No. 10-779

In The Supreme Court of the United States

WILLIAM H. SORRELL,
as Attorney General of Vermont, *et al.*,

Petitioners,

v.

IMS HEALTH INC., *et al.*,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

BRIEF OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES AND AMERICAN SOCIETY FOR AUTOMATION IN PHARMACY AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Prescription drug records, which contain information about patients, doctors, and medical treatment, exist because of federal and state regulation in a highly regulated field. This case is about information from prescription records known as "prescriber-identifiable data." This data identifies the doctor or other prescriber, links the doctor to a particular prescription, and reveals other details about that prescription. Pharmacies sell this information to data mining companies, and the data miners aggregate and package the data for use as an analytic marketing tool by pharmaceutical manufacturers. The law at issue in this case, Vermont's Prescription Confidentiality Law, affords prescribers the right to consent before information linking them to prescriptions for particular drugs can be sold or used for marketing. The Second Circuit held that Vermont's law violates the First Amendment, a holding that conflicts with two recent decisions of the First Circuit upholding similar laws. *See IMS Health Inc. v. Mills*, 616 F.3d 7 (1st Cir. 2010), *pet. for cert. filed*, No. 10-984 (Jan. 28, 2011); *IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008).

QUESTION PRESENTED – Continued

The question presented by Petitioner is: Whether a law that restricts access to information in nonpublic prescription drug records and affords prescribers the right to consent before their identifying information in prescription drug records is sold or used in marketing runs afoul of the First Amendment. *Amici* do not concede the information is nonpublic or that this case implicates any privacy interest to which the State of Vermont may give preference over the Respondents' right of free commercial speech.

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BRIEF OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES AND AMERICAN SOCIETY FOR AUTOMATION IN PHARMACY AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

INTEREST OF *AMICI CURIAE*[1]

NATIONAL ASSOCIATION OF CHAIN DRUG STORES

The National Association of Chain Drug Stores ("NACDS") is the nation's largest association of retail pharmacies. NACDS's mission is to represent the views and policy positions of its member pharmacies in order to advance their ability to provide quality and cost effective pharmacy service. In the State of Vermont, NACDS has eleven (11) members who operate nearly ninety (90) community retail pharmacies. Nationwide, NACDS members consist of over one hundred thirty (130) chain community pharmacy companies, and the thousands of pharmacies in those chains.

Collectively, chain community pharmacies are the largest providers of pharmacy services, with over

[1] This brief is filed with the filed written consent of all parties. Pursuant to the Court's Rule 37.6, counsel for *amicus curiae* authored this brief in whole, and no counsel for a party authored this brief in whole or part, nor did any person or entity, other than *amicus*, its members, or its counsel make a monetary contribution to the preparation or submission of this brief.

118,000 pharmacists nationwide and approximately 39,000 pharmacies. The chain community pharmacy industry is comprised of traditional drug stores, supermarket pharmacies, and mass-merchant pharmacies. Annual sales in this industry total over $830 billion for prescription and over the counter medications, and health and beauty aids. Chain-operated retail pharmacies fill over seventy two percent (72%) of the more than 2.6 billion prescriptions dispensed annually in the United States.

Eighty-nine (89) NACDS member pharmacies are located in the State of Vermont. These members' customers obtain medical and other health services in Vermont. The services include receiving prescription drug orders from prescribers such as physicians, advance practice nurses, physicians' assistants, dentists, and podiatrists. These prescriptions are filled by NACDS member pharmacies. Data from these prescriptions is maintained by NACDS member pharmacies. NACDS member pharmacies sell this data to Respondent data miners. And, NACDS member pharmacies utilize the aggregated data licensed by Respondent data miners. NACDS is interested in the outcome of this litigation because any restriction on the sale or use of prescriber-identifiable data will impair the ability of NACDS's member pharmacies to deliver quality and cost-efficient pharmacy care.

AMERICAN SOCIETY FOR AUTOMATION IN PHARMACY

The American Society for Automation in Pharmacy ("ASAP") was formed in 1987 to provide a national voice in support of the technological advancement of pharmacy practice. Today two hundred (200) organizations make up ASAP's membership, with individual members ranging from providers of technology solutions to the pharmacy market to the pharmacies that use the technology.

ASAP's mission is to foster understanding of the important role that technology plays in helping pharmacists: (1) advance patient safety and the proper use of medications, (2) comply with laws and regulations, and (3) operate their pharmacies more efficiently. ASAP accomplishes this mission by providing a forum for sharing diverse knowledge and perspectives on the modern practice of pharmacy.

Over the years, ASAP and its member organizations have maintained meaningful professional relationships with data mining companies. ASAP relies on data mining companies like Respondents to educate ASAP's membership on technology trends in the pharmaceutical industry. ASAP's member companies find these presentations of extreme value in helping chart market planning and product development.

ASAP's specific support of Respondents derives from the fact that, through automation in pharmacy, ASAP's members facilitate the collection of Prescriber Data for data miners, without disclosing protected

health information. Because this data is published by a broad spectrum of participants in the health care industry, including state and federal governments, ASAP believes Respondent data miners provide an important service in monitoring pharmaceutical trends not only to industry but society in general.

Accordingly, the outcome of this litigation is of interest to ASAP and its members because censoring the sale and use of Prescriber Data will cause profound financial detriment to its membership, and will negatively impact technology's contribution to the delivery of pharmaceutical care.

SUMMARY OF ARGUMENT

Vermont's prescription confidentiality law is an unconstitutional restriction on truthful speech communicated by a willing speaker related to prescription information collected, maintained, de-identified, and sold by pharmacies. Vt. Stat. Ann. tit. 18, §4631 (2010); *see* 2007 Vt. Acts & Resolves No. 80, §17 (Confidentiality of Prescription Information, referred to as "Section 17" herein). Specifically, Section 17 prohibits the sale of prescriber-identifiable data ("Prescriber Data") if the data will be used by a drug manufacturer for marketing purposes. When the law was enacted, Vermont stated that Section 17 was intended to protect prescriber privacy, improve public health, and lower health care costs. In the face of the present Constitutional challenge, however, Vermont

now contends that the law protects medical (including patient) privacy.

