09-1913-cv(L)

09-2056-cv(CON)

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

IMS HEALTH INCORPORATED, VERISPAN, LLC, SOURCE HEALTHCARE ANALYTICS, INC., a subsidiary of Wolters Kluwer Health, Inc., and PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Plaintiffs-Appellants,

v.

WILLIAM H. SORRELL, as Attorney General of the State of Vermont, JIM DOUGLAS, in his official Capacity as Governor of the State of Vermont, and ROBERT HOFMANN, in his capacity as Secretary of the Agency of Human Services of the State of Vermont,
Defendants-Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

BRIEF OF AARP, THE NATIONAL LEGISLATIVE ASSOCIATION ON PRESCRIPTION DRUG PRICES, COMMUNITY CATALYST, AND PRESCRIPTION POLICY CHOICES, AS AMICI CURIAE IN SUPPORT OF APPELLEES, URGING AFFIRMATION

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September 15, 2009

CERTIFICATE OF INTEREST

Counsel for *Amici Curiae* certifies the following:

- The full name of every party or *amicus curiae* represented by me is: AARP, the National Legislative Association on Prescription Drug Prices, Community Catalyst, and Prescription Policy Choices.

- The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is: AARP, the National Legislative Association on Prescription Drug Prices, Community Catalyst, and Prescription Policy Choices.

- All parent corporations and any publicly held companies that own 10 percent of the stock of the party or *amicus curiae* represented by me are: None.

- The names of all law firms and the partners or associates that appeared for the party or *amicus curiae* now represented by me in the trial court or are expected to appear in this court are:

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STATEMENT OF INTEREST

AARP is a nonpartisan, nonprofit membership organization of nearly 40 million persons, age 50 or older, dedicated to addressing the needs and interests of older persons. The National Legislative Association on Prescription Drug Prices is a nonpartisan, nonprofit organization of state legislators from across the country who advocate for lowering prescription drug costs and increasing access to affordable medicines. Community Catalyst is a national non-profit advocacy organization working in over 40 states to build consumer and community participation in shaping our health system to ensure quality, affordable healthcare for all. Prescription Policy Choices is a nonprofit, nonpartisan educational and charitable organization which provides educational and research materials to state legislators, academics, policymakers, and the public to assist them to reduce prescription drug prices and thereby increase access to effective, safe, and affordable prescription drugs in the U.S.

Counsel of Record, Sean M. Fiil-Flynn, has extensive experience in constitutional and consumer protection law and in pharmaceutical policy.

All parties have consented to the filing of this amicus brief.

SUMMARY OF ARGUMENT

This case turns on the constitutional distinction between public and private commercial uses of information. The ultimate aim of the First Amendment is to

support and promote public speech that creates a marketplace of ideas and contributes to the creation of opinions that aid self-government. In furtherance of this purpose, accurate and non-misleading commercial speech that informs the public sphere is deserving of a lesser degree of First Amendment protection. But purely private speech that does not support the public sphere is not subject to heightened scrutiny under the First Amendment.

Commercial communication can be private in two different dimensions, both of which have doctrinal implications under the First Amendment. First, communication is less deserving of First Amendment protection when it is private in the sense of being delivered to highly restricted audiences for purely commercial interests. *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.,* 472 U.S. 749 (1985) (credit report delivered to five clients under contractual non-disclosure requirements).

Second, communication can be private in relation to the source of the information it transfers. Governments have a much greater interest, and speaker's interest is concomitantly diminished, when the information sought to be disseminated is not already in the public domain and is of a traditionally confidential nature. When governments act to keep closely-held information confidential, they rarely transgress the First Amendment. *L.A. Police Dep't v. United Reporting Publ'g Corp.*, 528 U.S. 32, 40 (1999).

The regulated activity of Plaintiffs transfers information from medical records that by tradition, reasonable expectation, and operation of law are confidential. The challenged statute regulates the transfer of this information not to the general public, but to a limited number of business clients who accept contractual secrecy obligations. This is the epitome of private speech. The First Circuit was correct in holding that such speech serves no First Amendment purpose and therefore is not subject to heightened scrutiny under the commercial speech doctrine.

While the legislature deserves maximum deference in cases where it seeks to regulate only private communication of private information, in this case there is an exhaustive legislative record demonstrating the direct public harms sought to be regulated. This record includes thirty-one legislative findings that are supported by the overwhelming weight of social scientific research. This legislative record would be sufficient to justify much more invasive regulation of actual commercial speech, such as the complete ban on in-person solicitation upheld in *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978) and *Tennessee Secondary School Athletic Ass'n v. Brentwood Academy,* 551 U.S. 291 (2007). The fact that such an overwhelming record supports a minimal invasion of First Amendment interests makes this an easy case.

ARGUMENT

I. THE PRIVATE COMMERCIAL USE OF PRIVATE INFORMATION IN PRESCRIPTION RECORDS AT ISSUE IN THIS CASE SERVES NO FIRST AMENDMENT PROTECTED PURPOSE

Vermont's legislation protecting the confidentiality of prescription records from certain commercial uses (but not from public research or public disclosure) is due maximum judicial deference because it harms no First Amendment protected interest. *IMS Health, Inc. v. Ayotte,* 550 F.3d 42 (1st Cir. 2008) (holding that prescription privacy law does not regulate protected speech).

The ultimate aim of the First Amendment is to support and promote "public speech," *Dun & Bradstreet,* 472 U.S. at 761 n. 7, which is "constitutionally valued because it is itself a way of participating in the processes of democratic self-governance." Robert Post, *The Constitutional Status of Commercial Speech*, 48 UCLA L. Rev. 1, 48 (2000); *see Stromberg v. California*, 283 U.S. 359, 369 (1931) (describing the primary purpose of the First Amendment as the "maintenance of the opportunity for free political discussion to the end that government may be responsive to the people").

