#### IN THE

#### Supreme Court of the United States

WILLIAM H. SORRELL, AS ATTORNEY GENERAL OF THE STATE OF VERMONT; JIM DOUGLAS, IN HIS CAPACITY AS GOVERNOR OF THE STATE OF VERMONT; AND ROBERT HOFMANN, 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 Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit

#### PETITION FOR A WRIT OF CERTIORARI

DAVID C. FREDERICK SCOTT H. ANGSTREICH KELLOGG, HUBER, HANSEN, TODD, EVANS & FIGEL, P.L.L.C. 1615 M Street, N.W. Suite 400 Washington, D.C. 20036 (202) 326-7900 WILLIAM H. SORRELL
ATTORNEY GENERAL
BRIDGET C. ASAY
Counsel of Record
SARAH E.B. LONDON
DAVID R. CASSETTY
ASSISTANT ATTORNEYS
GENERAL
OFFICE OF THE ATTORNEY
GENERAL
109 State Street
Montpelier, Vermont 05609-1001
(802) 828-5500
(basay@atg.state.vt.us)

December 13, 2010

#### **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 "prescriberidentifiable 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 Vermont Attorney General William H. Sorrell, Vermont Governor Jim Douglas, and Vermont Secretary of Human Services Robert Hofmann were defendants in the district court and appellees in the court of appeals.

Respondents 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 were plaintiffs in the district court and appellants in the court of appeals.

#### TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
PARTIES TO THE PROCEEDING	ii
TABLE OF AUTHORITIES	vi
INTRODUCTION	1
OPINIONS BELOW	2
JURISDICTION	2
CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED	3
STATEMENT	3
REASONS FOR GRANTING THE PETITI	ON 14
I. THE DECISION BELOW IS ERRONI AND CONFLICTS WITH TWO RECENT F CIRCUIT DECISIONS UPHOLDING SUBS TIALLY SIMILAR STATE STATUTES	TIRST TAN-
A. The decision below explicitly jected the First Circuit's ground for upholding substantially single state statutes	unds nilar
B. The circuit conflict over drug mining laws arises amidst an going, deep, and mature conflict to whether government may preindividuals' privacy rights content with the First Amendment	on- ct as otect nsis-
C. The decision below is erron under applicable First Amenda doctrine	ment

II.	WH Api	E JUDGMENT BELOW CONFLICTS TH OTHER CIRCUITS' DECISIONS ON HETHER, IF THE FIRST AMENDMENT PLIES, THE CENTRAL HUDSON TEST IS PUSFIED	21
	A.	The circuits conflict over the sufficiency of the state interest	22
	В.	The circuits conflict over the directness needed to effectuate the state interest	23
	С.	The circuits conflict over the sufficiency of the State's tailoring of its restriction	25
III.	AR	E ISSUES RAISED IN THIS PETITION E OF SURPASSING AND GROWING PORTANCE	26
	A.	Other States are considering legislation to limit use of prescription information in the same ways as Vermont, New Hampshire, and Maine	26
	В.	Data mining is an ever-expanding threat to privacy, so clarifying the applicable First Amendment principles in this area is critical	28
CONC	LUS	SION	34
APPE	NDI	X:	
for the	e Se rell,	f the United States Court of Appeals cond Circuit, <i>IMS Health Inc.</i> , et al. et al., Nos. 09-1913-cv(L) & 09-2056-lov. 23, 2010)	1a

Memorandum Opinion and Order of the United States District Court for the District of Vermont, <i>IMS Health Inc.</i> , et al. v. Sorrell, et al., Nos. 1:07-CV-188 & 1:07-CV-220 (Apr. 23,	0
2009)	8a
Order of the United States Court of Appeals for the Second Circuit, <i>IMS Health Inc.</i> , et al. v. Sorrell, et al., Nos. 09-1913-cv(L) & 09-2056-cv(Con) (June 26, 2009)	9a
Ruling of the United States District Court for the District of Vermont on Motion for Injunc- tion Pending Appeal, <i>IMS Health Inc.</i> , et al. v. Sorrell, et al., Nos. 1:07-CV-188 & 1:07-CV-220 (June 5, 2009)	10
(buile 5, 2005) 12	1a
Statutory Provisions Involved	9a
Vt. Stat. Ann. tit. 18, § 4631 12	9a
2007 Vt. Acts & Resolves No. 80 (excerpt) 13	4a

#### TABLE OF AUTHORITIES

Page
CASES
44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484 (1996)
Bates v. State Bar of Ariz., 433 U.S. 350 (1977) 31
Bd. of Trs. of State Univ. of NY v. Fox, 492 U.S. 469 (1989)
Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557 (1980)passim
Cincinnati v. Discovery Network, Inc., 507 U.S. 410 (1993)
Edenfield v. Fane, 507 U.S. 761 (1993) 30
Florida Star v. B.J.F., 491 U.S. 524 (1989) 19
Greater New Orleans Broad. Ass'n, Inc. v. United States, 527 U.S. 173 (1999)26, 30
Houchins v. KQED, Inc., 438 U.S. 1 (1978) 31
IMS Health Inc. v. Ayotte:
550 F.3d 42 (1st Cir. 2008), cert. denied, 129 S. Ct. 2864 (2009)passim
129 S. Ct. 2864 (2009)
IMS Health Inc. v. Mills, 616 F.3d 7 (1st Cir. 2010)passim
Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001)
Los Angeles Police Dep't v. United Reporting Publ'g Corp., 528 U.S. 32 (1999)11
Mainstream Mktg. Servs. v. FTC, 358 F.3d 1228 (10th Cir. 2004)

Nat'l Cable & Telecomms. Ass'n v. FCC,
555 F.3d 996 (D.C. Cir. 2009)16, 17
$Reno\ v.\ Condon,\ 528\ U.S.\ 141\ (2000)32,\ 33$
$Rowan\ v.\ U.S.\ Post\ Office,\ 397\ U.S.\ 728\ (1970)\ 20$
Rubin v. Coors Brewing Co., 514 U.S. 476 (1995)
Seattle Times Co. v. Rhinehart, 467 U.S. 20 (1984)
Sorenson Commc'ns, Inc. v. FCC, 567 F.3d 1215 (10th Cir. 2009)
Thompson v. W. States Med. Ctr., 535 U.S. 357 (2002)
Trans Union Corp. v. FTC, 245 F.3d 809 (D.C. Cir. 2001)
Trans Union LLC v. FTC, 295 F.3d 42 (D.C. Cir. 2002)
U.S. West, Inc. v. FCC, 182 F.3d 1224 (10th Cir. 1999)
United States v. Miami Univ., 294 F.3d 797 (6th Cir. 2002)
United States v. Stevens, 130 S. Ct. 1577 (2010)
Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748 (1976)10, 31
Zemel v. Rusk, 381 U.S. 1 (1965)19, 31

## CONSTITUTION, STATUTES, REGULATIONS, AND RULES

#### <u>Federal</u>

U.S. Const.:
Art. I, § 8, Cl. 3 (Commerce Clause)8, 9, 32
Amend. Ipassim
Driver's Privacy Protection Act of 1994, 18 U.S.C. § 2721 <i>et seq.</i>
18 U.S.C. § 2721(a)
Fair Credit Reporting Act, 15 U.S.C. § 1681 et seq
Family Educational Rights and Privacy Act of 1974, 20 U.S.C. § 1232g
20 U.S.C. § 1232g(b)
Gramm-Leach-Bliley Act, Pub. L. No. 106- 102, 113 Stat. 1338 (1999)
15 U.S.C. § 6802(b)
18 U.S.C. § 2702(c)
18 U.S.C. § 2710(b)
21 U.S.C. § 353(b)(1)
28 U.S.C. § 1254(1)
42 U.S.C. § 1320d-6
47 U.S.C. § 551(c)(1)
21 C.F.R. § 310.200
21 C.F.R. § 1306.05