Prescriber Data is not confidential. Rather, it is publicly available data that pharmacies have historically collected and sold in furtherance of patient safety and quality healthcare without sanction from any jurisdiction. The Prescriber Data regulated by Section 17 does not compromise patient safety because it has nothing to do with patients. And, Prescriber Data is not governed by HIPAA because any potentially identifiable and protected patient information has been de-identified prior to its communication to the Respondent data miners.

Because Prescriber Data is not confidential under any theory advanced by Petitioner or supported by law, the only issue for the Court to decide is whether Section 17 is a permissible restriction on protected speech. The essence of the speech, and the debate surrounding it, is as follows: On one hand, pharmacies and data miners are both economically-inspired entities that desire to publicize truthful, non-misleading, and publicly-available information about a lawful activity that is practiced under learned professional licenses. On the other hand, the State of Vermont believes that the public is better served by partially suppressing – indeed, censoring – the information because the public might fail to interpret or apply it to the same ends that Vermont wants to achieve – i.e., to discourage over-prescribing of branded medications in favor of dispensing less-costly generic alternatives.

The Court has already decided that such paternalistic approaches to repressing dissemination of accurate information about drugs require particular vigilance. *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 375 (2002). Reviewing Section 17 with particular vigilance will reveal that the law's reach is too long for the perceived harm it seeks to avoid. Section 17 infringes upon the First Amendment rights of pharmacies, entities that support pharmacy practice, and Respondents.

ARGUMENT

Pharmacies, like physicians, are health care providers with ongoing relationships and obligations to patients. Patient safety and confidentiality are of primary concern for every pharmacy. Pharmacies play a critical role in improving the public health while reducing costs. Pharmacists regularly interact with patients by dispensing medications, educating patients about the use and side effects of medications, identifying potentially dangerous drug interactions, and responding to all types of patient questions. Pharmacies, like physicians, are required to safeguard private patient information. Neither pharmacies nor physicians, however, have any obligation to safeguard Prescriber Data simply because Vermont disagrees with the message that pharmaceutical companies communicate by and through use of the data.

To suggest that pharmacies take their responsibility to protect private patient information less seriously than other members of the health care community is simply untrue. Nonetheless, in an attempt to justify the imposition of its unlawful restraint on communication, Vermont now maintains that the purpose of Section 17 is to protect prescription confidentiality. Brief for Petitioners, at 23, 27, 45-46, *Sorrell v. IMS Health*, *et al.*, No. 10-779 (filed Feb. 11, 2011) (referred to herein as "Petitioner's Brief"). Contrary to the suggestions of the State of Vermont and numerous *Amici*, this case is not about protecting the medical privacy rights of patients but is instead about whether Section 17 infringes on the right to communicate Prescriber Data.

I. PRESCRIBER DATA IS PUBLICLY AVAILABLE DATA, AND DOES NOT HAVE ANYTHING TO DO WITH PATIENT PRIVACY

Petitioner has framed its appeal on the flawed foundation that *but for* federal and state regulation of pharmacy practice, prescription drug records would not exist; therefore, urges Petitioner, the records are nonpublic and the state may regulate their disclosure without running afoul of the First Amendment. *See generally* Petitioner's Brief at 22-23.

Moreover, Petitioner wrongly asserts that Prescriber Data is tantamount to individually identifiable patient data protected by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA")

and corresponding state laws. *See generally* Petitioner's Brief at 5-6. Neither assertion is true. As detailed below, Prescriber Data is public data that is readily available in the healthcare marketplace; it is *not* protected individually identifiable patient information ("Patient Data"). Therefore, Petitioner's argument lacks merit.

A. Prescriber Data Is Publicly Available

Pharmacies in the United States have always collected Prescriber Data, and have historically sold it to drug manufacturers, insurers, data miners, and other participants in the health care marketplace. Endeavoring to characterize Section 17 as a mere restriction on access to nonpublic information instead of a restriction on speech, it asserts the unsustainable argument that *but for* Vermont's regulation of pharmacy practice, pharmacies would not collect or maintain Prescriber Data, thereby making the information nonpublic. This argument tries, but fails, to align Section 17 with the restriction approved of in the Los Angeles Police Department case. *Los Angeles Police Dep't v. United Reporting Publ'g Corp.*, 528 U.S. 32 (1999) (upholding government restrictions on uses of nonpublic information in the government's possession).

In that opinion, the Court held that California's law restricting a publisher's access to police records withstood First Amendment scrutiny because it shielded public eyes from nonpublic documents in the

government's possession. Id. at 40. As the Second Circuit's majority opinion in this case correctly observed, Prescriber Data "is not in the government's possession" but is instead "in the hands of pharmacies." *IMS Health Inc. v. Sorrell*, 09-1913-cv (2d Cir. 11-23-2010) at 22-23. Thus, "[t]his is a case about the extent of the permissible government regulation of information in the hands of private actors." Id.

1. Pharmacies Have Always Collected And Communicated Prescriber Data

Pharmacy practice and drug dispensing have existed in this country since its independence. *See* Charles LaWall, Ph.M., Phar.D., Sc.D., F.R.S.A., Four Thousand Years of Pharmacy, an Outline History of Pharmacy and the Allied Sciences, at 448 *et seq.*, (J.B. Lippincott Company (1927)). Rhode Island, in 1870, was the first State in the Union to enact a Pharmacy Practice Act. *See* 1870 R.I. Acts & Resolves 120; *codified at* 1872 R.I. Pub. Laws 321; Glenn Sonnedecker, Kremer's and Urdang's History of Pharmacy 217 (American Institute of the History of Pharmacy 1986) (Describing the creation of the American Pharmaceutical Association's model pharmacy act and Rhode Island being the first state to pass such an act in 1870).

Vermont did not enact its Pharmacy Practice Act until 1894, over one hundred (100) years after it

became a State in 1791.[2] *See* Pub. Act 99 of the 13th Biennial Session of the Vermont General Assembly (November 24, 1894). Vermont's original enactment was under three (3) pages and related to the establishment of the Vermont State Board of Pharmacy and basic licensure requirements for pharmacists. It did not purport to require pharmacies or pharmacists to collect or retain Prescriber Data. 1894 Vt. Acts & Resolves No. 87-89. Nevertheless, pharmacies did collect such data because it was essential to providing quality and safe pharmacy care. *See* LaWall, at 491-93.

