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

THE NEW ENGLAND JOURNAL OF MEDICINE,
THE VERMONT MEDICAL SOCIETY,
THE MASSACHUSETTS MEDICAL SOCIETY,
THE NEW HAMPSHIRE MEDICAL SOCIETY,
THE NATIONAL PHYSICIANS' ALLIANCE, AND
THE AMERICAN MEDICAL STUDENTS ASSOCIATION,

AS *AMICI CURIAE* IN SUPPORT OF APPELLEES, URGING AFFIRMANCE

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IDENTITY OF *AMICI CURIAE*

The ***New England Journal of Medicine*** (NEJM) is the oldest continuously published medical journal in the world, and has published numerous scholarly articles on, among other things, advances in drug therapy, prescription drug side effects, and the role of the United States Food and Drug Administration and the pharmaceutical industry in our health care system. For nearly 200 years, physicians have turned to our journal as a source of important new information to guide their medical practice.

The **Vermont Medical Society** (VMS) was incorporated by an Act of the Vermont Legislature on November 3, 1813, but traces its roots back to October of 1784 when the "First Medical Society of Vermont" was recognized by the General Assembly of the Republic of Vermont. We are the largest membership organization of physicians in Vermont. We serve the public by facilitating and enhancing physicians' individual and collective commitments, capabilities and efforts to improve the quality of life for the people of Vermont through accessible and appropriate health care services. We supported the Prescription Privacy Law, and our members and staff testified in the Vermont Legislature about how data mining erodes physician-patient privacy, increases public health risks and increases spending on newer drugs.

The **Massachusetts Medical Society**, with some 22,000 physicians and student members, is dedicated to educating and advocating for the patients and physicians of Massachusetts. We publish the *New England Journal of Medicine*, a leading global medical journal and web site, and Journal Watch alerts and newsletters covering 13 specialties. We are also a leader in continuing medical education for health care professionals throughout Massachusetts, conducting a variety of medical education programs for physicians and health care professionals. Founded in 1781, we are the oldest continuously operating medical society in the country.

The **New Hampshire Medical Society** (NHMS) was incorporated in 1791. We bring physicians together to advocate for the well being of our patients, for our profession, and for the betterment of the public health. We envision a State in which personal and public health are a high priority, all people have access to quality healthcare, and physicians experience deep satisfaction in the practice of medicine. We supported the prescription privacy law in New Hampshire that was upheld by the First Circuit in *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163 (D.N.H. 2007).

The **National Physicians Alliance** (NPA) is a membership organization of physicians across specialties throughout the United States who seek to restore physicians' primary emphasis on the core values of our profession: service,

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The **American Medical Student Association** (AMSA) is the oldest and largest independent association of physicians-in-training in the United States, with more than 62,000 members. Founded in 1950, AMSA is a student-governed, non-profit organization representing the concerns of physicians-in-training. Our PharmFree Campaign advocates for evidence-based rather than marketing-based prescribing practices, the removal of conflicts of interest, and global access to essential medicines.

INTERESTS OF THE *AMICI CURIAE*

The *Amici Curiae* have obtained consent to file this brief from both the State and the appellants.

SUMMARY OF THE ARGUMENT

The Prescription Privacy Law protects the physician-patient relationship against unwanted invasions of privacy. Data mining of prescriber-identifiable (PI) medical records offends the privacy of the physician, but also permits companies to identify particular patients against their wishes. Data mining assists drug companies in illegal off-label promotion by identifying both high and low prescribers for promotional attention. Data mining has also supported the promotion of dangerous drugs. In addition to the privacy concerns, these practices are dangerous and raise health care costs.

The Prescription Privacy Law is part of a larger statutory framework of state and federal laws protecting medical privacy. Federal law has carved out a special role for state medical privacy laws, protecting them from federal preemption. Furthermore, the First Amendment does not protect speech when the underlying data was obtained illegally. Vermont satisfies the *Central Hudson* test and the Prescription Privacy Law should be upheld.

The First Amendment does not require this Court to overturn the legislative determination by the elected government of Vermont, especially when the State has extensive experience as a health care payor and is well versed in cost control options. Moreover, the Prescription Privacy Law does not ban data mining, but leaves this important decision in the hands of the person best able to decide

whether it helps the patient or not – the prescribing physician.

The *Amici Curiae* are leading organizations representing and educating physicians and medical students. We have followed these issues carefully for a number of years. We urge this Court to agree with Vermont, and leave the data mining decision to physicians.

