent below, respondents have not pressed a selective-access claim. Pet. App. 43a.

context, because the litigants had "gained the information they wish[ed] to disseminate only by virtue of the trial court's discovery processes." *Id.* at 32. Access to the information was thus "a matter of legislative grace," and the legislature could make the information available subject to constraints on its dissemination without raising "the same specter of government censorship that such control might suggest in other situations." *Ibid.* The Court concluded that the restriction "implicate[d] the First Amendment rights of the restricted party to a far lesser extent than would restraints on dissemination of information in a different context." *Id.* at 34.

Similarly, pharmacies in Vermont gain access to PI data by virtue of a comprehensive set of federal and state statutes and administrative rules. Indeed, those statutes and rules govern their participation in commercial activities that implicate public health and safety, personal and professional privacy, and substantial governmental interests in controlling health care costs. As part of that closed regulatory system governing prescription drugs, the State can make access to PI data subject to constraints on its subsequent dissemination, at least if those constraints satisfy intermediate scrutiny. See *Seattle Times*, 467 U.S. at 32-34 (upholding protective order under intermediate scrutiny). Because pharmacies have no absolute First Amendment right to disseminate PI data, it follows that pharmaceutical manufacturers and marketers likewise have no absolute First Amendment right to purchase PI data or use those data for commercial purposes. From their perspective as well, Section 4631(d)'s restrictions on the nonconsensual sale or commercial use of PI data are subject, at most, to intermediate scrutiny.

b. Nor would the applicable standard of review be different if PI data were considered information that pharmacies to some extent possess independently of the system of governmental regulation that requires the information to be furnished and maintained. The pharmacies' acquisition of the data would still have been in connection with commercial transactions (their sale of prescription drugs), and respondents' own purchase, sale, and use of PI data would likewise remain commercial in nature. For example, in *Rubin* v. *Coors Brewing Co.*, 514 U.S. 476 (1995), this Court considered whether a federal statute prohibiting beer labels from displaying alcohol content violated the First Amendment. The parties agreed, and the Court did not question, that the communication of truthful and nonmisleading factual information about alcohol content by brewers is commercial speech. *Id.* at 481-482. The Court therefore subjected the statute to intermediate scrutiny under *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557 (1980) (*Central Hudson*). *Coors Brewing Co.*, 514 U.S. at 482.

Here, to the extent that pharmacies' sale or dissemination of PI data constitutes speech rather than conduct, it is "commercial speech, that is, expression related solely to the economic interests of the speaker and its audience." *Central Hudson*, 447 U.S. at 561. Although this Court has described the category of commercial speech with varying breadth, see *City of Cincinnati* v. *Discovery Network, Inc.*, 507 U.S. 410, 421-423 (1993), respondents' transactions involving PI data qualify even under the narrowest definition as "speech that proposes a commercial transaction." *Board of Trustees of the State Univ. of N.Y.* v. *Fox*, 492 U.S. 469, 482 (1989) (emphasis omitted). Indeed, pharmacies' dissemination of

PI data does more than *propose* a commercial transaction; it occurs *as part of* a commercial transaction: namely, a sale of records containing PI data to data-mining companies. There is no evidence in the record of this case that respondent data-miners obtain PI data other than by purchasing it from Vermont pharmacies. To the extent that purchasing or selling private medical data is speech at all rather than conduct, but see *IMS Health Inc.* v. *Ayotte*, 550 F.3d 42, 50-54 (1st Cir. 2008), it is commercial speech, restrictions on which are subject to intermediate scrutiny under *Central Hudson*.

Much the same analysis applies to Section 4631(d)'s restriction on the use of PI data for marketing or promoting prescription drugs. Unlike the statutes involved in most of this Court's other cases concerning commercial speech, the Vermont statute does not prohibit or limit advertising by pharmaceutical manufacturers and marketers. At most, Section 4631(d) influences the contours of their detailing visits with physicians, by depriving them of limited information about those doctors' prescribing practices. See Pet. App. 18a. Assuming that indirect effect implicates the First Amendment where, as here, the impact on speech is intended rather than incidental, the promotion and marketing of prescription drugs involves quintessentially commercial speech: speech by or on behalf of a vendor (*i.e.*, a pharmaceutical manufacturer or marketer) that proposes a commercial transaction (*i.e.*, the prescription and consequent sale of a particular drug). Section 4631(d)'s restrictions on the use of PI data are therefore subject at most to the same level of scrutiny as its restrictions on the sale of PI data.

