No. 10-779

In The
Supreme Court of the United States

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

Petitioners,

v.

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

Respondents.

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

BRIEF FOR THE VERMONT MEDICAL SOCIETY, THE NEW HAMPSHIRE MEDICAL SOCIETY, THE MAINE MEDICAL ASSOCIATION, THE MEDICAL ASSOCIATION OF GEORGIA, THE AMERICAN ACADEMY OF FAMILY PRACTITIONERS AND THE AMERICAN ACADEMY OF PEDIATRICS AS AMICI CURIAE SUPPORTING PETITIONERS

EILEEN I. ELLIOTT
Counsel of Record
JESSICA A. OSKI
ELIZABETH H. CATLIN
SHEMS DUNKIEL RAUBVOGEL & SAUNDERS PLLC
91 College Street
Burlington, Vermont 05401
(802) 860-1003
eelliott@shemsdunkiel.com

Attorneys for Amici Curiae

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STATEMENT OF INTEREST OF AMICI CURIAE[1]

The Vermont Medical Society (VMS) is the largest physician organization in Vermont. VMS represents over 1600 physicians, which is roughly two-thirds of the physicians actively practicing in Vermont. VMS physician members have a strong professional interest in ensuring that patients receive the highest quality medical care available, which necessarily includes maintaining the confidentiality and integrity of the physician-patient relationship.

After discovering that marketing activities of pharmaceutical companies aimed at changing the treatment decisions that physicians make for their patients were driven in large part by data of individual physicians' prescribing patterns obtained from pharmacies without physician consent, VMS unanimously adopted a resolution urging the State to adopt the Prescription Confidentiality Law. JA 376-78.[2] VMS was also motivated to advocate for the Prescription Confidentiality Law as one way to address

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[1] This brief is filed with the written consent of all parties. Consent letters are on file with the Clerk of the Court. Sup. Ct. R. 37.3. No counsel for a party authored this brief in whole or in part, nor did any person or entity, other than *amici* or their counsel, make a monetary contribution to the preparation or submission of this brief. *Id*. 37.6.

[2] For consistency with the conventions used in Petitioner's brief, references in this brief to "App. __a" are to the appendix filed with the certiorari petition; to "JA __" are to the Joint Appendix filed with Petitioner's brief; and to "A-__" are to the appendix filed in the Second Circuit.

Vermont's increasing health care costs since prescription drugs were the fastest growing component of health care spending in Vermont.

VMS is concerned that intrusion into the confidentiality of the physician-patient relationship, which is inherent in physician-targeted marketing, is inextricably linked to the additional harms of ever-increasing health care costs and interference with drug-prescribing practices. The VMS resolution affirmed its belief that "the doctor-patient relationship requires confidentiality and privacy to work effectively," and expressed concern about the use of "detailed marketing profiles" by pharmaceutical representatives. *Id*. 376-77. VMS found that using physicians' prescribing histories for marketing purposes is "an intrusion into the way physicians practice medicine." *Id*. 378. Regulating the marketing of prescriber-identifiable data ("PI data") protects the integrity of the physician-patient relationship, improves public health by promoting evidence-based prescribing, and reduces health care costs.

Following the adoption of the resolution, VMS spent much of the 2007 Vermont legislative session championing the law that is the subject of this challenge. Because VMS physicians experienced detailing first-hand, and took part in the enactment of the Prescription Confidentiality Law, they have a unique perspective to offer this Court. VMS physicians have a considerable interest in seeing that their patient relationships remain uncompromised by unduly intrusive targeted marketing practices of

the pharmaceutical industry, that Vermont's health care costs are not driven higher by unnecessary and unwarranted prescription drug costs, and that Vermont physicians' prescribing practices are based on scientifically valid evidence and data. VMS believes that the Prescription Confidentiality Law plays an important part in achieving these goals and does not run afoul of the First Amendment.

Other medical associations join VMS in support of Vermont's law and this brief based on their interest in similar goals and the protection that similar laws in other states provide these goals.

The Maine Medical Association, with 3,400 members, is the statewide physician organization for Maine physicians.

The New Hampshire Medical Society, with 2,100 members, is the statewide physician organization for New Hampshire physicians.

The Medical Association of Georgia, with approximately 6,000 members, is the statewide physician organization for Georgia physicians.

The American Academy of Family Physicians, with 97,600 members, is the national physician association for family physicians.

The American Academy of Pediatrics, with 60,000 members, is the national physician association for pediatricians.

SUMMARY OF ARGUMENT

Vermont's Prescription Confidentiality Law, Vt. Stat. Ann. tit. 18, § 4631, directly advances the State's longstanding and substantial interest in protecting medical privacy, especially that aspect of medical privacy inherent in the physician-patient relationship. The data that the law is targeted at protecting is data that exists only because the State requires pharmacies to collect and maintain it for public health and safety reasons. Apart from the Prescription Confidentiality Law, there are multiple regulations and laws that exist to protect the confidentiality of this type of data. The Prescription Confidentiality Law became necessary as a belt-and-suspenders approach to protecting confidentiality after data-mining and pharmaceutical companies pursued this protected data despite the existing network of privacy laws. Because the data that the law protects is non-public data in the first place, the law is not properly characterized as a restriction on commercial speech. *See* Pet. Br. 22-41.

While there are ample grounds to conclude that the Prescription Confidentiality Law imposes no burden at all on any party's First Amendment rights, this brief is directed at establishing that the law satisfies this Court's standards for constitutional regulation of commercial speech. To the extent that this Court construes the law as a commercial-speech restriction, the law falls well within the boundaries set by this Court for permissible restrictions on commercial speech: the law directly

advances substantial state interests and is no more restrictive than necessary to serve those interests. This brief focuses primarily on the substantial state interest of medical privacy, the manner in which the Prescription Confidentiality Law advances that interest, and the reasons that the law is no more restrictive than necessary to protect medical privacy.

At the heart of this case are the practices of "data mining" and "detailing," two practices that go hand-in-hand in the marketing of new prescription drugs. Data mining is the process of purchasing prescription drug information from pharmacies, analyzing and repackaging the data, then selling it to pharmaceutical companies. *See* Pet. Br. 7-10 (describing data mining based on the evidence presented in this case). The information sold to pharmaceutical companies contains PI data, which includes, "the prescriber's name and address, the name, dosage, and quantity of the drug, the date and place the prescription is filled, and the patient's age and gender." App. 5a.

