No. 10-779

IN THE
Supreme Court of the United States

WILLIAM H. SORRELL, AS ATTORNEY GENERAL OF THE STATE OF VERMONT; PETER SHUMLIN, IN HIS CAPACITY AS GOVERNOR OF THE STATE OF VERMONT; AND DOUGLAS A. RACINE, IN HIS CAPACITY AS SECRETARY OF THE AGENCY OF HUMAN SERVICES OF THE STATE OF VERMONT,
Petitioners,
v.

IMS HEALTH INC.; VERISPAN, LLC; SOURCE HEALTHCARE ANALYTICS, INC., A SUBSIDIARY OF WOLTERS KLUWER HEALTH, INC.; AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Respondents.

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

BRIEF FOR PETITIONERS

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QUESTION PRESENTED

Prescription drug records, which contain information about patients, doctors, and medical treatment, exist because of federal and state regulation in this highly regulated field. This case is about information from prescription records known as "prescriber-identifiable data." Such data identifies the doctor or other prescriber, links the doctor to a particular prescription, and reveals other details about that prescription. Pharmacies sell this information to data mining companies, and the data miners aggregate and package the data for use as a marketing tool by pharmaceutical manufacturers. The law at issue in this case, Vermont's Prescription Confidentiality Law, affords prescribers the right to consent before information linking them to prescriptions for particular drugs can be sold or used for marketing. The Second Circuit held that Vermont's law violates the First Amendment, a holding that conflicts with two recent decisions of the First Circuit upholding similar laws. The question presented is:

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.

PARTIES TO THE PROCEEDING

Petitioners are Vermont Attorney General William H. Sorrell, Vermont Governor Peter Shumlin, and Vermont Secretary of Human Services Douglas A. Racine.*

Respondents are IMS Health Inc.; Verispan, LLC (now known as SDI Health LLC); Source Healthcare Analytics, Inc., a subsidiary of Wolters Kluwer Health, Inc. (now Source Healthcare Analytics, Inc., a subsidiary of Wolters Kluwer Pharma Solutions, Inc.); and Pharmaceutical Research and Manufacturers of America.

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* At the time the certiorari petition was filed, former Vermont Governor Jim Douglas and former Vermont Secretary of Human Services Robert Hofmann were listed as petitioners in their official capacities. Pursuant to this Court's Rule 35.3, counsel of record for petitioners notified the Clerk, by letter dated January 26, 2011, that Peter Shumlin and Douglas A. Racine were being substituted as petitioners in their official capacities as Governor and Secretary of Human Services of Vermont, respectively.

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INTRODUCTION

This case concerns Vermont's efforts to protect against the nonconsensual use of prescription records that reflect the prescribing decisions doctors make for their patients. A doctor typically writes a prescription after meeting with the patient to assess the patient's health. The prescription sets out confidential instructions for the patient's treatment, in a form required by law, to another health care provider – the patient's pharmacist. No part of this interaction is public. Yet, to the surprise and dismay of many physicians, some years ago pharmacy chains began selling prescription information to data mining companies. Those companies, in turn, sell the information to pharmaceutical manufacturers to use as a marketing tool for selling prescription drugs. Although patients' names are encrypted, the information sold by pharmacies identifies doctors and includes extensive details about their specific treatment decisions and prescribing practices. Pharmacies do not seek doctors' permission before selling this information, nor do they allow doctors to prevent the sale.

The Vermont law challenged here, like a similar Maine law the First Circuit recently upheld, takes a modest step that protects the traditional confidentiality of the doctor-patient relationship. The law allows doctors – not the government – to decide whether their prescribing information may be sold and used for marketing purposes. Absent the doctor's consent, the doctor's name must be redacted or encrypted, just like the patient's name, when Vermont pharmacies sell prescription records to data miners for commercial uses.

Pharmacies have no First Amendment right of access to doctors' prescribing information. They have the information only because state and federal law compels its creation and retention. Yet the Second Circuit concluded that Vermont's regulation of the nonconsensual use of this information violates the First Amendment rights of businesses that wish to purchase and use it for commercial transactions. The judgment is inconsistent with First Amendment principles and should be reversed.

OPINIONS BELOW

The opinion of the court of appeals (App.[1] 1a-67a) is not yet reported (but is available at 2010 WL 4723183). The memorandum opinion and order of the district court (App. 68a-118a) is reported at 631 F. Supp. 2d 434.

JURISDICTION

The judgment of the court of appeals was entered on November 23, 2010. The certiorari petition was filed on December 13, 2010, and granted on January 7, 2011 (131 S. Ct. 857). The jurisdiction of this Court rests on 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The First Amendment to the United States Constitution provides in relevant part:

> Congress shall make no law . . . abridging the freedom of speech[.]

Vermont's Prescription Confidentiality Law, codified at Vt. Stat. Ann. tit. 18, § 4631, and the legislative

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[1] References to "App. _a" are to the appendix filed with the certiorari petition; to "JA_" are to the Joint Appendix filed with this brief; and to "A-_" are to the appendix filed in the Second Circuit.

findings set forth in 2007 Vt. Acts & Resolves No. 80, are reproduced at App. 129a-140a.

STATEMENT

In autumn 2006, Vermont's largest physician organization expressed its serious concern about prescription drug data mining. JA376-78. The Vermont Medical Society had recently learned that pharmacies sell information from prescription drug records to data mining companies, which then sell the data to pharmaceutical manufacturers for use as a marketing tool. *Id.*; JA399-400, 421. Pharmaceutical manufacturers do not present the data to doctors, but instead use it in shaping marketing strategies intended to promote the sales of particular drugs. The Medical Society unanimously resolved that the use of these "detailed marketing profiles" by pharmaceutical sales representatives interfered with "the doctor-patient relationship," which requires "confidentiality and privacy to work effectively." JA376-78. The use of physicians' prescribing histories in this way is "an intrusion into the way physicians practice medicine." JA378. The Vermont legislature responded to the Medical Society's concerns by enacting the statute at issue here: a consent-based measure that allows doctors to block the nonconsensual use of their prescribing histories. Vt. Stat. Ann. tit. 18, § 4631.

A. Regulatory Context

To protect public health and safety, the dispensing of prescription drugs is thoroughly regulated. The federal Food and Drug Administration (FDA) approves new drugs and decides whether and for how long a prescription is required for each drug. *See*, *e.g.*, 21 U.S.C. § 353(b)(1) (requiring written prescription for certain drugs); 21 C.F.R. § 310.200 (duration of prescription requirement). Federal law also close-

ly regulates prescription drug labels and advertising. *E.g.*, 21 U.S.C. § 331(a)-(c) (misbranded drugs); *id.* § 352 (drug labels and advertising); 21 C.F.R. pts. 201-203 (regulating drug labeling, advertising, and marketing).

Prescription drugs may only be dispensed by licensed pharmacists and practitioners. *See* Vt. Stat. Ann. tit. 26, §§ 2041(a), 2022(14). Vermont's licensing requirement dates back to 1894. *See* 1894 Vt. Acts & Resolves No. 99. Vermont's current rules governing pharmacists cover every aspect of the profession, including licensing, physical space, security, staff, recordkeeping, reference materials, and advertising. *See generally* Vt. Bd. of Pharmacy Admin. Rules (eff. Oct. 2009) (Pharmacy Rules).[2]

Only a physician or other authorized health care provider may prescribe a drug. *Id.* § 8.16. A valid prescription is one that "aris[es] from a prescriber-patient relationship which includes a documented patient evaluation adequate to establish diagnoses." *Id.* § 9.2. A Vermont law first enacted in 1978 generally requires pharmacists to dispense a generic form of a drug if available, unless the prescriber requires a brand-name drug. *See* Vt. Stat. Ann. tit. 18, §§ 4605-4606.

The Pharmacy Rules specify the form and content of a valid prescription. The prescription must include the name and address of both patient and prescriber; the drug name, dosage, quantity, and refill information; instructions for the patient; and the prescriber's signature. Pharmacy Rules § 9.1. The

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[2] Both the 2009 Pharmacy Rules and the earlier rules that they replaced are available on the Vermont Secretary of State's website: http://vtprofessionals.org/opr1/pharmacists/rules.asp.

rules set forth requirements for prescription pads themselves as well as for electronic prescription orders. *Id.* §§ 9.5, 9.9, 9.11, 9.12.

Along with ensuring that prescriptions meet these requirements, pharmacists must adhere to mandated standards for their own records. A pharmacist must maintain a "patient record system" that "shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing." *Id.* § 9.24. The pharmacist must make a reasonable effort to obtain the patient's full name and address, age, gender, and other health information, including allergies. *Id.* The Pharmacy Rules require retention of this information, together with records of specific prescriptions, for no less than three years. *Id.* §§ 9.24-9.27.

These requirements that pharmacies collect and maintain information have long carried corresponding obligations to maintain privacy and confidentiality. "Prescription and other patient health care information shall be secure from access by the public and the information shall be kept confidential." *Id.* § 8.7(c); *see id.* §§ 9.14, 11.15 (requiring security measures); *id.* § 9.15 (limiting access to confidential information); *see also* Vt. Stat. Ann. tit. 18, § 4211 (restricting disclosure of records of regulated drugs). Professional discipline may be imposed on a pharmacist who "[d]ivulg[es] or reveal[s] to unauthorized persons patient or practitioner information or the nature of professional pharmacy services rendered." Pharmacy Rules § 20.1(i).

Vermont's regulation of prescription records supplements the federal regulation of prescription and other health care records. Prescription records are

health care records under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its regulations. *See* 45 C.F.R. § 160.103 ("health care" includes dispensing prescription drugs; "health information" includes "provision of health care").[3] HIPAA restricts access to and use of personally identifiable health information, and sets standards for removing that information from – or "de-identifying" – protected health information. *E.g.*, *id.* §§ 164.502-164.514.[4]

Of particular relevance to this case, HIPAA prohibits the sale of protected health information without consent for non-health care purposes, including marketing. *See* 42 U.S.C. § 17935(d); *id.* § 17936(a) (excluding "marketing" from definition of "health care operation"); 45 C.F.R. § 164.508 (requiring authorization for use of protected health information for marketing; exempting certain marketing by covered entities). Violations of HIPAA carry criminal penalties. 42 U.S.C. § 1320d-6(b).

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[3] HIPAA's privacy rules do not preempt state laws that are more protective of "the privacy of individually identifiable health information." *See* 42 U.S.C. § 1320d-7(a)(2)(B). *See also* 65 Fed. Reg. 82,462, 82,471 (Dec. 28, 2000) (explaining that HIPAA regulations are a "federal floor of privacy protections that do[] not disturb more protective rules or practices"). HIPAA creates "a mandatory floor, which other governments and any covered entity may exceed." *Id.*

[4] HIPAA's regulations require prior authorization or consent for many uses of protected health information. *See* 45 C.F.R. §§ 164.508, 164.510. The regulations also permit use of protected health information for a variety of purposes *without* authorization, including for "public health activities," "health oversight activities," and research in certain circumstances. *Id.* § 164.512(b)(1)(i) & (iii), (d)(1), (i).

