

CASE NO. 1:07-cv-00188

CONSOLIDATED WITH CASE NO. 1:07-cv-00220

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF VERMONT

IMS HEALTH INCORPORATED; VERISPAN, LLC; and SOURCE HEALTHCARE
ANALYTICS, INC. a subsidiary of WOLTERS KLUWER, HEALTH INC.

Plaintiffs,

v.

WILLIAM H. SORRELL, Attorney General for the State of Vermont
Defendant.

AMENDED BRIEF FOR AARP, COMMUNITY CATALYST, THE NATIONAL
LEGISLATIVE ASSOCIATION ON PRESCRIPTION DRUG PRICES, THE NATIONAL
PHYSICIANS ALLIANCE, THE VERMONT MEDICAL SOCIETY AND PRESCRIPTION
POLICY CHOICES AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS
WILLIAM A. SORRELL, ET AL.
SUPPORTING A FINDING FOR THE DEFENDANT ON ALL CLAIMS

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June 24, 2008

CERTIFICATE OF INTEREST

Counsel for *Amici Curiae* certifies the following:

- The full name of every party or *amicus curiae* represented by me is: AARP, Community Catalyst, the National Legislative Association on Prescription Drug Prices, the National Physicians Alliance, the Vermont Medical Society and Prescription Policy Choices.
- The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is AARP, Community Catalyst, the National Legislative Association on Prescription Drug Prices, the National Physicians Alliance, the Vermont Medical Society and Prescription Policy Choices.
- All parent corporations and any publicly held companies that own 10 percent of the stock of the party or *amicus curiae* represented by me are: None.
- The names of all law firms and the partners or associates that appeared for the party or *amicus curiae* now represented by me in the trial court or are expected to appear in this court are:

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STATEMENT OF INTEREST

All parties to this litigation have consented to this submission. *Amici* represent a broad range of interests affected by this litigation including state legislators, physicians, consumers and public policy advocates.

AARP is a nonpartisan, nonprofit membership organization of over 39 million persons, age 50 or older, dedicated to addressing the needs and interests of older persons. Community Catalyst (CC) is a national advocacy organization that builds consumer and community participation in shaping our health system to ensure quality, affordable healthcare for all. The National Legislative Association on Prescription Drug Prices (NLARx) 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. The National Physicians Alliance (NPA) is a national physician membership organization founded to restore the profession's primary emphasis on the core values of service, integrity and advocacy, as well as to promote evidence-based medicine. Prescription Policy Choices (PPC) is a nonprofit, nonpartisan educational and charitable organization which provides educational and research materials to state legislators, academics, policymakers, and the public to assist them to reduce prescription drug prices and thereby increase access to affordable prescription drugs in the United States. The Vermont Medical Society (VMS) is a membership organization of physicians in Vermont that serves 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.

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

SUMMARY OF ARGUMENT

This case turns on a key distinction between commercial speech and consumer surveillance. Only the former is protected by the First Amendment. The commercial speech doctrine serves consumer interests in being fully informed of products and services on the market by providing limited protection to speech “proposing a commercial transaction.” Pharmaceutical companies engage in commercial speech when they advertise their products through media and in-person sales calls to doctors. The commercial speech doctrine does not extend protection to use of information by private firms that do not communicate with potential buyers. The Plaintiffs are not communicating with potential buyers when they monitor the prescribing practices of physicians, and therefore this practice is not accorded protection under the First Amendment. Indeed, the First Amendment calculus weighs strongly on the other side – of protecting the autonomy right of individuals to decide when to speak and to whom. Vermont’s law provides a mechanism for prescribers to choose whether to share their prescribing information with pharmaceutical marketers and therefore serves rather than limits important First Amendment interests.

Even if the trade in prescription records was deemed to be speech, there are overwhelming societal justifications for its regulation. When governments require the disclosure of personally identifying information, such as that required on prescriptions, privacy interests demand that governments ensure that the information is safeguarded from unwarranted disclosure. In addition, an abundance of social science evidence demonstrates that undue

influence of pharmaceutical marketing over the prescribing choices of physicians and other health professionals compromises a central value of our health system – that medical decisions be based on evidence, not on personal relationships, marketing influence or the hope for pecuniary reward. Permitting pharmaceutical marketers to track prescribing choices and use that information to tailor commercial messages and target gifts and enticements amplifies the undue influence of pharmaceutical companies in our health system that raises health care costs, promotes irrational drug selection, threatens professional integrity, compromises patient privacy and increases the prevalence of harassing marketing practices. States have an overriding interest in combating these social ills.

There is no alternative policy that Vermont could have adopted to meet the full range of its interests. The law does not prohibit tracking prescriber identities for valid non-marketing related purposes, such as to enforce formulary compliance or to monitor evidence-based prescribing practices, and it therefore regulates no more than is necessary. Furthermore, the Vermont law allows physicians' to opt in to the collection of their data for marketing purposes if they choose to give such consent.

Other policies, including gift bans, public marketing and price regulations would not sufficiently serve Vermont's interests in eliminating the most corrupting uses of prescription data at the lowest cost to the state.

ARGUMENT

I. MONITORING OF PRESCRIBING PRACTICES THROUGH PHYSICIAN-IDENTIFYING PRESCRIPTION RECORDS IS NOT FIRST AMENDMENT-PROTECTED SPEECH.

The commercial speech doctrine was created by the Supreme Court to extend a lesser degree of First Amendment protection to commercial advertising *to the public*.¹ The justification for the doctrine turns on the consumer interest in receiving accurate information about the products and services available in the market to enable informed consumer choices. The First Amendment does not require heightened scrutiny of confidentiality laws that prohibit the commercial monitoring of individually identified data *from the public* without the consent of those being monitored.² Such monitoring does not involve an exchange of information between buyers and sellers that serves the objectives of the First Amendment in the commercial area, and is contrary to the First Amendment’s protections against forced speech.