ARGUMENT

I. Data Mining Weakens the Physician-Patient Relationship

A. Data Mining Invades Medical Privacy

The Vermont Medical Society unanimously resolved: "the use of physician prescription information by sales representatives is an intrusion into the way physicians practice medicine." Vermont Medical Society Resolution, Ensuring the Privacy of Prescription Information (Oct. 14, 2006) A-4197, quoted in 2007 Vt. Acts & Resolves, No. 80 § 1(20). This Resolution also stated: "the doctor-patient relationship requires confidentiality and privacy to work effectively." *Id.* *See also* Grande & Asch, *Commercial Versus Social Goals of Tracking What Doctors Do,* 360 New Eng. J. Med. (Feb. 2009);

Editorial, *Prescriber Profiling: Time To Call It Quits*, 146 Annals Int. Med. (2007).

Plaintiffs do not deny that prescriber-identifiable (PI) medical records show the intimate details of physicians' prescribing patterns for their patients. In Vermont, "in small communities identifying a drug prescription can equal release of the individual's diagnosis." Vermont Medical Society Resolution A-4197. Data mining exposes a patient's prescription history (and thus, their underlying medical conditions) to exploitation, allowing companies to match prescriptions with specific patients, even in larger cities. Freudenheim, *And You Thought a Prescription Was Private*, N.Y. Times, August 8, 2009. The Prescription Privacy Law directly protects patient privacy.

PI medical records are sold from pharmacies, health insurers and other intermediaries to the data mining plaintiffs, who then aggregate the data and organize it for sale to customers such as the drug companies that are members of plaintiff PhRMA. In all cases relevant to this litigation, the physician has not consented to this invasion of medical privacy.

The plaintiffs cannot plausibly deny that visits from sales representatives armed with PI data exert a powerful influence on physicians' prescribing practices. Indeed, that is the foundation of the data mining plaintiffs' multi-billion dollar business model. The medical literature confirms

this pervasive influence. Many peer-reviewed studies have demonstrated the substantial effect that detailing has on physician prescribing practices. *See* Moynihan, et al., *Selling Sickness: The Pharmaceutical Industry and Disease Mongering,* 324 BMJ. (April 2002); Campo, et al., *Physicians' Decision Process for Drug Prescription and the Impact of Pharmaceutical Marketing Mix Instruments*, 22 Health Market. Quarterly (Jan. 2005); Manchanda & Honka, *The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review*, 5 Yale J. Health Policy, Law & Ethics (2005); Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?,* 283 JAMA (Jan. 2000); Berndt, et al., *Information, Marketing, and Pricing in the US Antiulcer Drug Market,* 85 Am. Econ. Rev. (May 1995); Lurie, et al., *Pharmaceutical Representatives in Academic Medical Centers*, 5 J. Gen. Internal Med. (May 1990); Steinman, et al., *Characteristics and Impact of Drug Detailing for Gabapentin*, 4 PLoS Med. (April 2007); Campbell, et al., *A National Survey of Physician-Industry Relationships*, 356 New Eng. J. Med. (April 2007).

In short, detailing sells drugs. As the District Court noted:

> "This is the strongest evidence of the important role of PI data in pharmaceutical detailing. Put simply, if PI data did not help sell new drugs, pharmaceutical companies would not buy it." *IMS v. Sorrell,* -- F. Supp. 2d --, 2009 WL 1098474, 11 (D. Vt. April 23, 2009)

B. Data Mining Raises Safety And Cost Concerns

Off-label promotion is a safety issue because the FDA has not approved the drug as safe and effective for the unapproved "off-label" use.[1] Data mining is used extensively in off-label promotion, resulting in many lawsuits and enforcement actions against patent-based drug companies. Kesselheim & Studdert, *Whistleblower-Initiated Enforcement Actions Against Health Care Fraud and Abuse in the United States, 1996 to 2005*, 149 Annals Int. Med. (Sept. 2008); Mello, *Shifting Terrain,* at 1562-63, Table 2; Lurie, et al., *Violations of Exhibiting and FDA Rules at an American Psychiatric Association Annual Meeting*, 26 J. Public Health Policy (Dec. 2005). Pfizer, a member company of plaintiff PhRMA, recently agreed to plead guilty to off-label promotion of prescription drugs and pay a $2.3 billion dollar fine. Rockoff & Kendall, *Pfizer to Plead Guilty to Improper Marketing,* Wall St. J., Sept. 3, 2009. Researchers have also noticed selective publication of data from company-sponsored studies for some drugs, with negative studies being less likely to be published. Drug safety may be compromised by this bias. Turner,

[1] Detailers are supposed to limit their discussions to FDA-approved uses of drugs, the data for which has been reviewed by the FDA regulators and often by outside experts. However, despite these regulations, there is evidence that detailers promote uses of drugs apart from the FDA-approved label (so-called "off-label uses"), which may not have supporting evidence and have not been reviewed by the FDA. Mello, et al., *Shifting Terrain in the Regulation of Off-Label Promotion of Pharmaceuticals*, 360 New Eng. J. Med. (April 2009).

et al., *Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy,* 358 New Eng. J. Med. (Jan. 2008). Data mining permits companies to target specific physicians with such biased information.