3. Section 4631 is not subject to strict scrutiny

a. Respondent data-miners contend that "[a]lthough the pharmaceutical companies are marketing their products, Section 4631 is subject to strict scrutiny because that commercial message is 'inextricably intertwined with otherwise fully protected speech'—information regarding the drugs' merits." Br. in Opp. 12 n.1 (quoting *Riley* v. *National Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 796 (1988)). Setting aside that the data-miners do not claim that Section 4631 is subject to strict scrutiny as applied to them (if the statute can be applied to them at all), their call for strict scrutiny is misplaced. Commercial speech often conveys important information to its listeners, but that informational function has never been regarded as a justification for placing commercial and noncommercial speech on the same constitutional plane. See, *e.g.*, *Virginia State Bd. of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 765, 770-772 & n.24 (1976). It is undoubtedly true that, during detailing visits, pharmaceutical marketers make statements about the purported benefits of brand-name drugs—just as any salesman extols the virtues of his product. But statements about a product's "merits" do not convert a sales pitch into noncommercial speech. Such statements qualify for the more limited protection afforded to commercial speech when "made only in the context of commercial transactions." *Central Hudson*, 447 U.S. at 563 n.5.

b. Respondent PhRMA argues that because Section 4631(d) prohibits the use of PI data for "marketing or promoting a prescription drug," the statute "potentially encompasses educational, safety, and risk communications about a company's medicines." Br. in Opp. 15. Those types of communications, however, appear to be

carved out from Section 4631(d)'s prohibitions, see Vt. Stat. Ann. tit. 18, § 4631(e)(1) and (4), and in any event there is no reason to interpret the statutory definitions of "marketing" and "promotion" to cover communications that are not commercial in nature, see *id.* § 4631(b)(5) and (8). And to the extent that PhRMA's members include statements on issues of public concern in their marketing campaigns, that does not alter the commercial character of the speech taken as a whole. See *Bolger* v. *Youngs Drug Prods. Corp.*, 463 U.S. 60, 67-68 (1983) ("The mailings constitute commercial speech notwithstanding the fact that they contain discussions of important public issues."); *Fox*, 492 U.S. at 473-474 (same; houseware sales).

PhRMA incorrectly contends that educational, safety, and risk communications are "inextricably intertwined" with marketing or promotional messages—and thus that the whole of their speech is fully protected under the First Amendment. Br. in Opp. 15 (quoting *Riley*, 487 U.S. at 796). In *Riley*, the commercial speech was inextricably intertwined with fully protected noncommercial speech because the state law at issue required professional fundraisers to make certain commercial disclosures in their presentations. See *Fox*, 492 U.S. at 474 (noting that the commercial speech in *Riley* was "'inextricably intertwined' because the state law *required* it to be included"). By contrast here, there is nothing inextricable about any statements of public concern and the marketing campaigns of PhRMA's members. *Ibid.* PhRMA's members may decide how to present information about their prescription drugs, and any choice that they might make to include noncommercial speech in their marketing campaigns does not require application of strict scrutiny.

c. Finally, this Court's decision in *Dun & Bradstreet, Inc.* v. *Greenmoss Builders, Inc.*, 472 U.S. 749 (1985), counsels against application of strict scrutiny. In that case, a credit reporting agency was sued for libel after it disseminated a report mistakenly indicating that a private company had filed for bankrupcty. *Id.* at 751 (plurality opinion). The Court had previously held that when a private individual is libeled by speech involving a matter of public concern, the First Amendment requires the individual to prove "actual malice" in order to recover punitive damages. In *Dun & Bradstreet*, the Court declined to extend that actual-malice requirement to libel based on statements on matters of private concern. The plurality opinion reasoned that "not all speech is of equal First Amendment importance," and that while speech on matters of public concern "is at the heart of the First Amendment's protection," "speech on matters of purely private concern is of less First Amendment concern." *Id.* at 758-759 (internal quotation marks omitted); see *id.* at 760; see also *id.* at 764 (Burger, C.J., concurring in the judgment); *id.* at 774 (White, J., concurring in the judgment).

