

No. 10-779

**In the
Supreme Court of the United States**

WILLIAM H. SORRELL, ET AL.,
Petitioners,

v.

IMS HEALTH, INC., ET AL.,
Respondents.

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

**BRIEF OF AARP AND THE NATIONAL
LEGISLATIVE ASSOCIATION ON
PRESCRIPTION DRUG PRICES AS
AMICI CURIAE IN SUPPORT OF PETITIONERS**

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FEDERAL CASES

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<i>Florida Bar v. Went For It</i> , 515 U.S. 618 (1995)	8
<i>Florida Star v. B.J.F.</i> , 491 U.S. 524 (1989)	12

<i>Harper & Row Publishers, Inc. v. Nation Enterprises, Inc.</i> , 471 U.S. 539 (1985)	11
<i>Houchins v. KQED, Inc.</i> , 438 U.S. 1 (1978)	12
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<i>IMS Health, Inc., v. Sorrell</i> , 631 F. Supp. 2d 434 (D. Vt. 2009)	<i>passim</i>
<i>IMS Health, Inc. v. Sorrell</i> , 2010 U.S. App. LEXIS 24053 (2d. Cir., Nov. 23, 2010)	<i>passim</i>
<i>L.A. Police Dept. v. United Reporting Publ'g Corp.</i> , 528 U.S. 32 (1999)	2, 12, 15
<i>Lorillard Tobacco Co. v. Reilly</i> , 533 U.S. 525 (2001)	17
<i>Milavetz, Gallop & Milavetz, P.A. v. U.S.</i> , 599 U.S. ____ (2010)	24
<i>NASA v. Nelson</i> , 562 U.S. ____ (2011)	3, 18
<i>Nixon v. Adm'r of Gen. Servs.</i> , 433 U.S. 425 (1977)	19
<i>Northwestern Memorial Hospital v. Ashcroft</i> , 362 F.3d 923 (7th Cir. 2004)	20

<i>Ohralik v. Ohio Bar Ass’n</i> , 436 U.S. 447 (1978)	3, 7, 24, 31
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<i>Va. State Bd. of Pharmacy v. Va. Citizens Consumer Credit Council, Inc.</i> , 425 U.S. 748 (1976)	6, 24
<i>Whalen v. Roe</i> , 429 U.S. 589 (1977)	<i>passim</i>
<i>Wine and Spirits Retailers, Inc. v. State of Rhode Island</i> , 418 F.3d 39 (1st Cir. 2005)	7
<i>Zauderer v. Office of Disciplinary Counsel of Sup. Ct. of Ohio</i> , 471 U.S. 626 (1985) ...	6, 18

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---	----

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Supreme Court Rule 37.6	1

FEDERAL REGULATIONS

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--	----

MISCELLANEOUS

AARP, Rx Watchdog Report, May 2010, <i>available at</i> http://www.aarp.org/health/ drugs-supplements/rx_watchdog.html	2
G. Michael Allan, et al., <i>Physician Awareness of Drug Cost</i> , 4 PLOS Medicine 1486 (2007)	28
A.B.A. Privacy & Computer Crime Comm. Section of Sci. & Tech. Law, <i>Int'l Guide to Privacy</i> (2004)	16
Geoffrey Anderson, et al., <i>Newly Approved Does Not Always Mean New and Improved</i> , 299 JAMA 1598 (2008)	26
Jerry Avorn, <i>Powerful Medicines</i> 202 (rev. 2005)	26
Linda L. Barrett, Ph.D., AARP, Prescription Drug Use Among Midlife and Older Americans (2005), <i>available at</i> assets.aarp.org/rgcenter/health/ rx_midlife_plus.pdf	1

- David Blumenthal, *Doctors and Drug Companies*, 251 NEJM 1885 (2004)26, 27
- Becky Briesacher, et al., *Patients At-Risk for Cost-Related Medication Nonadherence*, 22 J. Gen. Internal Med. 864 (2007) 31
- Eric Campbell, et al., *A National Survey of Physician-Industry Relationships*, 356 New Eng. J. Med. 1742 (2007)32
- Abigail Caplovitz, *Turning Medicine Into Snake Oil: How Pharmaceutical Marketers Put Patients at Risk*, NJPIRG Law & Pol’y Center 5 (2006).....26
- Robert Cardarelli, John Licciardone & Lockwood Taylor, *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)..... 25, 29
- 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_40000873/0/38/78187147/Brand%20Planning%20Paper.pdf 22

Susan Chimonas, et al., <i>Physicians and Drug Representatives: Exploring the Dynamic of the Relationship</i> , 22 J. Gen. Intern. Med. 184 (2007)	31
Julie E. Cohen, <i>Examined Lives: Informational Privacy and the Subject as Object</i> , 52 Stan. L. Rev. 1373 (2000)	8
Susan Coyle, <i>Physician-Industry Relations, Part 1</i> , 136 Annals of Internal Med. 396 (2002).....	32
Jason Dana & George Lowenstein, <i>A Social Science Perspective on Gifts to Physicians from Industry</i> , 290 JAMA 252 (2003)	32
Carl Elliott, <i>The Drug Pushers</i> , The Atlantic, 82 (Apr. 2006)	32
<i>Evaluating Relationship Marketing Programs</i> http://www.imshealth.com/imshealth/ Global/Content/Document/LifeLink/ Evaluating_Relationship_Marketing_ Programs.pdf	20
<i>Families USA, Cost Overdose: Growth in Drug Spending for the Elderly, 1992-2010</i> (July 2000)	1

- Melissa Fischer et al., *Prescribers and Pharmaceutical Representatives: Why Are We Still Meeting?* 24 J. Gen. Inter. Med. 795 (2009)28
- Michael Fischer & Jerry Avorn, *Economic Implications of Evidence Based Prescribing for Hypertension: Could Better Care Cost Less*, 291 JAMA 1850 (2004).....26, 30
- Sen. Franken to Chair New Subcommittee on Privacy, Technology and the Law (Feb. 14, 2011) http://www.franken.senate.gov/?p=press_release&id=1315 16
- Adriane Fugh-Berman & Shahram Ahari, *Following the Script: How Drug Reps Make Friends and Influence Doctors*, 4 PLoS Med e150 (2007)..... 32
- Robert Gibbons, et al., *A Comparison of Physicians' and Patients' Attitudes Toward Pharmaceutical Industry Gifts*, 13 J. Gen. Internal Med. 151 (1998).....33
- Gardiner Harris & Robert Pear, *Drug Maker's Efforts to Compete in Lucrative Insulin Market are Under Scrutiny*, N.Y. Times, Jan. 28, 2006.....33