PI medical records were used to facilitate the illegal off-label promotion of gabapentin (Neurontin). Landefeld & Steinman, *The Neurontin Legacy – Marketing Through Misinformation***,** 360 New Eng. J. Med. (Jan. 2009); Steinman, et al., *Impact of Drug Detailing*. Significant budgets were allocated for detailing and promotion to physicians who were high prescribers of gabapentin. Steinman, et al., *Narrative Review: The Promotion of Gabapentin: An Analysis of Internal Industry Documents*, 145 Annals Int. Med. (Aug. 2006), at 287, Table 2. These "high prescribers" were identified through data mining.

PI medical records were used to facilitate the illegal off-label promotion of Xyrem, a drug approved for narcolepsy. The physician responsible for the off-label promotion was recruited by a detailer who "had noticed Gleason's high prescription rate for Xyrem in 2003 and hired him to give speeches and visit other physicians to discuss off-label uses of the drug." Mello, et al., *Shifting Terrain*, at 1561. He was hired by the detailers for this study to give similar talks all over the country to targeted physicians. Data

mining was used to identify both the physician-speaker (Gleason) and the audience.

PI medical records are also used to promote dangerous drugs. One such example is rofecoxib (Vioxx). Use of the drug was strongly promoted via detailers' meetings with physicians; data mining allowed Merck to target specific physicians for detailing based on their prescription history. Litigation following the withdrawal of rofecoxib has revealed the existence of elaborate sales training campaigns conducted by Merck (a member of the PhRMA plaintiff) to divert attention away from concerns about the cardiac risk posed by the drug during these detailer/physician meetings. *See* Kesselheim & Avorn, *The Role of Litigation in Defining Drug Risks*, 297 JAMA (Jan. 2007). As a direct result, rofecoxib was used widely as first-line treatment for pain control in many patients, when hidden studies showed that it was no better than established agents such as ibuprofen for controlling pain, had only marginal benefits with respect to gastrointestinal safety, and was associated with increased cardiovascular events. Congressional Report of Rep. Waxman, A-4636-4664 (concluding Merck provided "highly questionable information to physicians" and "used its sales force of thousands to counter growing evidence of concern over the safety of Vioxx"); A-344-346, 348 (Kesselheim). These sales calls were equipped with data mining to see who was and was not

prescribing the drug. Rofecoxib reached over a billion dollars in annual sales quickly after its launch. By the time it was removed from the market nearly 5 years later, many patients were needlessly exposed to substantial cardiovascular side effects. Krumholz, et al., *What Have We Learnt From Vioxx*, 334 BMJ (Jan. 2007).

An additional example of data mining-related safety problems is nesiritide (Natrecor), a medication approved for the treatment of acute exacerbations of congestive heart failure. Nesiritide entered the market in 2001, despite the fact that pre-marketing studies suggested increased rates of kidney failure and mortality among patients who received the drug. The product was immediately marketed by detailers to cardiologists, and sales of the drug reached $400 million in 2004. Its manufacturer helped persuade some cardiologists (with targeting assistance from data mining) to prescribe it for a much wider population of heart failure patients than it was approved for, including outpatients, who were given costly infusions in ambulatory settings. Topol, *Nesiritide – Not Verified*, 353 New Eng. J. Med. (July 2005). There was no evidence supporting the efficacy of nesiritide in these circumstances. Ultimately, in 2005, these off-label prescriptions decreased dramatically when the early findings were publicly re-analyzed and nesiritide was found to be associated with increased rates of kidney disease and death. Kesselheim, et al.,

The Rise and Fall of Natrecor for Congestive Heart Failure: Implications for Drug Policy, 25 Health Affairs (July/Aug. 2006).

Another example is Schering-Plough's drugs ezetimibe (Zetia) and a combination of this drug with simvastatin (simvastatin/ezetimibe or Vytorin). As a result of drug company promotion, driven in part by data mining, use of ezetimibe increased significantly in the United States, even in the absence of evidence of better clinical outcomes. In Canada, where promotion was less aggressive, uptake was much slower. Jackevicius, et al., *Use of Ezetimibe in the United States and Canada,* 358 New Eng. J. Med. (April 2008). Early clinical trials showed some reductions in cholesterol with these drugs, but a trial conducted in patients with hypercholesterolemia showed that the drugs did not work to reduce plaque in arteries. The manufacturer withheld the data for about 2 years; after its release in January 2008, there was a 15% drop in prescriptions over a few months. Berenson, *Doubt Cast on 2 Drugs Used to Lower Cholesterol*, New York Times, March 31, 2008.