The companies that buy data from pharmacies, analyze the data, and resell it to pharmaceutical companies are known as "data miners." The pharmaceutical companies' sales representatives are the "detailers" who take the repackaged prescribing data from the data miners and put it into practice in marketing their companies' drugs. Detailers with access to the mined data can receive weekly updates regarding the prescribing practices of physicians, and use this data to target their marketing. Pet. Br. 9 (citing JA 366, 473, 481-82, 488-90, 510).

The evidence presented in this case demonstrated that data mining and detailing have influenced prescribing practices and resulted in prescribing that is not evidence-based or cost-effective. Multiple prescription drugs, with either identical effectiveness to generic or over-the-counter drugs, or with serious health risks, have been widely prescribed as a result of pharmaceutical companies' PI-data-driven targeted marketing practices. Pet. Br. 49-50 (citing App. 95a; JA 289-91, 326-27, 353-60, 365-68). In sum, data mining and detailing have influenced physician choices in treating their patients. With unrestricted access to otherwise confidential data, pharmaceutical companies have been able to insert themselves as a third party in the physician-patient relationship in a way that would not be possible without access to PI data. The intrusion on this private relationship is harmful in itself because it calls into question the treatment choices made by physicians and therefore injures the integrity of the physician-patient relationship. Additionally, by resulting in the prescription of newer, riskier, or harmful drugs, and the over-prescription of other drugs, data mining and detailing harm public health and increase the costs of health care.

The Second Circuit incorrectly concluded that the Vermont Prescription Confidentiality Law is an unconstitutional restriction on commercial speech. Aside from the unfounded conclusion that the law restricts commercial speech at all, the fundamental error infecting the Second Circuit's decision is the

court's failure to recognize the importance of privacy and confidentiality in the practice of medicine, and the manner in which the Prescription Confidentiality Law promotes and protects that privacy. The confidentiality of the physician-patient relationship has long been recognized as a central tenet of the practice of medicine, not only by patients and physicians, but also by the government. Congress and the states have consistently acted to protect medical privacy. The use of confidential PI data, which is gleaned from the private physician-patient interaction, for marketing purposes aimed at influencing the private physician-patient interaction, causes real harm to medical privacy. The State has a substantial interest in protecting its citizens from this harm.

The other interests that Vermont seeks to protect through the enactment of the Vermont Prescription Confidentiality Law flow directly from the harm to medical privacy. Confidential PI data, collected and sold without the consent of the physician or the patient, and often without their knowledge, when used to develop and execute sophisticated marketing strategies, produces exactly the results that the pharmaceutical industry intends: physicians prescribe more expensive brand-name drugs. The over-prescribing of expensive brand-name drugs is not related to better patient health outcomes, yet it causes constantly increasing pressure on the State's health care budget.

By restricting access to confidential PI data, the Prescription Confidentiality Law advances the State's

interests in protecting medical privacy, reducing prescription-drug expenditures and protecting public health. At the same time, the law has no effect on the many other marketing information and opportunities available to the pharmaceutical industry.

In sum, medical privacy is unquestionably a substantial state interest. It is the foundation of medical practice and for centuries it has been recognized, protected, and even mandated by state and federal law. Vermont's Prescription Confidentiality Law is a constitutionally permissible method of protecting medical privacy.

ARGUMENT

I. INTRODUCTION.

Vermont's Prescription Confidentiality Law is a constitutionally permissible restriction on access and use of confidential medical information. It is fundamental to the First Amendment analysis here to recognize that the data that pharmacies, data miners, and pharmaceutical companies exchange – and the data they claim to have a First Amendment right to buy and sell – is data that exists only because the State requires pharmacies to keep prescription records for public health and safety reasons. The State has long sought to keep this information confidential via statutes and regulations aimed at protecting medical privacy.

The Prescription Confidentiality Law is simply aimed at maintaining the high standards of confidentiality and privacy that have always applied to the physician-patient relationship. It was enacted as a direct response to the aggressive efforts of data miners and pharmaceutical companies to circumvent this otherwise comprehensive medical privacy regime and surreptitiously buy access to private medical information. The law takes appropriately narrow steps to close an unintended loophole in the State's regulatory system, thereby closing the back door through which data miners buy access to the private patient-physician relationship.

Assuming for the sake of this argument that Vermont's law restricts commercial speech,[3] it easily withstands scrutiny under *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980). The law satisfies the *Central Hudson* standards because the state-imposed restriction on access and use of PI data directly advances Vermont's substantial interests and is not more restrictive than necessary to advance those interests. *Id.* at 564-66. In particular, the law advances the State's interest in protecting medical privacy by ensuring the integrity

[3] VMS does not concede that the Vermont Prescription Confidentiality Law regulates speech and VMS joins in and supports the position taken by Petitioner State of Vermont that pharmacies "do not have a First Amendment right to sell health care records or to allow their use for purposes unrelated to the provision of health care." Pet. Br. 22.

of the physician-patient relationship, which is not only a substantial state interest in itself, but is also inextricably linked with promoting public health and reducing health-care costs.

II. MEDICAL PRIVACY IS A SUBSTANTIAL STATE INTEREST.

There can be no question that medical privacy is and always has been viewed as central to the practice of medicine. The confidential core of the physician-patient relationship is protected by numerous state and federal laws, all of which speak to the substantial nature of the interest. Vermont's Prescription Confidentiality Law is a reasonable protection of the State's established interest in protecting medical privacy and the Second Circuit erred when it concluded that Vermont's interest in medical privacy is "too speculative to qualify as a substantial state interest." App. 23a.

In concluding that medical privacy is not a substantial state interest, the Second Circuit misapplied the *Central Hudson* test. Its analysis skipped over the threshold evaluation of whether medical privacy is a recognizable substantial state interest, and inappropriately conflated that initial question with the second step of the *Central Hudson* – namely whether Vermont's legislative approach effectively advances the identified state interest. App. 22a. In so doing, the Second Circuit failed to first engage in a thorough

analysis of the state's substantial interest in medical privacy, as required under *Central Hudson*.