In the middle of the last century, state legislatures enacted significant changes to their states' Pharmacy Practice Acts. *See* Jeremy A. Greene, MD, Ph.D., *Pharmaceutical Marketing Research and the Prescribing Physician* (The Annals of Internal Medicine 2007), at 146:742-48. These legislative changes introduced – for the first time – regulatory oversight of Prescriber Data. Id. Pertinent to this case, it was not until 1968 that Vermont first enacted a law establishing what data points must be on a prescription for it to be valid. Vt. Stat. Ann. tit. 18, §4201(26) (July 1, 1968). Thirteen years later, in 1981, Vermont's Legislature enacted its first law requiring pharmacies to maintain specific records, including

[2] To this point, pharmacy historian Charles LaWall observes "[a]n entire absence of legislative enactments" in the early history of the United States. He attributes this to "the freedom of our institutions, which places no restraint whatever upon private enterprise. . . ." *See* LaWall, at 448.

records with Prescriber Data. Vt. Stat. Ann. tit. 18, §4229 (1981).

These laws, however, did not significantly change pharmacy practice. Pharmacies have always collected and maintained Prescriber Data as part of good clinical practice.[3] *See* LaWall, at 491-93. A pharmacist cannot dispense a medication to a patient unless he or she knows (1) what drug to dispense, (2) in what amount, (3) the appropriate conditions to dispensing, and (4) whether there are any pharmacological or other health risks raised by the medication prescribed. Petitioner would have the Court believe that pharmacists are little more than people in lab coats who count pills, place them in bottles, and deliver the bottles to patients.

That understanding of pharmacy practice is incorrect. Pharmacists are highly trained and licensed health care professionals skilled in both the chemical composition of the drugs they dispense, as well as the health risks and benefits of those drugs to the patients they serve. *See* Code of Ethics of the American Pharmacists Association (October 27, 1994), *available*

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[3] *See* William Proctor, Jr. (ed.), *Editorial*, 40 Am. J. Pharmacy 473 (1868) ("The apothecary being responsible for want of skill in his art, as well as the physician, should exercise equal caution in compounding as the latter is required to do in prescribing. *Hence, it is . . . his duty . . . to keep a copy of every prescription*, with date and names of physician and patient.") (emphasis added); *see also* Charles Casparri, A Treatise on Pharmacy for Students and Pharmacists, 535-36 (5th ed. 1916) (instructing students and pharmacists to collect and retain all original prescriptions).

at http://www.pharmacist.com/AM/Template.cfm?Section=Search1&template=/CM/HTMLDisplay.cfm&ContentID=2903. Under current pharmacy practice, to qualify for licensure an applicant must possess a Doctor of Pharmacy degree from an accredited program and undergo lengthy residencies and rotations. The reality that pharmacists are highly skilled health professionals is reflected by: (1) the mandatory counseling requirements contained in every state's Pharmacy Practice Act and (2) the fact that many states allow pharmacists to prescribe medications to their patients.[4] If a pharmacist is nothing more than a person who counts pills on instructions from a prescriber, then why would every state require pharmacists to counsel patients on the risks, side effects, and proper usage of the drugs prescribed, and many states enable pharmacists to prescribe those drugs?

In addition to collecting Prescriber Data at individual pharmacies, pharmacists have historically communicated Prescriber Data to third parties, including Respondent data miners. *See* Greene at 743-44. Notably, IMS Health Inc. began purchasing, aggregating and licensing data to participants in the health care continuum – including pharmacies – in 1954. Id. Thus, the market for collecting and disseminating Prescriber Data emerged *prior to* Vermont's regulation

[4] *E.g.,* 04-030-230 Vt. Code. R. §9.30 (2011) (regulation governing counseling); Ariz. Rev. Stat. §32-1970 (2011) (statute governing collaborative practice); Ariz. Rev. Stat. §32-1974 (2011) (vaccines); Ariz. Admin. Code §§4-23-421 to 4-23-429 (2011) (regulations governing collaborative practice).

of Prescriber Data. This market emerged to enable manufacturers to make disciplined decisions about marketing their products, and to enable other health care providers – including pharmacies – to leverage other benefits inherent in the aggregated Prescriber Data. Those benefits include, *inter alia*, lowering a pharmacy's cost to dispense, improving patient outcomes, and providing insight into competitors' business information. [*See* J.A. at 249 (Testimony of Scott Tierney)].

Finally, because of the long held interest of pharmacies in patient safety, better care delivery, transparency, pricing, and the free flow of information, pharmacies would continue to collect and sell Prescriber Data even if Vermont did not regulate it. [*See* Wolfe Declaration at ¶ 9: "But for the existence of this law, Rite Aid would, after January 1, 2008, continue to provide to IMS Health and other similar companies data in prescription records that identifies Vermont prescribers without prohibiting IMS Health from using the data for marketing or promotion of prescription drugs or from making the information available to others who intend to use the information for those purposes."]. This is evident from the plain language of Section 17 itself, which specifically permits pharmacies to sell Prescriber Data to any willing purchaser, so long as it is not used for pharmaceutical marketing purposes. While Vermont disagrees with pharmacies that use of Prescriber Data for pharmaceutical marketing purposes benefits pharmacy care, pharmacies and Vermont both accept that such data serves other valuable purposes in furtherance of the delivery of quality health care.

2. Private Actors And Companies Retain Constitutional Rights, Even If They Possess A Professional License

Just because one submits to a state's jurisdiction by obtaining a license to practice a profession (in this case, Pharmacy), one does not forfeit his or her constitutional rights. *See Edenfield v. Fane*, 507 U.S. 761 (1993). American industry is regulated by government licenses, and millions of people and entities receive professional and occupational licenses every year. Licensing enables state and federal governments to: (1) establish minimum standards of professional conduct, (2) monitor compliance with those standards, and (3) discipline for breaches thereof. A survey of the types of people who stake their professional livelihood on government licenses ("Licensees") demonstrates that a license does no more than grant permission to undertake a regulated type of work.