Mike Hatch, Minn. Attorney General, <i>The Privatization of Big Brother: Protecting Sensitive Personal Information From Commercial Interests in the 21st Century</i> , 27 Wm. Mitchell L. Rev. 1458 (2001)	16
Harry Henderson, <i>Privacy in the Information Age</i> 117-130 (2006)	15
Sharona Hoffman and Andy Podgursky, <i>Information Security of Health Data: Electronic Health Information Security and Privacy</i> , in <i>Harboring Data: Information Security, Law and the Corporation</i> (2009)	16
IMS Health, Inc, <i>LifeLink</i> , available at http://www.imshealth.com/portal/site/imshealth/menuitem.a953aef4d73d1ecd88f611019418c22a/?vgnextoid=9826f8731739b110VgnVCM100000ed152ca2RCRD&vgnextfmt=default	20
Dana Katz, et al., <i>All Gifts Large and Small</i> , 3 Am. J. Bioethics 39 (2003).....	32
Harlan Krumholz, et al., <i>What Have We Learnt From Vioxx?</i> 334 BMJ 120 (2007)	30

C. Seth Landefeld and Michael Steinman, <i>The Neurontin Legacy – Marketing through Misinformation and Manipulation</i> , 360 NEJM 103 (2009)	25
Puneet Manchanda & Elisabeth Hokna, <i>Pharmaceutical Innovation and Cost</i> , 5 Yale J. Health Pol’y L. & Ethics 785 (2005).....	26, 27
Memorandum from Henry Waxman, to Democratic Members of the Gov’t Reform Committee, on the Marketing of Vioxx to Physicians (May 5, 2005)	25, 32
National Institute for Health Care Management, <i>Prescription Drug Expenditures in 2001: Another Year of Escalating Costs</i> (revised May 6, 2002)	29
NIHCM Foundation, <i>Factors Affecting the Growth of Prescription Drug Expenditures</i> , (July 1999) available at http://www.nihcm.org/pdf/ issuebrief.PDF	29
Robert O’Harrow, <i>No Place to Hide</i> (2006)	16
David Orentlicher, <i>Prescription Data Mining and the Protection of Patient Interests</i> , 38 J.L. Med. Ethics 74 (2010).....	26

Robert Post, <i>The Constitutional Status of Commercial Speech</i> , 48 U.C.L.A. L. Rev. 1 (2001)	24
Public Citizen, <i>Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry: 1991 to 2010</i> (Dec. 16, 2010)	25
Public Citizen, <i>Response to FDA Request for Comments on First Amendment Issues</i> , Sept. 13, 2002, available at http://www.citizen.org/publications/release.cfm?ID=7199	32
Neil Richards, <i>Reconciling Data Privacy and the First Amendment</i> , 52 UCLA L. Rev. 1149 (2005)	8
Joseph Ross, et al., <i>Pharmaceutical Company Payments to Physicians</i> , 297 JAMA 1216 (2007)	32
Jed Rubinfeld, <i>The Right of Privacy</i> , 102 Harv. L. Rev. 737 (1989)	19
Paul M. Schwartz & Joel R. Reidenberg, <i>Data Privacy Law: A Study of United States Data Protection</i>	14, 16
Michael Sokol, et al., <i>Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost</i> , 43 Med. Care 521 (2005)	31

Daniel J. Solove & Chris Jay Hoofnagle, <i>A Model Regime of Privacy Protection</i> , U. Ill. L. Rev. 357 (2006)	16
Daniel J. Solove, <i>A Taxonomy of Privacy</i> , 154 U. Pa. L. Rev. 477 (2006).....	14, 19
Daniel J. Solove, <i>The Virtues of Knowing Less: Justifying Privacy Protections Against Disclosure</i> , 53 Duke L. J. 967 (2004)	8, 14
Daniel J. Solove, <i>The New Vulnerability: Data Security and Personal Information</i> , in <i>Securing Privacy in the Internet Age (2008)</i>	16
Daniel J. Solove & Paul M. Schwartz, <i>Information Privacy Law</i> (3rd ed. 2008)	14
S. 115, 2007 Leg. Reg. Sess. (Vt. 2007)	24, 28, 29
Stanford Law Review Symposium on Information Privacy, 52 Stan. L. Rev. (2000).....	16
Michael Steinman, et al., <i>Of Principles and Pens: Attitudes and Practices of Medicine Housestaff Towards Pharmaceutical Industry Promotions</i> , 110 Am. J. Med. 551 (2001).....	27

Eugene Volokh, <i>Freedom of Speech and Information Privacy: The Troubling Implications of a Right to Stop People From Speaking About You</i> , 52 Stan. L. Rev. 1049 (2000)	9
Ashley Wazana, <i>Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?</i> , 283 JAMA 373 (2000).....	27, 30
Michael Ziegler, et al., <i>The Accuracy of Drug Information from Pharmaceutical Sales Representatives</i> , 273 JAMA 1296 (1995) ...	26, 28

INTERESTS OF *AMICI CURIAE*¹

AARP is a nonpartisan, nonprofit organization dedicated to addressing the needs and interests of people aged fifty and older. AARP has a long history of advocating for access to affordable health care and for controlling costs without compromising quality. Affordable prescription medication is particularly important to the older population which, because of its higher rates of chronic and serious health conditions, has the highest rate of prescription drug use. Persons over sixty-five, although only thirteen percent of the population, account for thirty-four percent of all prescriptions dispensed and forty-two cents of every dollar spent on prescription drugs. *Families USA, Cost Overdose: Growth in Drug Spending for the Elderly, 1992-2010* at 2 (July 2000). Significantly, in a 2005 AARP survey, one in four Americans 50+ who took a prescription drug in the past five years said they did not fill a prescription written by their doctor in the past two years. Cost was reported as the main deterrent. Linda L. Barrett, Ph.D., AARP, *Prescription Drug Use Among Midlife and Older Americans (2005)*, available at assets.aarp.org/rgcenter/health/rx_midlife_plus.pdf. Since prescription drug spending has skyrocketed over the last decade and a half, and national health

¹ In accordance with Supreme Court Rule 37.6, *Amici Curiae* state that: (1) no counsel to a party authored this brief, in whole or in part; and (2) no person or entity, other than *amici*, their members and counsel have made a monetary contribution to the preparation or submission of this brief. The written consents of the parties to the filing of this brief have been filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

expenditures on prescription drugs have quadrupled, AARP advocates for broader access to prescription drugs and lower prescription drug costs for consumers. *See e.g.*, AARP, Rx Watchdog Report, May 2010, *available at* http://www.aarp.org/health/drugs-supplements/rx_watchdog.html.