When analyzed, the facts compel the conclusion that maintaining and preserving medical privacy is, indeed, a substantial state interest. Medical privacy is at the center of the physician-patient relationship, and the primacy of its importance is revealed in the ethical commitments of physicians and physician organizations. Federal and state governments have long recognized that guarding the privacy of the physician-patient relationship is a substantial state interest, and have thus consistently implemented statutes and regulations aimed at preserving medical privacy. These facts undermine the Second Circuit's conclusion that medical privacy is too speculative to qualify as a substantial state interest. By protecting the physician-patient relationship from infringement by pharmaceutical marketing strategies, the Prescription Confidentiality Law advances this important and substantial state interest while also promoting public health and helping to reduce healthcare costs.

A. Medical Privacy is the Lynchpin of the Physician-Patient Relationship.

The physician-patient relationship is central to the practice of medicine, and the importance of confidentiality to the integrity of this relationship is extensively codified in the ethical and legal obligations of physicians and other health practitioners.

The Hippocratic Oath, which reflects the ethical commitment of physicians to the practice of medicine, contains a pledge to safeguard the confidentiality of patient health and other private information.[4] The American Medical Association's Code of Medical Ethics states: "The information disclosed to a physician by a patient should be held in confidence. The patient should feel free to make a full disclosure of information to the physician in order that the physician may most effectively provide needed services." Am. Med. Ass'n, *Opinion E-5.05 – Confidentiality* (updated June 2007), *in* Code of Medical Ethics, *available at* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion505.shtml (last visited Feb. 24, 2011). Similarly, the principles adopted by the American Medical Association as the "standards of conduct which define the essentials of honorable behavior for the physician" require physicians to "be honest in all professional interactions," to "safeguard patient confidences and privacy," and to "regard responsibility to the patient as paramount." Am. Med. Ass'n, *Principles of Medical Ethics*, §§ II, IV, VIII, *in* Code of Medical Ethics, *available at* http://www.ama-assn.org/

[4] "What I may see or hear in the course of treatment or even outside of the treatment in regard to the life of men, which on no account must be spread abroad, I will keep to myself, holding such things shameful to be spoken about." The Hippocratic Oath: Classical Version (Ludwig Edelstein, trans.) *available at* http://www.pbs.org/wgbh/nova/doctors/oath_classical.html (last visited Feb. 24, 2011).

ama/pub/physician-resources/medical-ethics/code-medical-ethics/principles-medical-ethics.shtml (last visited Feb. 24, 2011). And as VMS said in its resolution urging adoption of the Patient Confidentiality Law, "[t]he doctor patient relationship requires confidentiality and privacy to work effectively." JA 376.

The obligations of confidentiality and candor that characterize the physician-patient relationship are not simply ethical and fiduciary imperatives, they also serve a critical, practical purpose in the effective delivery of health care. As this Court recognized in *Jaffee v. Redmond,* 518 U.S. 1, 10 (1996), confidentiality and trust are not solely matters of principle: "the mere possibility of disclosure [of patients' confidences] may impede development of the confidential relationship necessary for successful treatment."[5] Successful diagnoses and treatments depend on the frank, honest, and open discussion of patients' histories, symptoms, and treatment options. Just as the attorney-client relationship depends on the attorney-client privilege to ensure open and honest communication for the resolution of legal issues, the physician-patient relationship needs its own protection for the full and effective resolution of medical issues. Health

[5] While the Court's statement in *Jaffee* was specifically targeted at psychotherapy, it is just as relevant to the present case given that many of the prescription drugs being marketed are for psychological disorders. Additionally, amici believe that the confidential relationship that the Court recognized as necessary for the successful treatment of psychiatric disorders is just as necessary for successful physical treatment.

care service often depends on the patient's willingness to reveal intimate personal details, and the physician's ability to evaluate the patient's unique individual circumstances. Protecting the confidentiality of this relationship is an end in itself wherever effective health care is a priority.

The information that is the subject of this appeal, PI data, is confidential information that arises directly from the private physician-patient relationship. Indeed, a physician's recommended treatments and prescriptions are the direct result of the confidential conversations between the physician and the patient; they reflect conclusions reached as to the best course of action for that patient after open and honest exchange of private information, and the prescription data itself provides a direct window into the core of this protected relationship. As discussed further in Section III, the sale or disclosure of this PI data, without physician consent,[6] to private parties who have never been recognized by the state or federal government as parties entitled to confidential medical

[6] By requiring consent prior to the release of PI data, the Prescription Confidentiality Law allows physicians, pursuant to their ethical and legal obligations to their patients, to ensure that data which could lead to identification of particular patients in particular communities not be revealed. Where, as here, there are legitimate questions about the protections attached to the release of prescription data – for example whether de-identification actually works – physicians would be able to ensure that such data is not released, or obtain patient consent for the release of such data pursuant to HIPAA and other regulatory and ethical obligations.

information, compromises the integrity of the physician-patient relationship and the foundation of medical practice.

B. Vermont's Restriction on the Use of PI Data for Marketing is Consistent With the Array of State and Federal Laws That Recognize and Protect Medical Privacy.

The ethical and medical-practice principles respecting confidentiality, described above, have also been codified in the law and regulations of the federal government and of many states, including Vermont. *E.g.*, Vt. Stat. Ann. tit. 12, § 1612; 45 C.F.R. §§ 164.501-164.520. These laws reflect the longstanding, well-established government interest in protecting medical privacy, and in preventing the harms that flow from intrusions to medical privacy. Vermont's Prescription Confidentiality law is not a new extension of privacy protection, it merely seeks to retain the status quo against an increasingly aggressive pursuit of confidential information by the pharmaceutical industry.

The Second Circuit held that the Prescription Confidentiality Law "plainly does not protect physician privacy" because it does not prohibit "the collection and aggregation of PI data for *any* purpose." App. 22a (emphasis added). The court also criticized the law because it does not ban "widespread publication to the general public . . . [or] the use of such data for

journalistic reports about physicians." *Id.* This holding reflects the Second Circuit's failure to take a close look at medical privacy issues, and completely ignores the extensive network of state and federal laws that recognize and protect medical privacy, while allowing for certain uses that do not compromise the fundamental foundation of the physician-patient relationship.

As the dissent observed:

> in an era of increasing and well-founded concern about medical privacy and the rampant dissemination of confidential information, the federal government has repeatedly acted on that interest and legislated to protect the privacy of medical records, *see*, *e.g.*, 45 C.F.R. §§ 164.501-164.520 (protecting information collected pursuant to the Health Insurance Portability and Accountability Act); 42 C.F.R. § 2000ff *et seq*. (protecting the privacy of genetic information); 42 C.F.R. §§ 431.300, 431.303 (protecting records of Medicaid patients), and thirteen states and the District of Columbia have considered or enacted bills aimed at protecting medical privacy in the very same way Vermont's statute does.

