No. 10-779

IN THE
Supreme Court of the United States

WILLIAM H. SORRELL ET AL.,

Petitioners,

v.

IMS HEALTH INC. ET AL.,

Respondents.

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

BRIEF OF RESPONDENTS IMS HEALTH INC., VERISPAN, LLC, AND SOURCE HEALTHCARE ANALYTICS, INC.

Thomas R. Julin
Jamie Z. Isani
Patricia Acosta
HUNTON & WILLIAMS LLP
1111 Brickell Avenue
Suite 2500
Miami, FL 33131

Mark A. Ash
MCGUIRE WOODS LLP
2600 Two Hanover Square
Raleigh, NC 27601

Thomas C. Goldstein
Counsel of Record
Kevin R. Amer
AKIN GUMP STRAUSS
HAUER & FELD LLP
1333 New Hampshire
Avenue, N.W.
Washington, DC 20036
(202) 887-4000
tgoldstein@akingump.com

Robert B. Hemley
Matthew B. Byrne
GRAVEL AND SHEA
76 St. Paul Street, 7th Fl.
Burlington, VT 05402

QUESTION PRESENTED

Does the First Amendment allow the government to freely permit the publication and use of prescription-history information, but ban the use of the identical information to promote prescription drugs, in order to correct a supposed "imbalance" in the "marketplace for ideas," Vt. Acts No. 80, §§ 1(4), 1(6) (2007)?

PARTIES TO THE PROCEEDING

Petitioners are William H. Sorrell, as Attorney General of the State of Vermont; Jim Douglas, as Governor of the State of Vermont; and Robert Hofmann, as Secretary of the Agency of Human Services of the State of Vermont.

Respondents are IMS Health Inc., Verispan, LLC, and Source Healthcare Analytics, Inc.

Pharmaceutical Research and Manufacturers of America was a plaintiff-appellant below and is expected to appear separately as a respondent in this Court.

RULE 29.6 DISCLOSURES

IMS Health Incorporated is wholly owned by Healthcare Technology Intermediate Holdings, Inc., which is wholly owned by Healthcare Technology Intermediate, Inc., which is wholly owned by Healthcare Technology Holdings, Inc. Verispan LLC was succeeded by merger by SDI Health LLC. SDI Health LLC is wholly owned by SDI Health Holdings LLC. Source Healthcare Analytics, Inc. is wholly owned by Wolters Kluwer Health, Inc., which is wholly owned by Wolters Kluwer N.V. No publicly held company owns 10 percent or more of the stock of any of these parties.

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BRIEF OF RESPONDENTS IMS HEALTH, INC., VERISPAN, LLC, AND SOURCE HEALTHCARE ANALYTICS, INC.

STATEMENT OF THE CASE

The State of Vermont generally permits the distribution and use of prescription-history information for any purpose. This case arises from the single exception: absent a prescriber's advance consent, that information may not be used to facilitate the marketing of prescription drugs. The state legislature openly specified that the statute's purpose is to correct a supposed "imbalance" in the "marketplace for ideas" relating to drug marketing. Vt. Acts No. 80, §§ 1(4), 1(6) (2007). The Second Circuit held that the statute violates the First

Amendment because the government cannot seek to inhibit truthful speech, obviously including speech about important issues such as the efficacy of prescription drugs. The court of appeals acknowledged that its decision squarely conflicts with the precedent of the First Circuit, which has upheld similar statutes enacted by New Hampshire and Maine.

1. Information relating to pharmaceutical prescriptions has long been widely distributed and used for numerous purposes. For example, researchers use the information to "identify overuse of a pharmaceutical in specific populations, to develop new drugs, and to facilitate identification of potential patients to participate in clinical trials." Pet. App. 7a. The government employs the "data to monitor usage of controlled substances and to identify prescribers who need time-sensitive safety information." *Id.* Pharmaceutical companies use the same information "to track disease progression, to aid law enforcement, to implement risk-mitigation programs, and to conduct clinical trials and post-marketing surveillance required by the United States Food and Drug Administration ('FDA')." *Id.* 6a.

Prescription-history information is also used to influence the sales of prescription drugs. It is regularly employed "to encourage the use of cheaper, generic medications." *Id.* 7a. Specifically, "insurance companies and state governments use [the] data" to identify prescribers who make heavy use of brand-name drugs for which there are generic alternatives. *Id.* Insurance companies, in particular, use the information "to manage formulary compliance" programs that require use of generic substitutes. *Id.*

Conversely, brand-name pharmaceutical companies use prescription-history information to promote their drugs. The companies employ the data "to identify audiences for their marketing efforts, and to focus marketing messages for individual prescribers." *Id.* 6a. These marketing communications – often in the form of in-person "detailing" visits – go well beyond merely providing pricing information. The companies instead "direct scientific and safety messages to physicians most in need of that information," *id.*, "including the use, side effects, and risks of drug interactions," *id.* This information is essential to prescribers, who must be aware of the most current data related to medications, including potential side effects and drug interactions. For example, a drug company might use prescription-history information to identify the principal physicians in a region who treat certain cardiological ailments in order to provide them with information on the benefits of specific medications designed to improve heart health. Alternatively, the company may become aware of adverse side-effects of certain medications and need to identify the prescribers who are most in need of that safety information. In turn, through detailing, the companies learn from prescribers' experiences with various treatments and use that information to improve their therapies. C.A. App. A 196 (Wharton).

2. Some states are hostile to pharmaceutical detailing. Their concern is not patient privacy. Federal and state law require that pharmacy companies remove all patient-identifying information before transferring prescription-history information. *See* C.A. App. A 221 (Tierney); *see generally* 45 C.F.R. pts. 160 & 164.