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.

SUMMARY OF ARGUMENT

This Court should refuse to apply the First Amendment to Vermont's Prescription Confidentiality Law based on two essential facts. First, the regulation at issue is limited to the commercial use or private-channel distribution of confidential data. It is thus governed by cases of this Court upholding the regulation of uses of information in purely private settings that do not inform or contribute to the public sphere. *Bartnicki v. Vopper*, 532 U.S. 514, 526-27 n.10 (2001); *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749 (1985). Second, it concerns the regulation of secondary uses of information where the government requires the initial disclosure. It is thus governed by cases in which this Court has affirmed a right of governments to restrict access to government held or mandated information. *L.A. Police Dept. v. United Reporting Publ'g Corp.*, 528 U.S. 32 (1999); *Seattle Times Co. v. Rhinehart*, 467 U.S. 20 (1984). This

Court has never held that a regulation at the intersection of these two lines of cases – where private channel exchanges and uses of private (government-mandated) records are at issue – is First Amendment protected “speech.” *Cf. Reno v. Condon*, 528 U.S. 141 (2000). The First Circuit, in a case parallel to the one before the Court now, decided the issue correctly – the private-channel use and trade of prescription records is economic conduct, not “speech.” *IMS Health, Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008), *cert. denied*, 129 S. Ct. 2864 (2009).

If this law were evaluated as regulating First Amendment protected speech, such speech should be given protection commensurate with its “nugatory informational value.” *Ayotte*, 550 F.3d at 52. In contrast, this Court should recognize the overriding interests of Vermont and other states in regulating the confidentiality of prescription records. The Vermont law directly advances its interest in protecting against disclosure of records containing the most personal of information as well as its interest in protecting individual autonomy in decision making on important personal matters. *NASA v. Nelson*, 562 U.S. __ (2011); *Whalen v. Roe*, 429 U.S. 589 (1977). Protecting the confidentiality of records advances important goals of our health system, including combating undue influence of in-person pharmaceutical marketing that raises costs and damages public health interests. *See Ohralik v. Ohio Bar Ass’n*, 436 U.S. 447 (1978).

ARGUMENT

I. DATA MINING COMPANIES LACK A FREE SPEECH INTEREST IN ACCESS TO PRESCRIPTION RECORDS.

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 limited degree of First Amendment protection. But extension of that protection to the use of prescription records to target marketing to doctors is inappropriate for two reasons. First, the information in this case is never delivered to consumers or the public sphere and therefore does not further the informational function the commercial speech doctrine is meant to serve. Second, the information Respondents seek to access and use is not willingly released by the original holders of the information, but rather is contained in government mandated records. Vermont's law to prevent the closed commercial uses of confidential information in records it requires the production of harms no First Amendment protected purpose.

A. Respondents' Conduct Does Not Serve a Public Informational Function.

The court below erred in applying the exacting standards reserved for regulation of public advertising, *Central Hudson Gas & Elec. Corp. v.*

Pub. Serv. Comm'n, 447 U.S. 557 (1980), to the closed commercial trade and use of confidential medical information from prescriptions to target marketing.

Respondents do not seek a right to disclose any information in their public advertising. They seek access to confidential records to track doctors and patients, not to communicate with them. Respondents use prescription records as a “targeting tool” to identify doctors that are most susceptible to sales messages and to evaluate whether they respond more positively to different tactics such as gifts, meals, samples and paid speaker programs. Pet. Br. at 9. The data allows pinpoint tracking of prescriptions for 200 million patients so that email alerts can be sent to a sales representative if a patient fills a prescription for a competing or generic drug. *Id.* at 8-9.² And the data is used to monitor sales quotas and compensate sales representatives for their success at increasing market share on a physician by physician basis. *Id.* at 9. None of the activities communicate with consumers or the general public and therefore none are speech protected by the First Amendment.

Modern First Amendment doctrine accords accurate and non-misleading commercial advertising a lesser degree of protection to serve an “informational function.” *Central Hudson*, 447 U.S. at 563. This function of contributing accurate and

² As described more fully in Section II, below, patients are identified and tracked by the records despite their names having been encrypted.

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 Credit Council, Inc.*, 425 U.S. 748, 765 (1976); see *First Nat’l Bank v. Bollotti*, 435 U.S. 765, 783 (1978) (“the 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”).

The protection of speech for its information function is primarily concerned with “public speech.” *Dun & Bradstreet*, 472 U.S. at 761 n. 7. Such speech contributes to the “free trade in ideas” that Justice Holmes described as “the best test of truth.” *Abrams v. United States*, 250 U.S. 616, 630 (Holmes, J., dissenting). But commercial purchases and uses of information in purely private commercial settings contributes few raw materials to the public sphere while at the same time being less subject to the cleansing power of the marketplace of ideas. Thus, the commercial speech doctrine allows more state regulation designed to thwart potentially misleading speech the more the communication in question takes place outside of the light of public debate. See *Zauderer v. Office of Disciplinary Counsel of Sup. Ct. of Ohio*, 471 U.S. 626, 642 (1985) (explaining that more regulation is permitted of in-person solicitation than of print advertising because the latter “poses much less risk of overreaching or undue influence”

because it is “more conducive to reflection and the exercise of choice on the part of the consumer than is personal solicitation”).

Commercial use of information that does not communicate with consumers is not speech protected by the First Amendment. The Court opined in *Ohralik*, for instance, that there are “[n]umerous examples . . . of communications that are regulated without offending the First Amendment,” listing several examples of commercial communication not made to consumers or the public: “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.” 436 U.S. at 456. Similarly, the Court in *Bartnicki* distinguished between the section of a law prohibiting the “naked disclosure” of intercepted communications, which it held to be “pure speech,” and the “use” of that same information to chart commercial strategy or other commercial purposes, which the court held to be “conduct.” 532 U.S. at 526-27. 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. The development and evaluation of commercial products and strategies, although they may be related to and intertwined with public advertising, are not themselves communication to the public. The First Amendment does not protect every activity that may shape a commercial advertising message – it only protects the message itself. See *Wine and Spirits Retailers, Inc. v. State of Rhode*

Island, 418 F.3d 39, 49 (1st Cir. 2005) (holding that franchise law limitation of corporate relations for “provision of advertising services” regulated conduct, not speech).