Id. 52a-53a (Livingston, J., dissenting).

Vermont has a number of laws that recognize and protect the public's interest in medical privacy. The patient-privilege statute, Vt. Stat. Ann. tit. 12, § 1612, provides greater protection than the Health Insurance Portability and Accountability Act ("HIPAA")

privacy rule, 45 C.F.R. §§ 164.501-164.520, and requires that physicians, chiropractors, dentists, nurses and mental-health professionals not disclose any information acquired in attending a patient unless the patient waives the confidentiality or it is waived by an express provision of law. Hospital patients and nursing home residents are further protected by the confidentiality provisions contained in the Patient Bill of Rights, Vt. Stat. Ann. tit. 18, § 1852(7), and the Nursing Home Bill of Rights, Vt. Stat. Ann. tit. 33, § 7301(8).

Vermont also has strict medical privacy protections specific to prescription records. Pharmacies and pharmacists operate in a highly regulated environment. By law, Vermont's pharmacists are required to collect and maintain a great deal of confidential medical information about the people whose prescriptions they fill, including the identity of the prescriber. Vt. Bd. of Pharmacy Admin. Rules §§ 9.1, 9.24 (eff. Oct. 1 2009) [hereinafter Pharmacy Rules], *available at* http://vtprofessionals.org/opr1/pharmacists/rules.asp. The Pharmacy Rules prohibit unauthorized "access to pharmacy records containing confidential information or personally identifiable information concerning the pharmacy's patients." *Id*. § 9.15. "Confidential information" is defined to include "information accessed, maintained by, or transmitted to the pharmacist in *the patient's record*." *Id*. § 1.10(a)(7) (emphasis added). The patient's record is required to include the name of the prescriber. *Id*. § 9.24(e)(5). In other words, Vermont's pharmacy regulations are intended

to keep pharmacy records confidential, and because pharmacy records include the name of the prescriber, the Pharmacy Rules should prevent the dissemination of PI data.

Thus, although the Second Circuit concluded that the Prescription Confidentiality Law did not protect the "widespread public dissemination" of confidential PI data, it ignored the already existing, highly protective restrictions in the Pharmacy Rules. Widespread public dissemination of confidential prescription information is already prohibited. Pharmacists are required to keep prescription and other patient health care information confidential and "secure from access by the public." Pharmacy Rules § 8.7(c). Prescription information includes what the prescription is for and who wrote it, and thus the Pharmacy Rules prohibit the "widespread public dissemination" of PI data.

Vermont's law prohibiting the sale and use of PI data is consistent with existing federal and state medical privacy protections already on the books. That data miners ever had access to pharmacy records in the first place is counter to the intent of Vermont's strict medical privacy protections. The existence of data mining is simply more evidence of the aggressive pursuit of confidential information by pharmaceutical companies for the purpose of pecuniary gain; it does not indicate that Vermont has ever ignored the importance of protecting medical privacy or failed to implement laws and regulations aimed at advancing that state interest. Rather, the

Prescription Confidentiality Law embodies Vermont's reasonable efforts to quickly respond to an unexpected loop-hole in the State's otherwise comprehensive protection of medical privacy. The State required that pharmacies collect this data for public health and safety reasons, and has now acted to ensure that this private data stays private when not used for the intended purposes of advancing public health and safety.

The Second Circuit also expressed doubt that medical privacy could be protected by the Prescription Confidentiality Law because the law exempts some uses of PI data. App. 22a. This perceived "shortcoming" in the law led the court to conclude that medical privacy is not a substantial state interest. The court's conclusion fails to recognize that the exceptions to the law do not undermine the State's interest in medical privacy, but instead protect other important state interests that necessitate the use of PI data while simultaneously ensuring that medical privacy is protected.

The law's exemptions include health care research, treatment, payment, law enforcement and safety-related uses. Vt. Stat. Ann. tit. 18, § 4631(e). The use of PI data for these activities promotes the State's substantial interests in cost containment and public health, or other important public interests, such as law enforcement. For example, under the law, pharmacies are not prohibited from disclosing PI data for "prescription drug formulary compliance" or "utilization review by a health care professional." *Id*.

§ 4631(e)(1). These uses clearly promote the State's interests in public health and cost containment. At the same time, many of the exempted uses require additional privacy protection and therefore continue to protect the State's interest in medical privacy while promoting these other state interests. For example, health care research that uses "identifiable private information" is considered human subject research that must be scrutinized by an institutional review board and requires informed consent of the participants. 45 C.F.R. § 46.102(f); *see also* 45 C.F.R. Part 46 (Health and Human Services "Protection of Human Subjects"), 32 C.F.R. Part 219 (Department of Defense, "Protection of Human Subject"), 21 C.F.R. Part 50 (Food and Drug Administration, "Protection of Human Subject Research"). Additionally, the exemptions for "pharmacy reimbursement . . . patient care management," and other uses related to treatment, payment, or health care operations are subject to the confidentiality protections of HIPAA. 45 C.F.R. § 164.502.

The Prescription Confidentiality Law's exemptions appropriately protect the state's interest in medical privacy while promoting other important state interests that may be served by the regulated use of PI data. Amici do not argue that all PI data should be protected from disclosure for all purposes, but when PI data is sold to data miners, then aggregated and resold to pharmaceutical companies whose sole use of the data is to convince physicians to prescribe a particular manufacturer's drug for reasons

that are not driven by the individual patients' needs, there is neither an important alternative state interest being served, nor the necessary protection of medical privacy. Therefore, this use of PI data is inconsistent with, and an unjustified intrusion on, the State's interest in medical privacy. The Prescription Confidentiality Law directly advances the State's interest in protecting medical privacy by regulating the use of information that arises from confidential physician-patient relationships.

III. THE PRESCRIPTION CONFIDENTIALITY LAW DIRECTLY ADVANCES VERMONT'S SUBSTANTIAL INTEREST IN PROTECTING MEDICAL PRIVACY, AS WELL AS THE STATE'S SUBSTANTIAL INTERESTS IN PUBLIC HEALTH AND REDUCING HEALTH-CARE COSTS.