Licensees range from pharmacists, doctors, dentists, builders, real estate brokers, massage therapists, nail technicians, cab drivers, architects, school teachers, long haul truckers and more. None of these individuals can be said to have forfeited a constitutional right to speak, or to receive speech, in exchange for the authority to earn a living. Similarly, pharmacies hold licenses to enable business organizations to provide pharmaceutical care under pharmacist supervision. These entities are private and are typically owned by individuals or shareholders, and are not government employees or contractors. *Cf. Los Angeles Police Dep't*, 528 U.S. 32 (1999). Therefore,

both individual and business Licensees are entitled to protection under the First Amendment.

To illustrate: long haul truck drivers and trucking companies must hold permits to engage in commerce in Vermont. Vt. Stat. Ann. tit. 23, §§4101 *et seq.*; 49 U.S.C. §§31301 *et seq.* Data about these drivers' routes and fuel usage is routinely sold to data miners who, in turn, sell the data to fuel brokers, state and federal governments, vehicle manufacturers, and other entities in the stream of commerce. Some purchasers of this data, fuel brokers or suppliers for instance, could use this data to develop marketing strategies to persuade the trucking companies to purchase their products, even though less expensive products exist in the marketplace. As fuel prices surge, the government may have a substantial interest in enacting laws that directly advance the purchase of low cost diesel in an effort to reduce rising fuel costs and their impact on the cost of other consumer products. The government, however, could not restrict a private supplier's ability to market its fuel but could potentially enact laws that required truck drivers (Licensees) to purchase the lowest cost fuel. The first law fails because it is an impermissible infringement on a private Licensee's right to speak and to hear; the second law, however, succeeds because it does not purport to manage speech at all.

In the context of this case, there is no principled difference between fuel suppliers and pharmaceutical manufacturers, trucking companies and pharmacies, or truck drivers and pharmacists. All are Licensees,

and all are selling and utilizing publicly-available regulated data in furtherance of regulated self-interest.

3. No State Has Ever Enforced Its Laws Against Pharmacies For Selling Or Disclosing Prescriber Data

Finally, Vermont's argument that Prescriber Data is nonpublic must fail when this Court considers the enforcement decisions of all state boards of pharmacy, as well as the decisions of the state and federal courts interpreting pharmacy laws. Specifically, no state or territorial adjudicating body has ***ever*** enforced a pharmacy law or regulation against a pharmacy or pharmacist for disclosing Prescriber Data.

B. Prescriber Data Does Not Compromise Patient Privacy

Petitioner contends that Section 17 is a lawful restraint on commercial speech because the law directly advances Vermont's substantial interest in "medical privacy." As the Court of Appeals correctly observed, Vermont's interest in "medical privacy" consists of two distinct interests: (1) its interest in the integrity of the prescribing process and (2) its interest in preserving patients' trust in their prescribers. *IMS Health, Inc. v. Sorrell*, 09-1913-cv, at 31. Recognizing that the record contains no proof to support the legitimacy of either interest, Petitioner wrongly steers the debate to one of patient privacy. Id. at 32; Petitioner's

Brief at 27-33. As explained *infra*, the restriction on communicating Prescriber Data in Section 17 has no connection to individually-identifiable Patient Data.

Petitioner takes two dead-end paths to convince otherwise. Petitioner's Brief at 6, 46-49. First, Petitioner suggests that Section 17 regulates patient privacy because pharmacy records are subject to government regulation, including certain confidentiality requirements. This path leads nowhere because Section 17 does not facially endeavor to regulate patient privacy.

Second, Petitioner wrongly contends that Section 17 intends to "supplement" HIPAA. *See generally* Petitioner's Brief at 5-6 (stating "Vermont's regulation of prescription records supplements the federal regulation of prescription and other health care records."). Despite its efforts, Petitioner cannot persuasively recast Section 17 as a supplement to HIPAA because the law's regulation of Prescriber Data is unrelated to HIPAA's protection of Patient Data.

Petitioner's attempts to re-categorize Section 17 as a patient privacy law ignore the single most important fact related to patient privacy: Patient Data is no better protected under Section 17 than it was without it.

1. On Its Face, Section 17 Does Not Protect Patient Privacy

Petitioner's characterization of Section 17 as a patient privacy law is unconvincing given that the law – on its face – is unrelated to the privacy of patient information. First, the plain language of the statute shows that the law does not protect patient information. The legislature's purpose in enacting the statute was, *inter alia*, "protecting the privacy of *prescribers and prescribing information*." Vt. Stat. Ann. tit. 18, §4631 (emphasis added). Moreover, the state's medical lobby pushed for this legislation – not patient advocacy groups or patients.

2. Prescriber Data May Be Sold To Any Purchaser For Any Use Other Than Pharmaceutical Marketing

Section 17 only restricts particular uses of Prescriber Data and does not touch upon uses of Patient Data. Specifically, Section 17 prohibits certain entities from selling, licensing, exchanging for value, or using Prescriber Data for purposes of *marketing or promoting a prescription drug* unless the prescriber consents. Id. at §4631(d). Section 17 permits any other sale, license, exchange, or use of Prescriber Data. This means that a pharmacy *could* distribute Prescriber Data to anyone it pleases – data miners included – without violating the law, so long as it does not do so for the purpose of marketing or promoting a specific drug.

This fact is inconsistent with the notion that Section 17 was motivated by a desire to protect the privacy of the information in general, and patient privacy in particular. Petitioner counters this inherent inconsistency in Section 17 by arguing that non-marketing uses have not been identified as a problem in Vermont. But Petitioner's argument fails to address the fact that the clear intent of the legislature was to draft a law that specifically addressed prescription drug cost containment, *not* patient privacy. The chapter in which the law is codified – Chapter 91: Prescription Drug Cost Containment – proves this point. If privacy was the impetus for this law, the legislature would have adopted it as part of Vermont's patient privacy laws.