In *Dun & Bradstreet*, the credit report involved matters of private concern because the financial information "was speech solely in the individual interest of the speaker and its specific business audience." 472 U.S. at 762 (plurality opinion). The same reasoning applies here, where the details of a particular physician's prescribing decisions ordinarily implicate only "the individual interest of the speaker [the pharmacy or data-miner] and its specific business audience [data-miners or pharmaceutical manufacturers and marketers]." Accord *Trans Union Corp.* v. *FTC*, 245 F.3d 809, 818 (D.C. Cir.) ("target marketing lists" sold by a consumer reporting

company for marketing purposes are not fully protected speech because "the information about individual consumers and their credit performance * * * is solely of interest to the company and its business customers and relates to no matter of public concern"), opinion respecting denial of reh'g, 267 F.3d 1138, 1140-1141 (D.C. Cir. 2001), cert. denied, 536 U.S. 915 (2002). Because the Vermont statute restricts only transactions in PI data that are commercial in nature and that involve matters of private concern, the statute is subject to no more than intermediate scrutiny.

B. Section 4631 Directly Advances Substantial State Interests In A Reasonably Tailored Manner

To the extent that the sale and use of PI data warrant protection as commercial speech, Vermont does not contend that such speech is "misleading []or related to unlawful activity." *Central Hudson*, 447 U.S. at 564. Accordingly, Section 4631 passes constitutional muster if the State has "assert[ed] a substantial interest" that is "directly advance[d]" by Section 4631 and that could not "be served as well by a more limited restriction." *Ibid.* Section 4631 satisfies that standard.

1. Vermont has asserted substantial interests in public health, cost containment, and prescriber privacy

The three interests asserted by Vermont—protecting public health, reducing health care costs, and safeguarding prescriber privacy—are substantial. See Pet. Br. 45; Vt. Stat. Ann. tit. 18, § 4631(a). Those interests are at least as weighty as other governmental interests that this Court has consistently found substantial for constitutional purposes. See, *e.g.*, *Virginia State Bd. of Pharmacy*, 425 U.S. at 766 (maintaining professional standards for pharmacists is a substantial state interest);

see also *Central Hudson*, 447 U.S. at 568-569 (same; conserving energy and promoting fair and efficient energy rates); *Posadas de Puerto Rico Assocs.* v. *Tourism Co. of Puerto Rico*, 478 U.S. 328, 341 (1986) (*Posadas*) (same; reducing demand for casino gambling); *Coors Brewing Co.*, 514 U.S. at 485 (same; preventing brewers from competing on the basis of alcohol strength).

2. Section 4631 directly advances Vermont's interests in cost containment and prescriber privacy in a reasonably tailored manner

The parties' dispute centers on whether Section 4631 satisfies "[t]he last two steps of the *Central Hudson* analysis," which require "a consideration of the 'fit' between the legislature's ends and the means chosen to accomplish those ends." *Posadas*, 478 U.S. at 341. Specifically, the remaining *Central Hudson* factors require that a valid restriction on commercial speech "directly advance[] the governmental interest asserted" through a means "that is not necessarily perfect, but reasonable." *Fox*, 492 U.S. at 475, 480. Section 4631 satisfies those dual requirements with respect to Vermont's interests in cost containment and prescriber privacy.[4]