State
Cal. Fin. Code § 4052.5
Conn. Gen. Stat. § 38a-988a(a) 33
N.J. Stat. Ann. § 48:3-85(b)(1)
2007 Vt. Acts & Resolves No. 80
Vt. Stat. Ann. tit. 18, § 4631passim
Vt. Stat. Ann. tit. 18, § 4631(c)(1)
Vt. Stat. Ann. tit. 18, § 4631(d)
Vt. Stat. Ann. tit. 18, § 4631(e)(1)
Vt. Stat. Ann. tit. 18, § 4631(e)(7_) 8
Vt. Stat. Ann. tit. 26, § 2022(14) 4
Vt. Stat. Ann. tit. 26, § 2041(a) 4
Fla. Admin. Code r. 61H1-23.001 19
105 Mass. Code Regs. 970.005(2)(g) 27
N.M. Code R. § 13.1.3.12
Vt. Bd. of Pharmacy Admin. Rules § 9.1 (eff. Oct. 2009)
Vt. Bd. of Pharmacy Admin. Rules § 9.24 (eff. Oct. 2009)
Vt. Bd. of Pharmacy Admin. Rules § 9.26 (eff. Oct. 2009)
LEGISLATIVE MATERIALS
S.B. 1234, 49th Leg. 2d Reg. Sess. (Ariz. 2010) $27$
Assem. B. 2112, 2009-10 Reg. Sess. (Cal. 2010) 27
S.B. 1046, Gen. Assem. Jan. Sess. 2009 (Conn. 2009)

B17-364, 2007 Council (D.C. 2007)	. 27
S.B. 1402, 111th Reg. Sess. (Fla. 2009)	. 27
H.B. 820, 115th Gen. Assem. 2009-2010 Reg. Sess. (Ga. 2009)	. 27
S.B. 449, 25th Leg., Reg. Sess. (Haw. 2009)	. 27
H.B. 1459, 95th Gen. Assem., 1st Reg. Sess. (Ill. 2007)	. 27
H. File 622, 83rd Gen. Assem., 2009 Sess. (Iowa 2009)	. 27
S.B. 229, Sess. of 2009 (Kan. 2007)	. 27
S.B. 1040, 427th Sess. (Md. 2010)	. 27
S.B. 17, 186th Gen. Court, 2009 Reg. Sess. (Mass. 2009)	. 27
S. File 1044, 86th Legis. Sess. (Minn. 2009)	. 27
H.B. 794, 95th Gen. Assem. 1st Reg. Sess. (Mo. 2009)	. 27
H.B. 394, 61st Leg. 2009 Reg. Sess. (Mont. 2009)	. 27
S.B. 231, 72d Reg. Sess. (Nev. 2007)	. 27
Assem. B. 3764, 213th Leg., 2d Ann. Sess. (N.J. 2009)	. 27
S.B. 4111, 231st Legis. Sess. (N.Y. 2009)	. 27
S.B. 159, 2007-2008 Sess. (N.C. 2007)	. 27
S.B. 379, 52d Leg., 1st Reg. Sess. (Okla. 2009)	. 27
H.B. 2680, 75th Legis. Assem., 2009 Reg. Sess. (Or. 2009)	. 27
H.B. 5093, 2009 Legis. Sess. (R.I. 2009)	. 27
S B 1620 77th Leg Reg Sess (Tex 2007)	27

H.B. 2452, 2009 Reg. Sess. (Va. 2009)
H.B. 1850, 60th Leg., 2007 Reg. Sess. (Wash. 2007)
S.B. 434, 2007 Sess. (W. Va. 2007)
OTHER MATERIALS
Editorial, Medical Files or Fishbowls?, Wash. Post, Sept. 23, 1997
Judy Foreman, Privacy Issues Loom in Push for Electronic Medical Records, Boston Globe, June 12, 2006
Milt Freudenheim, And You Thought a Prescription Was Private?, N.Y. Times, Aug. 9, 2009
Peter G. Goldschmidt, HIT and MIS: Implica- tions of Health Information Technology and Medical Information Systems, Com- munications of the ACM, Oct. 2005, http://www.worlddg.com/documents/622.pdf 29
Model Rules of Prof'l Conduct R. 1.6 18-19
Robert O'Harrow Jr., Are Data Firms Getting Too Personal?, Wash. Post, Mar. 8, 1998 29

The Vermont Attorney General, for himself and the other petitioners, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Second Circuit in this case.

#### INTRODUCTION

This case raises an important First Amendment question that has divided the lower courts: whether laws that restrict access to or commercial use of nonpublic drug prescriber information implicate First Amendment rights and, if so, what type of First Amendment review applies. The courts of appeals have reviewed several state laws that restrict access to or use of prescribing data for commercial marketing purposes, and have divided sharply on these issues. In creating an acknowledged conflict with the First Circuit, which has upheld similar laws, the Second Circuit's decision invalidating Vermont's law calls into question the constitutionality of numerous federal and state laws that protect information privacy by restricting access to or use of private information.

This marked split in the lower courts has emerged against the backdrop of an ever-increasing practice of commercial data mining and concomitant legal efforts to protect information privacy through laws like Vermont's. Data mining is a "burgeoning business," App. 66a, and the practice makes it increasingly difficult for any person to limit the dissemination of personal information in an age in which such information is routinely maintained and transferred through electronic means. To cite just one pertinent example, the use of electronic medical records is rapidly expanding, and more and more Americans are relying on private companies to maintain the privacy

of their personal health information. The court of appeals, however, rejected Vermont's significant interest in protecting medical privacy, despite the fact that Vermont's law regulates access to and use of nonpublic medical records that reveal the treatment decisions made by doctors for their patients.

The privacy interests at stake here are particularly keen – and the lower court's First Amendment analysis is particularly troubling – because prescription drug records are a product of government regulation. Neither doctors nor patients voluntarily provide information to pharmacies; rather, they are required to provide information to receive necessary health care services. If governments cannot restrict the confidentiality of information in this context, then it is difficult to conceive how any data privacy law would survive constitutional scrutiny.

Petitioners urge the Court to grant the petition both to resolve the conflict in the lower courts and to provide needed guidance on these important issues.

#### **OPINIONS BELOW**

The opinion of the court of appeals (App. 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 429.

#### **JURISDICTION**

The judgment of the court of appeals was entered on November 23, 2010. The jurisdiction of this Court is invoked under 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 findings set forth in 2007 Vt. Acts & Resolves No. 80, are reproduced at App. 129a-140a.

#### **STATEMENT**

Pharmacies are required by state and federal law to collect information when dispensing prescription drugs. These prescription drug records identify the prescribing physician, as well as details about the patient. Doctors and patients have no choice but to supply the information in order to obtain prescription medications.

The rapid transition to electronically stored records has, in recent years, allowed pharmacies to obtain additional profits by selling information from their prescription drug records to data mining companies. The data miners in turn sell the data to pharmaceutical manufacturers, and those companies use the data as a tool for the marketing of prescription drugs to doctors. The central question posed by this case is whether, consistent with the First Amendment, Vermont may require doctors' consent before the doctors' identifying information in prescription drug records may be sold and used for marketing purposes.

1. This case comes to this Court after a full evidentiary trial. The facts set forth in this Statement are drawn from the trial record, the legislative histo-

ry, and the findings of the courts that have reviewed these laws. Much of the evidence about the acquisition and use of prescriber-identifiable data comes from industry documents and employees.

