No. 07-1945

UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

IMS HEALTH INCORPORATED, a Delaware Corporation, and
VERISPAN, LLC, a Delaware Limited Liability Company
Plaintiff-Appellees,
v.

KELLY A. AYOTTE, Attorney General for the State of New Hampshire
Defendants-Appellant.

Appeal from the United States District Court
for the District of New Hampshire in

BRIEF FOR AARP, COMMUNITY CATALYST, THE NATIONAL LEGISLATIVE ASSOCIATION ON PRESCRIPTION DRUG PRICES, THE NATIONAL PHYSICIANS ALLIANCE, THE NEW HAMPSHIRE MEDICAL SOCIETY, AND PRESCRIPTION POLICY CHOICES AS *AMICI CURIAE* IN SUPPORT OF DEFENDANT-APPELLANT, KELLY A. AYOTTE.

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September 7, 2007

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 New Hampshire Medical Society and Prescription Policy Choices.

- The name in the caption is the real party in interest.

- 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 appeal have consented to this submission, and this Court granted *amici's* motion for extension of time to file this brief. *Amici* represent a broad range of interests affected by the District Court's decision including state legislators, physicians, consumers and public policy advocates. Specifically:

- 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. Approximately 220,000 AARP members live in New Hampshire. AARP conducts research and engages in educational activities and advocacy to increase access to affordable prescription drugs since older persons have the highest rate of prescription drug use.
- 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. Bills similar to the New Hampshire statute were sponsored by NLARx members and have passed in Maine and

Vermont.

- The National Physicians Alliance is a national physician membership organization founded to restore the profession's primary emphasis on the core values of service, integrity, and advocacy. NPA supports an approach to knowledge acquisition grounded in empirical research, evidence-based conclusions, professional peer review, and transparency of process that is at odds with the covert influence brought to bear by pharmaceutical manufacturers in possession of every detail of a physician's prescribing choices.
- The New Hampshire Medical Society (NHMS) is the largest physician organization in New Hampshire. NHMS supported HB 1346 in the New Hampshire Legislature, and its members testified on the use of data mining to erode physician privacy and promote irrational drug prescribing.
- 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.

Counsel of Record Sean M. Fiil-Flynn has extensive experience in

constitutional and consumer protection law gained in private practice as well through his research agenda at the Washington College of Law. He has extensive experience with pharmaceutical drug pricing concerns, having advised governments and NGOs on pharmaceutical pricing and in over ten countries.

SUMMARY OF ARGUMENT

New Hampshire was the first state in the nation to ban the trade in prescriber-identified prescription data for marketing purposes. By doing so, the state joined much of Canada and Europe in requiring that prescription tracking by pharmaceutical companies be done only in an aggregated fashion, with all patient and prescriber-identifying information removed.[1]

The collection and sale of complex databases tracking prescribing behaviors of health professionals is conduct subject to regulation by states, not First Amendment protected speech. When a pharmaceutical company uses prescriber data to rank its favored doctors and distribute lavish gifts to reward them for their loyalty, the company is engaging in conduct, not speech, to influence drug prescribing. Likewise, a pharmacy or intermediary is engaging in conduct subject to state regulation, not speech when it sells prescription records under its custody

[1] *See* Steve Niles, *No Way to Fill in the Blanks*, Euromoney Institutional Investor, 1 (May 1, 2006); Natalie Dunleavy, *Alberta Delivers New Blow to Prescription Data Mining*, 168 Can. Med. Ass'n J. 1169 (2003).

without notice or consent from the patients or prescribers identified in those records. States can and do ban commercial trade in many secondary uses of consumer and other data, including social security numbers, credit histories, video rental preferences, DMV records and other information. And the Supreme Court has specifically affirmed the right of states to regulate many commercial exchanges of information through securities, antitrust, antidiscrimination, and other marketplace regulations.

Even if the trade in prescription records was deemed to be speech, there are compelling reasons that justify its regulation by states. An abundance of social science evidence demonstrates that prescriber-identified prescription data trading gives pharmaceutical companies an undue influence over prescribing practices that raises health care costs, promotes irrational drug selection, threatens the professional integrity of the medical profession, compromises patient privacy, and increases the prevalence of harassing and invasive marketing practices. States have an overriding interest in combating these social ills.