Modern First Amendment doctrine accords accurate and non-misleading commercial advertising a lesser degree of protection to serve an "informational function." *Cent. Hudson Gas & Elec. Corp. v. Pub. Service Comm'n of N.Y.,* 447 U.S. 557, 563-564 (1980). This function of contributing accurate and non-

misleading information to the public sphere is valued because of its potential relation to core First Amendment purposes; "the free flow of commercial information" may be "indispensable to the formation of intelligent opinions" necessary for enlightened "public decision making in a democracy". *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 765-766 (1976); *see also Zauderer v. Office of Disciplinary Counsel of Sup. Ct. of Ohio*, 471 U.S. 626, 628 (1985) ("[T]he extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides."); *First Nat'l Bank v. Bollotti*, 435 U.S. 765, 783 (1978) ("[T]he First Amendment goes beyond protection of . . . the self expression of individuals to prohibit government from limiting the stock of information from which members of the public may draw.").

In contrast to speech that informs the public communicative sphere, the First Amendment provides no protection to purely private commercial communication that does not perform a public informational function. *See Ohralik*, 436 U.S. at 456 ("[N]umerous examples . . . of communications that are regulated without offending the First Amendment, such as the exchange of information about securities, corporate proxy statements, the exchange of price and production information among competitors, and employers' threats of retaliation for the labor activities of employees."); *Ayotte*, 550 F.3d at 52 (describing the unprotected class

of communications as deriving "from a felt sense that the underlying laws are inoffensive to the core values of the First Amendment . . . because they principally regulate conduct and, to the extent that they regulate speech at all, that putative speech comprises items of nugatory informational value"); *cf. Cent. Hudson*, 447 U.S. at 563 ("[T]he protection available for particular commercial expression turns on the nature both of the expression and of the governmental interests served by its regulation."); *44 Liquormart, Inc. v. R.I.*, 517 U.S. 484, 501 (1996) (joint opinion of Stevens, Kennedy, and Ginsburg, JJ.) ("Rhode Island errs in concluding that all commercial speech regulations are subject to a similar form of constitutional review.").

Commercial communication can be private in two different aspects. Private communication occurs when information is disseminated to highly restrictive or person-to-person communication channels that do not directly participate in the "marketplace of ideas." Private information is that which is not generally available in the public domain, such as information from private medical records, trade secret information, or illegally intercepted phone calls. Where governments regulate the private communication of private information, their actions pose the least threat to the First Amendment's concern with supporting public speech.

A. The Regulation of Private Commercial Communication is Entitled Greater Deference.

First, commercial communication is less deserving of First Amendment protection when it is private in the sense of being delivered to highly restricted audiences. This is because such communication has the least opportunity to inform the broader public communicative sphere and because the risk of the communication being used in a way that is biased or misleading is aggravated without exposure to the open marketplace of ideas that Holmes described as the "best test of truth." *Abrams v. U.S.*, 250 U.S. 616, 630 (1919) (Holmes J., dissenting); *see Zauderer*, 471 U.S. at 642 (distinguishing between "in-person solicitation" and "print advertising" because the latter "poses much less risk of overreaching or undue influence"); *cf. Shapero v. Ky. Bar Ass'n,* 486 U.S. 466, 475 (1988) ("[A]ssessing the potential for overreaching and undue influence, the mode of communication makes all the difference.").

In *Dun and Bradstreet*, for example, the Court reviewed a law punishing the false publication of a credit report to an audience of five business clients. Holding that the First Amendment standards requiring heightened evidence for proving libel did not apply, the Court explained:

> [S]ince the credit report was made available to only five subscribers, who, under the terms of the subscription agreement, could not disseminate it further, it cannot be said that the report involves any strong interest in the free flow of commercial information. There is simply no credible argument that this type of credit reporting requires

special protection to ensure that debate on public issues will be uninhibited, robust and wide open.

472 U.S. at 762 (citations omitted).

Vermont's law regulates communication similar to that in *Dun & Bradstreet* in that the audience is a select group of pharmaceutical companies that operate under contractual prohibitions on disclosing the information received. Therefore, there can be no argument that this information is necessary to inform the public communicative sphere, a key aim of the commercial speech doctrine. *See Ayotte*, 550 F.3d at 100 (Lipez, J., concurring) ("[T]his case differs from those in which the Court has rejected advertising bans that restrict the exchange of ideas in the 'commercial marketplace.'").[1]

B. Regulations Safeguarding the Confidentiality of Private Information are Entitled Greater Deference.

The information Plaintiffs trade is less important to First Amendment interests than that in *Dun & Bradstreet* because prescription records, unlike *Dun & Bradstreet's* publicly released court dockets are not information readily available

[1] To the extent the law regulates information dissemination through in-person solicitation of pharmaceuticals by sales agents, this context is also subject to heightened state regulatory interests because it is highly susceptible to misleading speech that is nearly impossible to police. *See Orhalik*, 436 U.S. at 455; *Edenfield v. Fane*, 507 U.S. 761, 768 (1993) (recognizing the state interest in ensuring information flows "cleanly as well as freely") (quoting *Va. State Bd. of Pharmacy*, 425 U.S. at 771-772); *Ayotte*, *550* F.3d at 100 (Lipez, J., concurring) (finding it constitutionally "significant that the Prescription Act restricts only private communications between the pharmaceutical detailer and prescribers, rather than a message disseminated to the public at large.").

in the public domain. 472 U.S. at 751-752. This raises the second way that commercial speech can be private.