3. Prescribers May Consent To Disclosure Of Prescriber Data But Cannot Consent To Disclosure Of Patient Data; Therefore, Prescriber Data Cannot Be Patient Data

The fact that Section 17 is unrelated to patient privacy is further shown by *who* can consent to the disclosure of information under the statute. Petitioner admits that, under the law "*doctors themselves*, not the government, control the commercial use of their prescribing data." Petition for Writ of Certiorari at 20, *Sorrell v. IMS Health*, *et al*., No. 10-779 (filed Dec. 13, 2010) (emphasis added). In contrast, prescribers are forbidden from disclosing Patient Data, except as necessary for treatment purposes or as otherwise

permitted by law. *See* Vt. Stat. Ann. tit. 18, §1852(7) (patients' bill of rights); Vt. Stat. Ann. tit. 12, §1612 (statutory doctor/patient privilege); 42 U.S.C. §§1320d *et seq*. If – as Petitioner suggests – there is no distinction between Prescriber Data, on the one hand, and Patient Data, on the other, then why will the law allow the disclosure of the former and prohibit disclosure of the latter?[5]

Accordingly, if patient privacy was really a motivating factor behind the legislation, Section 17 should allow *patients* to consent to the disclosure of Prescriber Data, and not their doctors. By Petitioner's own admission, the law aims to curb the commercial use of Prescriber Data, not to protect patient privacy.

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[5] This question's rhetoric is resolved by the fact that the doctor/patient privilege belongs to the patient. *See Mattison v. Poulen*, 134 Vt. 158, 353 A.2d 327 (1976) (holding that plaintiff waived patient privilege by bringing personal injury claim and noting that only the patient, not the doctor, may waive the privilege); *State v. Raymond*, 139 Vt. 464, 431 A.2d 453 (1981) (reversing defendant's conviction for drunk driving where trial court improperly admitted privileged information because only the patient may waive the privilege); *State v. Welch*, 160 Vt. 70 (1992) (Supreme Court of Vermont rejected "defendant's claim that her privacy interest in the pharmacy records is predicated upon doctor-patient confidentiality. . . . The reason may be that the communications involved in pharmacy records are between a prescriber and a pharmacist, not between a prescriber and patient.").

C. HIPAA Does Not Govern Or Protect Prescriber Data

HIPAA has no relation to Prescriber Data and does not govern its use or disclosure. The purpose of the HIPAA Privacy Rule is to protect the use and disclosure of "individually identifiable health information" also known as "protected health information", and referred to herein as Patient Data.[6] *See* 45 C.F.R. §160.103.

1. Section 17 Is Not A More Stringent Privacy Regulation Than HIPAA

Given that Section 17 is entirely unrelated to patient privacy, as described above, the notion that it offers privacy protections that are more stringent than HIPAA is plainly false. Moreover, the reliance on HIPAA preemption doctrine in this case is inappropriate. HIPAA preemption applies when a HIPAA requirement is contrary to a provision of state law, unless an exception applies. One such exception states that HIPAA will not preempt a state law that relates to the privacy of individually identifiable health information and is more stringent than HIPAA. 45 C.F.R. §160.203. For HIPAA to be contrary to state law, it must either be impossible to comply with both

[6] HIPAA governs both the privacy and portability of patient data. Because this argument only deals with the privacy aspects of HIPAA, any reference to HIPAA in this Brief is intended to refer only to the Privacy Rule approved by the Department of Health and Human Services ("DHHS").

laws, or the state law must be an obstacle to the purposes of HIPAA. Id. at §160.202. HIPAA is not contrary to state laws, like Section 17, that are entirely unrelated to patient privacy. Further, Section 17 does not relate to the privacy of "individually identifiable health information" nor is it more stringent than HIPAA, precisely because it is not a privacy law. It is strictly a regulation on the marketing use of Prescriber Data. Prescriber Data poses no threat to patient privacy. As a result, Petitioner's attempt to reclassify Section 17 as a patient privacy safeguard is meritless.

2. HIPAA Permits Disclosure of De-Identified Patient Data

Information that is not individually-identifiable is explicitly excluded from HIPAA's protections. 45 C.F.R. §164.514(a). Anyone may freely use or disclose such "de-identified information" without violating HIPAA. 45 C.F.R. §164.502(d). Applying HIPAA to only individually-identifiable health information establishes that information that does not identify a *patient* poses no threat to the confidentiality of patient information. As a result, sufficiently de-identified health information may be used and disclosed without compromising patient privacy.

Under HIPAA, health information that "does not identify an individual [patient] and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual [patient]" is not individually-identifiable information. 45 C.F.R. §164.514(a) (parentheses added).

HIPAA's Privacy Rule provides two (2) methods for covered entities such as pharmacies to "de-identify" health information. The first method involves a determination by a qualified statistician that the risk that the individual can be identified is very small. *See* 45 C.F.R. §164.514(b)(1). The second method is a regulatory safe harbor for pharmacies and other covered entities that provides a recipe for how to de-identify Patient Data. 45 C.F.R. §164.514(b)(2).

Under the safe harbor's recipe, health information is sufficiently de-identified if the covered entity (1) removes eighteen (18) enumerated identifiers and (2) lacks actual knowledge that the information remains identifiable. Id. The identifiers listed under the safe harbor include identifiers such as the patient's name, certain geographical information, social security number, phone number, and prescription number, but specifically do *not* include any

information relating to the prescriber or the drug prescribed.[7] 45 C.F.R. §164.514(b)(2)(i).