The regulated activity of Respondents in this case uses information in ways that neither serve the public informative interests of the First Amendment, nor is policed by the open scrutiny of public examination. The Respondents do not seek a right to share this information with consumers – either doctors or patients. Rather they seek a right to use the information to target marketing. The messages in targeted marketing appeals deserve more limited First Amendment protection than those in more diffused forms of advertising. *See Florida Bar v. Went For It*, 515 U.S. 618, 630 (1995) (“an untargeted letter to society at large is different in kind” from an individually targeted solicitation). But the use of information to create the targeted lists themselves deserves no First Amendment protection at all. *See* Neil Richards, *Reconciling Data Privacy and the First Amendment*, 52 UCLA L. Rev. 1149, 1165-82, 1190 (2005); Daniel J. Solove, *The Virtues of Knowing Less: Justifying Privacy Protections Against Disclosure*, 53 Duke L. J. 967 (2004); Julie E. Cohen, *Examined Lives: Informational Privacy and the Subject as Object*, 52 Stan. L. Rev. 1373, 1414 (2000) (arguing against heightened First Amendment scrutiny for regulation of the trade of personal data as “a tool for processing people” rather

than as a “vehicle for injecting communication into the ‘marketplace of ideas’”).³

Respondents go beyond the commercial speech doctrine, arguing that they are “publishers” that deserve protection for their activity equivalent to that due for the Wall Street Journal’s publication of stock quotes. Resp’t IMS Cert. Br. at 13; *IMS Health, Inc. v. Sorrell*, 2010 U.S. App. LEXIS 24053, at *6-7, n.2 (2d. Cir., Nov. 23, 2010). As described in section I(B) below, even if they were publishers they would lack a right to access confidential medical records for their publication activities. But their analogy obscures a key difference between their activities and those of public media outlets: the facts newspapers report, although sold for payment and profit, are contributions to the public domain. Copyright law restricts the copying of the expression itself, but “does not shield any idea or fact contained in the copyrighted work;” “[a] reader may make full use of any fact or idea she acquires from her reading.” *Eldred v. Ashcroft*, 537 U.S. 186, 197, 217 (2003) (internal citations omitted). Such reporting, therefore, contributes information that the wider public may use for discussion, commentary, and

³ Even critics of the general notion of data privacy laws generally support laws like Vermont’s that serve the constitutional value of ensuring a willing speaker by creating and enforcing implied contracts that certain kinds of data will not be traded without consent, Eugene Volokh, *Freedom of Speech and Information Privacy: The Troubling Implications of a Right to Stop People From Speaking About You*, 52 Stan. L. Rev. 1049, 1057-62 (2000), and placing conditions on the use or transfer of data that the government holds or requires, *id.* at 1055.

broad circulation. Not so with the prescription information traded in this case. “Data mining appellants actually *prohibit* their customers from disclosing the data they license to *anyone* else, much less the general public.” *Sorrell*, 2010 U.S. App. LEXIS 24053 at *67 (Livingston, J. dissenting, emphasis in the original). The Respondents are not publishers because they do not deliver their information in a manner that can ever enter public discourse. And because they are not publishers, the higher First Amendment standards applicable to publishers do not apply. *Dun & Bradstreet*, 472 U.S. at 762-63.

It need not be disputed that there are occasions when “[e]ven dry information, devoid of advocacy, political relevance, or artistic expression” may be protected by the First Amendment. *Sorrell*, 2010 U.S. App. LEXIS 24053 at *18-19 (citation and quotation marks omitted). But the use and trade of such information in entirely private settings, as a product rather than for any expressive or communicative purpose, serves no First Amendment value. *Sorrell*, 2010 U.S. App. LEXIS 24053 at *65-66 (Livingston, J. dissenting). As with the restricted trade in credit report information at issue in *Dun & Bradstreet*, there “is simply no credible argument” that the trade in prescription drug records “requires special protection to ensure that debate on public issues will be uninhibited, robust and wide open.” 472 U.S. at 762; see *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”).

Fundamentally, the conduct of the Respondents with the personally identified information at issue in this case is not speech because their commercial trade and use of confidential information is deliberately tailored to never inform the public sphere.

B. Prescription Records are Not Public Information.

The regulated prescription data mining activities lack First Amendment protection for an additional reason – the records Respondents seek to access are not public information.⁴ Recognition of a right to access and use information in such records would force patients and doctors to release information without their consent and therefore would implicate the “freedom not to speak publicly.” *Harper & Row Publishers, Inc. v. Nation Enterprises, Inc.*, 471 U.S. 539, 559 (1985); see *Riley v. Nat’l Fed’n of the Blind of N.C., Inc.*, 487 U.S. 781, 795-98 (1988).

Prescription records would not exist but for state laws preventing patients from filling

⁴ Respondents seek to artificially sever their purchase of the data from the pharmacies’ acquisition of the data in their role as government-regulated dispensers of controlled substances. They dispute that they seek a right “to access” government mandated records, describing their claim instead as one “to purchase” them. IMS Cert. Pet. at 20. This appears to be a distinction without a difference.

prescriptions without providing personal information. *Sorrell*, 2010 U.S. App. LEXIS 24053 at *58 (Livingston, J. dissenting). It is not disputed that, had the pharmacists and other holders of prescription records been government entities, there would be no right of the Respondents to access those records over government imposed restrictions. *United Reporting*, 528 U.S. at 40; *see also Florida Star v. B.J.F.*, 491 U.S. 524, 532, 537 (1989) (although state could not punish public disclosure of names of rape victims in public records, it could prohibit the records from being released); *Houchins v. KQED, Inc.*, 438 U.S. 1, 15-16 (1978) (affirming no right to “sources of information under government control”); *Cox Broadcasting Corp. v. Cohn*, 420 U.S. 469, 496 (1975) (states may regulate “exposure of private information”). Notably, the validity of such restrictions holds regardless of whether the recipients at issue are “publishers.” *Id.* Even the public media lacks a First Amendment right to access confidential information from government records.

The majority in the Second Circuit held that the outcome is different in this case because the holders of the information are private entities, not offices of government. *Sorrell*, 2010 U.S. App. LEXIS 24053 at *22-23. But that distinction was rejected in *Seattle Times Co.*, where the Court upheld a restriction on the dissemination of information from one private party to another “pursuant to a court order that both granted him access to that information and placed restraints on the way in which the information might be used.” 467 U.S. at

32. The Vermont law similarly grants pharmacies and other health care providers access to prescription information only with accompanying restraints on the purposes for which the information can be used.