The Supreme Court has frequently recognized that governments have a greater interest, and the speaker's interest is concomitantly diminished, when the information sought to be disseminated is not already in the public domain. *See United Reporting*, 528 U.S. at 40. When governments act to regulate the dissemination of closely held or traditional private information, they rarely transgress the First Amendment. *Id.*

Plaintiffs make much of the fact that the information being conveyed by prescription record data mining is "truthful." *But see, The Florida Star v. B.J.F.*, 491 U.S. 524, 532 (1989) (rejecting "that truthful publication may never be punished consistent with the First Amendment."). But the stronger constitutional protection for the disclosure of truthful information in commercial speech applies only when the information is in the public domain in the first instance. *Id.* at 534 ("where the government has made certain information publicly available, it is highly anomalous to sanction persons other than the source of its release . . . [I]t is a limited set of cases indeed where, despite the accessibility of the public to certain information, a meaningful public interest is served by restricting its further release by other entities, like the press.").

The information Plaintiffs mine from medical records is available only because government regulations require it as a condition of accessing medical care.[2] States have great leeway in defining, through confidentiality protections, limitations on the use or release of information it creates or holds. Thus, in *Florida Star*, the Court explained that although a state could not punish the public communication (through a newspaper) of the names of rape victims lawfully obtained from publicly records, it could prohibit the records from being released in the first instance:

> [T]he *Daily Mail* formulation only protects the publication of information which a newspaper has lawfully obtained, the government retains ample means of safeguarding significant interests upon which publication may impinge, including protecting a rape victim's anonymity. *To the extent sensitive information rests in private hands, the government may under some circumstances forbid its nonconsensual acquisition, thereby bringing outside of the* Daily Mail *principle the publication of any information so acquired*. To the extent sensitive information is in the government's custody, it has even greater power to forestall or mitigate the injury caused by its release. The government may classify certain information, establish and enforce procedures ensuring its redacted release, and extend a damages remedy against the government or its officials where the government's mishandling of sensitive information leads to its dissemination.

Id. (emphasis added).

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[2] Vermont Board of Pharmacy, Administrative Rules, 19.1.1 (adopted August 15, 2003) (requiring that a prescription drug order contain the "full name and street address of the patient . . . Name, address and telephone number. . . of the prescribing practitioner."); United States Drug Enforcement Agency, Practitioner's Manual, Section V, 18 (2006).

Similar conclusions were reached in *Cox Broadcasting Corp. v. Cohn*, 420 U.S. 469, 496 (1975) ("If there are privacy interests to be protected in judicial proceedings, the States must respond by means which avoid public documentation or other exposure of private information.") and *Houchins v. KQED, Inc.*, 438 U.S. 1, 15-16 (1978) (holding that there is no right to "sources of information under government control").

The same reasoning has been used by the Court to support state interests in protecting the confidentiality of information held by a third party only by virtue of a government requirement. Thus, in *Seattle Times Co. v. Rhinehart*, the Court held that there was no First Amendment right to disclose information obtained only by the "legislative grace" establishing civil discovery. 467 U.S. 20, 32-33 (1984) (describing pre-trial discovery as "private" and that the prohibition is therefore "not a restriction on a traditionally public source of information").

Properly conceived, it is the individuals identified in the records who have a recognized First Amendment interest – the "freedom not to speak publicly, which serves the same ultimate ends as freedom of speech in its affirmative aspect." *Harper & Row Publishers, Inc. v. Nation Enterprises, Inc.,* 471 U.S. 539, 559 (1985); *see also Va. State Bd. of Pharmacy*, 425 U.S. at 756 ("[F]reedom of speech presupposes a willing speaker."). This principle is particularly weighty in the context of requiring consent before the release of medical records, which are

traditionally highly confidential. Thus, in *Whalen v. Roe*, the Court suggested that a state may violate the Fourteenth Amendment by *failing to protect* the confidentiality of prescription records when it requires limited disclosures. 429 U.S. 589, 605 (1977) (explaining that prescription disclosure rules are "typically accompanied by a concomitant statutory or regulatory duty to avoid unwarranted disclosures," which "arguably has its roots in the Constitution").

C. The Regulation of the Private Commercial Communication of Private Information Does not Threaten any First Amendment Interest

This case stands at the crossroads of the two lines of cases in which the Court has found the least First Amendment protected interests – where commercial actors seek to privately communicate private information. The Supreme Court has never struck down such a confidentiality protection under the First Amendment. Indeed, they are rarely litigated.

The most directly analogous case at hand is *United Reporting*. In that case, a "private publishing service" that provided names and addresses of recently arrested individuals to clients challenged a California law limiting commercial uses (but not public disclosures) of arrestee identifying information. 528 U.S. at 34. On cursory review, the Supreme Court held that the plaintiffs failed to allege any First Amendment protected interest:

> [T]he section in question is not an abridgment of anyone's right to engage in speech, be it commercial or otherwise, but simply a law

> regulating access to information in the hands of the police department. . . .
> This is not a case in which the government is prohibiting a speaker from conveying information that the speaker already possesses. See *Rubin v. Coors Brewing Co*., 514 U. S. 476 (1995). The California statute in question merely requires that if respondent wishes to obtain the addresses of arrestees it must qualify under the statute to do so. . . For purposes of assessing the propriety of a facial invalidation, what we have before us is nothing more than a governmental denial of access to information in its possession. California could decide not to give out arrestee information at all without violating the First Amendment. Cf. *Houchins,* 438 U. S. at 14.