Vermont's Prescription Confidentiality Law survives scrutiny under the second prong of *Central Hudson* because the prohibition on the use of PI data for marketing will materially alleviate a real harm to several substantial state interests. *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993) (citing cases, including *Cent. Hudson*, 447 U.S. at 73). Vermont has met its burden here by showing that the "statute promises directly to advance an identified governmental interest." *IMS Health Inc. v. Ayotte,* 550 F.3d 42, 55 (1st Cir. 2008) (citing *Burson v. Freeman*, 504 U.S. 191, 211 (1992)). In the absence of the Prescription Confidentiality Law, VMS realized that the evidence was

growing that pharmaceutical marketing practices based on the use of PI data were exerting a greater influence on physicians' prescribing patterns. JA 376-78. The concerns expressed by VMS were confirmed by the findings of the Vermont Legislature when it enacted the Prescriber Confidentiality Law. 2007 Vt. Acts & Resolves No. 80, § 1. The nonconsensual use of confidential PI data to market prescription drugs to physicians does influence physicians' prescribing practices. *Id*. § 1(4), (14), (17)-(20). The result is more and unnecessary prescriptions for expensive brand-name drugs. *Id*. § 1(7), (14). These adverse public health and cost-containment outcomes reflect the breakdown in the integrity of the physician-patient relationship caused by the use of PI data by pharmaceutical marketers. Restricting access to the use of confidential PI data for marketing limits this intrusion into the physician-patient relationship and its excessive and covert influence on prescribing practices.

In particular, there are two ways in which the unrestricted use of PI data for marketing purposes invades medical privacy rights, and the Prescription Confidentiality Law directly combats both of these invasions. First, because patient "de-identification" does not actually remove all information by which a patient may be identified, the sale of PI data compromises patient confidentiality (and may violate HIPAA and other state regulations, including the Pharmacy Rules). Second, even assuming that patient "de-identification" was fully effective, the use of

prescriber-identifiable information in pharmaceutical marketing compromises the privacy between the patient and the physician by allowing a third party into that relationship. Vermont's law advances the substantial state interest in medical privacy by allowing physicians to establish another layer of privacy for their patients' prescription records, and by allowing physicians to avoid being targeted by personalized prescription-drug sales pitches that invade the physician-patient relationship.

A. Patient De-Identification of Prescription Records Does Not Effectively Protect Patient Privacy and the Prescription Confidentiality Law is an Effective Means to Provide a Greater Degree of Confidentiality for Patients.

Contrary to assurances from the pharmaceutical industry, de-identification does not protect patients from pharmaceutical company tracking. Respondents and the Second Circuit believe that by removing all patient-identifying information before transferring prescription information to the pharmaceutical companies, there is no harm to patient privacy. App. 5a, JA 80. VMS disagrees with this unsupported assumption and is very concerned about the invasion of medical privacy even with so called "de-identification."

Under HIPAA, de-identification of data requires removing all information that is explicitly linked to an individual as well as information for which there is a "reasonable basis to believe that the information

can be used to identify an individual." 45 C.F.R. § 164.514(a). The HIPAA privacy rule lists seventeen types of identifiers that must be removed from health information, as well as a catch-all category of "any other unique identifying number, characteristic or code." *Id*. § 164.514(b)(2)(i). Additionally, if a HIPAA-covered entity has "actual knowledge" that certain "information could be used alone or in combination with other information to identify an individual who is a subject of the information," then the entity must remove that information as well. *Id*. § 164.514(b)(2)(ii). In small Vermont communities, physician-identifying data on a prescription record may very well constitute a "unique identifying . . . characteristic" such that the disclosure of PI data would violate HIPAA.

VMS does not share Respondents' comfort with the level of de-identification that occurs in data mining. Although it appears that the information purchased from the pharmacies by the data-miners contains only encrypted patient names, the record is clear that data-miners do routinely track patients over time. App. 37a n.4. One data-miner boasted that it tracked the "activities of over two hundred million patients," by using special software that allowed it to link up any of the five "P's": patient, product, prescriber, payer and pharmacy. JA 156, 161. This ability to track patients calls into question whether the process of de-identification actually satisfies the HIPAA standards.

Even assuming that the de-identification carried out by the pharmacies who sell PI data to data-miners does meet HIPAA standards, there is growing concern among governmental agencies and health professionals that the HIPAA standards themselves are not sufficient to protect patient confidentiality. In a cover letter introducing a 2007 report on health-data protections to the Secretary of the U.S. Department of Health and Human Services, the Chairman of the National Committee on Vital Health Statistics (NCVHS) wrote:

> In our deliberations, we identified several areas that require further analysis. One area is the process of de-identifying health data. There are many interpretations of what de-identification means. We also heard concerns about the ability to re-identify data, even while applying the HIPAA definition of de-identification. A second area relates to uses, and particularly the sale, of health data that are de-identified and therefore outside of the protections of HIPAA . . . NCVHS will be further investigating and making subsequent recommendations in these areas.

Simon P. Cohn, *Cover Letter to* Nat'l Comm. on Vital and Health Statistics, Enhanced Protections for Uses of Health Data: A Stewardship Framework for "Secondary Uses" of Electronically Collected and Transmitted Health Data (Dec. 19, 2007), *available at* http://www.ncvhs.hhs.gov/071221lt.pdf.

Many recent commentators have raised similar concerns about the privacy risks of HIPAA-compliant de-identified health records and the risk that they can be re-identified to specific patients. Katherine Benitz and Bradley Malin, *Evaluating re-identification risks with respect to the HIPAA privacy rule*, 17 J. Am. Med. Informatics Ass'n 169, 169-77 (2010) (concluding that blanket de-identification protection policies leave organizations vulnerable to different re-identification risks); Fed. Trade Comm'n, *Protecting Consumer Privacy in an Era of Rapid Change: A Proposed Framework for Businesses and Policymakers*, Preliminary FTC Staff Report iv, 30-38 (Dec. 2010) (noting concerns about disclosure of medical information and the fact that the distinction between personally-identifiable information and "supposedly anonymous or de-identified" information is eroding); Paul Ohm, *Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization,* 57 UCLA Law Review 1701, 1736-38, 1740-45 (2010), (concluding it is indefensible from a technical, ethical and policy standpoint to continue to draw a bright line distinction between identified and de-identified health information); Mark A. Rothstein, *Is Deidentification Sufficient to Protect Health Privacy in Research?,* 10(9) Am. J. Bioethics 3, 3-11 (2010) (concluding the current strategy of de-identifying health records is insufficient to protect privacy).