The *Sorrell* majority opinion's distinction between the public or private nature of the holder of government-mandated information would lead to the absurd consequence of requiring, as a matter of constitutional law, dramatically different confidentiality laws for government-required educational, health, prison and other records depending on whether the service provider was public or private. *Sorrell*, 2010 U.S. App. LEXIS 24053 at *59-60 (Livingston, J. dissenting). The relevant distinction is not whether the holder of the record is part of government but rather whether the holder, public or private, is a recipient of the information only by virtue of a government requirement. Here, pharmacies possess prescription records because Vermont law requires them as a condition for accessing essential medical care. Vermont is therefore free to place secondary distribution restrictions on those same records.

C. Respondents' Theory Would Threaten a Complex Web of State and Federal Personal Information Privacy Protections.

Respondents' theory that strict scrutiny is warranted for any government regulation of the sale or use of truthful information or that "discriminates" between the "viewpoint" of commercial marketers

and other speakers, IMS Cert. Br. at 1, 10, 13, would threaten a massive amount of regulatory law, including every information confidentiality law in the nation.

Every confidentiality protection, from those protecting grand jury identities to the many rules foreclosing commercial uses of medical, financial, and other records, suppress the free flow of true information. Vermont's prescription privacy law is similar to a great body of regulations at every level of government that restrict secondary uses of personal information from marketing and other uses. Such laws are particularly prevalent in telecommunications, financial services, home entertainment, credit reporting, employment, medicine, and with respect to government held information. Paul M. Schwartz & Joel R. Reidenberg, *Data Privacy Law: A Study of United States Data Protection* 132-34, 229-230, 243-249, 270-273, 292-295, 317-323, 354-55, 370, 1998 Supp. 24-35, 35-45 (1996). *See also* Daniel J. Solove, *A Taxonomy of Privacy*, 154 U. Pa. L. Rev. 477, 526-30 (2006); Daniel J. Solove & Paul M. Schwartz, *Information Privacy Law* 715-824 (3rd ed. 2008); Solove, *The Virtues of Knowing Less*, *supra*, at 971-72.

The distinction Vermont's law makes between the treatment of commercial marketing and other uses of prescription data is not unconstitutional viewpoint discrimination. This distinction reflects this Court's doctrine and approval of prior information confidentiality laws. The law is carefully

tailored to focus its restrictions on the kinds of “uses” of private information that the Court has identified as “a regulation of conduct,” while avoiding broad prohibitions of “disclosure” which the Court has held to be a regulation of “pure speech.” *Bartnicki*, 32 U.S. at 527-28. The statute is also constructed to carefully parallel confidentiality laws previously upheld by this Court in *United Reporting*, 528 U.S. at 35 (allowing government mandated records to be used for “a scholarly, journalistic, political or governmental purpose,” but not “used directly or indirectly to sell a product”) and *Reno*, 528 U.S. at 148 (upholding under Commerce Clause scrutiny prohibition of recipients of regulated information from using it for prohibited purposes, including “marketing”). Accepting the Respondents’ theory would call into question these previously approved laws and the great body of restrictions on the secondary uses of personal information for marketing purposes. *See, e.g.*, Gramm-Leach-Bliley Act, 15 U.S.C. § 6802(d) (banning use of financial information for “marketing”).

In addition to striking down a host of current laws, the Respondents’ proposal would halt the development of data privacy standards in the U.S. at a time when they are at their infancy. The entire field of informational privacy law is relatively new, dating from the 1970s and the growth of computer technology. Harry Henderson, *Privacy in the Information Age* 117-30 (2006) (listing privacy law chronology). The current state of the law in the U.S. is “a complex patchwork of laws and regulations, administrative decisions, court orders, constitutional

rights, and state laws,” A.B.A. Privacy & Computer Crime Comm. Section of Sci. & Tech. Law, *Int’l Guide to Privacy* xx (2004), largely focused around “narrow rights addressing discreet issues.” Schwartz & Reidenberg, *Data Privacy Law*, *supra*, at 215. There is a sharp contrast between this patchwork of laws and the modern reality of life that creates a trail of identifiable data connected to everything we do and everywhere we go. See Robert O’Harrow, *No Place to Hide* 34-73 (2006); see also Sharona Hoffman and Andy Podgursky, *Information Security of Health Data: Electronic Health Information Security and Privacy*, in *Harboring Data: Information Security, Law and the Corporation* (2009). This state of affairs has led to a vibrant and active debate in policy spheres as to what the ideal set of information privacy rights should be in our modern networked world. See, e.g., Sen. Franken to Chair New Subcommittee on Privacy, Technology and the Law (Feb. 14, 2011) http://www.franken.senate.gov/?p=press_release&id=1315; Daniel J. Solove, *The New Vulnerability: Data Security and Personal Information*, in *Securing Privacy in the Internet Age* (2008); Daniel J. Solove & Chris Jay Hoofnagle, *A Model Regime of Privacy Protection*, 2006 U. Ill. L. Rev. 357 (2006); Stanford Law Review Symposium on Information Privacy, 52 Stan. L. Rev. (2000); Mike Hatch, Minn. Attorney General, *The Privatization of Big Brother: Protecting Sensitive Personal Information From Commercial Interests in the 21st Century*, 27 Wm. Mitchell L. Rev. 1458 (2001). A First Amendment right to sell and use for any purpose any information a company

transitorily possesses in the course of business would foreclose this entire debate.

This case does not require the Court to decide on the First Amendment application to the full range of data privacy regulations that exist or are being pondered by the policy-making branches. The facts of this case deal with the much narrower question of the ability of governments to regulate the re-use of highly personal information produced under governmental disclosure mandates. The Court should make clear that the First Amendment is not implicated when, having mandated the disclosure of medical information, the state protects that confidential information from non-consensual marketing uses.

II. STATES HAVE OVERRIDING INTERESTS IN MAINTAINING THE CONFIDENTIALITY OF PRESCRIPTION RECORDS.

Ultimately the determination of every First Amendment case involves the application of a balancing test and the jurisprudential work is done in determining the weights due each side of the scale. As argued above, this case does not fit into any of the fact patterns that would trigger intermediate scrutiny under the traditional commercial speech doctrine. To the extent that any commercial speech is affected by the law, it must only be afforded protection “commensurate with its position in relation to other constitutionally protected expression.” *Lorillard Tobacco Co. v. Reilly*, 533 U.S.

525, 553 (2001). Here, the effect on the speech is indirect and it applies only to commercial speech that takes place in in-person solicitations. *See Zauderer*, 471 U.S. at 641-42. Because Vermont has carefully tailored its law to regulate only conduct related to the trade in medical records rather than any speech, its law should be subject to a rational basis inquiry. Nonetheless, there is substantial evidence in the record that the law serves interests of the highest order. These include the “Constitutional privacy interest” in safeguarding personal information in state-mandated records, *NASA*, 562 U.S. ___ (2011)(Slip op. 1), protecting the efficacy and efficiency of its public health system from undue influence of pharmaceutical marketing, and promoting standards of conduct within the licensed professions.