528 U.S. at 32-33.

Another relevant statute was presented in *Reno v. Condon*, where the legislation prohibited states and private entities from using or releasing identifying information from DMV records for any commercial purpose, but not for various public purposes including disclosure through public media. 528 U.S. 141, 148 (2000). The First Amendment issues were dropped from that case before they reached the Court, which unanimously affirmed Congress's power to pass the Driver Privacy Protection Act. *Id.* (holding that identifying information in DMV records "is a thing in interstate commerce, and that the sale or release of that information in interstate commerce is therefore a proper subject of congressional regulation"). *See Amelkin v. McClure,* 330 F.3d 822 (6th Cir. 2003) (holding that a state law regulating use of DMV records "does not restrict or even regulate expression. Rather, it simply limits access to confidential information.").

Another directly relevant decision is *Bartnicki v. Vopper*. 532 U.S. 514 (2001). In *Bartnicki*, as here, the information at issue was unquestionably private – it was a communication intercepted by an illegal wiretap. *Id.* The holding of the Court was that the government could not suppress a public disclosure of that private information on a radio program. *Id.* at 534-35. The Court distinguished this regulation of speech from commercial "uses" of information, which the court described as "regulations of conduct," not subject to First Amendment scrutiny.[3]

The difference between the "disclosure" held to be "pure speech" and the "uses" held to be conduct is their relation to the First Amendment purpose of informing the public sphere. *Bartnicki* counsels that governments are free to regulate the commercial use of private information in settings that do not directly inform the public sphere. But governments may not issue a blanket ban on public disclosures of that same information for non-commercial purposes *into the public*

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[3] Such regulations of conduct included:

> [I]t is unlawful for a company to use an illegally intercepted communication about a business rival in order to create a competing product; it is unlawful for an investor to use illegally intercepted communications in trading securities; it is unlawful for a union to use an illegally intercepted communication about management (or vice versa) to prepare strategy for contract negotiations; it is unlawful for a supervisor to use information in an illegally recorded conversation to discipline a subordinate; and it is unlawful for a blackmailer to use an illegally intercepted communication for purposes of extortion. *Bartnicki*, 532 U.S. at 527 n. 10.

sphere. *Id.* at 533-34 (explaining that the ban on disclosure "implicates the core purposes of the First Amendment because it imposes sanctions on the publication of truthful information of public concern").

As the Vermont Attorney General notes, this statute is similar to the numerous state and federal laws that protect the private information from being disclosed or used in private commercial communication. Appellees Br. at 62-63. (cataloging federal protection of financial information, DMV records, individually identifying health information, video rental information, and cable subscriber information).

Reviewing all the cases together, as depicted in the summary table below, it is clear that the Court affords the most deference to government regulation of the private communication of private information. The Supreme Court has never struck down such a statute on First Amendment grounds. The First Circuit's conclusion that prescription privacy laws regulate only conduct and not speech is consistent with Supreme Court cases that uphold restrictions on non-public uses of private information and the Court's frequent statements that such communication is pure conduct not subject to First Amendment scrutiny.

Least 1st Amend. Scrutiny → Increased 1st Amend. Scrutiny

Least 1st Amend. Scrutiny → Increased 1st Amend. Scrutiny

	Private Communication In person solicitations, restricted subscribers (e.g. re-disclosure prohibitions); commercial "use" as distinguished from "disclosure."	**Public Communication** General advertisements, broadcast, newspapers, etc.
Private information Undisclosed government records, medical records, unlawfully obtained information (wiretaps), civil discovery of confidential information, trade secrets.	**[More deference]** *United Reporting* *Bartnicki* (commercial use) *Orhalik* ("numerous cases") *Reno v. Condon*	 *Bartnicki* (public disclosure) *Seattle Times Co.*
Public Information e.g. stock prices, open public records, news reporting, etc.	 *Dun & Bradstreet* *Edenfield* *Florida Bar* *Orhalik* *Anderson* (2d. cir.)	**[More scrutiny]** *Virginia Pharmacy* *Central Hudson* *Lorillard Tobacco* *44 Liquormart* *Cox Broadcasting* *Florida Star*

The regulated activity of Plaintiffs in this case is the paragon of private commercial communication of private information. They transfer information from medical records, which by tradition, reasonable expectation, and operation of law are confidential. The law regulates the transfer of this information not to the

general public, but to a limited number of business clients who accept contractual secrecy obligations. The First Circuit correctly held that such speech serves no First Amendment purpose and therefore is not subject to heightened scrutiny under the commercial speech doctrine.

The Plaintiffs' argument that all use of data by companies to target marketing is First Amendment protected speech is erroneous and, if adopted by this court, would have wide-ranging effects. Increasingly, the conduct of daily life creates a trail of identifiable data about everything from one's medical conditions, domestic travel, and purchasing choices.[4] A First Amendment right to sell any information a company transitorily possessed would dramatically restrict the ability of states to respond to regulatory challenges in the digital age. The future of privacy is dependent not on the ability to remain truly anonymous, but on the ability of the law to limit the use of data once collected.[5]

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[4] Neil Richards, *Reconciling Data Privacy and the First Amendment*, 52 UCLA L. Rev. 1149, 1190 (2005); *see* Frederick Schauer, *Commercial Speech and the Architecture of the First Amendment*, 56 U. Cin. L. Rev. 1181, 1183-84 (1988) (noting "a vast range" of exchanges of information between companies that do not implicate the First Amendment"); *see also* Robert Post, *The Constitutional Status of Commercial Speech*, 48 UCLA L. Rev. 1, 20-25 (2000); Frederick Schauer, *The Boundaries of the First Amendment: A Preliminary Exploration of Constitutional Salience*, 117 Harv. L. Rev. 1765, 1777-87 (2004).