II. Vermont Protects Medical Record Privacy Without Offending the First Amendment

A. The Prescription Privacy Law Fits Within A Larger Framework Of State and Federal Privacy Laws

The clinical encounter between physicians and their patients is the core relationship in medicine and health care. Our laws have long recognized that the patient visit also creates private health information, often of an intimate nature. Vermont protects private health information from unjustified invasion with a number of current laws, including the Vermont Patient Privilege Statute, Vt. Stat. Ann. Tit. 12, § 1612; the Vermont Patient Bill of Rights, Vt. Stat. Ann. Tit. 18, § 1852(7); and the Vermont Nursing Home Bill of Rights, Vt. Stat. Ann. Tit., 33 § 7301. Regulating the practice of medicine has long been a traditional state function under the police power.

The Prescription Privacy Law follows in this tradition, protecting privacy by making it illegal for health insurers, pharmacies, and intermediaries to "sell, license, or exchange for value regulated records containing prescriber-identifiable information" unless the "prescriber has provided consent for the use of that data as provided in subsection (c) of this section." Vt. Stat. Ann. Tit. 18, § 4631(d). Despite the focus on the *Central Hudson* factors in this case, all parties agree that Vermont has sought to create privacy rights in PI medical records. Since PI medical records can be used to interfere with the doctor-patient relationship,

invade privacy, and raise safety and cost issues, *see supra* Section I, Vermont has vested the disclosure decision solely in the hands of the prescribing physician. The State affirms that data mining is costly and dangerous; the plaintiffs argue otherwise. We strongly suggest that Vermont physicians are the best persons to weigh these factors and to make these decisions on behalf of themselves and their patients. Vermont hasn't banned data mining; rather, it has empowered physicians to protect their patients as they see fit.

Federal law also protects medical privacy. Examples include the Privacy Rule adopted pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191; 45 C.F.R § 160; 45 C.F.R. § 164, and the recently enacted Genetic Information Nondiscrimination Act (GINA), Pub. L. No. 110-233, 122 Stat. 881 (2008). While HIPAA and GINA are not challenged in this case, laws such as the Prescription Privacy Law were certainly anticipated and permitted under federal law, so a brief discussion is worthwhile. Under the HIPAA Privacy Rule, the federal government has identified no fewer than 18 sensitive data fields in medical records, and given these data fields special legal status as "protected health information" or "PHI." Data fields such as the patient's name, social security number, address, and zip code (beyond the first three digits) are identified as PHI. Improper disclosure of PHI violates federal law. Prescriber-identifiable data is not currently listed as PHI in the HIPAA Privacy Rule, but the

HIPAA statute includes an unusual "anti-preemption" provision clearly permitting states to adopt additional privacy rules that expand the scope of medical record privacy. HIPAA § 264(c)(2).[2] The Prescription Privacy Law is one such permissible law, adopted under the protective umbrella of the federal HIPAA Statute. The Prescription Privacy Law does not say so explicitly, but effectively it creates an additional category of PHI – "prescriber-identifiable information" – under state law, above and beyond the existing categories currently mandated under federal HIPAA. Notably, the plaintiffs do not mount a statutory pre-emption challenge in this Court against the Prescription Privacy Law. Moreover, given the explicit language in HIPAA, their dormant commerce clause claim should be dismissed.

B. The Plaintiffs Do Not Have A First Amendment Right to Sell or Use Medical Records Protected By Vermont Law

Of course, there are some important exceptions to statutory health privacy, primarily informed consent and important government interests such as public safety and prevention of crime. Vt. Stat. Ann. Tit. 18, § 4631(e)(5)-(6). These protections can be waived by written consent. Vt. Stat. Ann. Tit. 12, § 1612(a); Vt.

[2] *See* HIPAA § Sec. 264(c)(2), which provides that, "A regulation promulgated under paragraph (1) shall not supersede a contrary provision of State law, if the provision of State law imposes requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed under the regulation."

Stat. Ann. Tit. 18, § 1852(7). Common reasons for granting consent include medical treatment, insurance reimbursement, and research. Most people seeking health care in the U.S. in recent years will be somewhat familiar with similar privacy consent forms.