Nor is there a significant concern that detailing intrudes on physicians' practices. "[P]rescribers are free to decline meetings with detailers." Pet. App. 6a. Further, an American Medical Association (AMA) program permits prescribers to restrict pharmaceutical sales representatives' use of information about their prescribing practices. *See generally* American Medical Association, *PDRP: The Choice Is Yours*, *available at* http://www.ama-assn.org/ama1/pub/upload/mm/432/pdrp_brochure.pdf (last visited Dec. 15, 2010).

Similarly, "[t]here is no allegation that the commercial speech regulated by [these laws] is either misleading or related to an unlawful activity." Pet. App. 21a. The federal government prohibits any drug promotion that is false, misleading, or that lacks a "fair balance between information relating to side effects and contra-indications and information relating to effectiveness." 21 C.F.R. § 202.1(e)(5)-(6). *See generally* 21 U.S.C. §§ 332-337. The Food and Drug Administration has "unparalleled enforcement power" under the statute, including injunctive and criminal remedies. C.A. App. A 139, A 143 (Hutt).

Instead, opponents of detailing object to the success of the messages conveyed by drug companies. They maintain that promotion of brand-name drugs increases the cost of health care and, in some instances, leads to the use of therapies that are later determined to present health risks.

States subscribing to that view have not sought to prohibit detailing itself. Instead, they have adopted two less-direct regulatory responses.

First, states have developed "counter detailing"

programs, under which the government *itself* uses prescription-history data to identify and contact prescribers to persuade them to choose less-expensive (often, generic) medications. For example, Vermont has adopted an "evidence-based prescription drug education program" to utilize one-on-one communications between the State's representatives and health care providers to encourage the prescription of less expensive generic drugs. Vt. Stat. Ann. tit. 18, § 4622(a)(1). Among other functions, the program "notif[ies] prescribers about commonly used brand-name drugs for which the patent has expired within the last 12 months or will expire within the next 12 months." *Id.* § 4622(a)(2). *See also, e.g.*, N.H. Rev. Stat. Ann. § 126-A:5, XVII; W. Va. Code § 5-16C-9(a)(5).

Second, some states have sought to inhibit detailing by generally prohibiting the transfer of prescription-history information for use in drug marketing, as well as marketing on the basis of that information. Vermont's statute is illustrative. It provides:

> 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.

Vt. Stat. Ann. tit. 18, § 4631(d). Further, "[p]harmaceutical manufacturers and pharmaceutical

marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug," absent the prescriber's consent. *Id.*

By its terms, the statute authorizes the use of prescription-history information for any purpose other than marketing, including specifically "pharmacy reimbursement; prescription drug formulary compliance; patient care management; utilization review by a health care professional, the patient's health insurer, or the agent of either; . . . health care research"; transmissions "between licensed pharmacies"; and "care management educational communications." *Id.* § 4631(e). Indeed, recipients are perfectly free to publish the information publicly.

The Vermont state legislature specified the statute's purpose in a series of findings. The legislature expressed concern that the "marketplace for ideas on medicine safety and effectiveness is frequently one-sided" in favor of drug companies. Vt. Acts No. 80, § 1(4) (2007). Believing that the companies' interests are "often in conflict with the goals of the state," *id.* § 1(3), the legislature acted to correct what it viewed as a "massive imbalance in information presented to doctors and other prescribers," *id.* § 1(6).

3. The Vermont statute gave rise to this lawsuit filed by respondents against petitioners. Respondents do not now challenge the State's counter-detailing program. Instead, they maintain that the statutory provision permitting the distribution and use of prescription-history information except for use in marketing violates the

First Amendment.

Respondents IMS Health, Verispan, and Source Healthcare Analytics (collectively, "the Publisher Respondents") are among the world's largest publishers of information, research, and analysis for the health care and pharmaceutical industries. As is relevant here, the Publisher Respondents collect and analyze prescription-history information. The reports prepared by the Publisher Respondents are used for the many diverse purposes discussed above.

Respondent Pharmaceutical Research and Manufacturers of America (PhRMA) is a trade association representing brand-name pharmaceutical companies. The Publisher Respondents produce reports identifying, *inter alia*, the physicians who regularly treat particular conditions or prescribe specific prescription medications, as well as those who have shown themselves to be most willing to consider adopting new therapies. PhRMA's members use those reports in their detailing efforts.

The district court held a five-day bench trial, during which the parties developed an extensive factual record. Following the trial, the district court issued an opinion and order upholding the law's constitutionality. Pet. App. 68a-118a. Concluding that Section 4631 is properly understood as a regulation of commercial speech, the court held that the law survives intermediate constitutional scrutiny. Pet. App. 69a.

4. On respondents' appeal, the Second Circuit reversed. In so holding, the court expressly rejected the precedent of the First Circuit, which previously upheld similar New Hampshire and Maine statutes.

IMS Health Inc. v. Mills, 616 F.3d 7 (1st Cir. 2010); *IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008), *cert. denied*, 129 S. Ct. 2864 (2009).

Preliminarily, the court of appeals held that Section 4631 is a restriction on speech, not merely a limitation on access to information. The court of appeals reasoned that prescription-history information is within the category of constitutionally protected speech, which extends to "'[e]ven dry information, devoid of advocacy, political relevance, or artistic expression'." *Id.* 14a (citation omitted). The court reasoned that the statute cannot be analogized to measures that protect individual privacy for two reasons. It freely permits the distribution of prescription-history information for numerous purposes. Also, the avowed purpose of the statute is to inhibit speech: detailing visits by pharmaceutical companies. *Id.* 16a-17a.