The commercial speech doctrine is not applicable to all commercial processing of data or information. Recent Supreme Court cases have clarified that the commercial speech doctrine is properly applied only where the speech at issue informs the marketplace by “proposing a commercial transaction” through individual solicitation or advertising to the general public.³ This definition is in accord with earlier Court explanations that there are “[n]umerous examples”

¹ See *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976).

² Cf. *Zemel v. Rusk*, 381 U.S. 1, 17 (1965) (“[T]he right to speak and publish does not carry with it the unrestrained right to gather information.”).

³ *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 422-23 (1993) (disapproving of dicta in earlier cases that commercial speech is speech “solely in the economic interests of the speaker and audience”); see also *Bd. of Trustees v. Fox*, 492 U.S. 469, 473-74 (stating that the proposal of a commercial transaction is “*the test* for identifying commercial speech”) (emphasis added).

of the regulation of use of information, including “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,” that may be regulated “without offending the First Amendment.”⁴ The practice of exchanging and using data on prescribing patterns does not propose commercial transactions or otherwise communicate to consumers or the general public and therefore is not commercial speech. As Professor Julie Cohen explains, “personally-identified data is not collected, used, or sold for its expressive content at all; it is a tool for processing people, not a vehicle for injecting communication into the ‘marketplace of ideas.’”⁵

Where information processing is used to inform internal marketing agendas rather than to speak directly to potential buyers, the First Amendment does not apply. Thus, in *Bartnicki v. Vopper*,⁶ the Supreme Court held that the government could punish the private commercial use of confidential information “to create a competing product,” “to prepare strategy for contract negotiations” or “to discipline a subordinate” without triggering First Amendment scrutiny,⁷ even though the punishment of the public disclosure of the same information over a public affairs radio program was prohibited by the First Amendment.⁸ In *Reno v. Condon*, the Court

⁴ *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447, 456 (1978).

⁵ Julie Cohen, *Examined Lives: Informational Privacy and the Subject as Object*, 52 *Stan. L. Rev.* 1373, 1414 (2000).

⁶ 532 U.S. 514 (2001).

⁷ *Id.* at 527 n10; *id.* at 526-27 (explaining that such prohibitions of use of information is “a regulation of conduct”).

⁸ *Id.* at 527-34. Surely if IMS’s next venture was to collect and sell the records of wiretaps of doctor offices to guide pharmaceutical marketing it would be subject to the federal prohibition of “uses” of such records left in place by the Supreme Court, not the prohibition of public disclosures that was stuck down.

held that Congress had the authority to enact the Driver Privacy Protection Act (DPPA) to regulate the private commercial sale of personal identifying information in department of motor vehicle records because, in that context, the “identifying information that the DPPA regulates is a thing in interstate commerce, and that the sale or release of that information in interstate commerce is therefore a proper subject of congressional regulation.”⁹

Lower courts have largely followed this doctrinal distinction between commercial speech that proposes a transaction to buyers, and information exchange or processing that contains no similar expressive element. The First Circuit held that the “provision of advertising and [trade name] licensing services is not speech that proposes a commercial transaction and therefore does not constitute commercial speech.”¹⁰ The Sixth Circuit similarly refused a First Amendment challenge to a state law banning use or exchange of identifying information in DMV records, holding that the law “does not restrict or even regulate expression. Rather, it simply limits access to confidential information.”¹¹

Courts that have reached contrary decisions have done so through legal error. *Trans Union Corp. v. FTC* applied the First Amendment to (and upheld) a prohibition of the sale of targeted marketing lists based on credit reporting information by applying the *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, definition of commercial speech as “solely in the individual interest of the speaker and its specific business audience.”¹² But *Dun & Bradstreet* is not a commercial speech case, it is a defamation case where the question before the court was whether

⁹ *Reno v. Condon*, 528 U.S. 141, 148 (2000).

¹⁰ *See Wine and Spirits Retailers, Inc v. Rhode Island*, 418 F.3d 36, 49 (1st Cir 2005).

¹¹ *Amelkin v. McClure*, 330 F.3d 822 (6th Cir. 2003).

¹² *Trans Union Corp. v FTC*, 267 F.3d 1138, 1140 (D.C. Cir. 2001) (quoting *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.* 472 U.S. 749, 762 (1985)).

the speech in question was of a “public concern” (holding that purely private speech was not).¹³ *Dun & Bradstreet* did not define a new and broader range of commercial information use that is protected by the First Amendment. Similarly, *U.S. West, Inc. v. FCC*¹⁴ applied the First Amendment to an intra-firm exchange of consumer information by applying an effects test that has no place in the commercial speech doctrine.¹⁵ The commercial speech doctrine does not demand the application of First Amendment scrutiny to every action of a commercial entity that may “facilitate the marketing” of products to the public. Nearly every action of a modern commercial entity, from its research and development to product design and launch can be interpreted as part of an effort to facilitate marketing. There is no effects test for commercial speech – if commercial speech is not proposing a commercial transaction to consumers, it is not protected under the First Amendment.

The Vermont law is similar in nature to the numerous state and federal laws that prohibit companies from disclosing, selling or monitoring personally identifying information that, because they do not regulate advertising or other speech *to consumers*, are not subject to heightened scrutiny under the First Amendment. The Health Insurance Portability and Accountability Act prohibits a broad range of releases of individually identifiable health information.¹⁶ Federal law also prohibits disclosure of “personally identifiable information concerning any consumer” of a video rental establishment,¹⁷ disclosure of cable television viewer

¹³ *Dun & Bradstreet*, 472 U.S. at 756.

¹⁴ 182 F.3d 1224 (10th Cir. 1999).