Even when information is properly de-identified, there will always be a risk that it can be re-identified. DHHS accepts this risk. In the preamble to HIPAA's Privacy Rule, DHHS recognizes that there is "always some probability or risk that any information about an individual can be attributed to that individual." Standards for Privacy of Individually Identifiable Health Information; Final Rule, 65 Fed. Reg. 82,461, 82,542 (Dec. 28, 2000). This is why HIPAA does not require a covered entity to eliminate all risks of

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[7] The following is a summary of the identifiers that, pursuant to 45 C.F.R. §164.514(b)(2)(i)(A)-(R), must be removed from health records subject to HIPAA:

1. Name
2. Geographic subdivisions smaller than a State (except for the initial three digits of a zip code)
3. All elements of a date (except year)
4. Telephone numbers
5. Fax numbers
6. Email addresses
7. Social Security Numbers
8. Medical Record/ Rx Numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/ license numbers
12. VIN numbers/ Serial numbers
13. Device identifiers and serial numbers
14. Web URLs
15. IP address numbers
16. Biometric identifiers
17. Full face photographic images and any comparable images
18. Other unique IDs, characteristics, and/or codes

re-identification. Such a requirement would effectively prohibit the disclosure of any de-identified information. Instead, the law tolerates a small level of risk of re-identification in order to further other important interests. In the preamble of the Privacy Rule, DHHS states, "[t]he intent of the safe harbor is to provide a means to produce some de-identified information that could be used for many purposes with a very small risk of privacy violation." 65 Fed. Reg. at 82,543.

3. DHHS Acknowledges That It Is Better Policy To Disclose De-Identified Patient Data Than To Shield It From Disclosure, Even Where Disclosure Is For Commercial Gain, Such As Detailing

DHHS carefully considered the policy factors involved in creating the standards for de-identification of protected health information. In its initial Notice of Proposed Rulemaking for the HIPAA Privacy Rule, DHHS expressly recognized that there are important uses of de-identified information. According to DHHS:

> Large data sets of de-identified information can be used for innumerable purposes that are vital to improving the efficiency and effectiveness of health care delivery, such as epidemiological studies, comparisons of cost, quality or specific outcomes across providers or payers, studies of incidence or prevalence of disease across populations, areas or time, and ***studies of access to care or differing***

> ***use patterns across populations, area or time***.

Standards for Privacy of Individually Identifiable Health Information; Proposed Rule, 64 Fed. Reg. 59,917, 59,946 (Nov. 3, 1999) (emphasis added). DHHS has not since shied away from this statement.

DHHS also specifically endorsed the use of de-identified information for "commercial purposes (e.g., to identify areas for marketing new health care services)." 64 Fed. Reg. at 59,947. In fact, the agency expressly embraced the marketing use of de-identified information prohibited by Section 17, stating "[f]or example, providing de-identified information to a pharmaceutical manufacturer to use in determining patterns of use of a particular pharmaceutical by a general geographic location would be appropriate, even if the information were sold to the manufacturer." Id.

These appropriate and valuable uses and disclosures of health information depend upon HIPAA's de-identification standards. This is why the Privacy Rule "balance[s] the need to protect individuals' identities with the need to allow de-identified databases to be useful." Standards for Privacy of Individually Identifiable Health Information; Final Rule, 67 Fed. Reg. 53,181, 53,232 (Aug. 14, 2002). This balance comes from permitting entities to freely use and

disclose information that meets the de-identification standards.[8]

4. To Further The Benefits Served By Disclosing De-Identified Patient Data, The Standards Must Be Easy To Understand And Apply

The standards for de-identifying information must be easy to understand and comply with in order for covered entities, such as pharmacies, to disclose de-identified information to data users, such as pharmaceutical manufacturers (by and through data miners), in furtherance of DHHS-sanctioned purposes such as pharmaceutical marketing. Indeed, DHHS specifically states that the de-identification standards must be flexible enough that they are not "a disincentive for covered entities to use or disclose de-identified information ***wherever possible***." 67 Fed. Reg. at 53,232 (emphasis added).

If it is unclear when information is sufficiently de-identified, covered entities will be reluctant to exchange such information. This would undermine the entire purpose of excluding de-identified information from the Privacy Rule's protections. In fact,

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[8] The Food and Drug Administration ("FDA") is part of DHHS and regulates pharmaceutical marketing activities. As an interested agency, FDA presumably had sufficient opportunity to re-calibrate the de-identification balance if it believed that detailers' use of de-identified data for marketing would impair HIPAA's policy objectives.

this was the very reason why DHHS drafted the safe harbor "to involve a minimum of burden and convey a maximum of certainty that the rules have been met . . . produc[ing] an easily followed, cookbook approach" to rendering health information de-identified. 65 Fed. Reg. at 82,543.

5. The Prescriber Data Muzzled By Section 17 Is Fully De-Identified Consistent With HIPAA

The Prescriber Data that is regulated by Section 17 does not contain any of the eighteen (18) patient identifiers listed in the de-identification safe harbor. Scott Tierney, Director of Managed Care Operations at CVS Caremark Corporation ("CVS"), testified that CVS complies with HIPAA's de-identification standards for all data it sells to Respondent data miners. [J.A. at 248-49]. CVS is the country's largest pharmacy provider. During the bench trial of this dispute, Mr. Tierney testified that CVS further de-identifies data for patients of unique ages in small geographic areas to protect the patients' privacy rights. [*See* id. at 248]. Finally, Mr. Tierney confirmed that, prior to sale, all data is vigorously reviewed by CVS's privacy office. [*See* id. at 249].

Although there is always some level of risk that de-identified information can be re-identified, the Privacy Rule requires that there be actual knowledge that the information remains identifiable in order to step outside the safe harbor's protections. 45 C.F.R.

§164.514(b)(2)(ii). There is no such actual knowledge that the Prescriber Data regulated by Section 17 identifies patients. In fact, Petitioner does not allege that Respondents have ever identified any specific patient from the aggregated Prescriber Data that Respondents purchase and sell. As a result, the Prescriber Data regulated by Section 17 meets the de-identification safe harbor, and may be freely used and disclosed without affecting patient privacy.

6. Vermont's Section 17 And Similar Laws Seriously Impair Pharmacy And Other Health Care Enterprise Access To Speech That Is Essential To Improving The Delivery Of Health Care

If accepted, Petitioner's claim that Section 17 supplements HIPAA would hamstring the health care community in general, and the pharmacy community in particular. This claim would require this Court to decide that, despite complying with HIPAA's de-identification standards, Prescriber Data is nevertheless still Patient Data. Such a holding – explicit or implicit – would significantly undermine the clarity that DHHS recognized as fundamental to the necessary use of de-identified health information. 67 Fed. Reg. at 53,232.