The Second Circuit held that the Vermont statute is invalid under "even the lower intermediate scrutiny that applies to regulations of commercial speech." Pet. App. 20a. Vermont's asserted interest in "medical privacy," the court found, is "too speculative to qualify as a substantial state interest" because Vermont had not shown that detailing has any effect on the integrity of the prescribing process or the trust patients have in their doctors. *Id.* 23a. Further, the statute does not directly advance Vermont's interests in protecting public health and reducing health care costs because it seeks to alter prescribers' behavior through the indirect route of hampering detailers' marketing messages. That approach, the court concluded "is too indirect to survive intermediate scrutiny." Pet. App. 28a.

Noting that Vermont's avowed purpose in restricting pharmaceutical detailing is to make the debate over prescription drugs less "one-sided," the Second Circuit held that under the First Amendment Vermont is not free to "put [its] thumb on the scales of the marketplace of ideas in order to influence conduct." *Id.* 25a. *See also id.* 28a ("[T]he statute restricts protected speech when uttered for purposes the government does not approve of in order to reduce the effectiveness of marketing campaigns and, ultimately, alter the behavior of prescribers, who are not regulated by the statute.").

Finally, the court of appeals held that Vermont failed to demonstrate that its interests could not be as well served by a more limited restriction on speech. The statute applies "to *all* brand name prescription drugs, irrespective, for example, of whether there is a generic alternative or whether an individual drug is effective or ineffective." *Id.* 29a. At the same time, there are alternative, less speech-restrictive means, such as counter-detailing programs, available to Vermont that are more "directly targeted at encouraging the use of generic drugs the state wishes to promote." *Id.* 33a.

Judge Livingston dissented. She would have construed Section 4631 not as a speech restriction but instead as a permissible restraint on publishers' and pharmaceutical companies' right of access to prescription information in the possession of pharmacies. In her view, the publication of prescription-history information does not sufficiently "'advance[]' the 'values served by the First Amendment'" to constitute protected speech. *Id.* 45a-46a. In the alternative, Judge Livingstone would

have upheld the statute as a permissible regulation of commercial speech. *Id.* 50a.

The State of Vermont subsequently sought certiorari.

ARGUMENT

The Second Circuit correctly concluded that Vermont's general prohibition on the publication and use of prescription-history information to market brand-name drugs violates the First Amendment. Section 4631 restricts speech by limiting the Publisher Respondents' publication of reports on prescribing practices. The State also directly bans certain marketing communications, and does so with the avowed purpose of shielding prescribers from entirely truthful and non-misleading information and messages. The government simply disagrees with the informed choices physicians would make on the basis of that information.

There is no merit to petitioners' attempt to recast Section 4631 as merely a regulation of access to information. The statute is obviously not intended to control the distribution of information in order to preserve privacy, as it freely permits the distribution and use of prescription-history information for *any* person and for *any* purpose other than marketing.

The First Amendment does not permit the State to adopt such a paternalistic regime, particularly in the absence of evidence that the statute is necessary and effective to further an important governmental interest. The constitutional infirmity in the Vermont scheme is significantly compounded by the fact that the State engages in viewpoint discrimination, as it permits both the government and insurers to use the

identical prescriber-history information in order to convey a message of discouraging the use of brand-name drugs.

Though the Second Circuit's constitutional analysis was correct, petitioners are correct that this Court's review is warranted. The court of appeals properly recognized that its decision conflicts with the precedent of the First Circuit, which has upheld similar measures enacted by New Hampshire and Maine.

Review is also warranted because this case, in which the parties compiled an extensive evidentiary record and the court of appeals has entered a final judgment invalidating the statute, is an ideal vehicle in which to decide the question presented and to resolve the circuit conflict.

Finally, the importance of the question presented is beyond dispute. Pharmaceutical marketing has a significant impact on the public health. Further, the government's power to ban the collection, aggregation, and distribution of truthful information is a recurring question with great significance for virtually any commercial endeavor involving the analysis and publication of factual information.

Certiorari accordingly should be granted.

I. The Second Circuit Correctly Concluded That Vermont's Prescription Information Law Violates The First Amendment.

The Second Circuit properly concluded that Section 4631 is an unconstitutional restraint on speech, and not, as Vermont argues, merely a control on access to information. Under a uniform line of

this Court's precedents, the transmission of truthful factual information is protected speech under the First Amendment.[1]

A. Vermont's Prescription Information Law Is A Restriction Of Protected Speech.

1. Section 4631 restricts respondents' constitutionally protected speech in multiple respects. The statute presumptively bans every link in the chain of the communication of prescription-history information for marketing purposes: the communication between pharmacies and the Publisher Respondents, as well as the subsequent communication of reports analyzing that data between the Publisher Respondents and

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[1] While Section 4631 cannot satisfy even intermediate scrutiny, respondents adhere to their position that the statute should be subject to strict scrutiny because the speech it prohibits is not merely commercial speech. In *Board of Trustees of State University of New York v. Fox*, 492 U.S. 469, 473-74 (1989), and *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 422 (1993), this Court held that the category of "commercial speech" receiving lessened First Amendment protection is limited to statements that propose a commercial transaction. Because respondents' speech goes well beyond proposing a commercial sale, it falls outside that narrow category.

Although the pharmaceutical companies are marketing their products, Section 4631 is subject to strict scrutiny because that commercial message is "inextricably intertwined with otherwise fully protected speech" – information regarding the drugs' merits. *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 796 (1988). For that reason, this case would provide the Court with the opportunity to revisit the broader question whether commercial speech should remain subject to lessened First Amendment protection, or should instead be treated as fully protected speech.

pharmaceutical companies.

"Data miners do not themselves use [prescriber-identifiable] data in their own marketing efforts." Pet. App. 20a. Rather, the exchanges of information prohibited by Vermont constitute speech protected by the First Amendment. On Vermont's contrary view that prescription-history information is merely data unprotected by the First Amendment, the State is free to prohibit the *Wall Street Journal* from publishing stock prices.