But these consent forms are limited to particular purposes. When someone tries to access this protected health information for another purpose, they can suffer legal consequences. *See, e.g.,* Ornstein, *Ex-Worker Indicted in Celebrity Patient Leaks Former Employee of UCLA Medical Center is Accused of Selling Data to the Media*, L.A. Times, April 30, 2008; Cutler, *Kaiser Permanente Gets $187,000 Fine For Second Patient Privacy Violation,* 18 BNA Health L. Rep. (July 2009); Douglas, *Hospital Administrator Allegedly Stole Patient Records for Credit Card Fraud Scam*, 18 BNA Health L. Rep. (June 2009). Pharmacies have also been sanctioned for privacy violations. *CVS Privacy Practices Need Investigation Despite FTC Order, Pharmacist Group Says*, 18 BNA Health L. Rep. (March 2009) (noting the FTC Consent Order with CVS Caremark Corp., one of the country's largest pharmacy chains).

The plaintiffs cannot rely on consent to justify their invasion of health privacy. The plaintiffs assert the novel claim that private companies can use and sell private health information, violating state law, without the consent of any of the individuals involved. This case isn't fundamentally an issue of commercial

speech; our view as physicians and medical students is that data miners have wrongfully taken private health information for commercial purposes without consent. Data miners should not have a First Amendment right to use or sell private health information. Put another way, intent to use or sell is not a defense to violation of medical privacy laws.

Plaintiffs mischaracterize this case as commercial speech, hoping for First Amendment protection for their activities. The IMS Brief states: "The government could not ban the publication of the stock reports by *The Wall Street Journal* or a book on commodities trading when that information would be used to make commercial decisions." IMS Brief at 19. True enough, but not relevant in the least to this appeal. The cases cited by the plaintiffs require that the information be obtained lawfully in the first instance. To illustrate this point, assume that an IMS employee took a valuable IMS database without permission and released it on a website. Or perhaps a Merck employee obtained commercially valuable clinical trial data belonging to the company and improperly offered it for sale to the highest bidder. Both companies would have multiple legal actions against the employee to block the sale or use of illegally obtained data. If another person unwisely agreed to use or sell the data in any form, knowing that it had been obtained illegally, then they could be sued as well. No one has a First Amendment right to sell private health information obtained in violation of law.

Courts have long recognized the difference between legal and illegal conduct in the First Amendment context. *See* Kesselheim & Avorn, *Pharmaceutical Promotion to Physicians and First Amendment Rights,* 358 New Eng. J. Med. (April 2008). In *Universal City Studios v. Corley*, the First Amendment did not protect the publication of a DVD hacking program because the program enabled others to steal legally protected information:

> "But just as the realities of what any computer code can accomplish must inform the scope of its constitutional protection, so the capacity of a decryption program like DeCSS to accomplish unauthorized indeed, unlawful access to materials in which the Plaintiffs have intellectual property rights must inform and limit the scope of its First Amendment protection." 273 F.3d 429, 453 (2d Cir. 2001) (citation omitted).

The distinction between lawful and unlawful activities has always been featured in our commercial speech jurisprudence. As the Supreme Court noted in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, "there is no claim that the transactions proposed in the forbidden advertisements are themselves illegal in any way." 425 U.S. 748, 772 (1976). This distinction finds fuller expression in the first prong of *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York,* where the Court distinguished speech that is misleading or related to illegal activity:

> "The First Amendment's concern for commercial speech is based on the informational function of advertising. Consequently, there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity. The

> government may ban forms of communication more likely to deceive the public than to inform it, or commercial speech related to illegal activity." 447 U.S. 557, 563-64 (1980) (*citations omitted*).

Plaintiffs rely on several additional U. S. Supreme Court cases concerning commercial speech, including *Edenfield v. Fane*, 507 U.S. 761, 770 (1990); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 561 (2001); and *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371-73 (2002). PhRMA Brief at 30, IMS Brief at 33. Not one of these cases involves publication of illegally obtained private information. In each case, the government restricted advertising of a legitimate and entirely legal product. In *Edenfield*, the statute at issue prohibited in-person solicitation by CPAs. If the Prescription Privacy Law prohibited in-person detailing by drug companies, then perhaps *Edenfield* would be directly relevant, but the Act does nothing of the sort. The result in *Edenfield* would have been quite different if that law had merely prohibited CPAs from using private, commercially valuable information taken without the consent of the client. For example, if a CPA tried to solicit new clients using the potential client's stolen credit card information, the First Amendment would stand aside when the state moved to stop this criminal behavior.