- Pharmacies obtain information about doctors and patients because the dispensing of prescription drugs is extensively regulated by federal and state law. The federal Food and Drug Administration approves new drugs and decides whether and for how long a prescription is necessary to dispense a particular 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). Only licensed pharmacies and practitioners may dispense prescription drugs. See, e.g., Vt. Stat. Ann. tit. 26, §§ 2041(a) (requiring license for practice of pharmacy), 2022(14) (defining practice of pharmacy). In Vermont, as elsewhere, a pharmacy by law must collect and maintain detailed health and other identifying information from patients, including the name of the patient's doctor. E.g., Vt. Bd. of Pharmacy Admin. Rules §§ 9.1, 9.24, 9.26 (eff. Oct. 2009); see also 21 C.F.R. § 1306.05 (same for controlled substances). Although doctors and patients have no choice but to provide this information for the patient to receive a prescription drug, the same is not true for over-thecounter medications. If a doctor recommends an over-the-counter medicine, a patient may pay cash for the medicine at a pharmacy or grocery store, and leave without volunteering any information about herself or her doctor.
- **b.** The prescribing data sold by pharmacies and purchased by the respondent data miners is extraordinarily detailed and reveals substantial information about the doctor-patient relationship including

the treatment of individual patients. Each prescription record sold by a pharmacy contains "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. The patient's name is redacted using an encryption program that allows patient information to be monitored. App. 37a n.4; C.A. App. A3820, A3822. Because the encryption results in a unique identifier for each patient, data miners can compile information that "track[s] [a] person over time and determine[s] behaviors" – including the various drugs prescribed to that patient and the different doctors who wrote the prescriptions. C.A. App. A101-102. One of the respondent data miners has "track[ed] the activities of over two hundred million" patients, linking patients, products, prescribers, payers, and pharmacies. Id. at A98, A100-101.

Put in real terms, then, the data miner purchasing Vermont prescription records learns not only that Dr. Jones, in Montpelier, wrote 25 prescriptions for anti-depressants in the past month, 15 for a generic anti-depressant, 5 for one brand-name drug X, and 5 for another brand-name drug Y. The data miner also finds out that Dr. Jones prescribed a specific anti-depressant to a 50-year-old female patient who lives within a particular region in Vermont, and is further able to track the other drugs prescribed to that patient and the pharmacies where that patient fills the prescriptions.

**c.** The principal use pharmaceutical manufacturers make of such data – indeed, for some pharmaceutical manufacturers, the only use – is to market prescription drugs directly to doctors, a practice known as detailing. App. 72a; C.A. App. A217. Sales

representatives, known as detailers, use the data as part of targeted marketing campaigns aimed at increasing sales volumes for brand-name prescription drugs. App. 72a, 91a-92a. The pharmaceutical industry spends almost \$8 billion a year on marketing efforts directed at doctors, not counting direct-toconsumer advertising or the value of prescription drug samples given to doctors. App. 71a; C.A. App. A3808. "Coincident with the phenomenon of 'data mining,' pharmaceutical industry spending on direct marketing has increased exponentially." App. 72a. There is no dispute that the use of prescribing data amplifies the effectiveness of detailing; respondent data miners tout this fact as a reason to buy the data. As one data miner has said, the use of prescribing data in marketing "[m]aximize[s] the revenue per call and scripts per detail." C.A. App. A3834.

The evidence at trial in this case showed that prescribing data is used, without the consent of doctors or patients, to target certain doctors for marketing efforts; track (in nearly real-time) any changes in doctors' prescribing practices; adapt marketing messages and monitor the effectiveness of different marketing strategies; and determine the success, and therefore the compensation, of sales representatives. *E.g.*, *id.* at A101, A107-108, A112, A3780-3801, A3820-3853.

**d.** This prescribing data is not made public, and detailers do not tell doctors about it. Indeed, the data miners' licensing agreements prohibit detailers from telling a doctor about the doctor's own prescribing data. C.A. App. A93, A109, A118. According to respondents, the data may "not be shared with anyone," *id.* at A3398, a fact that led the district

court below to describe the use of prescribing data as "covert[]," App. 94a, 124a.

The Vermont legislature, along with state legislatures in New Hampshire and Maine, reviewed the practice of pharmaceutical data mining in response to media reports and complaints from doctors. The Vermont Medical Society, the professional organization for Vermont doctors, passed a unanimous resolution stating that "the use of physician prescription information by sales representatives is an intrusion into the way physicians practice medicine," and asked the legislature to end the practice. E.g., C.A. App. A4197; App. 91a. The legislature considered evidence from doctors, industry representatives, former sales representatives, and medical researchers, among others. C.A. App. A4020-4039. Based on a substantial body of evidence, the legislature found that restricting the availability of prescribing data for use in marketing would protect medical privacy, help control health care costs, and protect public health and safety.

After several months of hearings, the Vermont legislature passed the Prescription Confidentiality Law, which allows the use of prescriber-identifiable data in marketing only if the prescriber has consented. See Vt. Stat. Ann. tit. 18, § 4631. The law (as amended in 2008) provides in relevant part:

A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity shall not sell, license, or exchange for value regulated records containing prescriber-identifiable information, nor permit the use of regulated records containing prescriber-identifiable information for marketing or promoting a prescription drug, unless the

prescriber consents as provided in subsection (c) of this section. Pharmaceutical manufacturers and pharmaceutical marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents . . . .

Id. § 4631(d). Prescribers indicate on their licensing applications or renewal forms whether they consent. Id. § 4631(c)(1). The law does not restrict various non-commercial uses of the data, such as for health care research. Id. § 4631(e)(1). It further allows "the sale, license, exchange for value, or use of patient and prescriber data for marketing or promoting if the data do not identify a prescriber." Id. § 4631(e)(7).

The data-miner respondents, IMS Health, Verispan, and Source Healthcare, filed suit in August 2007, before the law took effect, claiming it violated the First Amendment and the dormant Commerce Clause. PhRMA, a trade organization for pharmaceutical manufacturers, filed its own lawsuit asserting a similar First Amendment claim. The district court consolidated the cases and held a five-day bench trial in July 2008. The court heard testimony from eighteen witnesses and admitted "reams of exhibits, including the entire legislative history" into evidence. App. 78a. The court also allowed several months of post-trial briefing, including briefs in response to the First Circuit decision upholding a similar New Hampshire law. See IMS Health Inc. v. Ayotte, 550 F.3d 42 (1st Cir. 2008), cert. denied, 129 S. Ct. 2864 (2009).

The district court upheld the Prescription Confidentiality Law. Applying the *Central Hudson* test, it concluded that the law directly advances the State's interests in protecting public health and reducing

health care costs. App. 82a, 95a, 97a (citing Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557 (1980)). The district court's decision explains how the pharmaceutical industry uses prescriber-identifiable data to market brand-name drugs directly to doctors. "Detailing leads to increased prescriptions for new drugs over generic alternatives which are often more cost-effective," and the use of the data "amplifies the influence and effectiveness of detailing." App. 91a. The district court also found, based on expert testimony at trial, that the use of prescriber-identifiable data in marketing threatens patient safety. App. 95a. New drugs are not only more expensive, but also riskier, because their use, risks, and side effects are not yet fully understood. App. 97a. After recounting evidence about drugs like Baycol and Vioxx, which were widely and unnecessarily overprescribed before being withdrawn from the market for safety reasons, 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. Turning to Central Hudson's narrow tailoring requirement, the court found that the law's "limited restraint," App. 87a, is "in reasonable proportion to the State's interests," App. 99a. The law is "a targeted response to the harm of overprescription caused by detailers' use of" prescriber-identifiable data. Id. The court also concluded that the law regulates Vermont transactions and thus does not violate the dormant Commerce Clause. App. 108a.