[5] Latanya Sweeney, *Privacy Technologies for Homeland Security*, Statement before the Privacy and Integrity Advisory Committee, Department of Homeland Security, June 15, 2005.

This radical rewriting of the First Amendment to impose a *Lochner*-like system of heightened judicial review over common economic laws should be emphatically rejected. *Cf. Cent. Hudson*, 447 U.S. at 589, 591 (1980) (Rehnquist, J., dissenting) (warning against using the commercial speech doctrine "to resurrect the discredited doctrine of cases such as *Lochner*" to strike economic regulations "based on the Court's own notions of the most appropriate means for the State to implement its considered policies"). The private communication of confidential medical records between contracting business parties to use as a tool in commercial marketing (not for its public informational value) is economic conduct subject to economic regulation.

The First Amendment inquiry in this case should rest there.

II. THE STATE HAS A COMPELLING INTEREST IN SAFEGUARDING THE DOCTOR-PATIENT RELATIONSHIP BY PROTECTING IT FROM INDUSTRY SURVEILLANCE AND MANIPULATION.

While the legislature deserves maximum deference in cases where it seeks to regulate only private communication of private information, in this case there is an exhaustive legislative record demonstrating the direct public harms sought to be regulated. The legislative record includes thirty-one express findings that have been reviewed and accepted by a district court, and are supported by the weight of social scientific research, as catalogued below. This legislative record would be sufficient to justify much more invasive regulation of actual commercial speech,

such as the complete ban on in-person solicitation upheld in *Ohralik* and *Tennessee*.

A. The Act Protects Against Undue Influence on Prescribing Choices that Increases Costs and Compromises Public Health

States may regulate commercial solicitation practices that are "only deceptive or misleading," *Va. State Bd. of Pharmacy*, 425 U.S. at 771-72 including practices that give marketers an "undue influence" through "one-sided" presentations that "may disserve the individual and societal interest . . . in facilitating informed and reliable decision making." *Ohralik*, 436 U.S. at 457-58, 461 (citations omitted). This interest in regulating the undue influence of marketing is at its peak when, as here, the effects of marketing excesses are provably harming public health and raising the cost of providing an essential public service.

There is overwhelming evidence that access to prescription records aggravates the negative public effects of in-person solicitation of brand-name pharmaceutical drugs to doctors. After conducting hearings and reviewing social science evidence, the legislature found that the practice of detailing "comes at the expense of cost-containment activities," S. 115, 2007 Leg. Reg. Sess. (Vt. 2007) (enacted) (Leg. Finding 3) and "contributes to the strain on health care budgets for individuals as well as health care programs"(Leg. Finding 15). The legislature also found that detailing "leads to doctors prescribing drugs based on incomplete and

biased information" (Leg. Finding 4) and increases the over-prescription of new drugs that "do not necessarily provide additional benefits over older drugs, but do add costs and as yet unknown side-effects." (Leg. Finding 7).

Upholding the Vermont Law, the District Court repeatedly noted the strong support for the legislative findings in the evidence presented at trial, concluding that "[d]etailing encourages doctors to prescribe newer, more expensive and potentially more dangerous drugs instead of adhering to evidence-based treatment guidelines." *IMS Health Inc. v. Sorrell*, 01:07-CV 2009 WL 1098474, 13 (D. Vt. Apr. 23, 2009). The court validated the legislature's common-sense reasoning that access to confidential prescription records increases the influence, and therefore the negative effects, of detailing:

> Put simply, if PI data did not help sell new drugs, pharmaceutical companies would not buy it. The Court finds the Legislature's determination that PI data is an effective marketing tool that enables detailers to increase sales of new drugs is supported in the record.
>
> *Sorrell*, 2009 WL 1098474 at 11.

While the findings of the legislature and the District Court could easily stand without further inquiry, there is consistent support in academic studies and popular press accounts for these conclusions.

Numerous studies and investigations have documented a significant, measurable, and increasing influence of direct-to-physician marketing in convincing doctors to adopt prescribing practices contrary to clinical guidelines

and the weight of objective scientific evidence.[6] Access to prescription record information is a key tool for increasing undue influence of in-person marketing and increasing the cost of medical care.[7]

Marketing influence also threatens public health. One study showed that using highly marketed medicines for hypertension, instead of *more effective* generics recommended by national treatment guidelines, increased U.S. health costs by $3 billion per year, while another found that approximately 40% of Pennsylvania Medicare patients on antihypertensive therapy were prescribed medications at odds with clinical guidelines.[8] A similar effect can be seen in the

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[6] *See* David Blumenthal, *Doctors and Drug Companies*, 251 New Eng. J. Med. 1885 (2004); Abigail Caplovitz, *Turning Medicine Into Snake Oil: How Pharmaceutical Marketers Put Patients at Risk*, NJPIRG Law & Pol'y Center 5 (2006) (reviewing studies); Dana Katz, et al., *All Gifts Large and Small,* 3 Am. J. Bioethics 39, 39-41 (2003) (summarizing research); Nicole Lurie, et al., *Pharmaceutical Representatives in Academic Medical Centers*, 5 J. Gen. Intern. Med. 240, 240-43 (1990); Puneet Manchanda & Elisabeth Hokna, *Pharmaceutical Innovation and Cost*, 5 Yale J. Health Pol'y L. & Ethics 785, 797-808 (2005) (reviewing studies); Helen Prosser, et al., *Influences on GP's Decisions to Prescribe New Drugs*, 20 Fam. Prac. 61 (2003); Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 JAMA 373 (2000); National Institute for Health Care Management, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs*, 2-3 (rev. 2002); *see* Geoffrey Anderson, et al., *Newly Approved Does Not Always Mean New and Improved,* 299 JAMA 1598 (2008).