¹⁵ *Id.* at 1233 n.4 (holding that because the creation of marketing lists was “to facilitate the marketing . . . , we find the speech integral to and inseparable from the ultimate commercial solicitation”).

¹⁶ Pub. L. No. 104-191, 110 Stat. 1936 (1996).

¹⁷ 18 U.S.C. §2710-2711.

preferences,¹⁸ internet subscriber information,¹⁹ and identifying information from department of motor vehicle records.²⁰ State laws similarly ban a broad range of public and private releases of identifying information found in a variety of records not intended for broad public release.²¹ Such laws have been upheld by courts²² and approved of by First Amendment scholars as “unproblematic from a First Amendment perspective” because the regulation of access to and conduct with identifying records not otherwise in the public domain is not a regulation of speech.²³

Properly conceived, it is the individuals identified in the records who have a recognized First Amendment interest – the interest in being able to *not speak*. There is no First Amendment protection for commercial data sifting that does not communicate directly to a consumer audience. But there is a recognized “freedom not to speak publicly, which serves the same ultimate ends as freedom of speech in its affirmative aspect.”²⁴ The Plaintiffs are not speaking in

¹⁸ Cable Communications Policy Act, 47 U.S.C. §551(c)(1).

¹⁹ 18 U.S.C.A. §2702.

²⁰ Driver’s Privacy Protection Act, 18 U.S.C. §§ 2721-25.

²¹ *See* Cal. Civ. Code § 1798.85(a) (prohibiting release of social security numbers); Ohio Rev. Code § 4501.27(A) (regulating use and disclosure of information “obtained in connection with a motor vehicle record”); Mo. Code Regs. Ann. tit. 20 §§ 2220-2 (“prescription records, physician orders and other records related to any patient care or medical condition(s) of a patient that are maintained by a pharmacy . . . shall be considered confidential”).

²² *See Condon*, 528 U.S. 141 (upholding federal Driver’s Privacy Protection Act as valid regulation of commerce); *Amelkin*, 330 F.3d at 827 (holding that Kentucky law regulating accident reports “does not restrict or even regulate expression”).

²³ Neil Richards, *Reconciling Data Privacy and the First Amendment*, 52 UCLA L. Rev. 1149, 1190 (2005); *see* Frederick Schauer, *Commercial Speech and the Architecture of the First Amendment*, 56 U. Cin. L. Rev. 1181, 1183-84 (1988) (noting “a vast range” of exchanges of information between companies that do not implicate the First Amendment”); *see also* Robert Post, *The Constitutional Status of Commercial Speech*, 48 UCLA L. Rev. 1, 20-25 (2000) (listing examples); Frederick Schauer, *The Boundaries of the First Amendment: A Preliminary Exploration of Constitutional Salience*, 117 Harv. L. Rev. 1765, 1777-87 (2004) (same).

²⁴ *Harper & Row Publishers, Inc v. Nation Enterprises, Inc.*, 471 U.S. 539, 559 (1985).

any constitutional sense when they purchase and examine prescription records; it is prescribers and patients that are being forced to speak. Vermont’s law, by creating a mechanism whereby individuals identified in prescription records can consent or not to the sharing of their identities with potential marketers, directly promotes a recognized free expression interest. The Plaintiffs’ claim of a right to access records that the identified individuals do not consent to sharing ignores the first principle of the First Amendment that “[f]reedom of speech presupposes a willing speaker.”²⁵

The Plaintiffs’ argument that all use of data by companies to target marketing is First Amendment protected speech is erroneous and, if adopted by this court, would have wide ranging effects. This radical rewriting of the First Amendment to impose a *Lochner*-like system of heightened judicial review over common economic laws should be emphatically rejected.²⁶ The private purchase of confidential information by commercial enterprises is economic conduct subject to economic regulation. The First Amendment inquiry in this case should rest there.

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

If this Court finds that the Act regulates some aspect of protected speech, the most lenient possible application of First Amendment scrutiny would be warranted.²⁷ There is, however,

²⁵ *Virginia State Bd. of Pharmacy*, 425 U.S. at 756.

²⁶ *Cf. Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 589, 591 (1980) (Rehnquist, J., dissenting) (warning against using the commercial speech doctrine “to resurrect the discredited doctrine of cases such as *Lochner*” to strike economic regulations “based on the Court’s own notions of the most appropriate means for the State to implement its considered policies”).

²⁷ Commercial speech must be afforded protection “commensurate with its position in relation to other constitutionally protected expression.” *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 555 (2001). Thus, the Court has required more substantial justifications and narrower tailoring for

ample evidence in the public record and the record of litigation in this case to demonstrate that the Vermont law serves governmental interests of the highest order.

A. The Act Protects Privacy Interests of Patients and Prescribers

The government requires that prescribers and patients identify themselves in prescription records, which creates an added interest of the government in ensuring the safeguarding of that information. In *Whalen v. Roe*,²⁸ the Supreme Court upheld the rights of governments to require disclosure of prescription records to the government to meet legitimate regulatory interests. But, the Court held that a correlative failure of the government to safeguard the information it requires may open it to liability under the Fourteenth Amendment’s privacy protections. The Court recognized constitutionally protected privacy interests “in avoiding disclosures of personal matters” in medical records and “in independence in making certain kinds of important decisions” that can be compromised if patients or doctors know that their decisions and identities will be released to the public.²⁹ Thus, the Court explained that prescription disclosure rules are “typically accompanied by a concomitant statutory or regulatory duty to avoid unwarranted

blanket bans on the substance of an industry’s public advertising than for laws that regulate one mode of advertising leaving other channels of communication open. Compare *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503-07 (1996) (bans on advertising must “significantly” advance a substantial state interest, be “no more extensive than necessary,” and “rarely survive constitutional review”), to *Edenfield v. Fane*, 507 U.S. 761, 767 (1993) (ban on in-person solicitations “need only be tailored in a reasonable manner to serve a substantial state interest”). Cf. *Dun & Bradstreet*, 472 U.S. at 762 (holding that heightened evidentiary standards not required to criminalize false speech in a credit report “solely in the individual interest of the speaker and its specific business audience”); *Trans Union*, 267 F.3d at 1140-41 (summarily upholding FTC’s ban on the sale of targeted marketing lists by credit reporting agencies as implicating minimal speech interests balanced against overriding state interests in regulating marketing-related disclosures).