Plaintiffs' reliance on *Thompson* and *Lorillard* are similarly misplaced, as those laws restricted advertising for a "legal activity," tobacco sales to adults, *Lorillard*, 533 U.S. at 564, and compounded prescription drugs, *Thompson,* 535

U.S. at 357. If these statutes had narrowly prohibited advertising for illegal activities – such as the sale of cigarettes to children – there is little doubt that such a law would be upheld. As Justice Thomas concurred in *Lorillard*:

> "A direct solicitation of unlawful activity may of course be proscribed, whether or not it is commercial in nature. *See Brandenburg v. Ohio,* 395 U.S. 444, 89 S.Ct. 1827, 23 L.Ed.2d 430 (1969) *(per curiam)*." *Lorillard*, 533 U.S. at 574 (Thomas, J., concurring in part and concurring in judgment).

Other major commercial speech decisions cited by the plaintiffs similarly relate to "legal activity" under the first prong of *Central Hudson*, and thus do not control the result in this case. *See 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996) (price advertising of legal liquor sales); and *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995) (advertising alcohol content on beer bottles). The distinction between lawful and unlawful conduct in First Amendment cases may also be seen in cases before this Court. In *Anderson v. Treadwell*, the government conceded that in-home solicitations by real estate agents "contain speech that is lawful and not misleading." 294 F.3d 453, 461 (2d Cir. 2002). *See also*, *Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87 (2d Cir. 1998) (advertising a beer brand using an obscene frog on the beer label).

While it is possible to imagine a State concocting a legal violation out of thin air in order to pretend to satisfy the first prong of *Central Hudson*, Vermont has done nothing of the sort. Vermont's law fits squarely in a well-established

state and federal tradition of protecting the privacy of medical records. Under the Prescription Privacy Law, it is illegal for health insurers, pharmacies and their electronic transaction intermediaries to "sell, license, or exchange for value regulated records containing prescriber-identifiable information." Vt. Stat. Ann. Tit.18, § 4631(d). This first sentence of § 4631(d) does not apply to either the PhRMA plaintiff or the data mining plaintiffs, but only to companies who are not parties to this litigation.

Furthermore, pharmacies, health insurers and their intermediaries hold PI medical records for limited purposes, including insurance reimbursement, filling prescriptions, scientific research, and the other exceptions described in subsection (e) of the Prescription Privacy Law. Vt. Stat. Ann. Tit. 18, § 4631(e). No one has given permission for this data to be used for any other purpose. If a pharmacy sells this private health information to the data mining plaintiffs, Vermont law has been broken under the first sentence of § 4631(d). At that point, drug companies have no legal right to purchase this illegally obtained private health information and then hide behind the First Amendment. Under Vermont law, the decision whether to share this information with data mining companies rests in the hands of the physician, who is best situated to make this decision.

C. Medical Record Privacy Is A Substantial State Interest

Privacy is a protected interest in our legal system and a substantial interest under the *Central Hudson* test. In *Anderson v. Treadwell*, this Court found the privacy interest of homeowners sufficient to uphold a tailored prohibition on in-home solicitation by real estate agents: "The homeowners' privacy interest is 'substantial' within the meaning of *Central Hudson.*" 294 F.3d at 461. As described above, the State's interests in protecting the physician-patient relationship, promoting privacy, reducing costs, and protecting safety are certainly substantial interests. *See supra* Section I.

PhRMA's Brief asserts that: "Protection of prescriber privacy is not a substantial state interest. *Ayotte*, 490 F. Supp. 2d at 179-80; *IMS Health Corp. v. Rowe*, 532 F. Supp. 2d 153, 172 (2008)," PhRMA Brief at 48, but this is mistaken on several grounds. First, the cited cases don't actually stand for this proposition. The New Hampshire Attorney General advanced a very narrow privacy claim. *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163, 178 (D.N.H. 2007). Trial strategy decisions by New Hampshire do not bind Vermont, or hinder this Court's full consideration of the interests of privacy for PI medical records. The First Circuit found the goal of cost containment to be sufficient, and did not fully take up the issue of privacy. *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 84 (1st Cir. 2008). In *IMS Health Corp. v. Rowe,* the District Court held that "patient confidentiality is a

substantial government interest," 532 F. Supp. 2d 153, 170 (D. Me. 2008), but the Attorney General of Maine did not broadly advance the Maine Legislature's findings on prescriber privacy. *Id.* at 170-72.