B. Prescription Drug Data Mining

Notwithstanding the confidentiality rules that govern access to and use of prescription records, pharmacies have profited in recent years by selling information from their regulated prescription records to data mining companies (or "data vendors," JA246). JA249. The information sold to data vendors includes "the prescriber's name and address, the name, dosage and quantity of the drug, the date and place the prescription is filled and the patient's age and gender." App. 70a; *see* JA133-34, 160. The trial evidence showed that pharmacies sell the data only to the three data vendors who brought this case, IMS, Verispan, and Wolters Kluwer. JA248, 255 (testimony of CVS witness). Pharmacies do not seek consent from doctors before selling this information. JA253-54.

The information the data vendors purchase, often called "prescriber-identifiable data," reveals the prescribing patterns of particular physicians. It shows, for example, the number of prescriptions written for a drug; prescriptions for similar drugs; duration and refills of prescriptions; and changes from one drug to another ("switching"). *E.g.*, JA160, 470-71, 473-76, 482-83.

Although the patient's name is encrypted, each patient identifier is unique, which allows data vendors to correlate prescriptions and doctors to individual patients. Data vendors "track [a] person over time and determine behaviors" – including the drugs prescribed and the doctors who wrote the prescriptions – and identify changes in prescribing patterns. JA145-46, 149, 157-58, 160-61. Because patients are tracked individually, respondents' data products show whether a given prescription is a new prescrip-

tion, a re-fill of an existing prescription, or a change in treatment for the patient (either a drug switch or an added drug). JA482-83 ("True Patient Measures" allows pharmaceutical manufacturers to see "who is switching to or from their companies' drugs").

A Verispan representative testified at trial that the company has "track[ed] the activities of over two hundred million" patients, and explained that its "linking codes" allow it to "link up" any of what it calls "the five P's" – the patient, product, prescriber, payer, and pharmacy. JA156, 158, 160-61. Indeed, Verispan describes its data products as a "scoreboard." JA161-62 ("[I]f you consider the marketplace a game that for-profit companies are taking on, our data . . . [is] essentially the scoreboard.").

Despite the encryption of patients' names, Verispan matches individual prescription records to patient surveys taken by a marketing company. JA164-65. This allows pharmaceutical manufacturers to learn "what was and was not discussed during the doctor appointment," and whether a prescription was filled. *Id.*; JA484 ("If you don't know what doctors are saying to their patients, you're missing part of the story.").

Data vendors license the data purchased from pharmacies to pharmaceutical companies, which pay a substantial fee to use it. JA134-35, 141. In fact, pharmaceutical manufacturers are "essentially the only paying customers of the data vendor industry." App. 92a. The data vendors treat their products as highly proprietary – the licensing agreements prohibit pharmaceutical manufacturers from publishing or disclosing data that identifies specific prescribers. JA135, 152-53, 166-67. Pharmaceutical manufacturers prohibit their sales representatives from discuss-

ing the data with doctors or "anyone." JA463. As one manufacturer explained, discussing a prescriber's prescription history with the prescriber is "not part of what the reps should be discussing with physicians" because "[i]t is not part of a sales call, it is not part of a selling process. That's an underpinning metric." *Id.*

The trial record reveals how doctors' names and prescribing habits travel from pharmacy records to the laptop computers of pharmaceutical sales representatives, or "detailers." *E.g.*, JA366, 510. Weekly data reports allow sales representatives to monitor the success of particular marketing strategies and tools, to allocate samples, gifts, and paid speaker programs in ways that increase sales, and to decide if doctors are "responding positively" to promotional tactics. JA469, 473, 481, 488. Email "alerts" tell sales representatives if doctors are "underperforming" or switching patients to other drugs. JA489-90. Detailers use this prescribing information as a "targeting tool," to identify and target the "most valuable" doctors with potential to drive market share. JA481-82; *see* JA525 (directing detailers to focus on high prescribers and "delete" others from target lists). They also use the data to "push the physician's behavior toward their product." JA325.

Pharmaceutical manufacturers use prescribing data to monitor sales quotas and set compensation. JA494-95. Sales managers use prescribing information for specific doctors to press detailers to achieve sales goals, by, for example, identifying doctors that "are not writing for you" and advising that "if you move 10 of these doctors by 5 percentage points, you will hit your goal easily." JA516. The record shows that pharmaceutical manufacturers employ thou-

sands of sales representatives and spend close to $8 billion annually (excluding the cost of free samples) marketing drugs to doctors. App. 71a; JA169; A-168.

C. Vermont's Prescription Confidentiality Law

1. During the 2007 legislative session, the Vermont legislature examined how prescription drug data is used, without consent, for marketing prescription drugs. Several committees spent months considering evidence from a range of interested parties, including the Vermont Medical Society, doctors, public officials, scholars, consumer groups, trade organizations, pharmacists, data vendors, and PhRMA and some of its members. A-4126-28, 4343-44 (witness lists); *see generally* A-405-1482 (committee hearing transcripts).

The legislature enacted the Prescription Confidentiality Law to "advance the state's interest in protecting the public health of Vermonters, protecting the privacy of prescribers and prescribing information, and to ensure costs are contained" in the health care context. Vt. Stat. Ann. tit. 18, § 4631(a); *see* 2007 Vt. Acts & Resolves No. 80, § 17 (Confidentiality of Prescription Information); 2008 Vt. Acts & Resolves No. 89, § 3 (amending Act 80). The legislature decided to achieve these goals by allowing doctors to consent before their prescription information can be sold or used for marketing prescription drugs.

The law addresses the sale and commercial use of prescriber-identifiable data in Vermont in two ways. First, the law directly regulates pharmacies' use of prescription records, which the statute terms "regulated records." Vt. Stat. Ann. tit. 18, § 4631(b)(9). Unless the prescriber consents, pharmacies cannot "sell, license, or exchange for value" regulated records that identify a prescriber or "permit the use"

of such information for marketing or promoting a prescription drug. *Id.* § 4631(d).[5]

Second, the statute regulates the use of prescriber-identifiable data by pharmaceutical manufacturers and pharmaceutical marketers. *Id.* Pharmaceutical manufacturers may obtain data that identifies prescribers for certain purposes, such as safety notices and drug recalls. *Id.* § 4631(e)(4). If manufacturers do receive data for such purposes, they are bound by the statutory restrictions on its use.

The law does not regulate data vendors. But because the data-vendor respondents purchase prescription information from pharmacies, the statute affects their data supply. *See* App. 39a n.5 (Livingston, J., dissenting) ("pharmacies are the principal, if not sole, source" of data aggregated and licensed by data vendors).

The statute permits prescribers to consent to the marketing use of their prescribing histories; prescribers may do so at any time and are asked for their preference on their license application and renewal forms. The Department of Health makes the list of consenting prescribers publicly available. Vt. Stat. Ann. tit. 18, § 4631(c).

The law does not prohibit uses of prescription records containing prescriber information for health care purposes, such as dispensing drugs, treatment,

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[5] The statute's restriction on the sale and use of prescriber-identifiable data also applies to insurers, self-insured employers, electronic transmission intermediaries, and similar entities. Vt. Stat. Ann. tit. 18, § 4631(d). "Electronic transmission intermediaries" provide computer infrastructure linking providers, pharmacies, and insurers for "secure transmission" of prescriptions, refills, claims, payments, and other prescription drug information. *Id.* § 4631(b)(1).

pharmacy reimbursement, formulary compliance, educational materials for patients, drug recalls, and safety notices. *Id.* § 4631(e)(1), (2), (4). The law also does not require prescriber consent for use of prescriber data in health care research and clinical trials, and for certain law enforcement and regulatory purposes. *Id.* § 4631(e)(1), (4)-(6).

The Prescription Confidentiality Law restricts only the use of information identifying the prescriber. If the data does "not identify a prescriber," a pharmacy may sell the data without consent. *Id.* § 4631(e)(7). The law applies only to prescription records written by a Vermont prescriber and dispensed within Vermont. *Id.* § 4631(b)(9).[6]

2. The Prescription Confidentiality Law was adopted near the end of the 2007 legislative session, as a section of Act 80. 2007 Vt. Acts & Resolves No. 80, § 17. Act 80 included several provisions addressing prescription drugs and health care. It funded an evidence-based education program for doctors and created a state-law remedy for prescription drug advertising that violates federal law, among other measures. *Id.* §§ 14, 21.

Section 17 of Act 80 originally included a provision requiring pharmaceutical marketers to provide information about alternative drug treatment options to doctors, including the benefits and costs of other drugs. *Id.* § 17. Early in the 2008 legislative session, the legislature amended the Prescription Confidentiality Law in part and removed this requirement

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[6] When the law went into effect in 2009, the Attorney General's Office advised that it did not apply to prescription information acquired before the effective date of the law.

entirely. 2008 Vt. Acts & Resolves No. 89, § 3 (removing § 4631(f)).

Act 80 included findings supporting the (later repealed) mandatory presentation of drug alternatives by detailers, the evidence-based education program, the statute at issue in this case, and other provisions of the Act. *Id.* § 1; App. 134a-140a. The findings address escalating prescription drug costs and explain Vermont's efforts to "control costs while maintaining best practices in drug prescribing." *Id.*, Findings 9-12, 14. The legislature documented concerns with pharmaceutical marketing. It observed that the "marketplace for ideas on medicine safety and effectiveness is frequently one-sided" because of the resources invested in marketing. Finding 4. In addition, the legislature addressed the nonconsensual use of doctors' prescribing information as a marketing tool. Findings 20, 22-29. The legislature found that health care providers have a "reasonable expectation" that prescription information "will not be used for purposes other than the filling and processing of the payment for that prescription." Finding 29. "Prescribers and patients do not consent to the trade of that information to third parties, and no such trade should take place without their consent." *Id.*

3. During their deliberations, legislators learned firsthand the objections by doctors to using their prescribing information for marketing. Vermont physicians, many of whom had no idea their prescription histories were being sold and used in this manner, felt it was an "invasion of the physician's privacy." JA419-20. Doctors found the practice "outrageous" (JA404-05) and "demeaning" (JA335), considered pharmaceutical companies to be "spying" on doctors

(JA407-08), and felt as though the sales representatives had information as sensitive as a bank account number (JA412). One doctor suggested that not two in a hundred doctors would approve of the practice. JA411. The Medical Society formally opposed respondents' practices. JA419-20.