A. Vermont’s Prescription Privacy Law Directly Advances Its Interest in Protecting Information Privacy.

Vermont’s law is a medical record confidentiality law. As such, the core interest it expresses is one in information privacy. This Court recently reaffirmed that protecting the privacy of information in government mandated records is a constitutional interest of governments. *NASA v. Nelson*, 562 U.S. __ (2011) (Slip op., 19-20). Although the Court has not expressly held this interest to be a right protected by the Due Process Clause, it has clearly affirmed its nature as a high-order justification for state regulation. *See id.* (Scalia, J. dissenting) (Slip op. at 1) (affirming interest of governments “to enact those laws, to

shape them, and when they think it is appropriate, to repeal them”); *Whalen*, 429 U.S. at 605-06; *Nixon v. Adm’r of Gen. Servs.*, 433 U.S. 425, 457-58 (1977). Vermont directly serves the Court’s articulation of at least two different kinds of information privacy interests: one, “the individual interest in avoiding disclosure of personal matters;” the other, “the interest in independence in making certain kinds of important decisions.” *Whalen*, 429 U.S. at 599-600.⁵

1. Vermont Protects Against the Disclosure of Personal Matters.

Vermont serves a vital interest in protecting patients from disclosure of their medical records. The Respondents claim that there are no patient privacy interests in the disclosure of prescription records because patient identities are encrypted at the pharmacy’s office prior to their transfer to the data mining and pharmaceutical marketing firms. *See Ayotte*, 550 F.3d at 45 (describing encryption practice). But the encryption of patient names is not sufficient to guard the patient’s interest against disclosure of personal matters.

Because medical records contain incredibly intimate details of personal life, patients have a strong privacy interest in avoiding their disclosure

⁵ For scholarship on the autonomy and dignity interest underlying informational privacy protections *see* Solove, *Taxonomy*, *supra*, at 522, Cohen, *supra*, at 1423-28; Jed Rubenfeld, *The Right of Privacy*, 102 Harv. L. Rev. 737, 753 (1989).

“[e]ven if there were no possibility that a patient’s identity might be learned.” *Northwestern Mem’l Hosp. v. Ashcroft*, 362 F.3d 923, 929 (7th Cir. 2004). In this case, it is not true that patient identities cannot be learned. As the EPIC *Amicus Curiae* Br. explains in detail, it is relatively easy to re-identify records with the amount of information that the respondents track.

Indeed, the data mining companies do not meaningfully de-identify the records at all. They encrypt the name of the patient, but attach to each an individual identifier to “track the patient over time.” Pet. Br. at 7. While names are encrypted, patient identifying numbers are permanent, allowing information to be linked across multiple information sources to build incredibly detailed portraits of individual patients, including the date and place that every prescription is filled and the patient’s age and gender. *IMS Health, Inc., v. Sorrell*, 631 F. Supp. 2d 434, 441 (D. Vt. 2009). IMS marketing materials display that they are also able to track the “diagnosis,” “ethnicity,” “address” and “insurance ID” for millions of patients, which can be used to monitor individual patient responses to direct to consumer advertising, “all the while remaining anonymous to avoid re-identification.” IMS Health, Inc, *LifeLink*, available at <http://www.imshealth.com/portal/site/imshealth/menutem.a953aef4d73d1ecd88f611019418c22a/?vgnextoid=9826f8731739b110VgnVCM100000ed152ca2RCRD&vgnnextfmt=default>; *Evaluating Relationship Marketing Programs* <http://www.imshealth.com/imshealth/Global/Content/Document/LifeLink/Evalu>

ating_Relationship_Marketing_Programs.pdf. Even without identifying physician names, this level of detail in the tracking of individuals implicates patients' interests in not having their personal information disclosed.⁶

The patient interest in avoiding disclosure is magnified by the linking of patient information with physician identifiers. Such linking of information allows pharmaceutical marketers to track individual patient treatment so that they can respond, to the patient's doctor, to any change in that treatment not in accord with the company's pecuniary interest. *Pet. Br.* at 9. (describing the use of anonymous patient data to send marketers email alerts for any shift in a patient's prescription). The Court should affirm that protecting against such practices legitimately and directly advances the constitutional interest in avoiding medical information disclosures articulated in *Whalen*. 429 U.S. 589.

2. Vermont Protects the Independence of Prescribing Decisions.

Vermont's regulation of the use of prescription data for marketing purposes serves a second information privacy interest – that of protecting “independence in making certain kinds of important

⁶ Indeed, the level of patient detail tracked by the Respondents appears to violate HIPAA. 45 C.F.R. §164.502(d)(1) (2006) (requiring that patient level data be stripped of numerous personal identifiers, including “subdivisions smaller than a state” and “all elements of date except year”).

decisions.” *Whalen*, 429 U.S. at 599-600. This is a core interest of all medical confidentiality laws. We protect the confidentiality of the physician-patient relationship because we want medical decisions to be based solely on the independent judgment of the doctor about the best interests of the patient.

Prescription tracking for marketing purposes is designed to influence the independence of prescribing decisions “to drive profitable brand growth.” 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. As described more fully below, the social scientific evidence is overwhelming that the interests of the physician-patient relationship and the pecuniary interest of brand growth are frequently at odds. *Sorrell*, 631 F.Supp. 2d at 449-52. The evidence is also overwhelming that influence of marketing is intruding on the autonomy of decisions as measured by adherence to public health clinical guidelines and objective appraisals of best evidence. *Id.* Vermont reasonably concluded that such evidence displays the presence of undue influence of marketing, which is increased with access to confidential prescription records, and which harms the independence of medical decision making. Responding to such implications of confidentiality breaches is an interest of the highest order. *Whalen*, 429 U.S. 589.

- B. Vermont Directly Advances Its Interest in Controlling Undue Influence and Misleading Communication in Pharmaceutical Marketing that Raise Costs, Harm Health, and Damage Professional Standards.**
- 1. Prescription Data Mining Accelerates and Incentivizes Undue Influence and Misleading Marketing.**

Respondents claim that Vermont's law must be struck down because the legislative findings express an intention to respond to an information "marketplace" that "is frequently one-sided" and that leads "doctors to prescribe drugs based on incomplete and biased information." *Sorrell*, 2010 U.S. App. LEXIS 24053 at *15 (internal citations and quotation marks omitted). There is some question as to whether these findings relate to the data privacy provisions at issue or to a section of the same law that was later repealed. Amicus Curiae NEJM Br. But even if accepted as applying to the challenged law, they do no more than articulate interests in curbing undue influence and misleading commercial speech that the Court has long identified as substantial state interests.