In Vermont, where small communities tend to be the norm, there are additional concerns about the

ease with which patients could be personally identified from their prescription records. In its 2006 Resolution urging adoption of the Patient Confidentiality law, VMS stated "while patient information is de-identified, in small communities identifying a drug prescription can equal the release of an individual's diagnosis." JA 377. Based on all of these concerns regarding insufficient patient privacy via HIPAA-compliant de-identification, the Prescription Confidentiality Law provides significant additional protection of patient confidentiality. By forbidding the nonconsensual disclosure of PI data for marketing purposes, patients gain an additional layer of privacy protection. Removing the prescriber's identifying information from prescription records takes away a small but significant piece of information that could otherwise be used to re-identify a patient, while having little impact on pharmaceutical companies' abilities to engage in other lawful marketing activities. Thus, the law directly advances the State's substantial interest in medical privacy on this front.

B. Assuming That HIPAA Sufficiently Protects Patient Privacy, the Unrestricted Use of PI Data Nonetheless Infringes on The Privacy of the Physician-Patient Relationship.

In spite of any claimed or technical "de-identification" of patients from PI data, it is still an invasion of medical privacy when data-miners and drug marketers use information derived directly from

the physician-patient relationship to insert an undisclosed non-patient perspective into a physician's treatment decisions. The HIPAA Privacy Rule, and its de-identification requirements, represents a floor when it comes to allowable efforts to protect medical privacy. 45 C.F.R. § 160.203(b); 65 Fed. Reg. 82,462, 82,471 (Dec. 28, 2000) (stating that the HIPAA Privacy Rule is merely a privacy "floor" and that other governments may enact more stringent privacy measures). Vermont's Prescription Confidentiality law provides more stringent protections to medical privacy than HIPAA, yet it is also entirely consistent with HIPAA's purpose. 65 Fed. Reg. at 82,462 (stating that HIPAA privacy "protections will *begin to address* growing public concerns that advances in electronic technology and evolution in the health care industry are resulting, or may result, in a substantial erosion of the privacy surrounding individually identifiable health information" (emphasis added)). Indeed, HIPAA regulations demonstrate that states may adopt more stringent medical privacy laws. 45 C.F.R. § 160.203(b).

The Second Circuit failed to recognize that this legislation protects the State's overarching medical privacy goals by correcting the unintended and unexpected misuse of otherwise highly confidential data that data-miners would not have access to but for the State's requirement that it be collected. As the record below documents, detailers use PI data to develop physician profiles that detail a physician's use of all prescription medication to treat his or her patients.

JA 381-82, 390; App. 95a. Detailers then use these physician profiles to craft sophisticated sales pitches designed to change the treatment decisions that physicians make for their patients. JA 382. These physician profiles are dangerously simplistic as they provide no clinical context, which is essential to understanding patient needs and making successful treatment decisions. Additionally, the detailers' goals are wholly unrelated to the best clinical treatment for any specific patient. When detailers are successful, the results can be dangerous for the patient and expensive for the State. App. 95a ("Detailing encourages doctors to prescribe newer, more expensive, and potentially dangerous drugs instead of adhering to evidence based treatment guidelines."). Certainly Vermont has a substantial interest in curbing an invasion of medical privacy that results in dangers to public health and increased public expenditures.

Detailers armed with PI data provide subjective, misleading, and often inaccurate information to physicians when making sales calls. Michael G. Ziegler et al., *The Accuracy of Drug Information from Pharmaceutical Sales Representatives*, 273 J. Am. Med. Ass'n 1296, 1296-98 (1995) (finding that 11% of detailers' statements to physicians were demonstrably inaccurate, and all such statements were favorable to the promoted product). As the Second Circuit acknowledged, "It cannot be seriously disputed that the primary purpose of detailing is to propose a commercial transaction – the sale of prescription drugs to patients." App. 19a. The detailer's job is not

to deliver unbiased information to physicians in the hopes of helping them find the right drug therapy for their patients. Detailers use very sophisticated sales strategies based on PI data to convince physicians to prescribe the pharmaceuticals the detailer is selling.

Physicians themselves do not always appreciate the extent to which their judgment is influenced by detailing. In one important study, researchers surveyed physicians' attitudes about two commonly prescribed drugs for which empirical studies found little benefit but promotional materials suggested substantially more benefit. J. Avorn et al., "*Scientific versus Commercial Sources of Influence on the Prescribing Behavior of Physicians*," 73(1) Am. J. Med. 4, 4-8 (1982). While the physicians claimed to be influenced by the medical data, their attitudes in fact often were more consistent with the promotional claims. *Id*. Not only were the physicians making inappropriate prescribing decisions, they were unaware that they were doing so. *Id*. In addition, some research has indicated that visits from sales representatives are more effective at increasing drug sales than advertisements directed to physicians in professional journals or advertisements directed to consumers on television or in other media. Puneet Manchanda and Elisabeth Honka, *The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review*, 5 Yale J. Health Pol'y, L. & Ethics 785, 798-99 (2005).

The influence of detailing on physician prescribing has been proven to compromise clinical decision-making. Researchers have found that the quality of prescribing decisions increases the more physicians rely on independent sources of information and decreases the more physicians rely on information from sales representatives. A. Figueiras et al., *Influence of Physician's Education, Drug Information and Medical-Care Settings on the Quality of Drugs Prescribed*, 56 Eur. J. Clinical Pharmacology 747 (2000); *see also* Manchanda & Honka, *supra* 17, at 809-10 ("While there seems to be little consensus about the size of the effect [of detailing on physician prescription behavior], it is clear that the effect is positive and significant in a statistical sense.")

One study found that, after meeting with pharmaceutical detailers, physicians were more likely to prescribe expensive new drugs instead of cheaper generic drugs, even when scientific evidence indicates the prescription is not advantageous or even desirable. Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift*?, 283 J. Am. Med. Ass'n 373, 373-80 (2000); *see also* David Orentlicher, *Prescription Data Mining and the Protection of Patients' Interests*, 38 J.L. Med. & Ethics 74, 77 (2010) (finding that detailing can result in patients receiving drugs they do not need, or that are less effective and potentially more dangerous than alternatives, or that are more expensive than clinical equivalents).