Vermont doctors were not alone. A physician in Maine, where legislation similar to Vermont's was enacted, testified that the marketing use of doctors' prescribing data results in doctors being "targeted" to prescribe newer medications over equally effective, cheaper drugs based on incomplete sales pitches, and that "the privacy and trust of the physician-patient relationship is disturbed." JA382-83. Another testified that, "like the majority of physicians, I don't want my prescribing habits monitored so that organizations and corporations can profit by selling or using that information with the goal of trying to then subvert what I do." JA380. A former president of the American College of Physicians succinctly opposed the use of prescribing histories for marketing: such use is "not about quality. It's about sales." JA379. Even PhRMA has recognized physicians' objection to the practice: "Many physicians are disturbed that pharmaceutical sales representatives have information about the individual physician's prescribing practices. There are persistent anecdotal reports of sales representatives using prescriber-identifiable information in ways that physicians find inappropriate or offensive." JA496.

Doctors also testified that limiting the nonconsensual use of prescribing information would help to contain health care costs and promote evidence-based prescribing. JA382-83, 402, 411, 420. Physicians explained how marketing using prescribing data

drives up prescription drug costs and threatens patient safety. The use of prescribing data as a marketing tool promotes the overuse of new and expensive prescription drugs that frequently do not enhance patient health and carry risks of unknown side effects. *See*, *e.g.*, A-4301-14.

D. District Court Proceedings

Respondents, plaintiffs below, sued to prevent the Prescription Confidentiality Law from taking effect.[7] The data-vendor plaintiffs and PhRMA brought separate facial challenges claiming Vermont's law violated the First Amendment and requesting injunctions barring its enforcement. JA72-74, 126-27. The data-vendor plaintiffs also asserted a claim under the dormant Commerce Clause. JA125-26. PhRMA sought to enjoin two other statutes that were part of Act 80, including the fee intended to fund the evidence-based education program for doctors. JA71-72. PhRMA abandoned these claims after losing in the district court.

The district court consolidated the cases and held a five-day bench trial. The court heard testimony from eighteen witnesses and admitted "reams of exhibits, including the entire legislative history," into evidence. App. 78a. The State submitted hundreds of pages of exhibits, including documents obtained from data vendors and pharmaceutical manufacturers. A-3779-4019. These documents, a small sampling of which is reproduced in the Joint Appendix, show how doctors' prescribing histories are used by respondents. The State also relied on testimony from three

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[7] The data-vendor plaintiffs had filed suits to block similar laws in New Hampshire and Maine.

practicing doctors and medical scholars, a health policy economist, and a former sales representative.

The court made extensive findings about prescription drugs, the pharmaceutical industry, and the use of doctors' prescribing information for pharmaceutical marketing. *E.g.*, App. 91a-99a. The court described the use of the data as "covert," because the "data vendor plaintiffs all prohibit detailers from disclosing [prescriber-identifiable] data to a prescriber." App. 94a & n.15. Although plaintiffs contended at trial that doctors are not influenced by detailing and that using prescribing histories makes detailing more educational and efficient, the court found otherwise. The "nature of the industry, plaintiffs' own documents, and scientific research" all show that marketing influences doctors. App. 92a. The use of prescribing information, the court found, "amplifies the influence and effectiveness of detailing but does not add to its purported educational value." App. 91a. The court further found that doctors' prescribing data "is not necessary to determine the specialty of a doctor or whether a prescriber would be interested in a particular drug." App. 95a. Sales representatives can "easily track a doctor's specialty" and talk to doctors' staff about the drugs being promoted. *Id.*

The court upheld the statute as a permissible regulation of commercial speech. Applying *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980), the court held that Vermont's law directly advances the State's substantial interests in controlling health care costs and improving patient safety.[8] App. 87a-99a. The court

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[8] The court did not address the State's privacy interest. App. 88a. *But see* App. 87a.

grounded this conclusion in industry documents; testimony of Vermont's experts, Dr. Kesselheim, Dr. Wazana, and Dr. Rosenthal; and testimony from plaintiffs' witnesses. *E.g.*, App. 90a-92a, 95a-96a. The court found, as the legislature had, that "new prescription drugs have a higher cost than older drugs but do not necessarily provide additional benefits." App. 90a-91a. Likewise, the evidence supported the legislature's findings about the public health risks caused by the "over-prescription of new drugs." App. 95a-96a. The court concluded that "[d]etailing encourages doctors to prescribe newer, more expensive and potentially more dangerous drugs instead of adhering to evidence-based treatment guidelines." App. 95a. The court recounted evidence about drugs like Baycol and Vioxx, which were widely and unnecessarily over-prescribed before being withdrawn from the market for safety reasons. App. 96a. Based on the record, the court found that the use of prescribing data "lead[s] to over-prescription of new drugs that may not be better than a generic alternative." App. 92a.

As to *Central Hudson*'s tailoring requirements, the court described the law's "limited restraint," App. 87a, as "a targeted response to the harm of over-prescription caused by detailers' use of" prescriber-identifiable data, App. 99a. The court emphasized that the law's restriction only applies to "prescribers who do not want to have their prescribing histories used for marketing." App. 98a. The law does not prohibit detailing, does not prevent detailers from providing information about drugs, and lets prescribers allow the use of their data for marketing if they wish. App. 99a.

The court accordingly held that the Prescription Confidentiality Law did not violate the First Amendment. The court also entered judgment for defendants on plaintiffs' other claims. App. 99a-118a.

E. Second Circuit Ruling

A divided panel of the Second Circuit reversed, ruling that the statute regulated speech, App. 14a-17a, and did not survive intermediate scrutiny under *Central Hudson*, App. 20a-34a. In reaching this holding, the Second Circuit declined to follow the approach taken by the First Circuit in two recent decisions upholding similar laws passed by Maine and New Hampshire. *See IMS Health Inc. v. Mills*, 616 F.3d 7 (1st Cir. 2010) (upholding Maine's restriction on the use of prescriber-identifiable data), *petition for cert. pending*, No. 10-984 (filed Jan. 28, 2011); *IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008) (upholding New Hampshire's restriction on the use of prescriber-identifiable data), *cert. denied*, 129 S. Ct. 2864 (2009).

The Second Circuit majority agreed that Vermont had important interests in controlling costs and promoting public health, but found the State's interest in privacy to be "too speculative." App. 23a. The court concluded that the State had no valid privacy interest because the law did "not forbid the collection of [prescriber-identifiable] data in the first instance." App. 22a. As to the two state interests it accepted as important, the court found that the law would not directly advance those interests, and was not narrowly tailored. App. 24a-34a. The Second Circuit analogized Vermont's restriction on the nonconsensual use of prescriber-identifiable data to advertising bans and to regulations that entirely suppress commercial

speech. App. 26a (citing *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002)). Vermont's law, according to the majority, was no "less categorical" than laws that ban advertising of legal products to the public. App. 32a.

Judge Livingston dissented, arguing that the majority misconstrued the statute, erred in applying *Central Hudson*, and created "precedent likely to have pernicious broader effects in a complex and evolving area of First Amendment law." App. 35a. Judge Livingston began her analysis with the recognition that the statute prevents pharmacies from selling regulated prescription records. App. 38a-40a. She sharply criticized the majority for not recognizing that "Vermont's law operates principally to prevent [plaintiffs] from obtaining otherwise private [prescriber-identifiable] data, and as such, does no more than restrict their unfettered *access* to information." App. 40a.

Judge Livingston further found that the majority "overstate[d]" the State's burden under *Central Hudson*, noting that both Supreme Court and circuit precedent called for "deference to legislative findings in the context of restrictions on commercial speech – and, particularly, commercial speech in a heavily regulated industry." App. 56a. Finally, Judge Livingston concluded that the statute directly advanced all three interests Vermont had identified, forcefully disagreeing with her colleagues' disregard for Vermont's interest in protecting privacy. App. 59a-60a, 52a-53a.

SUMMARY OF ARGUMENT

Vermont's law does nothing more than require a doctor's consent before the doctor's nonpublic prescribing information may be sold by pharmacies and used for marketing prescription drugs. Pharmacies have this prescription information only by virtue of government regulation. They do not have an unfettered right to sell or use it for purposes unrelated to the patient's care. Nor do respondents have a right to buy these health care records. Respondents' First Amendment claim should accordingly be rejected.

I. Respondents' claim in this case rests on the unpersuasive notion that, having required doctors and patients to disclose identifying information to pharmacies to obtain medicine, the government nonetheless violates the First Amendment by restricting what pharmacies do with that information. The Court has recognized that, when the government compels production of otherwise private information, it may permissibly restrict its further use or disclosure. *See Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 36 (1984). The Court's First Amendment precedents also recognize a right not to speak and a right to be let alone. Laws that allow individuals to control the use of their nonpublic information serve those interests and do not violate the First Amendment.

Based on these principles, Vermont's Prescription Confidentiality Law should be upheld. Prescription records exist because of state and federal law. They reveal information that traditionally has been private, namely, the doctor's treatment decision for the patient. The First Amendment does not give pharmacies or any health care providers a right to sell or use such health care records without consent. Because doctors and patients are compelled to pro-

vide information to pharmacies, and because pharmacies have no First Amendment right to use that information for non-health care purposes, Vermont's law does not offend the First Amendment. Rather, allowing doctors to control the commercial use of their prescribing information is consistent with First Amendment values.

The Second Circuit's contrary conclusion was erroneous. The court of appeals did not account for the fact that doctors are compelled to provide identifying information to pharmacies in the first place. Similarly, the Second Circuit failed to consider the law in the context of extensive and longstanding restrictions on use and disclosure of health care records.

II. Even if viewed as a restriction on commercial speech, the law withstands scrutiny and should be upheld.

To begin with, this consent-based restriction bears no resemblance to the categorical bans on advertising to the public that the Court has invalidated under *Central Hudson*. The law does not prevent pharmaceutical manufacturers from marketing drugs to doctors, nor does it control the information they provide. Instead, it allows doctors, if they choose, to avoid intrusive marketing strategies that make use of their nonpublic prescribing information.

The law directly advances the State's substantial interests in protecting medical privacy, controlling health care costs, and protecting public health. The legislative and trial records provide substantial support for the district court's findings regarding costs and safety. And, as the First Circuit concluded in *Mills*, allowing doctors to control the commercial use of their prescribing histories directly advances a real and substantial privacy interest. *See* 616 F.3d at 20.

Finally, the Second Circuit's *Central Hudson* analysis was gravely flawed. The court of appeals mistakenly reasoned that the statute reflected an effort by the State to control the information provided to doctors. It does not. Like statutes that allow consumers to avoid unwanted mail, unwanted commercial solicitations, and unwanted targeted marketing, Vermont's law allows doctors, not the government, to decide whether their nonpublic prescription information should be sold to pharmaceutical manufacturers for use as a marketing tool. This modest, consent-based restriction readily satisfies *Central Hudson*.