²⁸ 429 U.S. 589 (1977).

²⁹ *Id.* at 602-604.

disclosures,” which “arguably has its roots in the Constitution.”³⁰ This interest is no less paramount when the government requires disclosure of personally identifying information to other private entities. Government laws frequently require and protect the disclosure of social security numbers, for example. Similarly here, the government requires identifying information to be included on prescriptions, creating a heightened governmental interest in protecting individuals’ ability to limit disclose of such information to others.³¹

The privacy interests served by the Vermont law extend to patients as well as physicians.³² Although plaintiffs are correct that patient identities are normally removed from records before transmission to pharmaceutical companies, this provides incomplete protection for patients. As long as prescriber identities remain, individual patients can be tracked and marketed to without their consent. Press reports have divulged that even with patient identities removed, the plaintiffs can and do assign individual identifying numbers to patient records and track patient treatment, including whether and when patients see other care-givers or shift prescriptions.³³ This information can then be used to respond to individual treatment changes with marketing campaigns targeted at the patient through the prescriber. This insertion of the

³⁰ *Id.* at 605.

³¹ *Cf. Houchins v. KQED, Inc.*, 438 U.S. 1, 15-16 (1978) (holding that there is no right to “government information or sources of information under government control”).

³² Indeed, Medicaid has acknowledged that patient privacy interests extend beyond merely patient identity, and also restricts the disclosure of treatment choices, such as medicines prescribed to Medicaid patients. *See* 42 C.F.R. §§ 431.300, 431.303.

³³ *See* Jim Carroll & Tanya Foniri, *Infuse Anonymized Patient-Level Information into the Brand-Planning Process to Drive Profitable Growth*, IMS, http://www.imshealth.com/vgn/images/portal/cit_40000873/0/38/78187147Brand%20Planning%20Paper.pdf (June 1, 2006); Press Release, IMS, *IMS Announces Integration of Anonymized Patient-Level Data Across Global Portfolio of Offerings*, http://www.imshealth.com/ims/portal/front/articleC/0,2777,6025_3665_79490459,00.html (Nov. 28, 2006).

pharmaceutical company into the monitoring and influence of the patient’s treatment is an invasion of privacy of the most odious kind – one that directly affects the treatment course of the patient for the pecuniary interest of another through a breach of confidentiality that is nearly impossible to detect.

B. The Act Protects Against Undue Influence.

States may regulate commercial solicitation practices that are “merely deceptive and misleading,”³⁴ including practices that give marketers an “undue influence” through “one-sided” presentations that “may disserve the individual and societal interest . . . in facilitating informed and reliable decisionmaking.”³⁵

Nearly all direct-to-prescriber marketing is one-sided because only the most expensive and profitable medicines, i.e. branded blockbuster drugs, are marketed through in-person detailing. There is virtually no economic incentive for the manufacturers of generic drugs to send sales representatives to engage in the same kind of individualized marketing.³⁶ Access to prescribing data aggravates the negative impacts of this one-sided information market by permitting branded medicine marketers to observe and reward favored prescribing behavior.

Ninety-four percent of all doctors routinely receive gifts of significant value, such as meals, branded office supplies and free drug samples,³⁷ which create powerful psychological

³⁴ *Virginia State Bd. of Pharmacy*, 425 U.S. at 771-72.

³⁵ *Ohralik*, 436 U.S. at 458 (citations omitted).

³⁶ See Michael Fischer & Jerry Avorn, *Economic Implications of Evidence-Based Prescribing for Hypertension: Could Better Care Cost Less*, 291 JAMA 1850, 1854 (2004) (describing “vigorous marketing” of new branded drugs as “foremost” among the reasons for the “divergence between routine practice . . . and clinical trial data and evidence-based recommendations”).

³⁷ Eric Campbell et al, *A National Survey of Physician-Industry Relationships*, 356 New Eng. J. Med. 1742, 1742 (2007).

urges to reciprocate.³⁸ Prescriber data is used to guide this gift giving, so that the most profitable prescribers receive the highest rewards. One former sales representative explained:

Physicians are ranked on a scale from one to ten based on how many prescriptions they write. Reps lavish high prescribers with attention, gifts, and unrestricted “educational” grants. Cardiologists and other specialists write relatively few prescriptions, but are targeted because specialist prescriptions are perpetuated for years by primary care physicians, thus affecting market share.³⁹

The U.S. House of Representatives Committee on Government Reform’s investigation of Vioxx similarly revealed that Merck graded doctors from A+ to D for each product based on how reliably they prescribed Merck products.⁴⁰ Presumably, the high volume A+ prescribers could expect more valuable and frequent gifts from Merck.

The most favored prescribers can receive hundreds of thousands of dollars in payments from drug companies for speaking engagements, research, and sitting on various advisory boards.⁴¹ There is also “a large body of evidence from the social sciences that shows that

³⁸ David Blumenthal, *Doctors and Drug Companies*, 251 *New Eng. J. Med.* 1885 (2004) (discussing the insidious interplay between the sense of obligation created by even small gifts and the psychological tendency to discount one’s own susceptibility to bias).