The Second Circuit properly concluded that a prohibition on the distribution of factual information is subject to First Amendment scrutiny. In *Virginia State Board of Pharmacy v. Virginia Consumer Council, Inc.*, 425 U.S. 748 (1976), the Court held that a ban on the advertising of prescription drug prices violates the First Amendment. The Court expressly rejected the state's claim that the First Amendment is inapplicable because the advertising "merely reports a fact": "Purely factual matters of public interest may claim [First Amendment] protection," *id.* at 762, because it is "indispensable" to the "public interest" that there be a "free flow" of "information as to who is producing and selling what product, for what reason, and at what price," *id.* at 765. *Cf. Lowe v. SEC*, 472 U.S. 181, 210 (1985) ("[t]o the extent that the chart service contains factual information about past transactions and market trends, and the newsletters contain commentary on general market conditions, there can be no doubt about the protected character of the communications").

Further, the Vermont statute also bans pharmaceutical companies from engaging in

marketing that employs prescription-history information. Section 4631 directly alters the companies' speech by making it significantly more difficult to tailor marketing messages to individual prescribers. More broadly, the statute erects a substantial barrier to efforts to identify the best market for the drug companies' communications.

The information disseminated in these detailing visits that the State seeks to inhibit has significant social value and is protected by the First Amendment. Detailers discuss with physicians important scientific matters relating to prescription drugs, such as the results of clinical studies, and summaries of indications and contraindications for particular medications. C.A. App. A 125 (Cole); A 197 (Wharton); A 391 (Ciongoli). The very premise of Section 4631 is that the audience for these communications – physicians – will find the information valuable and make important prescribing decisions on the basis of it. *Id.* A 123 (Cole); A 195-198 (Wharton); A 391 (Ciongoli). The statute itself specifically recognizes that "physicians frequently rely on information provided by pharmaceutical representatives" in determining "which drugs are the best treatment for particular conditions." Vt. Acts No. 80 § 1(13).

The information flow is moreover a two-way street, as drug companies through detailing benefit from prescribers' descriptions of the efficacy of various treatments, information that the companies use to improve medical care. The conversations are often "engaging discussions over the latest science" relevant to various treatments, and often involve multiple physicians, who use the meetings as an

opportunity "to discuss with each other how we treat patients." A 196 (Wharton).

In *Edenfield v. Fane*, 507 U.S. 761 (1993), the Court invalidated a ban on solicitation by certified public accountants because it "threaten[ed] societal interests in broad access to complete and accurate commercial information." *Id.* at 766. "[T]he general rule is that the speaker and the audience, not the government, assess the value of the information presented." *Id.* at 767. More recently, in *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002), the Court held that the government may not prohibit pharmacists from advertising the availability of compounded drugs. "We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information." *Id.* at 374. *See, e.g.*, *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 564 (2001); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 489 (1996); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 481-82 (1995).

It is no answer to assert that Vermont's law is targeted at the collection and use of prescription-history information, and does not ban the conversations between detailers and physicians. This Court has repeatedly held that the First Amendment forbids both direct and indirect restraints on the activities that are necessary to the communication and sharing of information – the mechanics of speaking. In *Lorillard*, *supra*, for example, the Court gave no quarter to the claim that a regulation on the "placement" of cigarette advertising merely regulated

conduct, explaining that the First Amendment is triggered whenever regulation of conduct "would impose particularly onerous burdens on speech." 533 U.S. at 564. That decision simply echoed this Court's repeated holdings that legislation regulating or proscribing the actions necessary to engage in communication triggers First Amendment scrutiny. *E.g.*, *Minneapolis Star & Tribune Co. v. Minnesota Comm'r of Revenue*, 460 U.S. 575, 577, 592-93 (1983) (First Amendment applies to "use tax" on the cost of paper and ink products consumed in the production of a publication).

2. For two reasons, there is no merit to petitioners' attempt (Pet. 18) to recast Section 4631 as merely a "restriction on access to information." First, the very purpose of the statute is to inhibit speech, not to protect privacy or otherwise neutrally protect the confidentiality of prescription-history information. Petitioners are thus unwilling to grapple with – or indeed, even mention – the legislature's express intention to alter the "marketplace for ideas on medicine safety and effectiveness." Vt. Acts No. 80, § 1(6). "The findings expressly state the legislature's intent to interfere with the marketplace of ideas to promote the interests of the state." Pet. App. 12. Indeed, "the whole point of section 17 is to control detailers' commercial message to prescribers." Pet. App. 82a.

Second, the statute is not an effort by the government to control the flow of information to protect privacy. Because Vermont "does not prohibit the wide public dissemination of [prescriber-identifiable (PI)] data," "the statute plainly does not

protect physician privacy." Pet. App. 22a. As the court of appeals explained,

> Physician privacy might be protected if the statute prohibited the collection and aggregation of PI data for any purpose, or if the use of such data were permitted only in rare and compelling circumstances. The statute at issue here, however, does not forbid the collection of PI data in the first instance. Furthermore, the statute does not ban any use of the data other than for marketing purposes, including widespread publication to the general public.

Id.

For both of those reasons, the State's analogy to the attorney-client privilege, and restrictions on the disclosure of information by "[i]nsurance companies, financial institutes, and even utility companies" (Pet. 18-19) is deeply flawed, as is its invocation of statutes involving information held by, for example, financial institutions, educational records, and health care information (*id.* 32). Unlike Vermont's law, those legal principles and statutes rest on a neutral interest in preserving confidentiality, rather than restricting speech. Further, each makes the prohibition on disclosure the rule, not the exception tied to a particular category of speech. *See, e.g.*, 15 U.S.C. § 6802 (providing right to opt out of financial institution's disclosure of "nonpublic personal information to a *nonaffiliated third party*") (emphasis added); 42 U.S.C. § 1320d-6 (prohibiting the disclosure of "individually identifiable health information to *another person*" without authorization) (emphasis added); 47 U.S.C. § 551(c)(1) (cable operator "shall take such actions as are necessary to

prevent unauthorized access to such information *by a person other than the subscriber or cable operator*") (emphasis added); Cal. Fin. Code § 4052.5 ("a financial institution shall not sell, share, transfer, or otherwise disclose nonpublic personal information to or with *any nonaffiliated third parties*" without consent) (emphasis added). Vermont thus errs in contending that the ruling below "calls into question the constitutionality of numerous federal and state laws that protect information privacy" (Pet. 1) or otherwise conflicts with "decisions upholding" the "constitutionality of privacy protections" (*id.* 16).