ARGUMENT

I. VERMONT'S LAW IS A CONSTITUTIONAL RESTRICTION ON ACCESS TO NONPUBLIC INFORMATION.

The Court's analysis should begin with "the undisputed fact that Vermont pharmacies have access to and collect prescription information only under the direction and authority of state law." App. 40a (Livingston, J., dissenting). Indeed, the First Amendment inquiry both begins and ends with that fact. *See* App. 43a. Pharmacies do not have a First Amendment right to sell health care records or to allow their use for purposes unrelated to the provision of health care. Government regulations in this field are properly viewed as restrictions on access to information in an area where the government has substantial regulatory authority.

Vermont does not contend that all government restrictions on access to nonpublic information are exempt from First Amendment review. *See*, *e.g.*, *Los Angeles Police Dep't v. United Reporting Publ'g Corp.*, 528 U.S. 32, 43 (1999) (Ginsburg, J., concurring) (although State could decide not to give out information at all, it could not release "information only to those

whose political views were in line with the party in power"). Here, however, the challenged regulation applies to health care information that doctors and patients are forced to provide and is directed at the nonconsensual commercial use of that information by third parties. Given the close regulation of prescription records, and the tradition of confidentiality for all medical records, Vermont's statute does not restrict speech protected by the First Amendment.

A. Restricting access to or use of nonpublic information held by a regulated entity does not violate the First Amendment.

The First Amendment permits government restrictions on access to or use of nonpublic information, particularly where the information has been produced involuntarily. Such restrictions are common for information held by the government, *see*, *e.g.*, Privacy Act, 5 U.S.C. § 552a, and this Court has upheld restrictions on the use of nonpublic information in the government's possession, *see United Reporting*, 528 U.S. at 40; *cf. NASA v. Nelson*, 131 S. Ct. 746, 761-62 (2011) (describing restrictions on use of information obtained in background checks). Restrictions on access to or use of nonpublic information held by regulated entities are also common, *see infra* pp. 30, 35-36, but until now this Court has not considered a First Amendment challenge to such a law. Although this case presents an issue of first impression, several key principles that flow from the Court's rulings provide firm support for the constitutionality of Vermont's law.

1. When the government requires its citizens to provide information, to either the government or a private party, the First Amendment allows restrictions on use or further disclosure of that information.

The First Amendment's protection of the "free exchange of ideas," *Denver Area Educ. Telecomms. Consortium v. FCC*, 518 U.S. 727, 740 (1996), does not extend to all information that the government compels citizens to create or provide. When regulation has "coerced production of information" for a particular purpose, *see Seattle Times*, 467 U.S. at 36, the First Amendment does not mandate unrestricted access to and use of the information by others.

Seattle Times shows that a person's right, if any, to access nonpublic information is a crucial first inquiry in the First Amendment context. There, the Court upheld a protective order that barred publication of information a newspaper obtained through discovery. *Id*. at 34. Relying on *Zemel v. Rusk*, 381 U.S. 1, 16-17 (1965), the Court reasoned that a "litigant has no First Amendment right of access to information made available only for purposes of trying his suit." 467 U.S. at 32; *see also Fla. Star v. B.J.F.*, 491 U.S. 524, 534 (1989) (State could not ban publication of publicly available rape victim's name, but could restrict disclosure of information "entrusted" to it and "to the extent sensitive information rests in private hands, the government may under some circumstances restrict its nonconsensual acquisition").

Moreover, where the government has authority to restrict access to or use of nonpublic information, such restrictions may be based on the intended use of the information. This Court has not held that restrictions on access must be all-or-nothing. In *United Reporting*, the Court rejected a First Amendment challenge to a California statute that allowed access to arrestee information for "scholarly, journalistic, [and] political" purposes, but not for commercial use. 528 U.S. at 40-41. The Court held that the statute

did not abridge "anyone's right to engage in speech . . . commercial or otherwise," but instead "regulate[d] access to information in the hands of the police department." *Id.* at 40. A person seeking access had to "qualify under the statute to do so." *Id.*

2. The Court's First Amendment decisions recognize both a right not to speak, *see*, *e.g.*, *Wooley v. Maynard*, 430 U.S. 705, 714 (1977), and a right to be "let alone," *Rowan v. U.S. Post Office*, 397 U.S. 728, 736 (1970). "The essential thrust of the First Amendment is to prohibit improper restraints on the *voluntary* public expression of ideas . . . . There is necessarily, and within suitably defined areas, a concomitant freedom *not* to speak publicly, one which serves the same ultimate end as freedom of speech in its affirmative aspect." *Harper & Row Publishers, Inc. v. Nation Enters.*, 471 U.S. 539, 559 (1985) (quotations omitted). Both this Court and others have rejected First Amendment challenges to laws that allow for consumer control. *See Rowan*, 397 U.S. at 736 (upholding law allowing consumer to "exercise control over unwanted mail"); *Mainstream Mktg. Servs. v. FTC*, 358 F.3d 1228, 1242-43 (10th Cir. 2004) (upholding "Do Not Call" Registry, which "restricts only calls that are targeted at unwilling recipients"); *cf. United States v. Playboy Entm't Grp., Inc.*, 529 U.S. 803, 815 (2000) (invalidating restriction on transmission of sexually-themed programming because "targeted blocking [by household] is less restrictive than banning"). Where the government has compelled production of private information, consent-based restrictions on its further use serve these important interests and are constitutional.

3. The commercial use of nonpublic information is better described as commercial conduct than commercial speech. *See Ayotte*, 550 F.3d at 51-53. Regulations that allow individuals to limit commercial uses of their personal information should be evaluated in that context. This Court frequently has observed the close connection between commercial conduct and commercial speech. The commercial speech doctrine is grounded in the "common-sense distinction between speech proposing a commercial transaction, which occurs in an area traditionally subject to government regulation, and other varieties of speech." *United States v. Edge Broad. Co.*, 509 U.S. 418, 426 (1993) (quotations omitted); *see Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 n.24 (1976). In *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447 (1978), the Court noted that labor, securities, and antitrust laws permissibly regulate commercial activities notwithstanding their communicative elements. Not every commercial communication is a form of protected speech, because "the State does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of that activity." *Id.* at 456; *see also Rumsfeld v. Forum for Academic & Institutional Rights, Inc.*, 547 U.S. 47, 62 (2006) (noting that antidiscrimination laws regulate conduct, despite requiring removal of "White Applicants Only" signs); *cf. Reno v. Condon*, 528 U.S. 141, 148 (2000) (upholding Driver's Privacy Protection Act of 1994 against Commerce Clause challenge; holding that drivers' license information is "used in the stream of interstate commerce" and is, "in this context, an article of commerce"). Regulations that allow individuals to control the sale and commercial use of their nonpublic information are appropriately viewed

as regulations of commercial conduct. *Cf. Rumsfeld*, 547 U.S. at 64 (forum for recruiting services is not "inherently expressive").

B. Vermont's restriction on nonconsensual access to and use of nonpublic prescription information for marketing is constitutional.

These principles underscore the "plainly legitimate sweep" of Vermont's law. *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 449-51 (2008) (setting out standard applied to facial challenges, which are "disfavored").[9] Vermont may regulate pharmacies' use of nonpublic prescription drug records by allowing doctors to decide whether their prescribing practices may be used as a marketing tool. Prescription drug records are private health care records, and there is no tradition of public or commercial use of health care information. Because pharmacies have no First Amendment right of access to the information, Vermont's modest restriction on their use of the information is constitutional.

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[9] Because respondents brought a facial challenge, before the statute took effect, this case does not present a challenge to the application or enforcement of the statute. Respondents seek a declaration that the statute is unconstitutional and an injunction barring enforcement. JA74, 126-27. Although respondent data miners contend that their complaint includes "as-applied" claims, the district court could not have adjudicated such claims because it issued its judgment before the statute took effect. JA39-40; App. 121a-128a. Likewise, although the Second Circuit did not state that it was deciding a facial challenge, that is the only reasonable interpretation of its holding. *See* App. 34a. In any event, what respondents label "as-applied" challenges are indistinguishable from a facial challenge. *See* JA121, 126 (seeking declaration that statute is unconstitutional "as applied to commercial speech" and "as applied to non-commercial speech").

Respondents, in turn, have no First Amendment right to buy nonpublic health care records.

1. Pharmacies have information about doctors' prescribing practices only because the government requires doctors and patients to provide it. When a pharmacy dispenses a prescription, it conducts a transaction that is regulated in every respect, including collection and maintenance of the prescription record. *See supra* pp. 3-6; JA252-53. Pharmacies' acquisition of prescription information in this manner does not give them First Amendment rights in the further use of that information.

The Court's reasoning in *Seattle Times* applies here with equal force. There the newspaper petitioners "gained the information they wish[ed] to disseminate only by virtue" of the discovery process, which was a "matter of legislative grace." 467 U.S. at 32. "[D]iscovery is provided for the sole purpose" of litigation and both litigants and third parties have significant privacy interests in the information they are required to produce – information that would otherwise be private. *See id.* at 34-35. Doctors and patients are similarly required by law to give pharmacies private information – namely, the doctor's treatment decision for the patient. The fact that pharmacies have acquired this nonpublic information for a specific regulatory purpose does not give them a First Amendment right to sell or use the information for other purposes. As Judge Livingston observed, "[h]aving mandated the collection of that otherwise highly confidential information, the state unquestionably has an interest in controlling its further dissemination." App. 40a (Livingston, J., dissenting).

Indeed, Vermont's law simply adds one further restriction to a series of existing federal and state

restrictions on the use of nonpublic health care records. *See supra* pp. 5-6 & nn.3-4. Vermont pairs the obligation to collect prescription information with restrictions on pharmacies' use of it. The pharmacy's access to the information in prescription records comes with "conditions clearly attached," App. 42a, and those conditions include severe restrictions on disclosure and substantial penalties for violations of those restrictions. *E.g.*, Pharmacy Rules §§ 1.11, 20.5 (discipline for unprofessional conduct); 42 U.S.C. § 1320d-6(b) (criminal penalties for HIPAA violations). For this reason, pharmacies are like the newspaper in *Seattle Times*, which only received "access to . . . information" subject to "restraints on the way in which the information might be used." 467 U.S. at 32.

The real dispute here centers not on the constitutionality of these restrictions generally but on their permissible scope. No one disputes that the government may prevent pharmacies from selling prescription records in their original form, without redacting the patient's name. The First Amendment should not be interpreted in a way that makes a constitutional issue of the redaction requirements for each piece of information in a health care record.