**b.** Following the district court's ruling, plaintiffs sought an injunction to prevent the law from taking effect pending appeal. The district court denied this

request, reiterating its findings that the law would "protect the health of Vermonters and contain health care costs." App. 127a. Plaintiffs renewed their request for an injunction pending appeal with the court of appeals. A three-judge panel denied the request, concluding that plaintiffs did not demonstrate a clear or substantial likelihood of success on the merits. App. 120a. The Prescription Confidentiality Law took effect July 1, 2009.

In a split decision, the court of appeals invalidated the law on First Amendment grounds. In conflict with two recent decisions of the First Circuit, the panel majority held that the law regulates commercial speech, and further concluded that the State did not meet its burden of justifying the law under Central Hudson. The court did not dispute any of the findings of the district court but instead concluded that the restriction on the use of prescriberidentifiable data did not serve the State's interests in a sufficiently direct manner, because Vermont had neither "directly restrict[ed] the prescribing practices of doctors" nor directly restricted detailing. App. 25a. The court analogized the restriction on the nonconsensual use of prescriber-identifiable data to advertising bans and to regulations that "entirely suppress commercial speech." App. 25a-26a (quoting Central Hudson, 447 U.S. at 566 n.9; citing Thompson v. W. States Med. Ctr., 535 U.S. 357 (2002); 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484 (1996); Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748 (1976)). The court also found that the law was not narrowly tailored, reasoning that the law was a "categorical" restriction even though doctors are free to consent to the use of their data for marketing. App. 32a. The court suggested that the State had two other options: waiting to assess the impact of a new counter-detailing program or "mandat[ing] the use of generic drugs as a first course of treatment, absent a physician's determination otherwise, for all those patients receiving Medicare Part D funds." App. 30a-31a.

**d.** Judge Livingston dissented, arguing that the majority opinion 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.

First, Judge Livingston sharply criticized the majority for failing to recognize 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 relied on this Court's ruling in Los Angeles Police Department v. United Reporting Publishing Corp., 528 U.S. 32 (1999), which held that a statute that restricted access to arrestee information collected by police departments did not violate the First Amendment. Judge Livingston reasoned that, while prescriber data is in the hands of pharmacies rather than the government, pharmacies have the data only "because the state has directed them to collect it." App. 41a. Thus, "Vermont's interest in controlling the further dissemination of that information is not conceptually different" from California's interest in *United Reporting*. *Id*. "Having mandated the collection of ... otherwise highly confidential information, the state unquestionably has an interest in controlling its further dissemination." App. 40a. Because "pharmacies have access to and collect prescription information only under the direction and authority of state law," the statute's restriction on access to that information does not violate the First Amendment. *Id*.

Second, Judge Livingston observed that the majority opinion "overstate[d]" the State's burden under *Central Hudson*. App. 55a. Notwithstanding her own de novo review of the record, Judge Livingston nonetheless recognized 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.

Third, Judge Livingston concluded that the statute directly advances all three interests identified by the State, and in so doing forcefully disagreed with her colleagues' disregard for the State's interest in protecting privacy. Judge Livingston noted that, "[w]ithout question, the law restricts the flow of otherwise private information about doctors' prescribing habits and the care they provide to their patients" and "dramatically reduces the spread of [prescriberidentifiablel data." App. 59a-60a. The law also advances Vermont's interest in protecting patient safety and reducing health care costs, because it "makes it less likely that doctors will prescribe less cost-effective, and potentially riskier brand name drugs over generic class equivalents." App. 58a.

Finally, Judge Livingston argued that, in applying the narrow-tailoring requirement of *Central Hudson*, the majority failed to take into account the "minimal and indirect" nature of the restriction. App. 61a. She agreed with Judge Lipez of the First Circuit that Vermont's law is "inherently distinct from the sorts of 'categorical' and direct bans on commercial speech"

that this Court has invalidated. Id. Rather, the law, which does not directly restrict detailing, ban marketing, or prohibit in-person solicitation, "impose[s] exceedingly limited burdens on commercial speech." App. 62a. In finding the law to be a "reasonable fit" with the State's interests, Judge Livingston noted that many of the proposed alternatives were "actually far more restrictive" of plaintiffs' activities. Id. In noting her disagreement with the majority's opinion, Judge Livingston pointed out that the "transfer of data has become a burgeoning business" and expressed her concern that the majority's approach "will make it unduly and inappropriately difficult for states to properly and constitutionally regulate in furtherance of substantial interests, including a state's very serious interest in the protection of private information." App. 66a.

#### REASONS FOR GRANTING THE PETITION

This Court should grant review to resolve the split of authority in the lower courts and to address pressing First Amendment issues that have emerged at the intersection of information technology, information privacy, and commerce. The Second Circuit's decision in this case directly conflicts with decisions of the First Circuit upholding similar laws. Moreover, through its mistaken application of First Amendment principles, the decision calls into question other information privacy laws and creates doubt about the authority of states and the federal government to protect information privacy. The government's interest in protecting privacy is strongest where, as here, the government itself has required the collection of otherwise nonpublic information. By failing to acknowledge that interest, the lower court's decision casts doubt on the authority of states and the federal government to take meaningful steps to protect information privacy.

The Court's guidance is warranted here, and this case presents an ideal opportunity to address how the Court's precedents apply to restrictions on access to and commercial use of personal information.

I. THE DECISION BELOW IS ERRONEOUS AND CONFLICTS WITH TWO RECENT FIRST CIRCUIT DECISIONS UPHOLDING SUBSTANTIALLY SIMILAR STATE STATUTES.

The States of Vermont, New Hampshire and Maine enacted similar statutes, all designed to limit access to prescriber-identifiable data for use in marketing prescription drugs to doctors. App. 7a-11a; *IMS Health Inc. v. Mills*, 616 F.3d 7, 16 (1st Cir. 2010). Respondents IMS, Verispan, and Source Healthcare Analytics challenged each of these laws, raising the

same First Amendment claims in each case. The First Circuit has upheld the laws of New Hampshire and Maine. *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 45 (1st Cir. 2008), *cert. denied*, 129 S. Ct. 2864 (2009); *Mills*, 616 F.3d at 13. In the decision below, the court of appeals expressly rejected the reasoning of the First Circuit, *see*, *e.g.*, App. 15a-16a, and invalidated Vermont's law.

## A. The decision below explicitly rejected the First Circuit's grounds for upholding substantially similar state statutes.

The first point of disagreement between the First and Second Circuits in evaluating these substantially similar state laws is whether the restriction on obtaining information for marketing purposes restricts speech, and thus implicates the First Amendment. In its first ruling, the First Circuit held that New Hampshire's restriction on obtaining prescriberidentifiable data for marketing purposes regulates commercial conduct, not speech. Ayotte, 550 F.3d at 51-54. More recently, a different panel of the First Circuit adhered to the reasoning in Ayotte and held that Maine's restriction on access to prescriberidentifiable data is a regulation of commercial conduct. Mills, 616 F.3d at 19-20. The Mills court further held that this Court's recent decision in *United* States v. Stevens, 130 S. Ct. 1577, 1585-87 (2010), did not undermine the holding in *Ayotte*. 616 F.3d at 20.

In deciding this case, the Second Circuit expressly rejected the First Circuit's approach. The court reasoned that the acquisition, aggregation, and transfer of data by data miners is speech, and concluded that Vermont's law "restricts protected speech." App. 17a. Indeed, as the dissenting opinion observes, the majority opinion even suggests that the aggregating and

selling of this data might be appropriately viewed as *noncommercial* (that is, fully protected) speech. App. 19a. And, unlike the First Circuit in *Mills*, the majority below saw a conflict between *Ayotte* and this Court's reasoning in *Stevens*. App. 16a.