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[4] The United States disagrees with Vermont that Section 4631 directly and materially advances the State's interest in protecting the health of its citizens. Although it is true that pharmaceutical companies' marketing tactics increase the demand for new brand-name drugs, see Pet. Br. 49, 52, Vermont's position depends on the unwarranted view that the dangers of such new drugs outweigh their benefits to patients. See 2007 Vt. Acts & Resolves No. 80, § 1(7) ("Newer drugs on the market do not necessarily provide additional benefits over older drugs, but do add * * * as yet unknown side-effects."). Introduction of a new drug requires approval by the FDA, which in turn requires a showing by the manufacturer that the drug is safe and effective for its intended uses in accordance with its labeling. See 21 U.S.C. 355. Although there are

a. *Cost containment*. Section 4631 directly advances Vermont's interest in reducing health care costs, by decreasing demand for new brand-name drugs that are generally more expensive than generic alternatives. To sustain Section 4631 on that ground, Vermont must demonstrate "that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Florida Bar* v. *Went For It, Inc.*, 515 U.S. 618, 626 (1995) (internal quotation marks omitted). Based on the record in this case, Vermont met its burden of showing that (i) detailing by PhRMA's members increases spending on prescription drugs; (ii) use of PI data facilitates their detailing practices; and (iii) targeted detailing does not produce health benefits that result in offsetting savings.

At trial, Vermont presented expert testimony that detailing by the pharmaceutical industry decreases the prescription of generic drugs and increases the prescription of brand-name drugs. C.A. App. A241-A243; see *id.* at A4306. Those expert opinions comport with common sense. The pharmaceutical industry spends billions of dollars each year on detailing precisely because it increases the sale of brand-name drugs. See *Lorillard Tobacco Co.* v. *Reilly*, 533 U.S. 525, 555 (2001) (advertising restrictions may be justified "based solely on history, consensus, and 'simple common sense'"). That considerable spending on detailing in turn increases health care costs, because "[d]etailing is generally confined to high-margin, high-profit drugs, for which the manufac-

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occasions when an approved drug is subsequently found to have unanticipated side effects, see Pet. Br. 49-50, it does not follow that categorically reducing the volume of prescriptions for newly approved drugs materially advances public health.

turer has a substantial incentive to increase sales." C.A. App. A4306.

Likewise, it is beyond dispute that the pharmaceutical industry purchases PI data to facilitate its detailing practices. The use of PI data allows detailers both to target individual physicians and to tailor their messages in an effort to maximize prescriptions for their branded drugs. See C.A. App. A4354; see also *id.* at A297, A342. For branded drugs with generic alternatives, that use of PI data in detailing does not produce correlative health benefits that offset the increased spending on branded drugs, because less expensive generic alternatives generally are therapeutically equivalent to their branded counterparts. See *id.* at A280, A342. And physicians have access to other sources of information about the medical benefits of new brand-name drugs. *Id.* at A240, A1434. The record in this case thus supports Vermont's conclusion that Section 4631 directly advances the goal of containing health care costs.

Section 4631 also displays a reasonable "fit" with the State's objective of cost containment. The court of appeals speculated that Vermont could apply its restriction only to branded drugs for which there are generic equivalents. Pet. App. 29a. But the State is not required to employ the least restrictive means at its disposal, regardless of cost or feasibility. See *Fox*, 492 U.S. at 480 (governmental decisionmakers need not employ "necessarily the least restrictive means," but rather "a means narrowly tailored to achieve the desired objective"); *id.* at 479 (means may not be "substantially excessive") (internal quotations marks omitted). Here, there has been no showing that such a requirement would be easily administrable. Moreover, under the court of appeals' approach, the State would have to fend off drug-by-drug

challenges from pharmaceutical companies to any restriction on the use of PI data.