Nor is it relevant for First Amendment purposes that the statute allows pharmacies and others to use the unredacted information for health care purposes but not for commercial use. In *United Reporting*, the Court rejected a facial challenge to a law that allowed access to information for "scholarly, journalistic, [and] political" purposes, but not commercial use. 528 U.S. at 35, 40. Vermont's law, likewise, does nothing more than restrict access to and use of nonpublic information that neither pharmacies nor

respondents have a First Amendment right to obtain in the first place. *See id.* at 40 (on its face, law does nothing more than require person seeking access to information to "qualify under the statute to do so"; State was free not to release the information at all); *see also FEC v. Int'l Funding Inst., Inc.*, 969 F.2d 1110, 1114 (D.C. Cir. 1992) (upholding law that makes campaign donor lists publicly available but bans use for solicitations or commercial purposes; litigants "have no claim of right to the benefit of the compelled disclosure apart from the measure in which the concomitant use restriction is found").

Indeed, federal and state statutes restricting the use of nonpublic information normally turn on the intended use, because the information is typically collected for a particular purpose, and further use is permitted consistent with that purpose. For example, HIPAA Privacy Rules specify in great detail what uses of protected health information are permitted, allowing, for example, certain research and public health uses but not marketing uses. *See supra* p. 6 & n.4. Other statutes have a similar framework. *See*, *e.g.*, Family Educational Rights and Privacy Act of 1974 ("FERPA"), 20 U.S.C. § 1232g (restricting disclosure of student records, with exemptions for, among others, certain accrediting and testing organizations, student aid programs, and certain educational research); Driver's Privacy Protection Act of 1994, 18 U.S.C. § 2721 (restrictions on drivers' license information, with exemptions for, among others, safety matters, recalls, and some market research activities).

2. Also relevant is the fact that Vermont's statute, like HIPAA, restricts the nonconsensual use of traditionally private health care information. No

accepted understanding of the First Amendment gives health care providers a right to disclose their records or to use them for commercial purposes. The First Amendment has long coexisted with legal restrictions on the disclosure of health care information. As Justice Stewart put it decades ago: "I doubt that a physician who broadcast the confidential disclosures of his patients could rely on the constitutional right of free speech to protect him from professional discipline." *In re Sawyer*, 360 U.S. 622, 646-47 (1959) (Stewart, J., concurring).

Justice Stewart's observation is confirmed by a long history of court decisions recognizing the privacy of doctors' treatment decisions. *See*, *e.g.*, *Ariz. & N.M. Ry. Co. v. Clark*, 235 U.S. 669, 676-77 (1915) (describing "very delicate and confidential nature of the relation" between doctor and patient); *Williams v. Johnson*, 13 N.E. 872, 872 (Ind. 1887) (statutory privilege "sets the seal of secrecy and confidence" upon physician's communications); *Metro. Life Ins. Co. v. Boddie*, 139 S.E. 228, 229 (N.C. 1927) ("The disclosures of a physician as to what takes place between him and his patient had from time immemorial been held by the medical profession as inviolate.").

Medical records traditionally have been confidential, and public access to health information has been sharply limited. Pharmacists are health care providers, just like doctors, and accept the same professional obligations to maintain confidentiality. Given this history, pharmacists cannot plausibly assert a First Amendment right to sell health care records, even partially redacted ones, to data vendors.

3. Vermont's law protects doctors' right not to speak and their right to be let alone, by allowing them to decide whether pharmaceutical manufactur-

ers may use their prescription records to market to them. "Freedom of speech presupposes a willing speaker." *Va. State Bd. of Pharmacy*, 425 U.S. at 756. The paramount right of free expression that is protected by the First Amendment would be disserved by a holding that doctors have no choice but to surrender the details of their treatment decisions to data vendors and pharmaceutical manufacturers. *Cf. Houchins v. KQED, Inc.*, 438 U.S. 1, 11 (1978) ("There is an undoubted right to gather news . . . but that affords no basis for the claim that the First Amendment compels others – private persons or governments – to supply information."). Moreover, by putting control in the hands of doctors, Vermont's consent-based statute furthers the First Amendment interest in protecting the *voluntary* exchange of ideas. Its targeted approach is consistent with *Rowan* and with decisions of the courts of appeals that uphold consumer-based restrictions on marketing practices. *See Nat'l Cable & Telecomms. Ass'n v. FCC*, 555 F.3d 996, 999-1002 (D.C. Cir. 2009) ("*NCTA*") (upholding rule requiring consent before consumer calling information may be shared for marketing purposes); *Mainstream Mktg.*, 358 F.3d at 1242-43 (upholding "Do Not Call" Registry); *Trans Union Corp. v. FTC*, 267 F.3d 1138, 1143 (D.C. Cir. 2001) (upholding requirement for consumer consent for certain marketing uses of credit history information).

4. Lastly, Vermont's restriction on nonconsensual commercial use of doctors' prescribing information is best viewed as a restriction on commercial conduct. Assigning control over the commercial use of prescribing information to the doctor is just that: an assignment of rights within the commercial market-

place, not unlike trade secret and copyright protection. The manner in which data vendors and pharmaceutical companies use prescribing information confirms that Vermont's law principally regulates conduct. Far from contributing to the "free trade in ideas," doctors' prescribing information does not enter the public domain. Data vendors and pharmaceutical manufacturers use this nonpublic information to decide on confidential marketing strategies[10] and do so without disclosing the information to "anyone." JA463; *see Ayotte*, 550 F.3d at 52 (law principally regulates conduct because it "serve[s] only to restrict the ability of data miners to aggregate, compile, and transfer information destined for narrowly defined commercial ends"). As one example, the data is used to decide employee compensation, monitor sales quotas, and motivate detailers to "move" doctors so they achieve those quotas. JA516. Because prescribing data is not part of an advertising message, Vermont's restriction on its use does not limit the speech of pharmaceutical manufacturers. *Cf. Rumsfeld*, 547 U.S. at 60 (equal-access requirement for military recruiters regulates what law schools do, not what they say).

C. The Second Circuit's contrary reasoning is unpersuasive and leads to untenable results.

1. The Second Circuit erred by drawing a sharp distinction between access to information in the possession of the government and access to information

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[10] There is some irony, given respondents' First Amendment claims, in the fact that industry marketing documents were admitted as evidence at trial only with company names and identifying information redacted. *See*, *e.g.*, JA450, 453, 512, 514 (displaying confidentiality designations and redactions).

held in private hands. App. 16a-17a. That ruling is extraordinarily broad, because it treats all restrictions on information held by private parties as impinging on protected speech, without regard to the nature of the information or its source. Most health care information is held by private health care providers. Private colleges maintain information about their students, and financial institutions have detailed customer information. Lawyers and accountants are privy to confidential client information. The Second Circuit's approach treats all of this information as presumptively available for exchange between "willing sellers and willing buyers," App. 16a, and subjects restrictions on the sale of such information to stringent First Amendment scrutiny. Respondents endorse this view, analogizing Vermont's restriction on the sale of medical records to a ban on newspapers publishing publicly available stock prices. IMS Cert. Br. 13. The analogy and the Second Circuit's holding fail for similar reasons.

First, here "the information is only 'in the hands of' pharmacies because the state has directed them to collect it." App. 41a (Livingston, J., dissenting). The Second Circuit majority disregarded this point, focusing instead on the pharmacy's willingness to sell its records. As *Seattle Times* shows, however, it matters how the pharmacy obtained those records in the first place. Moreover, as explained above, Vermont's law applies to health care records that are historically private and already protected by confidentiality rules. Those restrictions on access to health care records held by regulated entities are nothing like a prohibition on publishing information that is in the public domain.

Second, the majority's approach unnecessarily calls into question the confidentiality rules and consumer protection laws that apply to a wide range of professions and regulated businesses. Lawyers and accountants must comply with restrictions on the use of their clients' information. *E.g.*, Model Rules of Prof'l Conduct R. 1.6 (lawyers); Vt. Stat. Ann. tit. 26, § 82(a) (accountants). Schools and universities must comply with restrictions on the use of student records. 20 U.S.C. § 1232g(b); *United States v. Miami Univ.*, 294 F.3d 797, 822-24 (6th Cir. 2002) (rejecting First Amendment challenge to FERPA). Businesses as disparate as insurers, utilities, and telephone and cable companies are subject to restrictions on the use of customer information. *E.g.*, 18 U.S.C. § 2710(b) (video rentals); 47 U.S.C. §§ 224 (telecommunications carriers), 551(c)(1) (cable subscribers); N.J. Stat. Ann. § 48:3-85(b)(1) (utilities); N.M. Code R. § 13.1.3.12 (insurers). Both States and the federal government regulate the use and disclosure of nonpublic financial information. *See*, *e.g.*, 15 U.S.C. § 6802(b) (customer right to opt-out of disclosure of personal information by financial institution); Cal. Fin. Code § 4052.5 (restricting nonconsensual sale, transfer, and disclosure of nonpublic personal information by financial institutions). In response to the "burgeoning business" of data mining, App. 66a, regulators frequently propose and adopt new measures to protect consumers and to give consumers control over the use of personal information. *See*, *e.g.*, 18 U.S.C. § 2702(c) (internet subscriber information); 42 U.S.C. §§ 17932-17935 (electronic medical records); Restore Online Shoppers' Confidence Act, Pub. L. No. 111-345, 124 Stat. 3618 (2010) (to be codified at 15 U.S.C. §§ 8401-8405); H.R. 654, 112th Cong. (2011) (proposed "Do Not Track Me Online Act").

The Second Circuit's approach calls into question laws like these, which restrict access to information in private hands. The protection of free speech should not restrict reasonable consumer privacy protections that give consumers control over nonconsensual uses of their information. *See* App. 66a (Livingston, J., dissenting) (majority's holding makes it unduly difficult to regulate in furtherance of "a state's very serious interest in the protection of private information").

2. Respondents argue, incorrectly, that Vermont's law is not properly viewed as a restriction on access to nonpublic information because the law restricts only the sale or use of prescription data for marketing. In making this argument, respondents place great weight on the Second Circuit's conclusion that Vermont law allows for "widespread publication to the general public." App. 22a; *see*, *e.g.*, IMS Cert. Br. 17. The Second Circuit erred, however, by focusing on the Prescription Confidentiality Law alone and not taking account of the state and federal laws that greatly restrict access to and use of health information generally and prescription records specifically. *See supra* pp. 5-6. Viewed against this background, the assertion that pharmacies disclose prescription information to journalists, *see* App. 22a, is implausible. A pharmacy that allowed publication of the detailed prescription information that is privately sold to data miners would run a substantial risk of exposing patients' identities. *See* JA377. If a small-town Vermont newspaper published a local doctor's prescription information, with the dates of the prescriptions and age and gender of the patient, local

residents would have little difficulty spotting neighbors, friends, and relatives.[11]

Not surprisingly, the record does not show that pharmacies disclose doctors' prescribing histories to journalists. The CVS representative who testified at trial said that CVS does not disclose its data to anyone other than the three data vendors that brought this litigation. JA248, 255. The data vendors, in turn, do not allow publication of the data. They license use of the data pursuant to contracts that bar its disclosure. JA152-53, 463. Respondents did not show at trial that this data enters the public domain, much less gets published in newspapers. JA142 (journalists have not received prescriber-level data).