One important difference in the Maine case was the District Court's statement that the Maine law "does not prevent the release of data on the prescribing patterns of Maine prescribers to countless individuals," *id.*, at 176, as if the careful and deliberate release of confidential medical information to physicians and health insurers destroys all privacy rights. This erroneous claim is repeated in the plaintiffs' briefs before this Court. PhRMA Brief at 48, IMS Brief at 28-29. The Vermont law certainly does not permit disclosure to "countless individuals" but carefully limits the disclosure of PI medical records. Vt. Stat. Ann. Tit. 18, § 4631(e). Plaintiffs' argument here would invalidate all health privacy rules simply because some health professionals and insurance company personnel have legal access to the data. The fact that confidential information is voluntarily made available to private groups demarked by contract and statute has never resulted in the loss of all privacy rights vis-à-vis other persons or the public. Indeed, the very purpose of these health privacy statutes is to protect the individual in precisely these circumstances.

The PhRMA Brief derides Vermont's effort as "'the removal of a few grains of [non-private] sand from a beach of' unfettered disclosure of prescriber-specific

information. *See Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87, 100 (2d Cir. 1998)." PhRMA Brief at 49. Plaintiff misapplies both *Bad Frog Brewery* as well as the Vermont law. The actual quote from *Bad Frog Brewery* concerned "the removal of a few grains of offensive sand from a beach of vulgarity." 134 F.3d at 100. The point was that vulgarity and underage drinking are rampant in our culture, and the removal of a cartoon frog with an obscene gesture from a beer label would have a very limited impact on the overall culture. The PhRMA brief attempts to twist this quote into the health privacy context, pretending that once your private health information is carefully released to your doctors and health insurance company, it might as well be posted on the Internet or sold to the highest bidder, a result somehow required by the First Amendment.

III. The First Amendment Does Not Require This Court To Overturn The Legislative Determinations of the State of Vermont

Plaintiffs attack Vermont's legislative findings as being insufficiently voluminous, PhRMA Brief at 21-22, while simultaneously offering their experts to say that Vermont made a policy mistake. The plaintiffs presented much of this evidence to the Legislature in hearings, and in many formal and informal meetings with their lobbyists. No complaint has been lodged concerning voting fraud or irregularity in legislative procedure. Indeed, plaintiffs concede that the Prescription Privacy Law was legally approved by both the House and Senate in

Vermont and signed by the Governor. PhRMA Brief at 22.

At the end of the process, Vermont disagreed with the plaintiffs and created the Prescription Privacy Law that is now before this Court. Plaintiffs ask this Court to ignore the elected representatives of Vermont, and take plaintiffs' side in many complex health policy issues such as the efficacy of various prescription drug cost saving measures, drug safety issues, and the wisdom of granting legal privacy protections to PI medical records. The Vermont law wisely leaves these decisions in the hands of the doctor.

We are also concerned about potential intimidation of legislative witnesses, including physicians. Plaintiffs deposed Vermont legislative personnel in this case, including full depositions of witnesses who testified in favor of the Act. Leaders from the Vermont Medical Society were also deposed, since they supported the Prescription Privacy Law. The District Court excluded that evidence from trial, and yet the plaintiffs' briefs in many places cite this excluded testimony. In future legislative debates in Vermont and other states, any witness willing to testify against the plaintiffs will know that personal depositions may follow, chilling the very legislative process at the core of our government.

The plaintiffs' briefs also display remarkably anti-democratic positions. For example, they quote several Vermont legislators as "evidence" that the legislative process was hurried. PhRMA Brief at n.8, IMS Brief at 8-9. This is profoundly

mistaken on many levels and attacks the core democratic process of legislation. Perhaps some of the quoted legislators ended up voting in favor of the Act, despite some misgivings. If a legislator ultimately votes in favor of a bill, a court should not pry behind that public vote (absent fraud) and speculate about their thought processes. In any event, raising questions during public deliberation demonstrates mindfulness of duties, not constitutional infirmity. Assume the remaining legislators voted against the bill. If so, the matter should not hold this Court's attention for another moment, since the disgruntled legislators lost in a vote that no one challenges as fraudulent or irregular. Most people will generally be unhappy with losing a vote in the Legislature, but that does not entitle a court to give their grumblings any constitutional weight. Our system doesn't overturn legislation simply because the losing side expressed some doubts.

In essence, plaintiffs demand that Vermont hire yet more expert witnesses and hold longer, more extensive hearings before legislation is passed, but nowhere does the Constitution require states to create elaborate legislative histories. Many states don't have full-time legislators or legislative staffs; citizen-legislators can't afford to take months to study every bill. But they will be accountable for their decisions in the next election. Even so, the Vermont Legislature's review of this bill spanned the entire legislative session, creating thousands of pages of legislative testimony alone. A-406-1482; *Ayotte*, 550 F.3d at 59 ("fanciful to suggest that the

congressional record in *Turner* represents the threshold for deference"); *id.* at 93 (Lipez, J., concurring) ("a state legislature cannot reasonably be expected to undertake an investigation of the scope conducted by Congress" with respect to the statute at issue in *Turner*).