Perhaps the key difference between the First Amendment's application to commercial speech restrictions and that applied to core speech is that in the former context the state can permissibly take

prophylactic measures to control communications that may be misleading or deceptive. *Va. Pharmacy* at 772; *Milavetz, Gallop & Milavetz, P.A., v. U.S.*, 559 U.S. __ (2010)(Slip op., at 20), *Edenfield v. Fane*, 507 U.S. 761, 769 (1993); *Ohralik.*, 436 U.S. at 457-58; Robert Post, *The Constitutional Status of Commercial Speech*, 48 U.C.L.A. L. Rev. 1, 26-34 (2001). This interest is heightened when the communication at issue takes place in the dark – in in-person exchanges, *Ohralik*, 436 U.S. 447 and through contracts bound to secrecy, *Dun & Bradstreet*, 472 U.S. 749. In such settings, the ability of the marketplace of ideas to play a cleansing role is diminished as is the contribution to public discourse the First Amendment seeks to foster. At the same time, the opportunity for and potential influence of misleading information is increased. For this reason, and particularly where there is evidence of the occurrence of misleading advertising, the Court has recognized an interest of governments to combat “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. These are almost precisely the terms that Vermont used in its legislative findings.

Vermont’s legislative findings clearly articulate the conclusion that in-person pharmaceutical detailing guided by access to prescription histories is exerting an undue influence on doctors by misleading them as to the true costs and risks of medicines. *See* S. 115, 2007 Leg. Reg. Sess. (Vt. 2007) (enacted) (Leg. Finding 4) (data

mining and detailing “leads to doctors prescribing drugs based on incomplete and biased information”); (Leg. Finding 7) (data mining and detailing lead to an irrational 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.”). The District Court similarly found that the litigation and legislative history records establish that prescription data “amplifies the influence and effectiveness of detailing” at convincing doctors to shift patients to new treatments that are more expensive, but not necessarily more effective, than generic equivalents, and that harm patients through irrational prescribing and increased risks associated with newer medicines. *Sorrell*, 631 F. Supp. 2d at 451-54.

The evidence of the occurrence of misleading speech in pharmaceutical detailing is voluminous. One can begin with the steady trend toward increasing criminal convictions and civil fines for false and misleading marketing. Public Citizen, *Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry: 1991 to 2010*, (Dec. 16, 2010); C. Seth Landefeld and Michael Steinman, *The Neurontin Legacy – Marketing through Misinformation and Manipulation*, 360 NEJM 103 (2009); Memorandum from Henry Waxman, to Democratic Members of the Gov’t Reform Committee, on the Marketing of Vioxx to Physicians (May 5, 2005). Empirical studies have shown that a large number (eleven percent) of observed statements by detailers to doctors were demonstrably false, but that only twenty six percent of

doctors could detect these false messages. *Ayotte*, 550 F.3d at 56, citing Michael Ziegler, et al., *The Accuracy of Drug Information from Pharmaceutical Sales Representatives*, 273 JAMA 1296 (1995).⁷

That such cases are not mere “bad apple” exceptions is evidenced by the numerous empirical studies documenting that higher exposure to in-person detailing measurably increases irrational prescribing behavior as measured by adherence to clinical guidelines and the best evidence. See David Orentlicher, *Prescription Data Mining and the Protection of Patient Interests*, 38 J.L. Med. Ethics 74 (2010); Geoffrey Anderson, et al., *Newly Approved Does Not Always Mean New and Improved*, 299 JAMA 1598 (2008); Abigail Caplovitz, *Turning Medicine Into Snake Oil: How Pharmaceutical Marketers Put Patients at Risk*, NJPIRG Law & Pol’y Center 5 (2006); David Blumenthal, *Doctors and Drug Companies*, 251 NEJM 1885 (2004); Puneet Manchanda & Elisabeth Hokna, *Pharmaceutical Innovation and Cost*, 5 Yale J. Health Pol’y L. & Ethics 785, 797-808 (2005) (reviewing studies); Michael Fischer & Jerry Avorn, *Economic Implications of Evidence-Based Prescribing for Hypertension: Could Better Care Cost Less*, 291 JAMA 1850, 1854 (2004); Jerry Avorn, *Powerful Medicines* 202 (rev. 2005).

⁷ A similarly high occurrence of misleading statements has been observed in pharmaceutical marketing publications. 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).

The extent of influence of this marketing can be further inferred from its frequency and cost. *Sorrell*, 631 F. Supp. 2d at 442 (finding that “[c]oincident with the phenomenon of ‘data mining,’ pharmaceutical industry spending on direct marketing has increased exponentially”); *Ayotte*, 550 F.3d at 47 (“the average primary care physician interacts with no fewer than twenty-eight detailers each week and the average specialist interacts with fourteen”); *Sorrell*, 631 F. Supp.2d at 441 (industry spends \$8 billion a year on direct in-person marketing to physicians); *Ayotte*, 550 F.3d at 56 (“The fact that the pharmaceutical industry spends over \$4,000,000,000 annually on detailing bears loud witness to its efficacy”); Manchanda, *supra*, at 785 (noting that pharmaceutical industry spends more on its sales force than any other industry).

Respondents argue that Vermont cannot have an interest in combating misleading speech and undue influence in pharmaceutical marketing because physicians are “highly trained.” IMS Cert. Pet. at 22. Although the sophistication of the target of marketing is a valid consideration in assessing the state’s interest in combating misleading commercial speech, it is clear that doctors are highly susceptible to misleading pharmaceutical detailing in its present setting. Studies show that prescribing doctors erroneously discount the effects of marketing on their prescribing habits, Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 JAMA 373, 375 (2000); Blumenthal, *Doctors and Drug Companies*, *supra*; Michael Steinman, et al., *Of Principles and Pens: Attitudes and Practices of*

Medicine Housestaff Towards Pharmaceutical Industry Promotions, 110 Am. J. Med. 551 (2001), have low awareness of the cost of the medicines they prescribe, G. Michael Allan, et al., *Physician Awareness of Drug Cost*, 4 PLOS Medicine 1486 (2007), generally trust the messages delivered by detailers, Melissa Fischer et al., *Prescribers and Pharmaceutical Representatives: Why Are We Still Meeting?*, 24 J. Gen. Inter. Med. 795, 797 (2009), and are very poor at detecting false and misleading messages within sales pitches. Ziegler, *supra*, at 1296.