The Vermont statute's exceptions for health care uses, such as drug dispensing, treatment, reimbursement, patient care management, utilization review, and formulary compliance, likewise do not change the fact that prescribing information is not public. As permitted by HIPAA, health insurers and health care providers use both patient and prescriber information for these purposes, to provide patient care and manage insurance benefits. *See* 45 C.F.R. § 164.506 (allowing use of protected health information for "treatment, payment, or health care opera-

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[11] The HIPAA standard defines de-identified protected health information as "[h]ealth information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual." 45 C.F.R. § 164.514(a). The ease with which de-identified data may be re-identified has been shown repeatedly. *See* Paul Ohm, *Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization*, 57 UCLA L. Rev. 1701, 1701 (2010) ("[Computer] scientists have demonstrated that they can often 'reidentify' or 'deanonymize' individuals hidden in anonymized data with astonishing ease.").

tions"). The information is not publicly disclosed, however, and its use for these purposes does not undermine the privacy interests of patients or doctors.

The Vermont legislature did not pass this law to single out and restrict the use of prescription information in marketing, while allowing its "wide public dissemination." App. 22a. The law was passed because doctors, and then legislators, realized that prescription information was being used for marketing, *notwithstanding existing confidentiality rules*. Indeed, a repeated theme from doctors, reflected in the legislative record, is their surprise when they learned that detailers have this information. JA379, 404-05, 420-21. While it is true that the legislature did not ban the publication of prescribing data in this statute, the statute must be viewed against this factual and regulatory backdrop. The legislature addressed the problem identified by doctors: that existing confidentiality provisions do not prevent the nonconsensual, covert use of prescription information for marketing. Surely the First Amendment does not require the legislature to enact a broader law addressing a problem that does not exist.

Vermont's statute is properly viewed as a restriction on access to nonpublic information. *See* App. 38a-40a, 42a (Livingston, J., dissenting). The first sentence of the operative provision directly regulates the pharmacies that maintain prescription records pursuant to state and federal law. Pharmacies may not sell records that identify prescribers or permit their use for marketing unless the prescriber has consented. Vt. Stat. Ann. tit. 18, § 4631(d). The second sentence of that provision prevents pharmaceutical manufacturers from using regulated records for marketing. As Judge Livingston recognized, the

second sentence of § 4631(d) complements the first. Pharmacies may not permit the nonconsensual use of this data for marketing, and pharmaceutical manufacturers, to the extent they obtain information for permitted uses such as safety notices or recalls, must continue to abide by that same restriction. App. 42a, 48a-49a (Livingston, J., dissenting). Vermont's law does no more than "restrict [respondents'] unfettered *access* to information," *id.* at 40a, and does not contravene the First Amendment.

3. In any event, restrictions on the commercial use of nonpublic information are not unconstitutional merely because other noncommercial uses are permitted. As noted above, the statute upheld in *United Reporting* allowed journalists access to arrestee information, but prohibited use for solicitation or other commercial purposes. 528 U.S. at 35. Several federal laws restrict the commercial use of information while permitting noncommercial uses. Federal election law, for example, bars "any person" from using publicly available campaign donor lists for political solicitations or commercial purposes. *See* 2 U.S.C. § 438(a)(4); *Int'l Funding Inst.*, 969 F.2d at 1115**.** The Ethics in Government Act of 1978 similarly prohibits any use of federal employees' public financial disclosures for commercial purposes or solicitation. *See* 5 U.S.C. app. 4, § 105(c)(1)(B)-(D). The D.C. Circuit upheld a Federal Trade Commission determination, pursuant to the Fair Credit Reporting Act, that consumer credit history information may be used for firm offers of credit, but may not be used for other kinds of targeted marketing. *See Trans Union*, 267 F.3d at 1141. The Second Circuit's suggestion that laws protect privacy only when the use of information is restricted to "rare and compelling" circum-

stances, App. 22a, is simply mistaken. Information privacy laws commonly allow for some uses while restricting others. *See supra* p. 30.[12]

4. Unlike the Second Circuit's novel and broad First Amendment holding, the approach advocated by Vermont is both reasonable and markedly limited. Vermont asks the Court to recognize that the government's authority to restrict access to nonpublic information extends to some limited categories of nonpublic information held by private parties. At a minimum, the government may restrict the nonconsensual use of information where the government has compelled the production of the information, and it is of a kind that is typically not public. This approach takes account of an individual's right not to speak and right to control the use of information produced involuntarily. And it in no way undermines the "freedom of expression upon public questions [that] is secured by the First Amendment." *New York Times Co. v. Sullivan*, 376 U.S. 254, 269 (1964).

Focusing on the right to access nonpublic information also avoids the risk of diluting the core First Amendment protections that ensure an open and vigorous public marketplace of ideas. The Court has made a similar point frequently in its commercial speech cases, holding, for example, that allowing the political branches "needed leeway" to regulate commercial speech "strengthens" rather than "erod[es]"

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[12] Although not an information privacy law, the federal "Do Not Call" Registry is another example of a privacy measure that distinguishes between commercial and noncommercial solicitations. *See* 16 C.F.R. §§ 310.4(b)(1)(iii)(B), 310.6(a); 47 C.F.R. § 64.1200(c)(2), (f)(9); *Mainstream Mktg.*, 358 F.3d at 1232-33 (upholding Registry, which allows consumers to block commercial telephone solicitations but not political or charitable ones).

the "essential protections of the First Amendment." *Bd. of Trs. v. Fox*, 492 U.S. 469, 481 (1989). "'To require a parity of constitutional protection for commercial and non-commercial speech alike could invite dilution, simply by a leveling process, of the force of the Amendment's guarantee with respect to the latter kind of speech.'" *Id.* (quoting *Ohralik,* 436 U.S. at 456). If nonconsensual data mining were treated as the equivalent of publishing for First Amendment purposes, courts would need to decide what privacy interests are strong enough to justify restrictions on the practice, using the same standard that applies to direct restrictions on speech. Yet the Court has been reluctant to allow privacy interests to justify the latter restrictions. *See Bartnicki v. Vopper*, 532 U.S. 514, 533-34 (2001) (privacy interest insufficient to restrict publication of intercepted phone call, where subject was of public concern); *Fla. Star*, 491 U.S. at 534 (privacy interest insufficient to ban publication of rape victim's name); *Smith v. Daily Mail Publ'g Co.*, 443 U.S. 97, 104-05 (1979) (confidentiality interest insufficient to ban publication of juvenile offender's name). Equating a data vendor's right to buy nonpublic information with a newspaper's right to publish may thus end up eroding the rights of newspapers.

II. IF TREATED AS A REGULATION OF COMMERCIAL SPEECH, VERMONT'S LAW SHOULD NONETHELESS BE UPHELD BECAUSE IT SATISFIES THE INTERMEDIATE SCRUTINY STANDARD OF *CENTRAL HUDSON*.

If this Court rejects Vermont's primary argument that the State's law should be upheld as a restriction on access to nonpublic information, it nonetheless should conclude that the law is a permissible regula-

tion of commercial speech. *See* App. 64a (Livingston, J., dissenting); *Mills*, 616 F.3d at 20-23; *Ayotte*, 550 F.3d at 60.

Although commercial speech receives First Amendment protection, "not all regulation of such speech is unconstitutional." *Thompson*, 535 U.S. at 367. This Court has long held that commercial speech occupies a "subordinate position in the scale of First Amendment values." *Fox*, 492 U.S. at 477 (quotations omitted). Accordingly, the "Court has afforded commercial speech a measure of First Amendment protection commensurate with its position in relation to other constitutionally guaranteed expression." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 553 (2001) (quotations omitted). A regulation of protected[13] commercial speech is constitutional if the government's interest is substantial, the regulation "'directly advances the governmental interest,'" and the restriction is "'not more extensive than is necessary to serve that interest.'" *Id.* at 554 (quoting *Central Hudson*, 447 U.S. at 566).

As correctly found by the district court, two panels of the First Circuit, and the dissenting judge below, restricting the use of doctors' prescribing information satisfies this standard. Because, however, "[m]embers of the Court have expressed doubts" about the *Central Hudson* test in certain contexts, *Thompson*, 535 U.S. at 367, we first explain how this statute's limited restraint differs sharply from the "broadly based" advertising restrictions that the Court has typically analyzed under *Central Hudson*. *See 44 Liquormart*, 517 U.S. at 497 (plurality op.).

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[13] Commercial speech is protected by the First Amendment to the extent that it concerns lawful activity and is not misleading. *See Lorillard*, 533 U.S. at 554.

Then we turn to the application of *Central Hudson* to the facts of this case.

A. Vermont's consent-based restriction on the use of doctors' prescribing information is nothing like broad restrictions on advertising to the public that this Court has invalidated under *Central Hudson*.

Beginning with *Virginia State Board*, in which this Court invalidated a ban on price advertising for prescription drugs, the Court has looked skeptically at broad bans on truthful advertising. The Court reasoned in *Virginia State Board* that consumers have a "keen interest" in the "free flow of commercial information," 425 U.S. at 763, and concluded that the State could not "completely suppress the dissemination of concededly truthful information about entirely lawful activity," *id.* at 773. Since then, the Court has applied similar reasoning to invalidate a number of bans on advertising to the public. *See*, *e.g.*, *Thompson*, *supra* (ban on advertisements for compounded drugs); *44 Liquormart*, *supra* (ban on price advertising for alcohol); *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995) (ban on labels containing alcohol content); *Bates v. State Bar of Ariz.*, 433 U.S. 350 (1977) (ban on lawyer advertising).

Vermont's law bears no resemblance to these categorical bans on disseminating information to consumers. *See Ayotte*, 550 F.3d at 97 (Lipez, J., concurring) (describing New Hampshire's law as "significantly more limited than similar restrictions on commercial speech that have been considered by the Supreme Court"). Vermont's law does not, in fact, prevent pharmaceutical manufacturers from providing any truthful information to doctors about their products. It does not regulate the content of messag-

es about prescription drugs or prevent pharmaceutical manufacturers from delivering those messages.[14] The "restriction imposed is both minimal and indirect." App. 61a (Livingston, J., dissenting). So long as pharmaceutical manufacturers are not using doctors' prescribing information without consent, their ability to communicate with doctors is unaffected. *See Ayotte*, 550 F.3d at 100 (Lipez, J., concurring) (law does not "prevent[] truthful advocacy by pharmaceutical representatives").