While we certainly recognize that *Central Hudson* requires some evaluative process, the cases cited in plaintiffs' briefs generally relate to a government making legislative determinations in an area where they didn't have particular expertise. For example, in *44 Liquormart; Rubin*; *Anderson*; *Lorillard*; and *Bad Frog*, the government was making decisions on the effectiveness of regulating alcohol or tobacco advertising. In *Anderson,* the topic was in-home real estate solicitations. *Edenfield* addressed solicitations by CPAs. *Thompson* concerned pharmacies advertising compounded drugs. Here, Vermont doesn't just have an *opinion* on health care cost and safety issues; they have decades of direct *experience*, with billions of dollars in health care costs provided by and through the State. Similarly, the national Blue Cross and Blue Shield Association represents substantial experience in health insurance, and they are very concerned about the cost and quality problems associated with drug promotion. Millenson, *Getting Doctors to Say Yes To Drugs: The Cost and Quality Impact of Drug Company Marketing To Physicians* (BlueCross BlueShield Association, 2003). This Blue Cross study cites PhRMA expert Frank Lichtenberg, *id.* at n.40, and others, but in

the end they largely reject the drug companies' positions. Based on their collective experience as health insurers to millions of Americans, Blue Cross sided instead with experts like Dr. Jerry Avorn. *Id.* at n.37. Vermont's experience as a health care payor demonstrates its expertise concerning health care costs in the State. If plaintiffs have winning policy arguments, let them make those arguments to the people paying the bills.

In an early commercial speech case, Justice Rehnquist warned of the danger of substituting a court's preferences for the judgments of a legislative body, warning of a return to the *Lochner* era:

> "In coming to this conclusion, the Court has overruled a legislative determination that such advertising should not be allowed and has done so on behalf of a consumer group which is not directly disadvantaged by the statute in question. This effort to reach a result which the Court obviously considers desirable is a troublesome one …
>
> "One need not disagree with either of these statements in order to feel that they should presumptively be the concern of the Virginia Legislature, which sits to balance these and other claims in the process of making laws such as the one here under attack. The Court speaks of the importance in a "predominantly free enterprise economy" of intelligent and well-informed decisions as to allocation of resources. *Ante*, at 1827. While there is again much to be said for the Court's observation as a matter of desirable public policy, there is certainly nothing in the United States Constitution which requires the Virginia Legislature to hew to the teachings of Adam Smith in its legislative decisions regulating the pharmacy profession.
>
> As Mr. Justice Black, writing for the Court, observed in Ferguson v. Skrupa, 372 U.S. 726, 730, 83 S.Ct. 1028, 1031, 10 L.Ed.2d 93, 97 (1963): "The doctrine . . . that due process authorizes courts to hold laws unconstitutional when they believe the legislature has acted

> unwisely has long since been discarded. We have returned to the original constitutional proposition that courts do not substitute their social and economic beliefs for the judgment of legislative bodies who are elected to pass laws." *Virginia State Board of Pharmacy*, 425 U.S. at 781-84 (Rehnquist, J., dissenting).

Professor Robert Post, now Dean at Yale Law School, raised similar concerns recently with regard to the data mining cases:

> "This last requirement [of *Central Hudson*] is so arbitrary that it constitutes an open invitation for judges to bring political prejudices to bear in resolving cases. Antiregulatory judges will tend to strike down statutes on the basis of this requirement; proregulatory judges will tend to uphold them. It seems apparent that if First Amendment coverage is indiscriminately applied to all channels of data transmission, and if the *Central Hudson* test is used to determine the First Amendment protection accorded such channels, we will face an increasingly capricious constitutional regime in which regulations will be constantly challenged and frequently invalidated." Post, *Prescribing Records And The First Amendment – New Hampshire's Data-Mining Statute*, 360 New Eng. J. Med. (Feb. 2009), at 747.

Finally, unlike some tort or patent lawsuits where a court is forced to evaluate scientific evidence, this Court is not required to do so today. We urge this Court to leave these complex matters of science and health policy in the hands of those best suited to make the decision – the prescribing physicians. Vermont's statute does exactly that, by giving the physician an opt-out privilege to decide whether or not PI medical records should be data mined. Let the individual physician decide whether data mining is detrimental or helpful to themselves and their patients. Do not usurp that intimate and private medical decision.

CONCLUSION

The Court should affirm the district court's decision and direct entry of judgment for the Defendants.

Respectfully submitted,

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Dated: September 15, 2009

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Docket Number: 09-1913-cv(L)

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/s/ Michael Kevin Outterson

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