For the same reason, the State fails in its attempted analogy to *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 32 (1984), which forbade the dissemination of information "obtained by [a] newspaper through pretrial discovery, where the trial court had entered a protective order" (Pet. 19). The information in *Seattle Times* was provided under governmental compulsion – a court order. It was moreover kept private between the parties in order to maintain privacy rather than inhibit speech. Section 4631, by contrast, freely permits the distribution of prescription-history information for purposes other than marketing.

Equally important, the analogy to privacy laws fails because, contrary to the State's suggestion (Pet. i), the data collected and analyzed by the Publisher Respondents does not "contain information about patients." The State's claim that the data "reveals substantial information about the doctor-patient relationship – including the treatment of individual patients" (Pet. 4-5) is false, to the extent that Vermont hopes to suggest that respondents are in

possession of any patient-identifying information. In fact, the Publisher Respondents never receive such information, because pharmacy companies are required to remove it before transferring the prescription data. *See* 45 C.F.R. pts. 160 & 164; C.A. App. A 221 (Tierney). Thus, as the district courts and Judge Lipez recognized in the New Hampshire and Maine cases, statutes of this type do nothing to advance patient privacy. *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 85 (1st Cir. 2008) (Lipez, J., concurring and dissenting) ("[T]he regulation does not in any cognizable way touch on the privacy of the examination room."); *IMS Health Corp. v. Rowe*, 532 F. Supp. 2d 153, 173 (D. Me. 2007) ("Regardless of the opt-out provisions of the new law, personal patient information has been and will continue to be encrypted and there is no evidence that the current practices of the [Publisher Respondents] and the pharmaceutical companies have had or realistically could have any effect on patient confidentiality."); *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163, 179 (D.N.H. 2007) ("[A]lthough the Attorney General asserts that prescriber-identifiable data is used to intrude upon the doctor-patient relationship, she does not claim that the data is being exploited to compromise patient privacy.").

Nor is there merit to the State's further submission (Pet. 2) that Section 4631 escapes First Amendment scrutiny because "[n]either doctors nor patients voluntarily provide information to pharmacies" but rather "are required to provide information to receive necessary health care services." In fact, prescribers enter into relationships with their patients, and patients visit pharmacies, none of which is compelled by the government. The

pharmacies in turn collect prescription information in the ordinary course of their business, and they indisputably would continue to do so in the absence of any governmental record-keeping requirement.

There is accordingly no merit to the State's claim (Pet. 31) that the First Circuit effectively conferred upon respondents a constitutional right to receive information. In fact, respondents "have not claimed a First Amendment right to obtain information. They challenge the restriction on their ability to purchase and use information otherwise available to them but for the State's restriction. The statute prevents willing sellers and willing buyers from completing a sale of information to be used for purposes that the state disapproves." Pet. App. 16.

Thus, in this case, and unlike in *LAPD v. United Reporting Publishing Corp.*, 528 U.S. 32 (1999), the information is not in the government's possession. Rather, the State seeks to limit the acquisition and use of information in the hands of pharmacies, data miners, and pharmaceutical companies. "This is a case about the extent of the permissible governmental regulation of information in the hands of private actors." Pet. App. 17a. *Contra* Pet. 18-19.

Nor, finally, is Vermont's case materially advanced by the fact that the statute permits individual prescribers to formally advise the State that they opt in to the use of their prescription-history information in marketing. That requirement presents a significant obstacle to respondents' speech. A state could not, absent a significant interest, ordinarily require every audience to notify the government in advance that it wants to receive particular speech. Instead, the ordinary rule is that

the audience can simply make the choice whether to listen. In this context, every prescriber can choose whether to receive detailing visits. Moreover, the American Medical Association permits prescribers to specify that their prescription-history information not be used in marketing; the State has made no showing that this non-governmental program is inadequate.

B. Vermont's Restriction On The Transfer And Use Of Prescriber Information Does Not Advance A Legitimate State Interest.

Vermont does not make a serious attempt to argue that its statutory scheme can survive First Amendment scrutiny. The legislature's openly stated rationale for enacting Section 4631 is its desire to correct what it perceives as a "massive imbalance in information" within the "marketplace for ideas on medicine safety and effectiveness." Vt. Acts No. 80, §§ 1(4), 1(6). Thus, as the Second Circuit properly recognized, "the statute seeks to alter the marketplace of ideas by taking out some truthful information that the state thinks could be used too effectively." Pet. App. 26a. Vermont is, quite literally, attempting to make it more difficult for drug companies and physicians to have an intelligent conversation. This Court has specifically rejected the "assumption that doctors would prescribe unnecessary medications" on the basis of drug advertising, because it "amounts to a fear that people would make bad decisions if given truthful information." *Western States*, 535 U.S. at 359.