Although the use of doctors' prescribing histories makes targeted detailing more effective, *see* App. 91a, a regulation that affects commercial speech is not suspect merely because it reduces the influence of advertising. In *Lorillard*, the Court invalidated broad restrictions on tobacco advertising because the regulations imposed "onerous burdens" on advertising intended to reach adults. 533 U.S. at 561-66. In so doing, however, the Court stopped far short of suggesting that *any* reduction in the effectiveness of advertising would be suspect:

> A careful calculation of the costs of a speech regulation does not mean that a State must demonstrate that there is no incursion on legitimate speech interests, but a speech regulation cannot unduly impinge on the speaker's ability to propose a commercial transaction and the adult listener's opportunity to obtain information about products.

Id. at 565.

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[14] Respondents agree, arguing below that "the principal effect of the statute is thus to make detailing more expensive and less efficient, not to block it or alter the content of the message delivered." IMS C.A. Br. 51.

Vermont's law cannot reasonably be described as unduly impinging the "protected interest in communication" between doctors and pharmaceutical manufacturers. *Id.* at 564. Pharmaceutical manufacturers have ample channels for identifying and contacting doctors. *See* App. 94a-95a; *cf. 44 Liquormart*, 517 U.S. at 501 (plurality op.) ("complete speech bans" are "particularly dangerous because they all but foreclose alternative means of disseminating certain information"). Nor is prescription data "necessary to determine . . . whether a prescriber would be interested in a particular drug." App. 95a.

Moreover, because doctors may allow the use of their prescription information for marketing, Vermont's law does not restrict any marketing to a willing listener. Vermont's law is thus very different from state efforts to prevent businesses from providing information to potential purchasers eager to receive it. The nonconsensual use of doctors' prescribing histories is fairly described as an "aggressive sales practice," *44 Liquormart,* 517 U.S. at 498 (plurality op.), and allowing doctors to avoid an unwanted use of their nonpublic information is a permissible form of consumer protection.

B. The law satisfies the first two prongs of the *Central Hudson* test because it directly advances Vermont's substantial interests in protecting medical privacy, reducing health care costs, and protecting public health.

The Vermont legislature found that allowing doctors to control the use of their prescribing information for marketing purposes would protect privacy and serve the public interest by reducing health care costs and protecting public health. The record shows

that the law directly advances all three of these interests.

1. The law directly advances the State's interest in protecting medical privacy.

a. By allowing doctors to decide whether their prescribing information should be used for marketing, the law protects a real and substantial privacy interest. The doctor's privacy interest is twofold. First, the doctor is, in this context, essentially a customer: by writing prescriptions, the doctor makes the "purchasing" decisions that are relevant to pharmaceutical manufacturers. Data vendors and pharmaceutical manufacturers regularly refer to doctors in these terms. *E.g.*, JA488, 512-13, 516-17, 519. Having prescribing data allows pharmaceutical manufacturers access to every doctor's detailed prescribing information, without the doctor's knowledge or permission. No different from a car salesperson who knows every car that a customer has ever purchased, what options they chose, how much they paid, and how they financed, such knowledge transforms straightforward advertising into marketing strategies that severely disadvantage customers. Like any consumer, a doctor has a substantial interest in avoiding this kind of involuntary disclosure. *See Mills*, 616 F.3d at 20 (prescribers "have a privacy interest in avoiding unwanted solicitations from detailers who have used their individual prescribing data to identify and target them"); *NCTA*, 555 F.3d at 1001 ("privacy deals with determining for oneself when, how and to whom personal information will be disclosed").

Doctors, of course, are not ordinary consumers buying cars, and that fact explains why the privacy interest at stake here has a deeper dimension. Doctors

did not express "surprise," "outrage," and "shock" at this practice merely because they do not want to be embarrassed or annoyed by detailers. JA336, 379, 404-05. What worries doctors, and what prompted them to lobby for this law, is that the use of prescribing information in marketing intrudes on the doctor-patient relationship. JA327, 378, 383, 413. Prescription records reveal extraordinarily detailed information about the treatment decisions that doctors make for their patients. And the reason pharmaceutical manufacturers want and use that information is to influence and *change* those treatment decisions. It is one thing for pharmaceutical companies to promote their products in the hopes of increasing sales. It is quite another for them to learn the private details of a doctor's interactions with patients and use that information to try to alter the treatment decisions doctors make with patients with specific conditions. One of the State's experts, Dr. Grande, testified about how this kind of marketing negatively affects patients, who "will only feel more anxious about whether or not . . . their interests are being put first." JA327.

Not surprisingly, given their primary obligation to care for patients, the record shows that many doctors find such uses of nonpublic information deeply troubling. As one doctor explained, his prescribing practices are "monitored" so pharmaceutical companies can try to "subvert what I do." JA380. Other doctors echoed this point, calling the practice "spying" and describing it as "underhanded." JA336, 407-08. Dr. Grande testified that allowing doctors to prevent this practice benefits patients and promotes medical professionalism by reducing undue commercial influences in the doctor-patient relationship. JA326-28.

The statute's provision for prescriber consent directly advances the State's interest in privacy because it gives doctors the right to control the use of their information. *See Mills*, 616 F.3d at 22-23 (Maine's restriction on use of prescribing information protects privacy); *Trans Union*, 267 F.3d at 1143 ("opt-in" rule protects consumer privacy). "The law restricts the flow of otherwise private information about doctors' prescribing habits and the care they provide to their patients." App. 59a-60a (Livingston, J., dissenting).

b. The Second Circuit erred in concluding that the statute does not protect physician privacy. The court reasoned primarily that physician information could be collected and aggregated for other purposes, like "journalistic reports on physicians." App. 22a. As explained above, however, doctors' prescribing information is not publicly available. *See supra* pp. 36-37. Moreover, so long as a regulation advances the State's interest to a material degree, the *Central Hudson* standard tolerates under-inclusiveness. *See Edge Broad.*, 509 U.S. at 434 (government advanced its purpose by "substantially reducing," though not "eradicating," lottery advertising); *see also Mainstream Mktg.*, 358 F.3d at 1238-39 ("Do Not Call" Registry directly furthers privacy interests even though consumers cannot block all unwanted solicitations; Registry allows consumers to block significant number of such calls). As Judge Livingston observed, the law "does not just reduce but *dramatically* reduces the spread of [prescriber-identifiable] data." App. 60a (Livingston, J., dissenting); *see also* A-82, A-100 (data vendors complied with Vermont and New Hampshire laws by redacting physician information in their databases). The record in this

case confirms that the legislature addressed the only use of physician prescribing information that is widespread, nonconsensual, and unrelated to the patient's health care: marketing. That is sufficient under *Central Hudson*.

2. The law directly advances the State's interests in controlling health care costs and protecting public health.

a. Although doctors' privacy interest alone is sufficient to sustain this law, the Act directly advances the State's independent interests in protecting public health and reducing health care costs. These interests provide an additional basis for upholding the law under *Central Hudson*. Doctors supported this law because they wanted to reduce the inappropriate influence of pharmaceutical marketing on doctors' prescribing decisions. As the record shows, pharmaceutical marketing has a strong influence on doctors' prescribing practices. "Detailing encourages doctors to prescribe newer, more expensive, and potentially more dangerous drugs instead of adhering to evidence-based treatment guidelines." App. 95a. Consistent with evidence in the legislative record, the State's experts testified that marketing has a proven effect on prescribing decisions, and that the specific harm of marketing using prescriber-identifiable data is that it "over-accelerates" the prescribing of newly approved brand-name drugs. JA289-91 (Dr. Wazana: peer-reviewed scholarship shows negative influence of marketing on prescribing practices), 326-27 (Dr. Grande: detailing using prescriber-identifiable data amplifies influence of marketing), 365 (Dr. Kesselheim: detailing using prescriber-identifiable data "over-accelerate[s]" prescriptions for new drugs). New drugs are not only expensive, but carry poten-

tial risks for patients. JA354-60, 365-68 (explaining risks associated with new drugs and discussing Vioxx, Baycol, and calcium channel blockers). For these reasons, the use of doctors' prescribing habits as a marketing tool increases health care costs unnecessarily and exposes patients to needless risks.

The State's evidentiary case was not theoretical. The State presented evidence about specific drugs that are or have been widely over-prescribed. Some of these examples illustrated unnecessary spending, to the tune of hundreds of millions of dollars. JA368-69 (Nexium), 367-68 (calcium channel blockers), 353-54 (Lipitor). Other examples showed how over-prescription of newly approved drugs can harm patient health. Millions of patients were needlessly exposed to the health risks of Vioxx before it was withdrawn from the market because the influence of marketing caused doctors to prescribe the drug inappropriately. JA366. The financial cost was also enormous. Although studies showed Vioxx was no more effective at controlling pain than over-the-counter ibuprofen, a single Vioxx pill cost as much as a bottle of generic ibuprofen. JA356-58. The statin drug Baycol is another example of a drug that was "determinedly promoted" and widely prescribed, even though many other statin drugs were available for use. JA366-67. The drug turned out to have serious and sometimes fatal side effects, and it was later removed from the market. *Id.*

Other evidence in the record provides firm support for the district court's findings[15] – and this evidence

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[15] In reaching its findings, the trial court acknowledged that this Court has counseled deference to predictive legislative judgments when applying intermediate First Amendment scrutiny. App. 85a-86a (citing *Turner Broad. Sys. v. FCC*, 512 U.S.

did not come only from the State. The "industry documents" cited by the district court confirm what doctors told the Vermont legislature: doctors' prescribing information is used to boost sales, not to educate doctors about drugs. The point of using prescriber-identifiable data in marketing is to "maximize the revenue per call and the scripts per detail." JA487. The training materials from pharmaceutical manufacturers show that prescribing data is used to motivate detailers to achieve sales quotas by getting doctors to "writ[e] for you" and to target marketing efforts on certain doctors while "delet[ing]" others from detailers' spreadsheets. JA514-15, 516, 525. The effectiveness of various promotional tactics is measured using prescribing information, and those tactics are adapted when sales do not measure up. JA481-89. That activity seeks to increase market share and revenues.

Doctors brought their concerns about the effects of this marketing practice to the legislature, *see supra* pp. 13-14, and the trial record confirmed that their concerns about unnecessary costs and risks are real and substantial. Allowing doctors to restrict this marketing practice if they choose directly advances the State's important interests in controlling the costs of health care and protecting public health.

622, 665 (1994)); *accord Ayotte*, 550 F.3d at 93 (Lipez, J. concurring) ("Although the contexts are different, the general principle of legislative deference also is compatible with the Court's commercial speech precedent."). Following this Court's guidance, the district court independently reviewed the record while declining to "'replace the legislature's factual predictions with its own.'" App. 86a (citing *Turner*, 512 U.S. at 566).

b. In finding that the law did not directly advance Vermont's substantial interests in controlling health care costs and protecting public health, the Second Circuit did not dispute the district court's findings that the use of doctors' prescribing information in marketing leads to higher prescription drug costs and increases risks to patients. *See* App. 24a-28a. Instead, the court of appeals emphasized a legislative finding describing the "one-sided" marketplace of ideas in pharmaceutical marketing and concluded that the finding revealed a "highly disfavored" legislative intent. App. 25a-26a. The Second Circuit's conclusion is flawed for several reasons.