The exchange of Prescriber Data is essential to many important aspects of pharmacy practice and quality health care. In day-to-day practice, pharmacies not only sell Prescriber Data to data miners, but

they rely on the purchased data to track utilization trends and anticipate the prescription needs of their patients. As described by Scott Tierney from CVS, pharmacies "benefit from the data in terms of leveraging or using the data to improve [ ] quality of care and [ ] costs to dispense. We feel it provides a better product, gives us insight into competitor information, . . . [and] market share information." [*See* J.A. at 249 (Tierney Testimony)].

And, health care providers, researchers, public health entities, insurers, state and local governments, and others regularly deploy analysis of de-identified data to improve the quality and efficiency of health care. *See IMS Health Inc. v. Sorrell*, 09-1913-cv (2d Cir. 11-23-2010), at 9. Likewise, commercial uses of Prescriber Data are valid methods of identifying inefficiencies in the health care marketplace and improving the safety of products for health care consumers. Without clear standards for what constitutes de-identified information, these uses will be muted.

This Court need not decide whether the Prescriber Data regulated by Section 17 contains patient identifiable information. By adopting the de-identification standards in the HIPAA Privacy Rule, DHHS has already decided it does not. The de-identification standards were adopted after DHHS carefully considered hundreds of comments on the Privacy Rule and independently evaluated the policy underlying the use and disclosure of de-identified information. If the Court determines that Prescriber Data, which has been de-identified according to HIPAA standards, is

actually identifiable patient information, then it would swing the door wide-open for other attacks on essential uses and disclosures of de-identified information in the health care community.

The effects of such a determination are predictable: it would cripple current and future research, public health, quality improvement and other critical health care activities that depend on the use of de-identified information and Prescriber Data.[9] If the Court finds that Prescriber Data is identifiable patient information, health care providers and others will be frightened away from relying upon the de-identification safe harbor method in the Privacy Rule. That result is clearly not the intent of DHHS. In fact, DHHS stated, it "believe[d] that these mechanisms for de-identification are sufficiently well-defined to protect covered entities that follow them from undue liability." 65 Fed. Reg. at 82,709. For these reasons, the Court should embrace the intentions of DHHS and reject any notion that information that has been

[9] The value of this data was so obvious to the charter members of the American Pharmaceutical Association ("APhA") that they imposed a duty upon their membership to share data in APhA's original Code of Ethics: "We hold that every apothecary and druggist is bound to contribute his mite towards [advancing pharmacy practice], by noting the new ideas and phenomena which may occur in the course of his business, ***and publishing them***, when of sufficient consequence, ***for the benefit of the profession***." *See* LaWall at 501 (parenthetical and emphasis added).

de-identified according to HIPAA standards is nevertheless identifiable patient information.

II. Section 17 Unlawfully Restricts Free Speech By Prohibiting Pharmacies From Communicating Accurate, Truthful, Useful, And Non-Confidential Information Used For Marketing

As explained at length, *supra*, this case has nothing to do with the use, release or disclosure of private patient information. Instead, this is a First Amendment case that examines a state's ability to restrict communications by pharmacies about the prescribing practices of prescribers – communications that pharmacies believe improve the level of care provided in the health care continuum. [*See* J.A. at 250 (Tierney Testimony), confirming that the country's largest pharmacy provider only sells data to data miners because it recognizes that use of the data results in improved health outcomes and lower costs for patients].

Specifically, Section 17 restricts the communication of truthful, accurate, non-confidential information by pharmacies that lawfully possess and maintain that information, *if* (*but only if*) the information will be used to directly market drugs to physicians.

1. Prescribers Have No Right To Privacy, And Data Mining Does Not Disturb The Confidences Of The Doctor/Patient Relationship Or The Pharmacy/Patient Relationship

Pharmacies are required by law to collect and maintain prescriber information, including: (1) the name and address of the prescriber and (2) the name, dosage, and quantity of the drug prescribed. None of this information is confidential. None of the information identifies by name, address, or otherwise the patient for whom a prescription is written. *Cf.*, footnote 7, *supra*. The privileged relationship between physician and patient remains secure.

Similarly, the relationship of professional trust between the pharmacy and the patient remains undisturbed. Prescriber Data focuses solely on the prescriber and the prescription patterns associated with the prescriber, not on the patient. There is no confidentiality protection associated with prescriber information in federal law. And, there is no reason for Vermont to assign special protections to Prescriber Data. In fact, offering such special protection to information concerning health care providers is antithetical to the position the federal government has taken with respect to hospitals and nursing homes, where greater transparency has not only been encouraged but mandated for Medicare and Medicaid certified institutions.

For example, the federal government directly operates a website known as "Hospital Compare"[10] for the purpose of allowing comparisons of specific hospitals within a geographic area, or within a state, or nationally on certain quality and payment measures. The government-operated website proclaims that soon it will include information on "hospital acquired conditions" (medical conditions such as bed sores and falls acquired by patients while they are receiving treatment at the hospital) and, in October 2011, it will publish information on "serious complications and death."

As in this case, the information published by the government derives from a specific patient served by a specific hospital. Yet, there is no argument that providing information about the numbers and types of hospital acquired conditions, deaths or complications in a specific hospital on a publicly-available website violates patient confidentiality nor any privacy right of the hospital. The same is true here. Prescribers have no explicit nor inherent privacy right with respect to the prescriptions they write. Simply stated, the communication of such information by a

[10] The Hospital Compare website is found at www.hospitalcompare.hhs.gov. A comparable website for nursing homes is found at www.medicare.gov/NHCompare. As with the hospital compare site, the nursing home compare site provides "detailed information" about Medicare and Medicaid certified nursing homes. The data published by the government includes staffing information, health inspection information and rankings on quality measures.

pharmacy does not violate patient confidentiality. And, it does not violate any recognized right of privacy of the prescriber.