The use of PI in detailing has been proven to increase sales. The pharmaceutical industry admits that using PI data to develop pitches directly increases prescriptions for expensive brand-name drugs. JA 147-48, 150. As the First Circuit observed: "[t]he fact that the pharmaceutical industry spends over $4,000,000,000 annually on detailing bears loud witness to its efficacy."[7] *Ayotte*, 550 F.3d at 56. One industry market-research study has indicated that physician profiling with PI data can increase the sales of new drugs by 30%. David Grande, *Limiting the Influence of Pharmaceutical Industry Gifts on Physicians: Self-Regulation or Government Intervention?*, 25 J. Gen. Intern. Med. 79, 81 (2009). It seems fair to conclude that if PI data were not a highly effective marketing tool, this case would not be before this Court.

The combination of pharmaceutical marketing with physician prescribing data "allows marketers to influence prescribing in ways that threaten medical professionalism." David Grande, *Prescriber Profiling: Time to Call it Quits*, 146 Annals of Int. Med. 751, 752 (2007). Fundamentally, it is the intrusion of this undue and unchecked third-party influence into the physician-patient relationship that the State sought to protect against when it enacted the Prescription Confidentiality Law. When salespeople use the

[7] The Second Circuit found that "the pharmaceutical industry's annual detailing budget was approximately $8 billion." *App. 33a.*

prescriptions a physician writes for his or her patients as a basis to "tailor" their pitches, they are actively seeking to exploit confidential treatment information to gain influence and press their advantage over the physician's subsequent treatment decisions. This practice has introduced a third party into the physician-patient relationship whose goals are not aligned with the physician's or the patient's goals, and who has been shown to corrupt the treatment process and increase medical costs.

Vermont's Prescription Confidentiality Law redresses these injuries to the State's interest in medical privacy because by taking the nonconsensual use of PI data away from data miners, detailers can no longer link the prescription data back to a specific physician prescriber who chooses to remain anonymous. It is the physician-targeted sales pitch aimed only at increasing sales of certain drugs that directly harms the confidential nature of the physician-patient relationship to the greatest degree, and impacts the State's other substantial interests in public health and health care costs. The law is a direct response to those harms.

C. The Prescription Confidentiality Law Directly Alleviates the Harm to Vermont's Interests by Restricting Access to PI Data for Pharmaceutical Marketing Purposes.

The Prescription Confidentiality Law restricts pharmacies from selling one element of its prescription

records – prescriber-identifiable data – and prevents this one piece of data from being used surreptitiously by detailers to track patients and convince physicians to prescribe expensive brand-name drugs. As laid out above, PI data plays a major role in detailing, and detailing drives the uptake of the newest and most expensive brand-name drugs. In terms of directness, there is no question that the law hits the target.

The State's interests are to safeguard medical privacy, protect the public health, and save money. Removing PI data from the marketing equation alleviates the harm caused to all three state interests. Removing PI data from marketing protects medical privacy by both protecting against the potential release of patient-identifiable information, and removing the influence of pecuniary interests from confidential physician-patient prescribing and treatment decisions. This in turn promotes public health by ensuring that treatment decisions are based on clinical evidence and the best interests of the patient. Removing the influence of pecuniary interests from prescribing and treatment decisions also reduces the State's health care costs by reducing the number of prescriptions for new, expensive brand-name drugs when less expensive therapeutic equivalents or generic drugs would be equally effective. App. 6a. This causal chain is supported by more than just "common sense." *Burson*, 504 U.S. at 211.

The Second Circuit, however, concluded that Vermont's law does not directly advance the State's interest because "[t]he state's approach to regulating

the interaction between detailers and physicians is premised on limiting the information available to physicians as a means of impacting their conduct." App. 26a. And this, the court said, is contrary to First Amendment jurisprudence which is "skeptical of government efforts to prevent the dissemination of information in order to effect conduct." App. 26a. But the Second Circuit's assumptions and its resulting conclusions are not correct. Vermont's Prescription Confidentiality Law does not "limit the information available to physicians." Physicians created the information in the first place. Physicians know their prescribing patterns and what they are prescribing for each patient. They know the patient's allergies and tolerances. They know what other medications that patient is using. They know the patient's medical history. The Prescription Confidentiality Law does not keep physicians "in the dark . . . for their own good." *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996). In fact, it doesn't keep physicians in the dark at all. By requiring consent prior to release of PI data, the law shines a light on the pharmaceutical industry's marketing strategies.

The Prescription Confidentiality Law shores up one weakness in the State's network of confidentiality protections for medical information. By restricting the use of PI data, the law directly advances the State's interest in medical privacy, health care costs and public health. Consequently, the law satisfies the second prong of the *Central Hudson* test for permissible restriction of commercial speech.

IV. THE PRESCRIPTION CONFIDENTIALITY LAW IS PROPORTIONAL AND RESTRICTS NO MORE SPEECH THAN NECESSARY TO PROTECT MEDICAL PRIVACY AND THE STATE'S OTHER SUBSTANTIAL INTERESTS.

Vermont's restriction on the use of PI data for pharmaceutical marketing survives scrutiny under the third prong of *Central Hudson*, because it is tailored to be "in reasonable proportion to the interest served." *Edenfield*, 507 U.S. at 767. Satisfying this prong does not require a perfect fit, "'but [one that is] reasonable.'" *Greater New Orleans Broadcasting Ass'n, Inc. v. U.S.*, 527 U.S. 173, 188 (1999) (quoting *Bd. of Trustees of State Univ. of N.Y.* v. *Fox,* 492 U.S. 469, 480 (1989)).

Restricting the sale and use of PI data for marketing is a narrow and proportionate means of advancing the State's substantial interests. By removing the one piece of data that links otherwise confidential prescription information to a physician (and potentially a patient), and by requiring consent to use PI data for marketing, Vermont's interests in controlling costs, promoting public health and protecting medical privacy are advanced without interfering with any non-marketing-related beneficial uses for PI data or with any non-PI-data-based pharmaceutical marketing.