³⁹ Adriane Fugh-Berman & Shahram Ahari, *Following the Script: How Drug Reps Make Friends and Influence Doctors*, 4 *PLoS Med.* 0621, 0623 (2007).

⁴⁰ See Memorandum from Henry Waxman, to Democratic Members of the Gov’t Reform Committee, on the Marketing of Vioxx to Physicians, (May 5, 2005); see, e.g., Public Citizen, *Response to FDA Request for Comments on First Amendment Issues*, September 13, 2002, available at <http://www.citizen.org/publications/release.cfm?ID=7199> (detailing the use of prescription data to reward doctors for prescribing Neurontin for unproven uses).

⁴¹ See Joseph Ross, et al., *Pharmaceutical Company Payments to Physicians*, 297 *JAMA* 1216, 1216 (2007) (analyzing public records of payments to physicians in Vermont and Minnesota); Emily Clayton, CALPIRG, *‘Tis Always the Season for Giving: A White Paper on the Practice and Problems of Pharmaceutical Detailing* (2004) (describing “five and even six figure checks” to doctors to reward prescribing); Gardiner Harris & Robert Pear, *Psychiatrists, Children, and Drug Industry’s Role*, *N.Y. Times*, May 10, 2007 (“In Minnesota . . . total payments to individual psychiatrists ranged from \$51 to more than \$689,000, with a median of \$1,750.”); Carl Elliot, *The Drug Pushers*, *Atlantic Monthly* (Apr. 2006) at 7-8, available at www.theatlantic.com/doc/print/200604/drug-reps; Stephanie Saul, *Drug Makers Pay for Lunch*

behavior can be influenced by gifts of negligible value,”⁴² particularly when precisely calibrated to reward specifically observed behavior that the sales representative wants to reinforce.

The extensive medical and scientific training that health professionals receive does not insulate them from being unduly influenced by pharmaceutical marketers. Numerous studies and investigations have documented a significant, measurable, and increasing influence of direct-to-physician marketing at convincing doctors to adopt prescribing practices that are contrary to clinical guidelines and the weight of objective scientific evidence.⁴³ An exhaustive data synthesis from over 500 published studies found conclusive evidence that pharmaceutical detailing guided by access to prescribing data “impact[s] the prescribing practices of residents and physicians in terms of prescribing cost, nonrational prescribing, awareness, preference and rapid prescribing of new drugs, and decreased prescribing of generic drugs.”⁴⁴ The same study concluded that meetings with pharmaceutical representatives had a direct relationship to physician requests to add drugs to a formulary that had “little or no therapeutic advantage over

as They Pitch, N.Y. Times, July 28, 2006, at A1; Jake Whitney, *How Drug Reps Know Which Doctor to Target*, New Republic Online, ¶7 (2006), www.tnr.com/doc.mhtml?i=w060828&s=whitney082906.

⁴² Dana Katz, et al., *All Gifts Large and Small: Toward an Understanding of the Ethics of Pharmaceutical Industry Gift Giving*, 3 Am. J. Bioethics 39, 39 (2003).

⁴³ *See id.*; Blumenthal, *supra* note 38; Abigail Caplovitz, *Turning Medicine Into Snake Oil: How Pharmaceutical Marketers Put Patients at Risk*, NJPIRG Law & Pol’y Center, 5 (2006) (reviewing studies); Katz, *supra* note 42 (summarizing research); Nicole Lurie, et al., *Pharmaceutical Representatives in Academic Medical Centers*, 5 J. Gen. Intern. Med. 240, 240-43 (1990); Puneet Manchanda & Elisabeth Hokna, *Pharmaceutical Innovation and Cost*, 5 Yale J. Health Pol’y L. & Ethics 785, 797-808 (2005) (reviewing studies); Helen Prosser, et al., *Influences on GP’s Decisions to Prescribe New Drugs – the Importance of Who Says What*, 20 Fam. Prac. 61 (2003); Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 JAMA 373 (2000) (reviewing studies).

⁴⁴ Wazana, *supra* note 43 at 375.

existing formulary drugs.”⁴⁵ Despite the volume of evidence showing that pharmaceutical marketing is effective at shifting prescribing habits away from the best evidence-based practices, most physicians deny that pharmaceutical marketing has any affect on their prescribing practices (while reporting that marketing does affect their colleagues).⁴⁶ They generally trust the messages delivered by pharmaceutical representatives,⁴⁷ and are very poor at detecting false and misleading messages within sales pitches.⁴⁸

Undue influence by pharmaceutical marketing results in enormous costs to society. One study 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 per year.⁴⁹ Another study found that approximately forty percent of Pennsylvania Medicare patients on antihypertensive therapy were being

⁴⁵ *Id.*

⁴⁶ See Jerry Avorn, et al., *Scientific Versus Commercial Sources of Influence on the Prescribing Behavior of Physicians*, 73 *Am. J. Med.* 4, 4-8 (1982); S. Suresh Madhavan, et al., *The Gift Relationship Between Pharmaceutical Companies and Physicians: An Exploratory Survey of Physicians*, 22 *J. Clinical Pharmacy & Therapeutics* 207 (1997); Michael Stienman, et al. *Of Principles and Pens: Attitudes and Practices of Medicine Housestaff Towards Pharmaceutical Industry Promotions*, 110 *Am. J. Med.* 551 (2001) (reporting that sixty-one percent of medical residents believe their own prescribing practices are unaffected by pharmaceutical marketing, although eighty four percent believe marketing affects the practices of their colleagues).

⁴⁷ Wazana, *supra* note 43 at 375.