First, the Second Circuit's description of the legislature's intent is not borne out by the findings or the statute itself. The findings were adopted as part of a multipart Act that, among other things, created an evidence-based education program and included a (later repealed) measure requiring pharmaceutical marketers to discuss drug treatment options with doctors. *See supra* pp. 12-13. Moreover, the legislature did not evince an intent to "put the *state's* thumb on the scales of the marketplace of ideas" through the statutory provision at issue here. App. 25a (emphasis added). To the contrary, the legislature found that *doctors* should be able to control whether marketers have access to their prescribing histories. *See* App. 139a-140a (Finding 29) (trade in prescription information should not take place without consent); App. 140a (Finding 31) ("act is necessary to protect prescriber privacy by limiting marketing to prescribers who choose to receive that type of information"). The statute thus does not "ban" the use of prescribing information or "limit[] the information available to physicians," as the Second Cir-

cuit found. *See* App. 26a, 30a, 32a. The statute lets each doctor, not the government, control the use of her prescribing history for marketing.

Second, where supported by a factual record, an expression of legislative concern about the undue influence of advertising is not inherently suspect. *Cf. Lorillard*, 533 U.S. at 557-61. Pharmaceutical manufacturers would be hard-pressed to argue that the legislature's concern was misplaced. In recent years, manufacturers have paid millions of dollars to settle allegations of improper marketing practices, and Congress has investigated industry ghostwriting of journal articles.[16] Respected, peer-reviewed research shows that pharmaceutical marketing influences the prescribing practices of doctors. App. 91a-92a. One can hardly fault the Vermont legislature for reaching a conclusion supported by good science.[17]

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[16] *See*, *e.g.*, Duff Wilson, *Novartis Settles Off-Label Marketing Case Over 6 Drugs for $422.5 Million*, NYTimes.com, Oct. 1, 2010, *available at* http://www.nytimes.com/2010/10/01/health/policy/01novartis.html?_r=1&scp=6&sq=pharmaceutical%20settlement&st=Search (listing recent settlements); Minority Staff Report, S. Comm. on Finance (Sen. Grassley, Ranking Minority Member), 111th Congress, Report on Ghostwriting in Medical Literature (June 24, 2010).

[17] In 2009, the Institute of Medicine published its report on conflicts of interest in medical research and practice. *See* Institute of Medicine, *Conflict of Interest in Medical Research, Education, and Practice* (Bernard Lo & Marilyn J. Field eds., 2009). The report describes pharmaceutical companies' "sophisticated" marketing strategies, including using physicians as "marketing agents" and tracking "physicians' prescribing habits . . . through commercial databases." *Id.* at 12. The report finds that "[p]ublished studies of these strategies are limited but suggest the risk of undue industry influence on physician prescribing behavior with little or no benefit to patient care." *Id.* The report supports the Vermont legislature's concerns about the

Third, the relevant inquiry here is on the nature and scope of the statute, not on the wording of legislative findings or what that wording might imply about legislative intent. *See United States v. O'Brien*, 391 U.S. 367, 383 (1968) (legislative motive is not a basis for invalidating an otherwise constitutional statute). The legislature did not address its concerns about pharmaceutical marketing by banning detailing or otherwise suppressing truthful information about prescription drugs. *Cf. Thompson*, 535 U.S. at 377 (ban on advertising of compounded drugs did not satisfy *Central Hudson*). Instead, the legislature adopted a modest restriction allowing doctors to prevent the use of their prescription information for targeted marketing efforts that many consider intrusive and inappropriate.

C. The law satisfies the third prong of the *Central Hudson* test because it is narrowly tailored and has minimal impact on core First Amendment values.

1. A restriction on commercial speech is "narrowly tailored" if it is in "reasonable proportion" to the State's interests. *Edenfield v. Fane*, 507 U.S. 761, 767 (1993). The standard requires a "reasonable fit between the means and ends of the regulatory scheme." *Lorillard*, 533 U.S. at 561; *accord Fox*, 492 U.S. at 480 (Court's decisions require "fit that is not necessarily perfect, but reasonable"). Vermont's law is carefully designed to advance the State's interests

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influence of industry marketing strategies, citing the withholding of "unfavorable results in some major industry-sponsored trials," *id.* at 24; ghostwriting of scientific articles by pharmaceutical companies, *id.* at 154; medical faculty serving as paid industry speakers, *id.* at 153-54; and the use of clinical trials as marketing tools, *id.* at 173-74.

without restricting "substantially more speech than is necessary," *Fox*, 492 U.S. at 478 (quotations omitted), and easily satisfies this standard.

The law's careful tailoring is evidenced by its provision for prescriber consent.[18] Even in the face of doctors' strong objections to this marketing practice, the legislature did not adopt a uniform rule that barred all use of prescription information for marketing. *Cf. Lorillard*, 533 U.S. at 563 (lack of tailoring shown by "uniformly broad sweep" of rule and restrictions on "unduly broad" range of communications). Any doctor that finds this form of marketing beneficial may consent, and communications to that doctor will be unaffected. By letting doctors, rather than the State, control the use of this information for marketing, the legislature avoided impinging on the "protected interest" in communication between pharmaceutical manufacturers and willing doctors. *See id.* at 564.

The record further shows that the State did not adopt this restriction as a "first" resort. *See Thompson*, 535 U.S. at 373 (describing advertising ban as government's "first strategy"). Respondents' own witness acknowledged that Vermont has been a national leader in efforts to control the costs of prescription drugs. JA306. Vermont's efforts to "control costs, while maintaining best practices in drug prescribing," include preferred drug lists, formularies, multistate purchasing pools, generic substitution requirements, and disclosure laws for drug prices and

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[18] Although respondents now suggest that a voluntary American Medical Association program that affords doctors certain control over the use of their information for marketing is a less restrictive alternative to Vermont's law, IMS Cert. Br. 4, 21, they stipulated in the district court that it was not. JA129-30.

pharmaceutical marketing expenditures. *See* App. 135a-136a (Findings 10-12). Act 80 itself included other measures, such as funding for evidence-based educational programs for doctors. 2007 Vt. Acts & Resolves No. 80, § 14. Vermont both considered and adopted other mechanisms to advance these state interests before taking this step. *Cf. Thompson*, 535 U.S. at 373 (observing "there is no hint" that government "even considered" alternatives to ban on advertising).

The limited scope of the law is particularly relevant to this part of the *Central Hudson* test. Again, the law does not prevent pharmaceutical manufacturers from marketing their products to anyone. "[S]ales representatives may continue to pitch their drugs directly to doctors." *Ayotte*, 550 F.3d at 97 (Lipez, J., concurring). The law does not undermine "the informational function of advertising." *Central Hudson*, 447 U.S. at 563. As the district court found, the use of prescriber-identifiable data does not add to the "purported educational value" of detailing. App. 91a; *see* JA342-43 (testimony of former sales representative), 349-50, 362-63 (Kesselheim), 463 (discussion of data with doctors is "not part of a sales call"). Industry marketing materials contravene the claim that prescribing data is used to make sales calls more informative or educational. *See*, *e.g.*, JA489-90 (describing email "alerts" about doctors who are "underperforming"), 516 (advising managers to tell detailers to "move" doctors who "aren't writing for you"), 525 (instructing detailers to "delete" physicians who do not have potential to "move share").

Rather, the mining of doctors' prescribing histories lets sales representatives use nonpublic information to convey subtle but targeted messages and induce-

ments to persuade the doctor to change the medicines being prescribed to patients. *See* JA325-26 (using this data, sales representatives present drug information in a "selective" manner and target message to "push" physician toward company's drug). A former sales representative explained how he used prescribing data to present his company's drug "in the best possible light" compared to a drug preferred by a doctor, but without mentioning the other drug by name or disclosing his knowledge of the doctor's prescribing practices. JA341-43. Because doctors consider their prescribing information "confidential," detailers "pretend [they] don't know and . . . make . . . comparisons seemingly coincidental." JA343. He described these presentations as "[f]actually . . . true" but "skewed" and "distorted." *Id.*

The law allows doctors, if they choose, to avoid these "offensive" and "disturb[ing]" marketing practices, JA496 – and it does so without blocking the dissemination of information about prescription drugs. This limited, targeted measure represents a "careful calculation of the speech interests involved," *Lorillard*, 533 U.S. at 562, and should be upheld.

2. In holding otherwise, the Second Circuit applied an "aggressive form of *Central Hudson* that affords insufficient deference to legislative findings and determinations." App. 66a (Livingston, J., dissenting). The court of appeals assigned no importance at all to the law's consent provision, even though this Court and the courts of appeals have consistently held that restrictions based on consumer choice are less restrictive of First Amendment interests. *See supra* pp. 25, 32. Instead, the Second Circuit deemed the law a "categorical ban" and criticized the legislature for not adopting a law that allows prescriber infor-

mation to be used for some drugs but not for other drugs, depending on the State's view of each drug's benefits. App. 30a-32a. As a practical matter, neither the State nor pharmacies could possibly implement such a law, and, in any event, such a scheme would not advance the State's interest in protecting medical privacy or address doctors' concerns about the influence of marketing. The Second Circuit also suggested that the State could mandate generic prescriptions for patients receiving (federal) Medicare Part D funding. Leaving aside Vermont's authority to manage the Medicare program – and the fact that Vermont already requires substitution of bioequivalent generic drugs in most cases, *see supra* p. 4 – the "reasonable fit" standard of *Central Hudson* does not require that Vermont "unduly interfer[e] in the prescribing habits of doctors" in this way. App. 62a (Livingston, J., dissenting); *see also Ayotte*, 550 F.3d at 60.

3. Finally, respondents argue that Vermont's law discriminates on the basis of viewpoint, even though it applies evenhandedly to all marketing for prescription drugs, brand-name or generic. The Court has not held that the selling of a product is a viewpoint for First Amendment purposes. Nor do the Court's precedents suggest that regulating product advertising in this manner discriminates on the basis of viewpoint.

Respondents' argument also brings into sharp relief the breadth of their First Amendment claim. Their "viewpoint discrimination" claim is largely based on the fact that insurers, both public and private, use prescribing information to manage prescription drug claims and benefits. That is unquestionably true. As the record shows, Vermont's public

insurance programs use prescription information as well as other patient health information in a variety of ways to help manage both patient care and patient benefits. JA426-32, 448. But insurers, both public and private, have this information because of their relationships with the patients they insure – and the information insurers have is supplied by patients and doctors. JA436-37 (explaining how patient information is used). Data vendors and pharmaceutical manufacturers do not have these relationships with patients, and neither patients nor doctors provide them with health care information. Respondents do not have a First Amendment right to have the same access to nonpublic health care records that health insurers have.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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