Beyond that, Vermont's effort to protect prescribers from truthful messages during voluntary conversations with detailers does not advance any

legitimate state interest. Indeed, if the government has no cognizable interest in prohibiting professionals such as accountants from soliciting lay persons (*Edenfield v. Fane*, *supra*), then it manifestly has no such interest in the context of pharmaceutical companies' discussions with highly trained prescribers regarding the merits of particular drugs. *See* Brief for Coalition for Healthcare Communication as *Amicus Curiae* Supporting Petitioners at 16, *Ayotte*, 129 S. Ct. 2864 (08-1202) ("A paternalistic desire to have consumers, let alone industry professionals, make different market choices among goods and services is not the type of interest that can sustain a restriction on truthful and non-misleading commercial speech."). That is all the more true given that physicians can – and regularly do – simply decline to meet with a drug company representative. Thus, in practice, Vermont's law bars *only* truthful communications between drug companies and knowledgeable and willing prescribers desirous of the information.

Likewise, Vermont's avowed desire to correct the "imbalance in information" created by drug companies' financial wherewithal directly parallels the premise repeatedly rejected by this Court that the government may limit individual expenditures in political campaigns. Under the First Amendment, the government may not inhibit speech just because it considers its influence to be economically outsized. *McConnell v. Fed. Election Comm'n*, 540 U.S. 93, 217-18 (2003); *Fed. Election Comm'n v. Massachusetts Citizens for Life, Inc.*, 479 U.S. 238, 263 (1986); *Buckley v. Valeo*, 424 U.S. 1, 39-51 (1976).

The disconnect between Section 4631 and

Vermont's legitimate interests is particularly apparent given the lack of evidence of the need for such legislation or its effectiveness. Before the Second Circuit, Vermont sought to justify the statute on the ground that it advanced a state interest in "medical privacy," which, the court noted, "is actually two distinct interests. The first is an interest in the integrity of the prescribing process itself, and the second is an interest in preserving patients' trust in their doctors by preventing patients from believing that their physicians are inappropriately influenced by . . . data-driven marketing." Pet. App. 23a. The court correctly found no evidence suggesting that Section 4631 advanced those interests. "Vermont's own expert was unaware of any instance in which a detailing interaction caused a doctor to prescribe an inappropriate medication." *Id.* And, "[t]o the extent that the record might suggest that [prescriber-identifiable] data has damaged the relationship between doctors and patients, the evidence is either speculative or merely indicates that some doctors might not approve of detailing or the use of [prescriber-identifiable] data in detailing." *Id.*

Furthermore, even if Vermont's asserted interests were legitimate, Section 4631 would still fail First Amendment scrutiny because it discriminates on the basis of the speaker's viewpoint. The statute bars the dissemination of prescription information for the purpose of advocating the use of brand-name drugs. At the same time, however, the State has adopted its own "counter detailing" program, which uses prescription-history data to discourage brand-name drug use and promote the use of generics. Vt. Stat. Ann. tit. 18, § 4622. Vermont also permits insurance companies to use the same

data to promote "formulary compliance." *Id.* § 4631(e)(1). Those companies routinely use prescription-history information to locate prescribers and encourage them to prescribe generics over brand-name medications. C.A. App. A 188 (Kolassa) ("[I]nsurance companies are using physician-identifiable information to call physicians to try to get them to comply with . . . formularies, [to] try to get them to change their prescribing in a way that may or may not be in the patient's best interests.").

If the First Amendment means anything, it means that the government cannot so significantly disfavor the one side in a debate that it disfavors. Vermont's statute creates "a bias in the democratic process designed to achieve the state's desired result, which is exactly the opposite of what the First Amendment is intended to do." Brief for Pacific Legal Foundation et al. as *Amicus Curiae* Supporting Petitioners at 15, *Ayotte*, 129 S. Ct. 2864 (08-1202). "Even under the degree of scrutiny that we have applied in commercial speech cases, decisions that select among speakers conveying virtually identical messages are in serious tension with the principles undergirding the First Amendment." *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 193-94 (1999).

C. Vermont's Law Is Not Narrowly Tailored.

The Second Circuit also correctly held that Section 4631 fails under *Central Hudson*'s narrow tailoring prong. Vermont's statute bears no reasonable "fit" in relation to the State's asserted interests, *see Greater New Orleans*, 527 U.S. at 188 (1999), but in fact is grossly overinclusive.

Far from confining its focus to detailing that drives up health care costs, Section 4631 applies to detailing that either does not implicate or actually furthers the State's interests. The statute is not limited to restricting those instances of detailing that cause prescribers to make inappropriate prescribing decisions. The State's broad-brush assertion that "[n]ew drugs" are "also riskier, because their use, risks, and side effects are not yet fully understood" (Pet. 9) is unsupported by the record and contrary to the experience of modern health care. The statute moreover equally applies when the detailing identifies a *less expensive* alternative medication and when it conveys valuable information about drug treatments that improve public health, which is itself a significant state interest. *See* Pet. App. 30a ("The statute prohibits the transmission or use of [prescriber-identifiable] data for marketing purposes for all prescription drugs regardless of any problem with the drug or whether there is a generic alternative."). In such instances, the statute inhibits speech without furthering – and often while undermining – Vermont's own claimed interests.

The Second Circuit also properly recognized that Vermont had failed to meet its burden of showing that its interests could not be as well served by a less speech-restrictive alternative. One such option is the State's "counter-detailing" program, which is designed to encourage doctors to prescribe generic drugs. Alternatively, Vermont "could mandate 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." *Id.* 30a-31a. The State also could look to the array of cost-containment measures in effect in other states

that do not restrict speech, many of which Vermont has not adopted.[2]

The statute is equally under-inclusive. Vermont objects to the effectiveness of detailing visits, but those communications are not prohibited so long as they are not conducted on the basis of prescription-history information. A drug company thus remains free to promote expensive therapies for which generic substitutes exist, or for which safety issues have been raised.

In sum, the Second Circuit properly concluded that Section 4631 violates the First Amendment, even under the intermediate scrutiny applicable to regulations of commercial speech.

II. Certiorari Is Nonetheless Warranted Because the Ruling Below Directly Conflicts With The Settled Precedent Of The First Circuit.