The court of appeals also concluded that the State had ignored more direct and less speech-restrictive alternatives. Pet. App. 30a-31a. But as the First Circuit has explained, the problem of overprescription of branded drugs has proven extremely resistant to a number of different regulatory approaches. See *Ayotte*, 550 F.3d at 59-60. Vermont and other States have restricted gifts to physicians. *Id.* at 59; Vt. Stat. Ann. tit. 18, § 4632(a)(1). They also have established "counter-detailing" programs to encourage physicians to prescribe generic equivalents. *Ayotte*, 550 F.3d at 60; Vt. Stat. Ann. tit. 18, § 4622; *id.* tit. 33, § 2004 (Supp. 2010). In addition, Vermont has regulated prescribing decisions in state-funded programs through a preferred drug list and a requirement for prior authorization of non-listed drugs. *Id.* § 1998 (Supp. 2010). Vermont even requires pharmacists to fill prescriptions with generic equivalents under certain circumstances. *Id.* tit. 18, 4605(a) (Supp. 2010). None of those alternatives, however, has proven or is likely to prove fully effective in containing health care costs. See C.A. App. A4310; cf. *Posadas*, 478 U.S. at 344 (holding that a legislature may decide whether "a 'counter-speech' policy would be as effective" as restrictions on commercial speech).

To be sure, this Court has generally been skeptical of statutes that prevent dissemination of truthful commercial information in an effort to influence consumer choices. See, *e.g.*, *Thompson* v. *Western States Med. Ctr.*, 535 U.S. 357, 374-375 (2002) (*Western States*); *44 Liquormart, Inc.* v. *Rhode Island*, 517 U.S. 484, 503 (1996). The Vermont statute, however, does not prevent pharmaceutical manufacturers or marketers from mak-

ing any truthful statement in their marketing pitches to physicians. It simply prevents them from exploiting for their own commercial purposes aggregated data derived from information that was furnished to pharmacies pursuant to comprehensive regulation for health and safety purposes.

Moreover, the consumer-sovereignty rationale of cases like *Western States* and *44 Liquormart* does not apply with equal force to the market for prescription drugs. In that market, the ultimate "consumers" of health care from a medical perspective are patients—and from a cost perspective are patients, insurers, and governments—not physicians. Yet in their capacity as prescribers, physicians make the critical decisions about which drugs patients will take and insurers will pay for. In that context, where consumers do not make the choices that manufacturers seek to influence, the State should have greater latitude in designing measures to protect its citizenry and the public fisc.

b. *Prescriber and prescription privacy*. Section 4631 also directly advances Vermont's interest in prescriber and prescription privacy. There are two separate interests at stake: first, the interest of physicians (and, to a lesser extent, patients) in ensuring that prescribing practices remain private and confidential; and second, the interest of physicians in being free from solicitation based on the commercial exploitation of their individual prescribing practices. See Vt. Stat. Ann. tit. 18, § 4631(a) (asserting a state interest in protecting the privacy of "prescribers" as well as "prescribing information"). Section 4631 directly advances both of those interests in a sufficiently tailored way.

i. A State reasonably may recognize a limited privacy interest on the part of physicians in the confidenti-

ality of information about prescribing practices. Like any other individual, a physician has an interest in the "control of information concerning his or her person." *United States Dep't of Justice* v. *Reporters Comm. for Freedom of the Press*, 489 U.S. 749, 763 (1989) (*Reporters Comm.*). With respect to physicians, that interest extends to how they practice their profession. See *New York Times Co.* v. *NASA*, 920 F.2d 1002, 1007 (D.C. Cir. 1990) (Freedom of Information Act exemption for "medical files" where disclosure "would constitute a clearly unwarranted invasion of personal privacy" protects the authors of such files as well as their subjects); cf. 42 U.S.C. 11137(b)(1) (treating as "confidential" and limiting disclosure of information about disciplinary actions against physicians).

To be sure, physicians' privacy interest in their prescribing practices is diminished—especially as against the government itself—by the extensive regulation of those practices under federal and state law. See *United States* v. *Argent Chem. Labs., Inc.*, 93 F.3d 572, 575 (9th Cir. 1996), cert. denied, 520 U.S. 1115 (1997). But Vermont is nevertheless free to protect that limited privacy interest, especially with respect to the subsequent sale or dissemination of information that physicians are required by law to report. Cf. *NASA* v. *Nelson*, 131 S. Ct. 746, 755-756, 761-762 (2011); *Whalen* v. *Roe*, 429 U.S. 589, 600-601, 605 (1977). The interference with the physician's interest in controlling the use of information about his prescribing (and therefore treatment) practices is augmented here by the fact that the data-mining companies assemble and aggregate such information from various pharmacies, typically selected by the patients themselves. Cf. *Reporters Comm.*, 489 U.S. at 763-765, 770-771. An individual physician thus has

little opportunity to insist that his PI data be kept confidential, as he has no direct contractual relationship with the various pharmacies.