[7] *See* Jane Coutts, *Pharmaceutical Group's Head Defends Sale of Medical Data*, Globe & Mail, Mar. 28, 1996, (describing how knowing prescribing practices "would enable drug companies to direct a real campaign toward getting him or her to switch to a more expensive - even if less effective – drug").

[8] *See* Michael Fischer & Jerry Avorn, *Economic Implications of Evidence-Based Prescribing for Hypertension: Could Better Care Cost Less*, 291 JAMA 1850, 1854 (2004) (citing the ALLHAT study of antihypertensive therapy).

marketing push and resultant prescription surge for Vioxx, Bextra, and other COX-2 inhibitors, despite the lack of any conclusive medical evidence that they were more effective than older pain medications, or that the reduction in gastric side effects were significant for most patients.[9]

Cost and public health concerns are linked. Patients, especially the poor and elderly, often make choices about which prescriptions to fill or whether to split pills depending on the affordability of the medication.[10]

While Plaintiffs argue that physicians are educated, sophisticated marketing targets who are less susceptible to misleading messages, studies have found that doctors are highly susceptible to marketing messages while simultaneously discounting the effects of those efforts on their prescribing habits. [11] Physicians generally trust the messages delivered by detailers[12] and are very poor at detecting

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[9] Gardiner Harris*, Pfizer Pays $2.3 Billion to Settle Marketing Case*, N.Y. Times, Sept. 2, 2009; Jerry Avorn, Powerful Medicines 202 (rev. 2005); Memorandum from Henry Waxman, to Democratic Members of the Gov't Reform Committee, on the Marketing of Vioxx to Physicians (May 5, 2005).

[10] Becky Briesacher, et al*., Patients At-Risk for Cost-Related Medication Nonadherence,* 22 J. Gen. Internal Med. 864 (2007)(finding that up to 32% of seniors took less medicine than prescribed in a effort to reduce costs).

[11] Wazana, *supra* note 6 at 375. Katz, *supra* note 6; *See* Jerry Avorn, et al., *Scientific Versus Commercial Sources of Influence on the Prescribing Behavior of Physicians*, 73 Am. J. Med. 4, 4-8 (1982); Michael Steinman, et al. *Of Principles and Pens: Attitudes and Practices of Medicine Housestaff Towards Pharmaceutical Industry Promotions*, 110 Am. J. Med. 551 (2001) (reporting that 61% of medical residents believe themselves unaffected by marketing, although 84% believe it affects colleagues).

[12] Wazana, *supra* note 6 at 375.

false and misleading messages within sales pitches.[13] Ninety-four percent of all doctors routinely receive gifts of significant value, such as meals and free drug samples,[14] which are guided by access to prescription data and create powerful psychological urges to reciprocate.[15] Physicians generally have low awareness of the cost of the medicines they prescribe.[16] A 2007 study of physician awareness of drug cost found that the median estimates of cost were highly inaccurate, little more than "wild guesses", with physicians consistently overestimating the cost of cheaper medicines and underestimating the costs of the most expensive medicines.[17]

When Plaintiffs present their marketing as analogous to the adversarial system, where the truth is ascertainable through examining the diligently presented arguments of each side, they obscure the reality that in this marketing blitz, there is

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[13] Michael Ziegler, et al., *The Accuracy of Drug Information from Pharmaceutical Sales Representatives*, 273 JAMA 1296 (1995) (finding that 11% of statements by detailers to doctors were inaccurate, but only 26% of doctors could detect them), *see* Roberto Cardarelli, et al., *A Cross-Sectional Evidence-Based Review of Pharmaceutical Promotional Marketing Brochures and Their Underlying Studies: Is What They Tell Us Important and True?*, 7 BMC Fam. Prac. 13 (2006) (finding that the research presented by sales representatives obscured risk/benefit analysis).

[14] Eric Campbell, et al., *A National Survey of Physician-Industry Relationships*, 356 New Eng. J. Med. 1742, 1742 (2007).

[15] Blumenthal, *supra* note 6 (discussing the tendency to discount one's own susceptibility to bias).

[16] G. Michael Allan, et al., *Physician Awareness of Drug Cost*, 4 PLOS Medicine 1486 (2007).

[17] *Id*. at 1491 "With only 31% of estimates within 20% or 25% of the true drug cost and the median estimate 243% away from the true cost, many of the estimates appear to be wild guesses."

no voice for the lower-cost or older options[18], and no advocate suggesting that increased medication may not be in the patient's best interest.[19]

B. The Act Protects the Privacy of the Doctor-Patient Relationship

States have a compelling interest, and likely a constitutional duty, to safeguard the privacy of medical records. *See Whalen,* 429 U.S. 589. The Vermont Legislature found that physicians have "a reasonable expectation that [prescription data] will not be used for purposes other than the filling and processing of the payment for that prescription," and that "[p]rescribers and patients did not consent to the trade of that information to third parties." (Leg. Finding 29).