⁴⁸ Michael Ziegler, et al., *The Accuracy of Drug Information from Pharmaceutical Sales Representatives*, 273 *JAMA* 1296 (1995) (finding that eleven percent of statements by detailers to doctors were inaccurate, but only twenty-six percent of doctors who had heard inaccurate statements could detect them), see Roberto Cardarelli, et al., *A Cross-Sectional Evidence-Based Review of Pharmaceutical Promotional Marketing Brochures and Their Underlying Studies: Is What They Tell Us Important and True?*, 7 *BMC Fam. Prac.* 13 (2006) (finding that the research presented by sales representatives was often framed so that real patient risk/benefit conclusions could not be drawn).

⁴⁹ See Fischer, *supra* note 36 at 1854 (citing the ALLHAT study of antihypertensive therapy from 1994-1998).

prescribed medications at odds with clinical guidelines at a cost of \$11.2 million per year in that state alone.⁵⁰ 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.⁵¹ 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.⁵²

The aggregate financial costs to society of undue influence by pharmaceutical marketers is enormous. Nearly a third of the five-fold increase in U.S. spending on drugs over the last decade can be attributed to shifts to more expensive medications, which are often no better than older cheaper medications but which are heavily marketed to doctors.⁵³ A significant amount of these irrational choices are enabled by pharmaceutical marketers knowing that an individual doctor is favoring the less expensive treatment and mounting a campaign in response to convince the doctor to switch treatments.⁵⁴ There can be no doubt that states have an overriding interest in responding to these harmful social trends.

⁵⁰ Fischer, *supra* note 36 at 1854.

⁵¹ Jerry Avorn, Powerful Medicines 202 (rev. 2003).

⁵² Waxman, *supra* note 40.

⁵³ National Institute for Health Care Management, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs*, 2-3 (rev. May 6, 2002); see Geoffrey M. Anderson, et al., *Newly Approved Does Not Always Mean New and Improved*, 299 JAMA 1598 (2008).

⁵⁴ See Jane Coutts, *Pharmaceutical Group's Head Defends Sale of Medical Data*, *Globe & Mail* (March 28, 1996) (describing how “[k]nowing an individual doctor favours thiazide diuretics would enable drug companies to direct a real campaign toward getting him or her to switch to a more expensive - even if less effective - drug”).

C. The Act Polices Standards in the Medical Profession.

Many physician organizations advocate an end to prescriber-identified data trading for marketing purposes because the practice threatens the ethical standards of the profession and jeopardizes their relations with patients.⁵⁵ In *Ohralik*, the Supreme Court explained that “the State bears a special responsibility for maintaining standards among the members of the licensed professions.”⁵⁶ The Court held that this interest in enforcing ethical standards of the profession justifies measures to “avoid situations where the [professional’s] exercise of judgment on behalf of the client will be clouded by his own pecuniary interest.”⁵⁷

There may be no greater affront to the ethical basis of the medical profession than permitting pharmaceutical companies to give pecuniary rewards to medical professionals based on their prescribing habits. Prescription data mining provides the key tool for pharmaceutical companies to literally pay prescribers – with meals, gifts, vacations, high-value low-work “consultancies” and board appointments – for the use of their products. High prescribers and influential specialists can receive tens and even hundreds of thousands of dollars for consultancies and lectures each year, a cycle that not only rewards high prescribers, but also uses those physicians’ prominence to influence other doctors’ prescribing choices.⁵⁸ This

⁵⁵ See Susan Coyle, *Physician-Industry Relations, Part 1: Individual Physicians, Position Paper*, 136 *Annals of Internal Med.* 396 (March 2002) (statement of the American College of Physicians); National Physicians Alliance, *The Sale of Physician Prescribing Data Raises Health Care Costs—The National Physicians Alliance Calls for a Ban*, http://npalliance.org/images/uploads/IssueBrief-Prescribing_Data_low_res.pdf; No Free Lunch, <http://www.nofreelunch.org/aboutus.htm>; American Medical Students Ass’n, Pharm Free Campaign, <http://www.amsa.org/prof/focus.cfm>.

⁵⁶ *Ohralik*, 436 U.S. at 460.

⁵⁷ *Id.* at 461.

⁵⁸ See *supra* note 41.

incorporation of prescribers into the commission structure of pharmaceutical sales debases the medical profession and, the more the practice becomes public, breaks the chain of trust between doctor and patient.⁵⁹

Indeed, there is an increasing realization in the medical profession that physician-industry relationships have been both intentionally and unintentionally growing unchecked.⁶⁰ It is essential that, in this fight against industry influence, physicians have the option to protect the confidentiality of the prescribing choices they make for their patients. This confidentiality is central to both the perception and the reality that physician prescribing choices are made only for the best interest of their patients and not as a result of the enormous efforts of marketers to affect those choices.

D. The Act Protects Doctors Against Vexatious Sales Practices

The Supreme Court has repeatedly held that states have a legitimate interest in regulating marketing that is “pressed with such frequency or vehemence as to intimidate, vex, or harass the recipient.”⁶¹ Doctors are pushing many of the reforms in this area in part because a substantial number feel harassed by the increasing frequency and aggressiveness of detailing forces fueled by the use of prescribing data to track prescription writing and calculate sales bonuses.

⁵⁹ Robert Gibbons, et al., *A Comparison of Physicians’ and Patients’ Attitudes Toward Pharmaceutical Industry Gifts*, 13 J. Gen. Internal Med. 151, 152 (1998); Katz, *supra* note 42.

⁶⁰ Catherine DeAngelis, *Impugning the Integrity of Medical Science: The Adverse Effects of Industry Influence*, 299 JAMA 1833-35 (2008); see Gardner Harris & Benedict Carey, *Researchers Fail to Reveal Full Drug Pay*, N.Y. Times, Jun. 8, 2008, at A1.

⁶¹ *Edenfield*, 507 U.S. at 769; see *Ohralik*, 436 U.S. at 458 (“State has a legitimate and indeed ‘compelling’ interest in preventing those aspects of solicitation that involve fraud, undue influence, intimidation, overreaching, and other forms of ‘vexatious conduct.’”).