The court of appeals effectively held that Section 4631 is too narrowly drawn to advance an interest in prescriber privacy, because it prohibits the nonconsensual use of PI data only for marketing purposes. Pet. App. 22a. But use of information about a physician's professional practices for commercial purposes—particularly for the purpose of targeting that physician for commercial messages—is a qualitatively different and greater invasion of the physician's privacy than use of that same information for governmental or research purposes. And as a matter of reality, the record in this case makes clear that PI data are not being widely disseminated for uses other than promoting brand-name drugs. See, *e.g.*, C.A. App. A82. Section 4631 thus addresses the only true threat to the confidentiality of prescribing information. The Vermont statute is simply not a law so riddled with irrational exceptions as to undermine the law's own goals. See, *e.g.*, *Greater New Orleans Broad. Ass'n, Inc.* v. *United States*, 527 U.S. 173, 190 (1999).[5]

Section 4631 is also reasonably tailored to Vermont's interest in protecting the confidentiality of prescribing information. Less restrictive alternatives are simply not available when it is the very identities of physicians and their prescribing practices that the State seeks to shield. Cf. *Trans Union*, 267 F.3d at 1142. Moreover, Ver-

[5] It is common for laws regulating the dissemination of private information to prohibit nonconsensual uses for commercial purposes. See, *e.g.*, *United Reporting*, 528 U.S. at 34-35; 18 U.S.C. 2721(b)(12) (Driver's Privacy Protection Act of 1994); 20 U.S.C. 1232g (Family Educational Rights and Privacy Act of 1974); see also *infra*, Part C.

mont's mechanism for physician consent entails negligible effort: a physician need only provide his signature and a few lines of identifying information as part of the mandatory biennial license renewal process. As a result, it is extremely unlikely that doctors who wish to have their PI data disseminated for marketing purposes will fail to consent. Simply put, Vermont has ensured that its restriction applies no more broadly than is necessary to achieve its objective.

ii. Section 4631 also protects a second aspect of physician privacy: the physician's interest in avoiding unwanted forms of commercial solicitation. The legislative findings refer to "harassing sales behaviors by pharmaceutical sales representatives toward doctors," an "increase in the aggressiveness" of such representatives, and reports that some doctors "felt coerced and harassed" by detailers. See 2007 Vt. Acts & Resolves No. 80, § 1(20), (28). The government's interest in enabling individuals to shield themselves from unwanted commercial messages is well established. See *Rowan* v. *United States Post Office Dep't*, 397 U.S. 728 (1970) (upholding federal "do-not-mail" list); *FTC* v. *Mainstream Mktg. Servs., Inc.*, 345 F.3d 850 (10th Cir. 2003) (upholding federal "do-not-call" registry); see also *United States Dep't of Defense* v. *FLRA*, 510 U.S. 487, 500-501 (1994). Although the individual's interest in freedom from unwelcome solicitation has "special force" in the context of the home, *Hill* v. *Colorado*, 530 U.S. 703, 717 (2000), that interest is not confined to the domestic setting, see *ibid.*, and reasonably extends to the premises of a physician's own professional practice.

Section 4631 directly advances Vermont's interest in shielding physicians from unwanted commercial solicitation by prohibiting the particular marketing technique

that Vermont doctors told the General Assembly was most intrusive: the use of their own PI data to target individual physicians for detailing presentations crafted on the basis of those physicians' prescribing practices. C.A. App. A1183-A1184, A1309, A1433, A4197. Although Vermont could have given physicians the option of refusing all detailing visits, that would have required doctors to forgo detailing that they find useful, see *id.* at A1182, A1310, in order to avoid commercial intrusions targeted and shaped to respond to and alter their own prescribing practices. Those are the types of intrusions that Vermont physicians find especially manipulative and even intimidating, *id.* at A1183, A1437, and Section 4631 is framed accordingly.