Although the statutes vary slightly – New Hampshire bans the use of prescriber-identifiable data for marketing, Vermont requires the doctor's consent to that use, and Maine allows doctors to prevent such use – those differences do not explain the outcomes or minimize the conflict in the court of appeals' judgments. The First Circuit found that New Hampshire's outright prohibition on the use of the data for marketing restricted commercial conduct, not speech, whereas the court below reached the opposite conclusion for Vermont's less restrictive, consent-based law. As a result, the courts of appeals directly conflict over whether the statutory restriction on access to data for marketing purposes restricts protected speech.

# B. The circuit conflict over drug data mining laws arises amidst an ongoing, deep, and mature conflict as to whether government may protect individuals' privacy rights consistent with the First Amendment.

In addition to reaching a judgment directly contrary to the First Circuit, the decision below extends an existing conflict about the constitutionality of privacy protections. The D.C. Circuit has issued several decisions upholding such laws. See Nat'l Cable & Telecomms. Ass'n v. FCC, 555 F.3d 996, 1003 (D.C. Cir. 2009) (denying review of FCC rule requiring affirmative consent before consumer's calling history can be disclosed to certain third parties for marketing purposes); Trans Union LLC v. FTC, 295 F.3d 42, 53 (D.C. Cir. 2002) (upholding, against First Amend-

ment challenge, Gramm-Leach-Bliley Act privacy rules, including restriction on disclosure of consumer account numbers); Trans Union Corp. v. FTC, 245 F.3d 809, 818 (D.C. Cir. 2001) (upholding, against First Amendment challenge, restriction on sale of targeted marketing lists under Fair Credit Reporting Act). In National Cable, the most recent of these rulings, the D.C. Circuit acknowledged that its line of holdings, and specifically its understanding of the privacy interests at stake, conflicts with Tenth Circuit precedent: "we do not agree that the interest in protecting customer privacy is confined to preventing embarrassment as the Tenth Circuit thought.... It is widely accepted that privacy deals with determining for oneself when, how and to whom personal information will be disclosed to others." 555 F.3d at 1001. Accordingly, notwithstanding that the Tenth Circuit had previously invalidated an FCC rule requiring consumer consent for disclosures of telephone calling information, see U.S. West, Inc. v. FCC, 182 F.3d 1224 (10th Cir. 1999), the D.C. Circuit declined judicial review of a similar FCC rule implementing a new federal statute, National Cable, 555 F.3d at 1003.1

In this case, the Second Circuit declined to accept the State's privacy interest as substantial for purposes of the *Central Hudson* standard. Its ruling thus aligns the Second Circuit with the Tenth Circuit. The D.C. Circuit, in contrast, expressly recognizes that privacy encompasses the determination of how, when, and with whom personal information is

<sup>&</sup>lt;sup>1</sup> In a subsequent ruling addressing FCC privacy rules, the Tenth Circuit adhered to *U.S. West. See Sorenson Commc'ns, Inc. v. FCC*, 567 F.3d 1215, 1225 (10th Cir. 2009) (following *U.S. West* in striking FCC rule restricting use of customers' telecommunications relay services data).

shared. The First Circuit in *Mills* likewise recognized a substantial state interest in privacy. 616 F.3d at 20. Granting certiorari in this case will allow the Court to provide necessary guidance that will inform how those issues should be decided as well.

## C. The decision below is erroneous under applicable First Amendment doctrine.

The decision below stands as a seriously flawed application of First Amendment jurisprudence. The court's determination that Vermont's law restricts protected speech misconstrues the statute and mistakenly analogizes this limited regulation on access to and commercial use of data to broad restrictions on public information conveyed through advertising. The Prescription Confidentiality Law does not limit the information that pharmaceutical manufacturers may provide about the products they sell. It instead imposes a restriction on access to and commercial use of private medical information without consent. And, as Judge Livingston correctly observed in her dissenting opinion, the restriction applies to information that traditionally has not been publicly available and that pharmacies obtain in the first place only because of government regulation.

The court below refused to view Vermont's law as a restriction on access to information because the prescribing data at issue is maintained by private entities (typically, pharmacies) that are willing to sell it to data miners. In fact, restrictions on the dissemination of nonpublic information held by private persons have long coexisted with the First Amendment. Many regulated professions have confidentiality rules; these rules, for example, prevent lawyers and accountants from disclosing client information without consent. *See, e.g.*, Model Rules of

Prof'l Conduct R. 1.6 (attorneys); Fla. Admin. Code r. 61H1-23.001 (CPAs). Insurance companies, financial institutions, and even utility companies hold non-public information that cannot be disclosed without consent under state and federal law. *See infra* pp. 32-33 (collecting statutes).

This Court has recognized that the "right to speak and publish does not carry with it the unrestrained right to gather information." Zemel v. Rusk, 381 U.S. 1, 17 (1965); see also Seattle Times Co. v. Rhinehart, 467 U.S. 20, 32 (1984). This Court's decisions do not stand for the proposition that the government may restrict access to or use of nonpublic information only when the information is in government hands. In Seattle Times, the Court held that a newspaper did not have a First Amendment right to disclose information obtained by the newspaper through pretrial discovery, where the trial court had entered a protective order restricting disclosure. See id. at 32-37. And in Florida Star v. B.J.F., 491 U.S. 524, 534 (1989), the Court acknowledged that, "[t]o the extent sensitive information rests in private hands, the government may under some circumstances forbid its nonconsensual acquisition."

Petitioners do not contend that restrictions on access to or acquisition of information from private parties can *never* trigger First Amendment review. The lower court, however, plainly erred when it held that restricting access to information in health care records – records created for a government purpose – necessarily restricts protected speech merely because the records are not in the government's possession.<sup>2</sup>

<sup>&</sup>lt;sup>2</sup> Under the lower court's reasoning, state and federal laws that restrict private health care providers from disclosing

The Second Circuit likewise erred in disregarding the role of the prescriber under Vermont's law. The court's opinion rests on its stated view that Vermont acted improperly by restricting the use of prescriber data in "an attempt to influence the prescribing conduct of doctors." App. 28a. The court reasoned that "courts must be very skeptical of government efforts to prevent the dissemination of information in order to affect conduct." App. 26a. But, in taking that approach, the court mistakenly minimized the importance of a key feature of Vermont's law: the law is a consent-based restriction, such that doctors themselves, not the government, control the commercial use of their prescribing data and decide what kind of marketing they will accept. Requiring consent for the use of a person's data in targeted marketing does not restrict any commercial speech to a willing audience. Cf. Mainstream Mktg. Servs. v. FTC, 358 F.3d 1228, 1238 (10th Cir. 2004) (upholding "Do Not Call" registry against First Amendment challenge, and noting registry "does not inhibit any speech directed at the home of a willing listener"); Rowan v. U.S. Post Office, 397 U.S. 728, 737 (1970) ("[n]othing in the Constitution compels us to listen to or view any unwanted communication, whatever its merit").3

patient information also are necessarily viewed as restrictions on protected speech.

<sup>&</sup>lt;sup>3</sup> This discussion of the merits necessarily is truncated. For the additional reasons set forth in Parts II and III, including the Second Circuit's erroneous application of *Central Hudson* to this facial challenge, and to be developed further in merits briefing, the Vermont statute should be held constitutional.

## II. THE JUDGMENT BELOW CONFLICTS WITH OTHER CIRCUITS' DECISIONS ON WHETHER, IF THE FIRST AMENDMENT APPLIES, THE CENTRAL HUDSON TEST IS SATISFIED.