2. Pharmacies Are Willing Speakers Of Commercial Speech

Prescriber Data has economic value in the commercial marketplace because data mining companies are willing to purchase Prescriber Data from pharmacies. By providing Prescriber Data the pharmacies communicate information. Not only does the First Amendment protect the communication of information, this Court has described the right to receive such information as "fundamental to our free society." *Stanley v. Georgia*, 394 U.S. 557, 564 (1969). In a later decision involving the advertisement of prescription drug prices, this Court noted, "Freedom of speech pre-supposes a willing speaker. But, where a speaker exists, . . . the protection afforded is to the communication, to its source and to its recipients, both. This is clear from the decided cases." *Va. State Bd. of Pharmacy v. Va. Consumer Council*, 425 U.S. 748, 756 (1976).

Here, as in the bedrock *Virginia Board of Pharmacy* case, the pharmacy is a willing speaker and the data mining firms are willing recipients of the information, as are downstream purchasers who license and use the aggregated data. The fact that the communication from the pharmacy is for profit does not diminish the protection afforded by the First

Amendment. It is well-settled that commercial speech is entitled to First Amendment protection. *See Va. State Bd. of Pharmacy*, 425 U.S. 748, 761 ("Speech is protected even though it is carried in a form that is 'sold' for profit"); *Thompson v. Western States Med. Ctr.,* 535 U.S. 357, 366 (2002), and *Central Hudson Gas & Electric Corporation v. Public Service Commission of N.Y.*, 447 U.S. 557, 561 (1980) ("The First Amendment . . . protects commercial speech from unwarranted governmental regulation.").

Vermont now maintains that Section 17 regulates conduct and not speech. This is inconsistent with the statements made by the Vermont Legislature at the time the law was enacted. Then, the State maintained that the purpose of the Act was to correct the imbalance in information presented to the physician in an effort to curb healthcare costs. *See* 2007 Vt. Acts & Resolves No. 80, §1(6). Indeed, during debate about the doubtful constitutionality of the law, a legislator exclaimed: "I almost feel that this is flaunting free speech." [*See* PX 11-Tab Q, CD 7-164-67 at 18; *see also* Appendix at 404]. Clearly, this law is directed at limiting certain types of speech (communications from drug detailers to physicians). The only thing Section 17 restricts is the sharing of accurate, truthful information by pharmacies (and others enumerated in the law), *if* (*but only if*) that information may subsequently be used for marketing purposes. The law does not preclude the collection, retention, or non-marketing-purposed distribution of the information in the first instance. Accordingly,

pharmacies will continue to collect, maintain, and sell Prescriber Data.

3. Section 17 Paternalistically Restricts Independent Prescriber Judgment

The law impedes the use of Prescriber Data for marketing purposes only. It does not restrict other uses of the data. Thus, pharmacies will continue to communicate Prescriber Data for research, payment, and safety-related purposes. This Court has long held that a government restraint on the communication of information is suspect. *See Va. State Bd. of Pharmacy,* 425 U.S. at 770 (1975); *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 373 (2002); and *Central Hudson Gas & Electric Corporation v. Public Service Commission of N.Y.*, 447 U.S. 557, 561 (1980). In *Thompson v. Western States Med. Ctr.*, this Court noted that restrictions on truthful, non-misleading commercial speech have often been grounded on the assumption by government that keeping information from people is for their own good. The Court cautioned that the First Amendment requires particular vigilance in those situations. *Thompson,* 535 U.S. at 375 (2002).

Vermont's law directly censors the communication of Prescriber Data information when – and only when – the ultimate use of the information is for marketing. The danger posed by this governmental limit on the sharing of truthful information is obvious. In effect, the government has decided that it must protect highly educated physicians from drug

representatives armed with honest information about the physicians' prescribing patterns.[11]

Thus, Vermont effectively regulates the conduct of physicians with respect to the drugs they prescribe by restricting the speech of pharmacies. Imposing a restriction like this reflects the exquisitely-paternalistic belief that if truthful information about a physician's own prescribing practices is available to drug manufacturers who use that information in discussions with the physician it will somehow exert too great an influence on the physician's decision-making. This mindset assumes that a physician will not use independent medical judgment when determining a proper course of care for an individual patient. It is unwarranted and unfair to all parties.

4. Section 17 Serves No Substantial Government Interest And Is Too Restrictive

Finally, if doctors already know their own prescribing histories as the *Amici* States suggest [*See Amici* Brief for the States of Illinois, Alabama, Arizona, *et al*., at 21], and if one assumes that doctors will make independent, informed treatment decisions

[11] The drug representative possesses the information because data mining companies purchase the information from pharmacies. The data mining companies then aggregate information about prescribing patterns and sell that information to drug manufacturers who provide physician-specific information to drug representatives who call on physicians.

based on the needs of their patients and their own professional training, then the direct restraint imposed by Vermont serves no substantial governmental interest and, at a minimum, is more restrictive than necessary. *Central Hudson,* 447 U.S. 557, 566 (1980).

Ultimately, the physician has control over visits by drug representatives. If the physician does not want to discuss prescribing patterns with drug representatives, the physician can limit the visit, limit the discussion, or simply ignore the information provided. The State should not assume the physician is unable to put the patient's needs first, thereby necessitating a governmental lid on the communication of the information from the pharmacy.[12]

As Justice Blackmun wrote in *Virginia State Board of Pharmacy*, 425 U.S. 748, 770 (1975):

> There is, of course, an alternative to this highly-paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to

[12] Petitioner's argument also presupposes that prescribers always have the last word in deciding which drug gets dispensed. In Vermont, as in the majority of states, a pharmacy may substitute a less costly equivalent drug for a prescribed brand name product, unless the prescriber specifically instructs the pharmacy to dispense the medication as written. 20-4-1400 Vt. Code R. §9.19(d). The effect of this reality in how care is delivered is that Vermont overstates the supposed risk of the detailers' influence on drug product selection.

> that end is to open the channels of communication rather than to close them. . . . It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us.

Pharmacies are critical players in the delivery of quality patient care. They have come forward in the past to advocate that the sharing of truthful information about prescriptions is communication protected by the First Amendment. *See* id.; *and Thompson*, 535 U.S. 357 (2002). Once again, pharmacies are compelled to step forward to urge the Court to apply these and other well-reasoned decisions which protect their right to share commercial information that is accurate and informative.

CONCLUSION

The Court should affirm the Court of Appeals' decision.

Respectfully submitted,

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