3. The legislative findings do not undermine Section 4631's constitutionality

The Vermont General Assembly made 31 legislative findings in support of Section 4631, see 2007 Vt. Acts & Resolves No. 80, § 1, and the relevant findings support Vermont's interests in cost containment and prescriber privacy. Respondents place undue weight, however, on the fourth and sixth findings: specifically, that "[t]he marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that brand-name companies invest in expensive pharmaceutical marketing campaigns to doctors," which in turn "leads to doctors prescribing drugs based on incomplete and biased information." *Id.* § 1(4); see *id.* § 1(6) ("Public health is ill served by the massive imbalance in information presented to doctors and other prescribers."). On the basis of those findings, respondents repeatedly frame Section 4631 as a paternalistic attempt to regulate "[t]he mar-

ketplace for ideas." IMS Br. in Opp. i, 1, 10-11, 21-24; PhRMA Br. in Opp. i, 2, 13, 17-18, 26-27.

But the legislative findings at issue relate to a disclosure obligation that was *repealed* in 2008. As originally enacted, Section 4631(f) required pharmaceutical marketers to "disclose to the prescriber evidence-based information * * * describing the specific health benefits or risks of using other pharmaceutical drugs." Section 4631(f) thus previously required pharmaceutical marketers to correct the "imbalance" in "[t]he marketplace for ideas" by giving doctors information about alternatives to branded drugs, *i.e.*, generic equivalents and over-the-counter medicines. That requirement, however, was repealed in March 2008. Respondents therefore err by emphasizing legislative findings that are not tied to the present version of the statute.

C. Federal Provisions That Regulate The Dissemination Or Use Of Information By Private Parties Are Not Analogous To Section 4631

There are a number of federal statutory and regulatory provisions that regulate the dissemination or use of information by private parties for various reasons, including to protect individual privacy or to deter unwanted commercial solicitation. See Pet. Br. 35 (collecting federal statutes). For instance, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations limit the nonconsensual dissemination and use of patient-identifiable health information by health plans, health clearinghouses, and most health care providers. See 42 U.S.C. 1320d-2; 45 C.F.R. Pts. 160 and 164. In the communications context, the Telephone Consumer Protection Act of 1991 and its implementing regulations establish a national do-

not-call registry and restrict commercial telemarketers from calling numbers entered into the registry by residential telephone subscribers. See 47 U.S.C. 227(c); 47 C.F.R. 64.1200(c)(2).

Regardless of whether Section 4631 survives constitutional scrutiny, those federal provisions are distinguishable from Section 4631. HIPAA's regulations, for example, generally restrict the disclosure or use of patient-identifiable health information without that patient's written authorization. See 45 C.F.R. 164.502(a). The governmental interest in protecting patient privacy is clearly a substantial one. Moreover, HIPAA's regulations directly advance that interest, because they permit the nonconsensual disclosure or use of patient-identifiable information only in limited circumstances such as "treatment, payment, or health care operations," 45 C.F.R. 164.502(a)(1)(ii), or national "public health activities," 45 C.F.R. 164.512(b)(1)(i). Even in most of those circumstances, entities covered by HIPAA may release only the minimum necessary information. See 45 C.F.R. 164.502(b).

Thus, to the extent that respondents challenge the Vermont statute as so underinclusive that it genuinely fails to advance the proffered state interests, those arguments do not apply to federal statutes designed to restrict the dissemination or use of information by private parties. HIPAA and other such federal statutes directly advance substantial federal interests in a narrowly and reasonably tailored way. See, *e.g.*, *Mainstream Mktg. Servs., Inc.* v. *FTC*, 358 F.3d 1228, 1236-1246 (10th Cir.) (upholding the national do-not-call registry's telemarketing restrictions under *Central Hudson*), cert. denied, 543 U.S. 812 (2004). Accordingly, this Court's analysis of the "fit" between the Vermont stat-

ute and the State's legislative objectives should not affect those federal provisions.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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