The conflict as to whether the Vermont, New Hampshire, and Maine statutes restrict speech is itself sufficient to warrant granting the petition in this case, but the conflict is not confined to this important All three circuit court opinions considered whether these laws restricting the use of prescriberidentifiable data for marketing satisfy the Central Hudson test for regulations of commercial speech. The First Circuit found that the laws of New Hampshire and Maine serve substantial government interests, directly advance those interests, and restrict speech no more than necessary to advance those interests. Ayotte, 550 F.3d at 55-60; Mills, 616 F.3d at 18-23. Judge Lipez, who dissented from Ayotte's holding that New Hampshire's law restricts only conduct, and not speech, nonetheless agreed with the majority opinions on this point and held that both the Maine and New Hampshire laws satisfied the Central Hudson test. Ayotte, 550 F.3d at 84-102 (Lipez, J., concurring); Mills, 616 F.3d at 36-39 (Lipez, J., concurring). In direct contrast, the Second Circuit found that Vermont's law did not withstand constitutional scrutiny. App. 4a.

The lower courts did not just reach different outcomes, but along the way reached markedly different conclusions at each step in the *Central Hudson* analysis. All three States have advanced the same three interests in enacting their statutes: protecting prescriber privacy; cost containment; and ensuring quality health care. *Ayotte*, 550 F.3d at 55; *Mills*, 616 F.3d at 17; App. 21a. Yet, although the three

statutes were all designed to address the same problems, see Mills, 616 F.3d at 16-17, the opinions diverge considerably in analysis of each of Central Hudson's three prongs.

### A. The circuits conflict over the sufficiency of the state interest.

The First Circuit accepted both privacy and cost containment as substantial state interests for purposes of *Central Hudson*. *See Ayotte*, 550 F.3d at 55 (addressing cost containment); *Mills*, 616 F.3d at 20 (finding substantial state interest in shielding prescribers who object to "invasive use" of their information). Although Vermont's law allows providers to decide whether their data may be used for marketing purposes, the Second Circuit flatly rejected privacy as even a valid state interest under *Central Hudson*. App. 23a. Accordingly, the decision below directly conflicts with the *Mills* opinion on the existence of a state interest in prescriber privacy.

In her dissenting opinion below, Judge Livingston readily accepted the State's substantial interest in privacy "in an era of increasing and well-founded concern about medical privacy and the rampant dissemination of confidential information." 52a. As she observed, Vermont's law "restricts the flow of otherwise private information about doctors' prescribing habits and the care they provide to their patients." App. 59a-60a. The majority opinion focused on the fact that the law does not address the use of the data for purposes other than marketing. Judge Livingston, however, correctly emphasized that the law "dramatically reduces the spread of [prescriber-identifiable] data." App. 60a. The record provides strong support for this conclusion, because Vermont doctors repeatedly told state legislators of their strong objection to the use of prescribing data by pharmaceutical marketers. See, e.g., C.A. App. A1183, A1304, A1433, A1435, A4197, A4262, A4323 (testimony from doctors and Medical Society; resolution of Medical Society). By disregarding this evidence and rejecting the position taken by the dissent, the Second Circuit's decision directly conflicts with Mills. See 616 F.3d at 15 (finding that majority of Maine prescribers "did not want pharmaceutical manufacturers to be able to use their individual prescribing histories for marketing purposes"; citing doctor objections to invasion of privacy).

Moreover, as the *Mills* court correctly recognized, the privacy interest "is not solely about protecting prescribers' expectation that their identifying data will remain categorically private." 616 F.3d at 20. The First Circuit concluded that prescribers "have a privacy interest in avoiding unwanted solicitations from detailers who have used their individual prescribing data to identify and target them." *Id.* Vermont advanced this concern as well, showing that the use of prescribing data in marketing intrudes on the doctor-patient relationship, but the Second Circuit, in contrast to the First, rejected this argument. *See* App. 22a-23a.

## B. The circuits conflict over the directness needed to effectuate the state interest.

The opinions also conflict on whether the statutes directly advance the States' interests. The *Ayotte* court held that New Hampshire's law was "reasonably calculated to advance its substantial interest in reducing overall health care costs." 550 F.3d at 59. The court's holding rests on the "causal chain" of evidence advanced by New Hampshire: that detailing substantially increases prescriptions for more

expensive brand-name drugs; that detailing using prescriber-identifiable data is "more adversarial" and less focused on clinical information, and further increases sales of brand-name drugs; and that this "dramatic[]" increase in prescriptions of brand-name drugs does not "confer[] any corresponding public health benefit." *Id.* at 56-57. The Second Circuit rejected the same chain of reasoning accepted by the First Circuit, finding that Vermont's law did not advance the State's interests "directly." App. 22a.<sup>4</sup>

The lower courts' conflicting conclusions on the "directly advance" prong of Central Hudson do not reflect mere disagreement about the proper evaluation of the evidence. Rather, the lower courts applied the test in markedly different ways. Adhering to this Court's precedent, the First Circuit asked whether the harms cited by the State are real and whether the statute would alleviate them to a material degree. Ayotte, 550 F.3d at 55-58; id. at 88-93 (Lipez, J., concurring); Mills, 616 F.3d at 22-23. In the decision below, the majority did not conduct that analysis and, in fact, did not dispute Vermont's position (as accepted by the district court and the dissenting judge) that limiting access to prescriber-identifiable data would benefit patients and reduce health care costs. Instead, the court of appeals simply concluded that the First Amendment does not permit Vermont to achieve its stated interests by restricting access to or use of prescribing data. See App. 24a-28a.

<sup>&</sup>lt;sup>4</sup> In *Mills*, the First Circuit held, as a separate ground for rejecting plaintiffs' First Amendment claim, that Maine's law directly advanced the State's substantial interest in protecting privacy. 616 F.3d at 22.

## C. The circuits conflict over the sufficiency of the State's tailoring of its restriction.

Finally, the lower courts take contrasting approaches to applying Central Hudson's narrow-tailoring prong. The decision below faulted Vermont for not imposing direct requirements on doctors' prescribing practices - that is, for not simply mandating generic prescriptions. App. 30a-31a. The First Circuit, however, like the dissent below, recognized that such an approach burdens doctors by "[i]nserting one more laborious step" into the prescribing process. Ayotte, 550 F.3d at 60; see also App. 62a. The First Circuit also rejected the notion that government-sponsored efforts to educate doctors would accomplish the statute's goals, noting that as a matter of "simple economics" New Hampshire could not match the billions of dollars spent marketing prescription drugs. Ayotte, 550 F.3d at 60; see id. at 98-100 (Lipez, J., concurring). The Second Circuit contradicted the First Circuit on this point, not only by identifying counter-detailing as an alternative but also by holding that Vermont was required to "wait" and see what effect a counterdetailing program might have. App. 30a.

And, again, the conflict between the two decisions reflects divergent approaches to *Central Hudson*. The First Circuit carefully considered the degree to which proposed alternatives would achieve the State's goals, and in so doing focused on the specific problem of the use of prescriber-identifiable data in marketing. *Ayotte*, 550 F.3d at 59-60. The Second Circuit, to the contrary, rejected out of hand the notion that Vermont's law is narrowly tailored because it targets only the use of prescriber-identifiable data in marketing, saying the argument was "not responsive to the inquiry under *Central Hudson*." App. 33a;

cf. App. 60a-61a (Livingston, J., dissenting) (arguing that the majority failed to balance the state interest against the burden imposed on speech, as required to determine if the imposition is "in proportion to the interest served") (quoting Greater New Orleans Broad. Ass'n, Inc. v. United States, 527 U.S. 173, 188 (1999)); Ayotte, 550 F.3d at 97-98, 100 (Lipez, J., concurring) (emphasizing law's "limited scope," as distinguished from broad bans on commercial speech).