There are a host of federal and state laws that combat harassing and frequent marketing calls on consumers by limiting marketers' access to identifying information.⁶² In the case of medicines, it is doctors who make the purchasing decisions for the ultimate consumers of the product, and therefore they receive the large majority of all marketing efforts.

Although marketing to doctors has long been a key focus of pharmaceutical company marketing budgets,⁶³ the availability of digitized prescribing data beginning in the early 1990s made the practice more profitable and invasive.⁶⁴ Access to prescribing data has stoked a massive increase in spending and sales force size for individualized marketing that has become harassing in its sheer volume. In 2004, the industry spent \$27 billion on drug marketing, more than any other sector in the U.S., on its sales force or media advertising.⁶⁵ Over eighty-five percent of pharmaceutical marketing budgets are targeted at doctors.⁶⁶ In the decade after IMS unveiled its flagship prescriber tracking program in 1993,⁶⁷ spending on detailing increased by nearly three hundred percent,⁶⁸ doubling the number of pharmaceutical sales representatives to

⁶² See, e.g., Fair Credit Reporting Act, 15 U.S.C. § 1681 et seq. (2000) (credit reporting information); Family Educational Rights and Privacy Act of 1974, 20 U.S.C. § 1232g (2000 & Supp. III 2003) (educational information). See also *supra* notes 16-20 (citing laws banning the secondary use of consumer data for marketing and other commercial purposes).

⁶³ Jeremy Greene, *Pharmaceutical Research and the Prescribing Physician*, 146 *Annals Internal Med.* 742 (2007).

⁶⁴ See Elliott, *supra* note 41; PricewaterhouseCoopers, HCFA Study of the Pharmaceutical Benefit Management Industry, Contract No. 500-97-0399/0097, at 5 (June 2001) (noting that by the end of the 1990s, PBMs were managing about 90% of all drug benefit plans, and that their influence drove pharmacies to use of electronic records).

⁶⁵ Manchanda, *supra* note 43.

⁶⁶ Kaiser Family Foundation, *Trends and Indicators in the Changing Health Care Marketplace* exhibit 1.20, <http://www.kff.org/insurance/7031/print-sec1.cfm> (2005)[hereinafter *Trends*].

⁶⁷ *IMS America Introduces Xponent, the First and Only True Prescriber Level Prescription Sales Database*, PR Newswire, Feb. 9, 1993, available at Lexis.

⁶⁸ *Trends*, *supra* note 66.

over 100,000.⁶⁹ There is one pharmaceutical sales representative for every four to five office based physicians in the nation.⁷⁰ But because low prescribers often do not receive sales attention, it has been estimated that the effective ratio of sales representatives to targeted doctors is closer to one for every 2.5 doctors.⁷¹ The average primary care physician in 2004 interacted with a staggering 28 sales representatives each week.⁷²

In addition to radically increasing the volume of physician-directed marketing, access to prescriber-identified prescription records increases the prevalence of coercive marketing practices in individual sales calls. Database products sold to pharmaceutical companies by IMS and other companies are now so advanced that “[y]ou can literally find out if a rep makes a call at 9:00 am, whether the doctor wrote a script that afternoon.”⁷³ Sales representatives use this data in increasingly obnoxious ways to hold prescribers “accountable” for their marketing messages and gifts, including by telling prescribers that they are being monitored and that the free lunches and gifts will dwindle if they do not meet the marketers’ expectations.⁷⁴

⁶⁹ Rayna Herman & Nick Dabruzzo, *2006 Access Report: The State of the Selling Environment*, Pharmaceutical Representative, July 2006, available at <http://www.pharmrep.com/pharmrep/article/articleDetail.jsp?id=353927>; Manchanda, *supra* note 43.

⁷⁰ Herman, *supra* note 69; Manchanda, *supra* note 43.

⁷¹ Fugh-Berman, *supra* note 39 at 624.

⁷² Consumers Union; *Prescription for Change*, Mar. 2006, <http://www.consumersunion.org/pdf/drugreps.pdf> (citing Herman, *supra* note 69).

⁷³ *Looking Back. Looking Forward; Interview with Irwin Gerson, Chairman Emeritus of Lowe McAdams Healthcare*, Medical Marketing & Media, Apr. 1998, 70, available at Lexis.

⁷⁴ Gardiner Harris & Richard Pear, *Drug Maker’s Efforts to Compete in Lucrative Insulin Market are Under Scrutiny*, N.Y. Times, Jan. 28, 2006, at A14 (quoting an email message from a pharmaceutical executive encouraging sales reps to “[h]old [doctors] accountable for all the time, samples, lunches, dinners, programs and past preceptorships that you have paid for and get the business!”); see also Stephanie Saul, *Doctors Object as Drug Makers Learn Who’s Prescribing What* (alternate title, *Doctors Object to Gathering of Drug Data*), N.Y. Times, May 4, 2006, at A1 (describing physician anger at aggressive marketing tactics based on knowledge

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

As described above, the Vermont Act does not implicate the First Amendment and therefore this court need not investigate the alternative approaches that Vermont could have considered to meet its purposes. It is worth noting, however, that law does not prohibit tracking prescriber identities for valid non-marketing related purposes, such as to enforce formulary compliance or to monitor evidence-based prescribing practices, and it therefore restricts no more speech than is necessary to meet its purposes. The law further allows those prescribers who so choose to opt-in to the collection and sale of their prescribing data for marketing purposes.