The Second Circuit recognized that its decision is irreconcilable with the precedent of the First Circuit,

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[2] *See, e.g.*, D.C. Code § 48-831.04 (2006) (requiring use of aggregate purchasing to negotiate lower prices of prescriber drugs); Fla. Stat. Ann. § 465.025 (2006) (requiring pharmacists to substitute generic drugs for bioequivalent brand-name drugs); N.H. Rev. Stat. Ann. § 318:47-d (2003) (authorizing pharmacists to substitute bioequivalent generic drugs); Me. Rev. Stat. Ann. tit. 22, § 2697 (2006) (prohibiting profiteering in prescription drugs); Me. Rev. Stat. Ann. tit. 22, § 2700-A (2006) (providing for consumer education about prescription drugs); Minn. Stat. § 151.461 (1994) (prohibiting gifts from drug manufacturers to health care practitioners); Vt. Stat. Ann. tit. 33, § 2005a (2006) (requiring sales representatives to disclose prices to prescribers); W. Va. Code Ann. § 5-16C-9 (2006) (setting forth a variety of strategies to reduce unnecessary prescription drug costs).

which has upheld similar statutes on the theory that prescription-history information merits little, if any, First Amendment protection. That conflict on an important question of federal constitutional law is entrenched and can be resolved only by this Court.

1. The Second Circuit in this case expressly rejected the contrary precedent of the First Circuit. The Second Circuit concluded that Vermont's statute must be subject to significant constitutional scrutiny because it "is . . . clearly aimed at influencing the supply of information, a core First Amendment concern." Pet. App. 16a. The Second Circuit also rejected Vermont's reliance on the First Circuit's conclusion that a State could permission pursue an interest in altering the "imbalance in information" available to prescribers by "put[ting] the state's thumb on the scales of the marketplace of ideas." *Id.* 25a.

Like Vermont's Section 4631, the New Hampshire statute sustained by the First Circuit in *Ayotte* prohibited the transfer or use of prescription data for the purpose of "any activity that could be used to influence sales or market share of a pharmaceutical product." N.H. Rev. Stat. § 318:47-f. While the *Ayotte* court acknowledged that the dissemination of factual information has been held protected by the First Amendment, it deemed that principle inapplicable in "a situation in which information itself has become a commodity." *Ayotte*, 550 F.3d at 53. In that circumstance, the First Circuit concluded, the transfer of information is entitled to no greater First Amendment protection than a shipment "of, say, beef jerky." *Id.*

On the basis of *Ayotte*, the First Circuit

subsequently upheld Maine's similar prescription information law. *IMS Health Inc. v. Mills*, 616 F.3d 7, 19 (1st Cir. 2010). The Maine statute provides that pharmacies, data publishers, and others may not use or sell prescriber-identifiable information "for any marketing purpose" if a prescriber so elects. Me. Rev. Stat. Ann. tit. 22, § 1711-E(2-A).

In conflict with the Second Circuit's decision in this case, the First Circuit held in *Ayotte* that New Hampshire was free to "level the playing field" in the debate over the benefits of brand-name medications by limiting drug companies' access to information, and thereby "improve the quality" of the discussions between detailers and physicians. 550 F.3d at 48, 54.

The Second Circuit also conducted a substantially more searching assessment of whether the State had a factual basis for adopting its prescription restraint law. Looking to the record developed at trial, the court of appeals in this case found that "Vermont has not shown any effect on the integrity of the prescribing process or the trust patients have in their doctors from the use of [prescriber-identifiable] data in marketing." Pet. App. 23a. Although the State presented some testimony at trial that sought to show that less speech-restrictive alternatives would not sufficiently advance its asserted interests, the court found that "the testimony fell far short of demonstrating that the alternatives would be inadequate." *Id.* 33a. Further, the court noted that although the statute bars the use of prescriber data to market *any* brand-name prescription drug, the State provided no evidence about whether particular brand-name medications are more or less effective than their

generic counterparts. Thus, "[e]ven if the Court defers to the legislature's determinations, those determinations cannot support banning speech in circumstances that the state's evidence does not address." *Id.* 30a.

In stark contrast, the First Circuit held that New Hampshire's parallel statute sufficiently advanced the State's asserted interests, notwithstanding that "there was no direct evidence on" the statute's effect on health care costs. *Ayotte*, 550 F.3d at 57. Despite those deficiencies, the First Circuit concluded that "this is more a matter of policy than of prediction," *id.* at 58, so that the appropriate course was to "defer to the New Hampshire legislature," *id.* at 59. In the First Circuit's view, "[a] state need not go beyond the demands of common sense to show that a statute promises directly to advance an identified governmental interest." *Id.* at 55. The First Circuit deems intermediate scrutiny to be satisfied when a state relies on "common sense" to show that a statute "promises" to advance such interests. *Id.* at 55.

The First Circuit denied applications for rehearing en banc in both *Ayotte* and *Mills*. The court of appeals' ruling in *Mills* moreover eliminated any prospect that the court might revisit its prior precedent in light of this Court's intervening decision in *United States v. Stevens*, 130 S. Ct. 1577 (2010). *Mills* squarely "reject[ed]" the contention that *Stevens* "undermines *Ayotte*'s holding." *Mills*, 616 F.3d at 20. While acknowledging that *Ayotte* "did suggest that any speech regulated was of such minimal value that it likely fell outside of First Amendment protections," the First Circuit believed that statement was consistent with *Stevens* because

it "was in service of *Ayotte*'s holding that the New Hampshire statute regulated conduct, not speech, an argument not at issue in *Stevens*." *Id.*

Nor is there any prospect that the Second Circuit will resolve the conflict through en banc proceedings. That court has a nearly inviolate practice of reserving en banc review to intra-circuit conflicts. *See generally* Jon O. Newman, *In Banc Practice in the Second Circuit: The Virtues of Restraint*, 50 Brook. L. Rev. 365 (1984). The State of Vermont accordingly made the sound judgment to seek review directly in this Court. Equally important, because no other state in the Second Circuit has adopted a similar statutory scheme, the court of appeals will never again have the opportunity to decide the question presented.