The conflict here could not be sharper. Close in time, and responding to concerns from the public and from the medical profession, Vermont, New Hampshire, and Maine enacted similar laws with similar purposes. All three laws have been tested in court proceedings, and the lower courts have arrived at inconsistent results, based on several incompatible conclusions of law. The issues raised in these cases have been fully developed not only in the three majority opinions from the circuits, but in the separate concurring and dissenting opinions of Judge Livingston and Judge Lipez. The Court should accordingly grant Vermont's petition to resolve these conflicts.

- III. THE ISSUES RAISED IN THIS PETITION ARE OF SURPASSING AND GROWING IMPORTANCE.
  - A. Other States are considering legislation to limit use of prescription information in the same ways as Vermont, New Hampshire, and Maine.

The same concerns that led Vermont, New Hampshire, and Maine to enact restrictions on the commercial use of prescriber-identifiable data have prompted state legislators across the country to consider similar measures. In the last three years, bills banning or restricting access and commercial use of prescriber-identifiable data have been proposed

in Arizona, California, Connecticut, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Iowa, Kansas, Maryland, Massachusetts, Minnesota, Missouri, Montana, Nevada, New Jersey, New York, North Carolina, Oklahoma, Oregon, Rhode Island, Texas, Virginia, Washington, and West Virginia. See also 105 Mass. Code Regs. 970.005(2)(g) (manufacturer must provide prescriber opportunity to prohibit use of prescriber's data for marketing purposes). Given likely state legislation on this subject and the resulting litigation over its constitutionality, this Court's guidance is urgently needed.

<sup>&</sup>lt;sup>5</sup> See S.B. 1234, 49th Leg., 2d Reg. Sess. (Ariz. 2010); Assem. B. 2112, 2009-10 Reg. Sess. (Cal. 2010); S.B. 1046, Gen. Assem. Jan. Sess. 2009 (Conn. 2009); B17-364, 2007 Council (D.C. 2007); S.B. 1402, 111th Reg. Sess. (Fla. 2009); H.B. 820, 115th Gen. Assem. 2009-2010 Reg. Sess. (Ga. 2009); S.B. 449, 25th Leg., Reg. Sess. (Haw. 2009); H.B. 1459, 95th Gen. Assem., 1st Reg. Sess. (Ill. 2007); H. File 622, 83rd Gen. Assem., 2009 Sess. (Iowa 2009); S.B. 229, Sess. of 2009 (Kan. 2007); S.B. 1040, 427th Sess. (Md. 2010); S.B. 17, 186th Gen. Court, 2009 Reg. Sess. (Mass. 2009); S. File 1044, 86th Legis. Sess. (Minn. 2009); H.B. 794, 95th Gen. Assem. 1st Reg. Sess. (Mo. 2009); H.B. 394, 61st Leg. 2009 Reg. Sess. (Mont. 2009); S.B. 231, 72d Reg. Sess. (Nev. 2007); Assem. B. 3764, 213th Leg., 2d Ann. Sess. (N.J. 2009); S.B. 4111, 231st Legis. Sess. (N.Y. 2009); S.B. 159, 2007-2008 Sess. (N.C. 2007); S.B. 379, 52d Leg., 1st Reg. Sess. (Okla. 2009); H.B. 2680, 75th Legis. Assem., 2009 Reg. Sess. (Or. 2009); H.B. 5093, 2009 Legis. Sess. (R.I. 2009); S.B. 1620, 77th Leg., Reg. Sess. (Tex. 2007); H.B. 2452, 2009 Reg. Sess. (Va. 2009); H.B. 1850, 60th Leg., 2007 Reg. Sess. (Wash. 2007); S.B. 434, 2007 Sess. (W. Va. 2007).

#### B. Data mining is an ever-expanding threat to privacy, so clarifying the applicable First Amendment principles in this area is critical.

The importance of the issues raised in this case is perhaps best illustrated by the concurring opinion of First Circuit Judge Lipez in *Mills* and the dissenting opinion of Second Circuit Judge Livingston below. While disagreeing in some respects about the appropriate legal analysis, both judges expressly recognize the importance of the precedent set by the panel opinions and the widespread, significant impact of Judge Livingston expressed "serious the rulings. concern" that the majority's decision "will make it unduly and inappropriately difficult for states to properly and constitutionally regulate in furtherance of substantial interests, including a state's very serious interest in the protection of private information." App. 66a. Judge Livingston accordingly warned that the majority's ruling created "precedent likely to have pernicious broader effects in a complex and evolving area of First Amendment law." App. Judge Lipez, responding to a very different majority opinion, likewise deemed the issues "serious" and described these laws as "present[ing] a challenge to the Supreme Court's commercial speech jurisprudence that warrants the Court's attention and guidance." Mills, 616 F.3d at 49 (Lipez, J., concurring). Indeed, Judge Lipez did not merely ask for this Court's guidance but opined that the Court's consideration of the issues was "inevitabl[e]." *Id.* at 33.

The concerns of both judges are well-founded and justify the Court's review. Information technology has created new and unprecedented opportunities for data mining companies to obtain, monitor, transfer,

and use personal information. Indeed, one of the defining traits of the so-called "Information Age" is this ability to amass information about individuals. Computers have made the flow of data concerning everything from personal purchasing habits to real estate records easier to collect than ever before. Compilations of this data provide marketers with detailed information about potential customers. The "burgeoning business," App. 66a, of data mining is a multi-billion dollar industry in the United States.

The increased ability to gather, aggregate, and sell potential customer information also applies to health care records and is likely to grow as more medical records become electronic.<sup>8</sup> Commentators have argued that, without proper protection, electronic medical systems could become "the most valuable motherlode of information for data mining on [E]arth" and that, "[o]f all the threats posed to

<sup>&</sup>lt;sup>6</sup> As the executive of a major data mining company, Acxiom Corp., stated: "Today it's almost unbounded, our ability to gather, sort and make sense of the vast quantities of information." Robert O'Harrow Jr., *Are Data Firms Getting Too Personal?*, Wash. Post, Mar. 8, 1998, at A1.

<sup>&</sup>lt;sup>7</sup> Sales of prescriber-identifiable data by respondent IMS Health alone produced \$1.75 billion in revenue in 2005. *Mills*, 616 F.3d at 44-45 (Lipez, J., concurring).

<sup>&</sup>lt;sup>8</sup> It is estimated that approximately 50% of healthcare providers will use electronic health records by 2020. Peter G. Goldschmidt, *HIT and MIS: Implications of Health Information Technology and Medical Information Systems*, Communications of the ACM, Oct. 2005, at 73, http://www.worlddg.com/documents/622.pdf.

<sup>&</sup>lt;sup>9</sup> Judy Foreman, *Privacy Issues Loom in Push for Electronic Medical Records*, Boston Globe, June 12, 2006, at C1 (quoting Dr. Deborah Peel, founder of the Patient Privacy Rights Foundation).

personal privacy by new information technologies, the threat to the privacy of medical records is by far the most urgent."<sup>10</sup> At the same time that health care providers are expanding their use of electronic medical records to improve the quality of care, media reports continue to document inappropriate disclosures of health information, including the use of prescription information for marketing purposes.<sup>11</sup>

The court of appeals found that Vermont's law allowing doctors to decide whether their prescribing practices should be sold and used for commercial purposes violates the commercial speech rights of data miners and drug marketers. The decision thus reviews asserted commercial speech rights in one of the most sensitive and regulated spheres of information – medical records. And it invalidates a law that allows individual doctors – not the government – to control the use of their prescribing information for marketing. While this Court's review of commercial speech regulations has become somewhat more stringent over time, these cases address government restrictions on the commercial messages *provided to consumers* about products or services. <sup>12</sup> The applica-

 $<sup>^{10}</sup>$  Editorial, Medical Files, or Fishbowls?, Wash. Post, Sept. 23, 1997, at A16.