While the American Medical Association's Prescribing Data Restriction Program (PDRP) is often raised as an alternative to state regulation, the PDRP is structurally flawed, as well as protecting only physician prescribers, not nurse practitioners or physician's assistants.⁷⁵ The PDRP allows physicians to request that their specific prescribing data not be released to sales representatives, but regardless of opt-out status the AMA continues to include all physician information in the Physician Masterfile that is transferred to data mining companies. The AMA relies on pharmaceutical companies to check an updated "opt-out" list and keep the physician-

of prescribing habits); Shannon Brownlee & Jeanne Lenzer, *Spin Doctored: How Drug Companies Keep Tabs on Physicians*, Slate (May 31, 2005), www.slate.com/id/2119712/ (same); Elliott, *supra* note 41 at 7-8 (same); Requiring Certain Persons to Keep the Contents of Prescriptions Confidential, Hearing on HB 1346 Before the Senate Committee on Executive Departments and Administration, 2006 Leg.(N.H. 2006) at 33 (Testimony of Ms. Finocchiaro); Sheryl Stolberg & Jeff Gerth, *High Tech Stealth Being Used to Sway Doctor Prescriptions*, N.Y. Times, Nov. 16, 2000. at A1 (including statement of "outrage[]" by former president of American College of Physicians); Liz Kowalczyk, *Drug Companies' Secret Reports*, Boston Globe, May 25, 2003, at A1; Robert Steinbrook, *For Sale: Physicians' Prescribing Data*, 354 New Eng. J. Med. 2745 (2006).

⁷⁵ See Steinbrook, *supra* note 74 at 2745; David Grande, Editorial, *Prescriber Profiling: Time to Call it Quits*, 146 *Annals Internal Med.* 751 (2007).

identified prescribing data from their sales representatives while allowing data access to higher level marketing officials that direct and compensate sales representatives.⁷⁶

Until physician criticism, the program had dissuaded doctors from using it through a requirement for renewal every three years and through a warning to doctors that using it “may result in a reduction of drug samples, Continuing Medical Education programs and speaking engagements.”⁷⁷ In addition to inherent weaknesses in the PDRP, the AMA has done an insufficient job promoting it, with less than one-third of physicians aware of the existence of the program.⁷⁸ Indeed, despite polls suggesting that approximately two-thirds of doctors oppose prescriber identified prescription tracking for marketing purposes,⁷⁹ less than two percent of physicians in the country have utilized the AMA’s opt-out program.⁸⁰

⁷⁶ See American Medical Association, *PDRP: The choice is yours*, 2007 available at http://www.ama-assn.org/ama1/pub/upload/mm/432/pdrp_brochure.pdf; see also Robert Musacchio & Robert Hunkler, *More Than a Game of Keep-Away*, *Pharmaceutical Executive*, May 2006. (tracing the growth of the PDRP from an AMA best-practices guideline, to a condition for leasing the physician masterfile).

⁷⁷ Kevin O’Reilly, *AMA Opt-Out Program will Keep Prescribing Data From Drug Reps*, *Am. Med. News*, May 22/29, 2006, at 1-2; American Medical Association, Resolution before the AMA, *AMA’s Prescribing Data Restriction Program “Opt-out” Policy*, Resolution 606, Oct. 5, 2006, available at <http://www.ama-assn.org/ama1/pub/upload/mm/475/606.doc> (resolution proposed by New England delegates objecting to warnings introducing PDRP), see also Greene, *supra* note 63.

⁷⁸ Letter from Michael Maves, Executive Vice President of AMA, to Senator Herb Kohl, Chairman U.S. Special Committee on Aging (May 7, 2008, on file with Sean Flynn) (responding to a U.S. Senate Special Committee on Aging Committee inquiry the AMA touted surveys that revealed that only between 26 and 31 percent of physicians were even aware of the program).

⁷⁹ Kaiser Family Foundation, *National Survey of Physicians, Highlights and Chartpack*, chart 3 (2002) (conducted March-November 2001); American Medical Association, *Reports of Board of Trustees, Use of Physician and Patient Prescribing Data in the Pharmaceutical Industry*, Resolution 606, I-03, Interim Meeting of the AMA House of Delegates, Dec. 2004 (reporting on results from Gallup poll)

⁸⁰ See Edward Langston, Chair of the AMA, Letter to the Editor, *AMA Responds*, *S.F. Chron.*, Aug. 7, 2007 (stating “nearly 9,000” physicians had signed up for the PDRP); see also Greene, *supra* note 63 (citing that “7,000 out of roughly 650,000 actively prescribing physicians” had

Gift bans or gift value limits are not adequate substitutes. Evidence shows that even the smallest gift creates a reciprocal relationship that affects prescribing practices.⁸¹ And even if all gifts were banned, such a measure would not advance the state's interests in prohibiting the use of prescribing data to target other finely tuned messages of appreciation or discipline to influence prescribing behavior to specifically identified practitioners.

Counter-detailing programs (aka academic detailing), where the state hires trained individuals to provide objective factual information to prescribers, are not a wholly effective substitute for restrictions on access to prescriber data. Government detailing programs do not have the resources to mount targeted marketing campaigns based on the kind of individualized data compiled by pharmaceutical companies and therefore will always remain an inadequate solution that must be supported through other regulatory responses to marketing abuses.

Medicaid formularies can help address the high cost of drugs in state programs and promote evidence-based prescribing, but they do not address the problem that formularies themselves are subject to influence by pharmaceutical marketing. Additionally, Medicaid formularies only affect state spending and therefore do not serve the interest that Vermont has in the cost and efficacy of prescriptions for all of its residents.

Ultimately, addressing the deeply flawed information markets for prescription drugs that are pushing spiraling prices and distorting evidence-based prescribing practices will require a

enrolled).

⁸¹ Katz, *supra* note 42.

host of state interventions, one of which must be to curb the use of prescriber-identified prescription data to target marketing campaigns and gift giving.

CONCLUSION

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