The Second Circuit concluded that the Prescription Confidentiality Law was not narrowly tailored because it affected all prescription drugs, not just the

newest ones or those without generic equivalents. The Court's reasoning is not well-founded and misconstrues the law. App. 30a. The law restricts all marketing using PI data without consent. The record is clear that only new and expensive brand-name drugs are marketed directly to physicians with the use of PI data. App. 6a, 72a. Older drugs and generics are generally not detailed. App. 6a, 72a. The law narrowly restricts PI data from one use, and in so doing, aims to reduce overprescribing and the patient, provider and public ills that flow from it.

The "widespread use of new brand name prescription drugs" contributes significantly to Vermont's unsustainable overall health costs. App. 38a. Detailing has been proven to be a significant driver of this overprescribing, and PI data is touted as the "most powerful tool" in the detailer's tool box. Stephanie Saul, *Doctors Object to Gathering of Drug Data*, N.Y. Times, May 4, 2006, *available at* http://www.nytimes.com/2006/05/04/business/04prescribe.html?pagewanted=2&sq=dat. Reducing the use of PI data in detailing is, therefore, a reasonable and proportionate way of addressing and combating increasing costs associated with unnecessary prescribing of brand-name drugs.

Apparently to illustrate potentially narrower alternatives, the Second Circuit hypothesized about two measures it thought would be better suited than the Prescription Confidentiality Law to advance the State's purposes. App. 30a-31a. Both of the court's proposals have been put in place in Vermont. Indeed, Vermont has an impressive history of prescription

drug cost-containment efforts.[8] But the very measures proposed by the Second Circuit are inadequate alone to address and protect the State's substantial interests in this arena. Indeed, as the First Circuit found with regard to New Hampshire's similar law restricting the sale of PI data, Vermont's Prescription Confidentiality Law is also "a targeted legislative response to a particular problem that had proven resistant to a number of different regulatory approaches." *Ayotte*, 550 F.3d at 59.

The Court suggested implementing a counter- or academic-detailing effort. Vermont has tried to do this for years but it has lacked the funding. The same Act that contained Vermont's Prescription Confidentiality Law finally developed a method to fund such an effort by establishing a fee on pharmaceutical manufacturers whose prescription drugs are paid for by the State. 2007 Vt. Acts & Resolves No. 80, §§ 20, 20a. The fee is 0.5% of the previous calendar year's prescription drug spending by the State for its Medicaid and other prescription drug programs and will be

[8] Some examples of the numerous Medicaid and public health care cost-containment efforts Vermont has instituted in recent years include: joining a multi-state drug purchasing pool, Vt. Stat. Ann. tit. 33, § 1998(c); contracting with a Pharmacy Benefits Manager, *id*. § 2002; covering over-the-counter drugs and generics in the preferred drug list when they are less costly, medically appropriate alternative to other drugs, *id*. § 2076; implementing a maximum allowable cost program for generics and other prescription drugs, *id*. § 1998(a)(4); enacting a generic substitution law, Vt. Stat. Ann. tit. 18, § 9472; and enacting a price disclosure law, *id*. § 4634.

used for "evidenced based education."[9] *Id*. Given the disparity between this small fund and the manufacturers' $8 billion annual detailing budget it is unlikely that this effort will be wholly effective in combating the problems associated with detailing. Indeed, Vermont's escalating drug expenditures could quickly swallow any savings achieved through counter-detailing.

The court also suggested a formulary. Vermont has long had a Preferred Drug List and prior authorization requirements in place for Medicaid and its other public health care and pharmacy programs. Vt. Stat. Ann. tit. 33, § 1988. This means that if there is a therapeutically equivalent or generic drug available, the appropriate drug will be substituted unless a prescriber orders otherwise. While formularies and other laws aimed at reducing prescription drug costs are helpful, they are not the only constitutional tools available to a state, and neither addresses the State's privacy concerns related to the use of PI data.

It is important to remember that detailers do not need PI data for marketing and promotion. This information commodity is relatively new, as there was historically no way to acquire this information. Indeed, until Vermont acted to require pharmacies to

[9] These provisions were promptly challenged by the Pharmaceutical and Manufacturers Association of America (PhARMA) in a lawsuit that merged with the present case. The District Court upheld the fee, App. 113a, and PhARMA did not appeal.

collect the data for independent public health and safety reasons, the data was not otherwise available to data miners. For example, detailers can easily uncover most of the data concerning a physician's practice areas with a little effort, and without disclosure of any confidential patient and prescription information. Physicians' practice areas are set out in phonebooks, available through the AMA, and posted on State Medical Board and insurer websites. *See, e.g.,* BlueCross BlueShield of Vermont, Find a Doctor Page, http://www.bcbsvt.com/member/MemberBenefits/FindADoctor.html (last visited Feb. 24, 2011). There is no reason that the Vermont law will lead pharmaceutical companies to waste resources by marketing anti-depressants to ophthalmologists.

The law also does not prohibit detailers from meeting with and talking to physicians. They can have legitimate, two-way conversations with physicians, in which they ask about their areas of concern, their practices, and their prescribing emphases, preferences, and conundrums. There are simple lawful communication strategies already available for detailers to "identify audiences for their marketing messages, to focus marketing messages for individual prescribers," and "to direct scientific and safety messages to physicians most in need of that information." App. 6a. These strategies, importantly, do not depend on confidential PI data for their success.

In fact, limiting the use of PI data may actually improve the distribution of scientific and safety

messages to physicians. Pharmaceutical companies have shown an uneven concern for insuring physicians receive important information about drugs. Detailers are urged to focus on "top potential" physicians and not bother visiting physicians who do not "help move [market] share." JA 523.

In sum, the Prescription Confidentiality Law affects only a narrow piece of information and one use of that information. That use has serious ramifications for the physician-patient relationship and medical privacy, the costs of drugs caused by calculated overprescribing, and public health. Detailing can continue even where a prescriber decides not to allow his or her PI data to be used. This is a narrow and carefully tailored law that regulates speech minimally while at the same time advancing the State's substantial interests in medical privacy, health care cost containment, and public safety.

CONCLUSION

For the reasons stated above, as well as those set forth in Petitioner's brief, amici respectfully request that this Court reverse the Second Circuit Court of Appeals.

Respectfully submitted,

EILEEN I. ELLIOTT,
Counsel of Record
JESSICA A. OSKI
ELIZABETH H. CATLIN
SHEMS DUNKIEL RAUBVOGEL
& SAUNDERS PLLC
91 College Street
Burlington, VT 05401
(802) 860-1003
eelliott@shemsdunkiel.com

Attorneys for Amici Curiae