The current state of the law is particularly intolerable given that the Publisher Respondents are the plaintiffs in all three of the federal appellate rulings that make up the circuit conflict over the constitutionality of prescription-restraint statutes. The Publisher Respondents now face irreconcilable legal obligations, on the basis of conflicting interpretations of the First Amendment, depending entirely on the particular state to which specific data happens to relate.

Further, the conflict has significant practical consequences, as it materially and unjustifiably interferes with respondents' daily operations. The Publisher Respondents operate data centers that collect, aggregate, and publish information on a national and international basis. Differentiating among states to account for the inconsistent legal regimes that now exist requires a significant

expenditure of resources. Equally important, the forced exclusion of data relating to certain states in analyses of nationwide prescribing behavior creates material administrative difficulties and threatens the accuracy of the data respondents publish.

III. This Case Is An Ideal Vehicle To Decide The Question Presented, Which Is Profoundly Important.

Certiorari is further warranted because the record in this case makes it an ideal vehicle in which to resolve the constitutional question it presents. The district court conducted a five-day bench trial, during which the parties presented extensive documentary and testimonial evidence regarding the operation of statutory schemes like the one at issue. *See* Pet. App. 78a ("The parties presented testimony from numerous witnesses and introduced reams of exhibits, including the entire legislative history of Act 80."). Particularly in a case in which a statutory scheme rests on supposed effects of pharmaceutical marketing upon prescribing behavior, it is essential that the Court have the benefit of a concrete factual record.

Review in this case is also proper because the Vermont statutory scheme is representative of the other legislative efforts to restrict the use of prescriber information for marketing purposes. Section 4631 operates in substantially the same manner as the prescriber data laws in New Hampshire and Maine, both of which prohibit the transfer and use of such information for marketing purposes. *See* N.H. Rev. Stat. § 318:47-f (prescriber-identifiable information "shall not be licensed, transferred, used, or sold by any pharmacy benefits

manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose"); Me. Rev. Stat. Ann. tit. 22, § 1711-E(2-A) ("a carrier, pharmacy or prescription drug information intermediary may not license, use, sell, transfer or exchange for value" prescriber information "for any marketing purpose"). *Accord* Pet. 26 ("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."). Thus, this case gives the Court an ideal opportunity to provide guidance on the constitutional issues common to all of these statutory schemes, similar versions of which have been introduced for consideration in the legislatures of more than half the states.

Finally, this case presents issues of surpassing importance. The record demonstrates that pharmaceutical marketing provides substantial public health benefits. Detailing directly contributes to prescribers' awareness of new treatment options, and in turn helps to educate pharmaceutical companies about prescribers' experiences with particular medications. That interchange of information facilitates the adoption of vital new treatments for a wide range of medical conditions, and in turn immeasurably benefits the health and well being of the Nation. The efforts of Vermont and other States to interfere with that process trigger public health concerns of the highest order. *See* C.A. App. A 284 (Frankel) (Vermont's law "will slow the dissemination of new drugs and . . . people will die"); Brief for Council of American Survey Research Orgs.

et al. as *Amici Curiae* Supporting Petitioners at 2, *Ayotte*, 129 S. Ct. 2864 (08-1202) (prescriber information restrictions threaten "legitimate pharmaceutical survey research by eliminating a valuable information and data resource.").

Moreover, the implications of Vermont's constitutional position extend far beyond drug marketing. The evaluation and publication of factual information is one of "the top ten emerging fields in today's technological world." Tal J. Zarsky, *"Mine Your Own Business!": Making the Case for the Implications of the Data Mining of Personal Information in the Forum of Public Opinion*, 5 Yale J. L. & Tech. 4 (2003). This speech has "entered a golden age, whether being used to set ad prices, find new drugs more quickly or fine-tune financial models." Ashlee Vance, *Data Analysts Are Mesmerized by the Power of Program R*, N.Y. Times, Jan. 7, 2009, at B6. In the information-based economy of the twenty-first century, the accumulation, analysis, and distribution of various forms of data is an activity of vital importance to a broad and growing range of commercial enterprises. *See* Brief for New England Legal Foundation et al. as *Amici Curiae* Supporting Petitioners at 22, *Ayotte*, 129 S. Ct. 2864 (08-1202) ("In our 'information age,' sales and other voluntary transfers of data by and between businesses are fundamental to the efficient operation of the free enterprise system and often serve, as in this instance, societal needs as well as the interests of individual businesses."). The proposition that such communications are wholly devoid of constitutional protection, such that they may be prohibited wholesale any time the government disagrees with choices made by

consumers of that information, raises far-reaching constitutional concerns that warrant this Court's prompt attention and guidance.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

Thomas C. Goldstein
Counsel of Record
Kevin R. Amer
AKIN GUMP STRAUSS HAUER & FELD LLP
1333 New Hampshire Avenue, N.W.
Washington, DC 20036
(202) 887-4000
tgoldstein@akingump.com

Robert B. Hemley
Matthew B. Byrne
GRAVEL AND SHEA
76 St. Paul Street, 7th Fl.
Burlington, VT 05402

Thomas R. Julin
Jamie Z. Isani
Patricia Acosta
HUNTON & WILLIAMS LLP
1111 Brickell Avenue
Suite 2500
Miami, FL 33131

Mark A. Ash
MCGUIRE WOODS LLP
2600 Two Hanover Square
Raleigh, NC 27601

December 15, 2010