Even if the commercial speech doctrine were applied, it would not disable Vermont from acting in response to these clear showings of public need.

2. Prescription Data Mining Increases Health Care Costs and Hurts Patients.

Undue influence by pharmaceutical marketing results in enormous costs to society that states have a vital interest in controlling. These costs are measured not only in dollars, but in the degradation of public health that flows from increased prescribing of drugs that are less effective, and sometimes harmful, to patients.

The Vermont legislation detailed many of these findings in its law. After documenting the presence of undue influence of marketing, the legislature found that these practices come “at the expense of cost-containment activities,” (Leg.

Finding 3) and “contribute[] to the strain on health care budgets for individuals as well as health care programs”(Leg. Finding 15). These findings are well supported in the record.

There is little debate that cost care concerns of states are real and substantial. As the district court noted, U.S. spending on prescription drugs has been increasing at higher rates than inflation over the last decade while the number of prescriptions has risen far less dramatically. *Sorrell*, 631 F. Supp. 2d at 449-50, n.12. This evidences the steady shift in prescribing toward more expensive medicines which, in turn, is driven by the influence of marketing. *Id*; see National Institute for Health Care Management, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs* (revised May 6, 2002); NIHCM Foundation, *Factors Affecting the Growth of Prescription Drug Expenditures*, (July 1999) available at <http://www.nihcm.org/pdf/issuebrief.PDF>.

There are many examples of the successes of our super-charged pharmaceutical marketing system at shifting massive amounts of prescriptions toward newer, more expensive drugs that do not benefit patients. One study included in the legislative history showed that using highly-marketed branded medicines for high blood pressure instead of less expensive generic therapies rated as *more effective* by national treatment guidelines increased U.S. health costs by \$3 billion in 1996. Robert Cardarelli, John Licciardone & Lockwood Taylor, *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, 14 (2006). Another study found that approximately forty percent of Pennsylvania Medicare patients on antihypertensive therapy were being prescribed medications at odds with clinical guidelines at an additional cost of \$1.2 billion per year when calculated nationally. Fischer, *supra*, 291 JAMA at 1854.

A similar effect can be seen in the incredible marketing push and resultant prescription surge for Vioxx, Celebrex, 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. Harlan Krumholz, et al., *What Have We Learnt From Vioxx?*, 334 BMJ 120, 120-123 (2007). And in the case of Vioxx, aggressive marketing using prescriber data helped facilitate the widespread adoption of a drug that was far more dangerous to patient health than existing alternatives or than the company's marketing messages admitted. *Id.* Overall, the evidence is clear: after interactions with sales representatives physicians are more likely to prescribe newer and more expensive drugs over generic alternatives, even when the alternative would be as good or better than the more expensive drug. *See Wazana, supra*, at 373-380.

These undue influences harm public health. As the district court found, the record demonstrates that marketing with access to prescription records

encourages the prescription of newer and “potentially more dangerous drugs instead of adhering to evidence-based treatment guidelines.” *Sorrell*, 631 F. Supp. 2d at 453. 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 based on the affordability of the medication, Becky Briesacher, et al., *Patients At-Risk for Cost-Related Medication Nonadherence*, 22 J. Gen. Internal Med. 864, 864 (2007), which in turn contributes to higher costs on the health system through increased hospitalizations and sub-optimal treatment. Michael Sokol, et al., *Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost*, 43 Med. Care 521, 525-28 (2005).

3. Physician-Identifiable Data Increases Ethical Pitfalls of Physician-Industry Interactions.

Vermont’s law also furthers its “special responsibility for maintaining standards among the members of licensed professions,” *Ohralik*, 436 U.S. at 460, including among physicians and pharmacists.

Prescriber profiling is used to reinforce pecuniary and other relationships between physicians and pharmaceutical companies which threaten the ethical standards of the profession and jeopardize their relations with patients. See Susan Chimonas, et al., *Physicians and Drug Representatives: Exploring the Dynamic of the*

Relationship, 22 J. Gen. Intern. Med. 184, 188-89 (2007); Susan Coyle, *Physician-Industry Relations, Part 1*, 136 Annals of Internal Med. 396, 400 (2002). Prescription histories allow marketing representatives to identify their best and worst prescribers and tailor rewards or pressure accordingly. Waxman, *supra*, at 13 (revealing Merck graded doctors from A+ to D based on how reliably they prescribed Merck products); Public Citizen, *Response to FDA Request for Comments on First Amendment Issues*, Sept. 13, 2002, available at <http://www.citizen.org/publications/release.cfm?ID=7199> (detailing the use of prescription data to reward doctors for off-label prescribing of Neurontin). Ninety-four percent of all doctors routinely receive gifts of significant value, such as meals and free drug samples. Eric Campbell, et al., *A National Survey of Physician-Industry Relationships*, 356 New Eng. J. Med. 1742, 1742, 1746 (2007). These gifts are guided by access to prescription data, Carl Elliott, *The Drug Pushers*, The Atlantic, 82, 90-91 (Apr. 2006), and create powerful psychological urges to reciprocate, Jason Dana & George Lowenstein, *A Social Science Perspective on Gifts to Physicians from Industry*, 290 JAMA 252, 253 (2003); Dana Katz, et al., *All Gifts Large and Small*, 3 Am. J. Bioethics 39, 39-41 (2003). Physicians whose prescribing behavior is especially favorable to companies may receive tens, even hundreds of thousands of dollars for consultancies and lectures each year. Adriane Fugh-Berman & Shahram Ahari, *Following the Script: How Drug Reps Make Friends and Influence Doctors*, 4 PLoS Med e150 (2007); Joseph Ross, et al., *Pharmaceutical*

Company Payments to Physicians, 297 JAMA 1216, 1219-20 (2007).

This perversion of the pecuniary incentives in medical care debases the medical profession and, as the practice becomes more public, breaks the chain of trust between doctor and patient. Robert Gibbons, et al., *A Comparison of Physicians' and Patients' Attitudes Toward Pharmaceutical Industry Gifts*, 13 J. Gen. Internal Med. 151, 152-53 (1998); Gardiner Harris & Robert Pear, *Drug Maker's Efforts to Compete in Lucrative Insulin Market are Under Scrutiny*, N.Y. Times, Jan. 28, 2006. Vermont has a vital interest in setting high standards in the medical professions that ensure patient trust and ethical dealing by health care providers, including by ensuring medical record confidentiality.

CONCLUSION

For the foregoing reasons, *amici* respectfully urge that the judgment below be reversed.

March 1, 2011

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