The privacy interests served by the Vermont law extend to patients as well as physicians.[20] Although patient identities are normally removed from records before transmission to pharmaceutical companies, this provides incomplete protection. As long as prescriber identities remain, individual patients can be tracked and marketed to without their consent. Press reports have divulged that the plaintiffs often assign individual identifying numbers to patient records and track patient treatment, including whether and when patients see other care-givers or

[18] Fischer, *supra* note 8 (describing "vigorous marketing" as a primary reason for "divergence between routine practice and evidence-based recommendations").
[19] Avorn, *supra* note 9.
[20] Medicaid has acknowledged that patient privacy interests extend beyond patient identity, and also restricts the disclosure of treatment choices, including medicines prescribed to Medicaid patients. *See* 42 C.F.R. §§ 431.300, 431.303.

shift prescriptions.[21] The insertion of the pharmaceutical company into the monitoring and influence of the patient's treatment is an invasion of privacy of the most odious kind – one that directly affects treatment courses for the pecuniary interest of another through a breach of confidentiality that is nearly impossible for the patient to detect.

C. The Act Polices Standards in the Medical Profession

"[T]he State bears a special responsibility for maintaining standards among the members of the licensed professions." *Ohralik*, 436 U.S. at 460. This interest in enforcing ethical standards of the profession justifies measures to "avoid situations where the [professional's] exercise of judgment on behalf of the client will be clouded by his own pecuniary interest." *Id*. at 461.

The Vermont Legislature found that the use of prescription data allowed sales representative to select "the most efficient set of rewards" (Leg. Finding 24) to influence prescriber behavior and noted that Vermont Medical Society resolved that "the use of physician prescription information is an intrusion into the way that physicians practice medicine." (Leg. Finding 20).

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[21] *See* Jim Carroll & Tanya Foniri, *Infuse Anonymized Patient-Level Information into the Brand-Planning Process to Drive Profitable Growth* , IMS, http://www.imshealth.com/vgn/images/portal/cit_40000873/0/38/78187147Brand%20Planning%20Paper.pdf (June 1, 2006).

There is growing public concern about conflicts of interests that arise when the pharmaceutical industry becomes too entrenched in the education of physicians and when the line between physicians acting as researchers and educators, and physicians acting as drug company marketers is blurred. [22] Many physician organizations advocate an end to prescriber profiling for marketing purposes because the practice threatens the ethical standards of the profession and jeopardizes their relations with patients.[23] High prescribers and influential specialists can receive tens, even hundreds of thousands of dollars for consultancies and lectures each year, a cycle that not only rewards high prescribers, but also uses those physicians' prominence to influence other doctors' prescribing choices. [24] This attempt to enlist doctors in the pharmaceutical

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[22] Catherine DeAngelis & Phil Fontanarosa, *Impugning the Integrity of Medical Science*, 299 JAMA 1833 (2008); *see* Gardner Harris & Benedict Carey, *Researchers Fail to Reveal Full Drug Pay*, N.Y. Times, Jun. 8, 2008 ; Ibby Caputo, *Probing Doctors' Ties to Industry*, Wash. Post, Aug. 18, 2009.

[23] *See* Susan Coyle, *Physician-Industry Relations, Part 1*, 136 Annals of Internal Med. 396 (March 2002) (statement of the American College of Physicians); National Physicians Alliance, *The Sale of Physician Prescribing Data Raises Health Care Costs*, http://npalliance.org/images/uploads/IssueBrief-Prescribing_Data_low_res.pdf ; No Free Lunch, http://www.nofreelunch.org/aboutus.htm; American Medical Students Ass'n, Pharm Free, http://www.amsa.org/prof/focus.cfm.

[24] Adrian Fugh-Berman & Shahram Ahari, *Following the Script: How Drug Reps Make Friends and Influence Doctors*, 4 PLoS Med e150 (2007) *See* Waxman, *supra* note 9 (revealing Merck graded doctors from A+ to D based on how reliably they prescribed Merck products.); *see, e.g.*, Public Citizen, *Response to FDA Request for Comments on First Amendment Issues*, September 13, 2002, *available at* http://www.citizen.org/publications/release.cfm?ID=7199 (detailing the use of prescription data to reward off-label prescribing of Neurontin); Joseph Ross, et al.,

marketing team debases the medical profession and, as the practice becomes more public, breaks the chain of trust between doctor and patient.[25]

D. The Act Protects Doctors Against Vexatious Sales Practices

Finally, the Supreme Court has repeatedly held that states have a legitimate interest in regulating marketing that is "pressed with such frequency or vehemence as to intimidate, vex, or harass the recipient." *Edenfield*, 507 U.S. at 769; *see Ohralik*, 436 U.S. at 458 ("[T]he State has a legitimate and indeed 'compelling' interest in preventing those aspects of solicitation that involve fraud, undue influence, intimidation, overreaching, and other forms of 'vexatious conduct.'"). The Vermont Legislature found that the use of prescription information "increased the aggressiveness of pharmaceutical sales representatives" (Leg. Finding 20), "added unwanted pressure" to physicians who were informed of monitoring (Leg. Finding 27), and could "result in harassing sales behaviors." (Leg. Finding 28). Doctors advocate reforms in part because many feel harassed by the increasing frequency

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Pharmaceutical Company Payments to Physicians, 297 JAMA 1216 (2007); Emily Clayton, CALPIRG, *'Tis Always the Season for Giving: A White Paper on the Practice and Problems of Pharmaceutical Detailing* (2004); Gardiner Harris et al., *Psychiatrists, Children, and Drug Industry's Role*, N.Y. Times, May 10, 2007; Carl Elliott, *The Drug Pushers*, The Atlantic, April 2006, 82, 90-91, http://www.theatlantic.com/doc/200604/drug-reps; Stephanie Saul, *Drug Makers Pay for Lunch as They Pitch*, N.Y. Times, July 28, 2006.