<sup>&</sup>lt;sup>11</sup> Milt Freudenheim, And You Thought a Prescription Was Private?, N.Y. Times, Aug. 9, 2009, at BU1.

<sup>12</sup> See, e.g., Thompson v. W. States Med. Ctr., 535 U.S. 357 (2002) (ban on advertisements for particular drugs); Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001) (effective ban on tobacco product advertisements); Greater New Orleans Broad. Ass'n, 527 U.S. 173 (ban on advertising lawful casino gambling); 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484 (1996) (ban on advertising liquor prices); Rubin v. Coors Brewing Co., 514 U.S. 476 (1995) (ban on labels containing alcohol content); Edenfield v. Fane, 507 U.S. 761 (1993) (ban on in-person CPA)

tion of the *Central Hudson* test to Vermont's law imports this jurisprudence into a new and distinct field – restrictions on commercial access to or use of information about individuals.

Moreover, Vermont's law is not a blanket ban on data mining but rather affords individuals the right to control access to or use of personal information for marketing. While advertising is something that consumers can usually mute, throw out, or click-through if they so choose, data mining without consent is a covert practice over which the persons most directly affected – here, doctors and their patients – lack control. The lower court's recognition of a First Amendment right to mine data without the customer's consent appears at odds with the long-standing principle that "[t]he right to speak and publish does not carry with it the unrestrained right to gather information." Zemel, 381 U.S. at 17; see also Houchins v. KQED, Inc., 438 U.S. 1, 11 (1978) (although "[t]here is an undoubted right to gather news from any source by means within the law, ... that affords no basis for the claim that the First Amendment compels others - private persons or governments - to supply information") (internal quotations and citation omitted)). This case presents an excellent opportunity to resolve these apparently conflicting lines of First Amendment principles.

solicitations); Cincinnati v. Discovery Network, Inc., 507 U.S. 410 (1993) (ban on distribution of commercial handbills); Bd. of Trs. of State Univ. of NY v. Fox, 492 U.S. 469 (1989) (ban on "Tupperware parties"); Central Hudson, 447 U.S. 557 (ban on utility advertising); Bates v. State Bar of Ariz., 433 U.S. 350 (1977) (ban on lawyer advertising); Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748 (1976) (ban on prescription drug price advertisements).

The legal issues presented in this case thus extend beyond the constitutionality of restrictions on prescriber-identifiable data.<sup>13</sup> The federal government, for example, has enacted numerous laws that restrict the sale and use of information without consent. See, e.g., 15 U.S.C. § 6802(b) (customer right to opt-out of disclosure of personal information by financial institution); 18 U.S.C. § 2702(c) (restricting use of Internet subscriber information without consent); 18 U.S.C. § 2710(b) (prohibiting disclosure of "personally identifiable information concerning" consumer of video rental establishment without consent); 20 U.S.C. § 1232g(b) (prohibiting release of educational records without consent); 42 U.S.C. § 1320d-6 (prohibiting use and disclosure of "individually identifiable health information" without authorization); 47 U.S.C. § 551(c)(1) (prohibiting disclosure of "personally identifiable information" concerning cable subscriber without consent). See also United States v. Miami Univ., 294 F.3d 797, 823 (6th Cir. 2002) (rejecting First Amendment challenge to Family Educational Rights and Privacy Act of 1974, because there is no "First Amendment right of access" to student disciplinary records).

<sup>&</sup>lt;sup>13</sup> Of note, this Court previously upheld a privacy law in a case that did not address First Amendment issues. In *Reno v. Condon*, 528 U.S. 141 (2000), the Court reviewed the Driver's Privacy Protection Act of 1974 ("DPPA") against a federalism challenge by the State of South Carolina. The DPPA restricts the disclosure, without consent, of personal information obtained from a motor vehicle record. 18 U.S.C. § 2721(a). Chief Justice Rehnquist, writing for a unanimous court, determined that the DPPA is a valid exercise of Congress's authority to regulate interstate commerce under the Commerce Clause, because motor vehicle records are "a thin[g] in interstate commerce." 528 U.S. at 148 (internal quotations omitted).

A small sampling indicates similar enactments by States. See, e.g., Cal. Fin. Code § 4052.5 (restricting sale, transfer, and disclosure of nonpublic personal information by financial institutions, absent explicit consent of consumer); Conn. Gen. Stat. § 38a-988a(a) (barring sale and disclosure of individually identifiable medical record information for marketing purposes absent prior written consent); N.J. Stat. Ann. § 48:3-85(b)(1) (barring utility providers from selling or disclosing customer information without consent, including customer's name, address, payment history, and energy usage); N.M. Code R. § 13.1.3.12 (requiring affirmative consent before licensed insurer may disclose nonpublic personal financial information).

Notably, nearly all these laws address the use of information that is held by private entities, such as insurers and telecommunications providers, not by the government. *Cf.* App. 17a (refusing to treat Vermont's law as restriction on access to information because pharmacies, not the government, have prescription information). Without clarification as to the scope of any First Amendment right to collect and use data without consent, each of these laws may be constitutionally suspect.

This Court's resolution of the merits of this case would provide timely guidance as States and other regulators seek to respond to rapidly developing technologies that make the collection of information, including medical information, more widespread than ever before. The collecting, aggregating, and selling of data has become a multi-billion dollar industry since the Court last addressed information itself as "an article of commerce." *Reno*, 528 U.S. at 148. As the ability to amass volumes of information

about prospective customers – including health care providers – grows, States and other regulators need guidance as to the scope of their ability to allow individual Americans to control access to and use of their information.

Not only are the issues pressing and important, but this case provides an excellent vehicle for their review. Unlike at the time this Court denied a petition for certiorari in Ayotte,14 the circuits are now in stark conflict on the issues presented by state statutes that seek to limit the commercial disclosure of private information regarding doctors' prescription of drugs to their patients. Moreover, unlike in Ayotte, where the First Circuit had expressed some doubts about the standing of data miners to raise drug manufacturers' First Amendment rights in challenging these state laws, see 550 F.3d at 48-50, in this case the plaintiffs also include PhRMA, the trade organization for pharmaceutical manufacturers. In addition, the district court here held a five-day trial, in which it amassed an evidentiary record that includes the extensive legislative record as well the testimony of trial witnesses and numerous exhibits. Ayotte did not provide the Court with such a complete record on which to base its review of challenges to the constitutionality of the state law.

#### CONCLUSION

The petition for a writ of certiorari should be granted.

<sup>&</sup>lt;sup>14</sup> IMS Health Inc. v. Ayotte, 129 S. Ct. 2864 (2009).

#### Respectfully submitted,

DAVID C. FREDERICK SCOTT H. ANGSTREICH KELLOGG, HUBER, HANSEN, TODD, EVANS & FIGEL, P.L.L.C. 1615 M Street, N.W. Suite 400 Washington, D.C. 20036 (202) 326-7900 WILLIAM H. SORRELL
ATTORNEY GENERAL
BRIDGET C. ASAY
Counsel of Record
SARAH E.B. LONDON
DAVID R. CASSETTY
ASSISTANT ATTORNEYS
GENERAL
OFFICE OF THE ATTORNEY
GENERAL
109 State Street
Montpelier, Vermont 05609-1001

(802) 828-5500

(basay@atg.state.vt.us)

December 13, 2010