[25] *See* Robert Gibbons, et al., *A Comparison of Physicians' and Patients' Attitudes Toward Pharmaceutical Industry Gifts*, 13 J. Gen. Internal Med. 151, 152 (1998); Katz, *supra* note 6.

and aggressiveness of detailing forces fueled by the use of identifiable data to track prescribing and calculate sales bonuses.

There are a host of federal and state laws that combat harassing and frequent marketing calls on consumers by limiting marketers' access to identifying information.[26] In the case of medicines, doctors make the purchasing decisions for patients, and therefore receive the majority of all marketing efforts.

Although marketing to doctors has long been a focus of pharmaceutical company budgets,[27] the availability of digitized prescribing data beginning in the early 1990s made the practice more profitable and invasive.[28] In 2004, the industry spent $27 billion on marketing, more than any other sector in the United States.[29] Over 85% of pharmaceutical marketing budgets are targeted at doctors.[30] In the decade after IMS unveiled its prescriber tracking program in 1993,[31] spending on

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[26] *See* Fair Credit Reporting Act, 15 U.S.C. § 1681 et seq. (2000) (credit reporting information); Family Educational Rights and Privacy Act of 1974, 20 U.S.C. § 1232g (2000 & Supp. III 2003) (educational information). *See also* Appellees Br. at 62-63 (citing laws banning the secondary use of consumer data for marketing and other commercial purposes).

[27] Jeremy Greene, *Pharmaceutical Research and the Prescribing Physician*, 146 Annals Internal Med. 742 (2007).

[28] Elliott, *supra* note 24.

[29] Manchanda, *supra* note 6.

[30] Kaiser Family Foundation, *Trends and Indicators in the Changing Health Care Marketplace* exhibit 1.20, http://www.kff.org/insurance/7031/print-sec1.cfm (2005)[hereinafter *Trends*].

[31] *IMS America Introduces Xponent,* PR Newswire, Feb. 9, 1993, *available at Lexis*.

detailing increased by nearly 300%,[32] doubling the number of pharmaceutical sales representatives to over 100,000.[33] One report estimated that the average primary care physician in 2004 interacted with a staggering 28 sales representatives each week.[34]

In addition to radically increasing the volume of physician-directed marketing, access to prescriber-identified prescription records increases the prevalence of coercive marketing practices in individual sales calls. Database products sold to pharmaceutical companies by IMS and others are now so advanced that "[y]ou can literally find out if a rep makes a call at 9:00 am, whether the doctor wrote a script that afternoon."[35] Sales representatives use this data to hold prescribers "accountable" for their marketing messages and gifts, including by telling prescribers that they are being monitored and that the availability of

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[32] *Trends, supra* note 30.
[33] Rayna Herman & Nick Dabruzzo, *2006 Access Report*, Pharmaceutical Representative, July 2006, http://www.pharmrep.com/pharmrep/article/articleDetail.jsp?id=353927; Manchanda, *supra* note 6.
[34] Consumers Union; *Prescription for Change*, Mar. 2006, http://www.consumersunion.org/pdf/drugreps.pdf.
[35] *Looking Back, Looking Forward; Interview with Irwin Gerson, Chairman Emeritus of Lowe McAdams Healthcare*, Medical Marketing & Media, Apr. 1998, 70, *available at* Lexis.

samples, CME, and consulting opportunities will dwindle if they do not meet the marketers' expectations.[36]

III. THE VERMONT ACT IS SUFFICIENTLY TAILORED TO THE STATE'S COMPELLING INTERESTS.

Vermont was not required to adopt the "the single best disposition but one whose scope is 'in proportion to the interest served,' that employs not necessarily the least restrictive means but ... a means narrowly tailored to achieve the desired objective." *Florida Bar v. Went For It, Inc*. 515 U.S. 618, 632 (1995). The legislature specifically found that voluntary measures to protect data confidentiality were not sufficient to meet the public purpose. (Leg. Findings 10-12, 30).[37] Accordingly, to the extent that any First Amendment speech in in-person solicitations is affected, its regulation is demonstrably reasonable.

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[36] Gardiner Harris & Robert Pear, *Drug Maker's Efforts to Compete in Lucrative Insulin Market are Under Scrutiny*, N.Y. Times, Jan. 28, 2006 (quoting an email from an executive encouraging detailers to "[h]old [doctors] accountable for all the time, samples, lunches, dinners, programs and past preceptorships that you have paid for and get the business!"); *see also* Stephanie Saul, *Doctors Object to Gathering of Drug Data*, N.Y. Times, May 4, 2006; Hearing on HB 1346, 2006 Leg.(N.H. 2006) at 33 (Testimony of Ms. Finocchiaro); Sheryl Gay Stolberg & Jeff Gerth, *High Tech Stealth Being Used to Sway Doctor Prescriptions*, N.Y. Times, Nov. 16, 2000 (statement of "outrage[]" by former president of American College of Physicians); Liz Kowalczyk, *Drug Companies' Secret Reports,* Boston Globe, May 25, 2003; Robert Steinbrook, *For Sale: Physicians' Prescribing Data*, 354 New Eng. J. Med. 2745 (2006).

[37] *See* Steinbrook, *supra* note 36 at 2745; David Grande, *Prescriber Profiling: Time to Call it Quits*, 146 Annals Internal Med. 751 (2007).

CONCLUSION

For the foregoing reasons as well as those set out by the Appellees, amici respectfully urge that this Court find for the Appellees.

Dated: September 15, 2009

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