There is no alternative policy that New Hampshire 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

restricts no more speech than is necessary. Other policies, including gift bans, public marketing, and price regulations would not sufficiently serve New Hampshire's interests in eliminating the most corrupting uses of prescription data at the lowest cost to the state.

ARGUMENT

I. THE COLLECTION AND SALE OF PHYSICIAN-SPECIFIC PRESCRIPTION DATA IS NOT SPEECH PROTECTED BY THE FIRST AMENDMENT.

The regulation of prescription data trading is a regulation of conduct, not First Amendment protected speech. The New Hampshire Prescription Confidentiality Act[2] does not regulate the substance of what pharmaceutical companies seek to convey to doctors, patients or any other recipient of their in-person or media advertising. It affects only how companies can target and compensate the recipients of their marketing, which is not a form of speech protected by the First Amendment.

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.[3] It has never been applied by the Supreme Court to protect every

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[2] N.H. Rev. Stat. Ann. § 318:47-f (2006).

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

exchange of commercial information between contracting parties. On the contrary, the Court has indicated that there are "[n]umerous examples . . . of communications that are regulated without offending the First Amendment."[4]

Perhaps the closest analogues to the New Hampshire Act are the numerous "secondary use" regulations that prohibit records and information, from consumer purchasing histories to social security numbers, from being traded or used for another commercial purpose without consent.[5] Such laws have been upheld by courts[6] and approved of by First Amendment scholars as "unproblematic from a

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

[5] *See* 13 U.S.C. §8(c) (prohibiting information furnished to the Census from being "used to the detriment of any respondent"); Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (prohibiting release of individually identifiable health information); Video Privacy Protection Act, 18 U.S.C. §2710-2711 (prohibiting disclosure of "personally identifiable information concerning any consumer" of a video rental establishment); Cable Communications Policy Act, 47 U.S.C. §551(c)(1) (prohibiting commercial disclosure of cable viewer preferences); 18 U.S.C.A. §2702 (internet subscriber information); Driver's Privacy Protection Act, 18 U.S.C. §§ 2721-25; 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"); 20 Mo. Code of State Regulations 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").

[6] *See Reno v. Condon*, 528 U.S. 141 (2000) (upholding federal Driver's Privacy Protection Act as valid regulation of commerce); *Amelkin v. McClure*, 330 F.3d 822, 827 (6th Cir. 2003) (holding that Kentucky law regulating accident reports "does not restrict or even regulate expression").

First Amendment perspective" because they regulate conduct with business records, not speech.[7]

The District Court wrongly concluded that the New Hampshire Act regulated speech because it banned the "transfer" of prescriber identities in prescription records for marketing purposes, which it found was "a form of disclosure"[8] protected by the First Amendment under *Bartnicki v. Vopper*.[9] The District Court misinterpreted *Bartnicki*. In that case, the Supreme Court held that is was unconstitutional to penalize a public disclosure of information from a regulated wiretap on a radio program, but approved of a section of the same law that prohibited "use" of the same information for a variety of commercial purposes.[10] These prohibitions did not implicate the First Amendment, the Supreme Court explained, because "the prohibition against the 'use' of the

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[7] 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).

[8] *IMS v. Ayotte*, No. 06-CV-280-PB, 2007 Lexis 31779, at *34 (D. N.H. April 30, 2007).

[9] 532 U.S. 514 (2001).

[10] *Id.* at 527.

contents" of a regulated record is "a regulation of conduct," not speech.[11]

The New Hampshire Act limits the use of prescriber identities in prescription records only for commercial marketing purposes, including to prepare "advertising, marketing, [or] promotion" campaigns, to "evaluate the effectiveness of a professional detailing sales force," or to create customized marketing products "to influence sales or market share" of a drug.[12] These are almost identical to the commercial "uses" of regulated records that the Supreme Court approved of in *Bartnicki* as not implicating the First Amendment.[13] 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.

The District Court's rule that every transfer of information is necessarily a form of First Amendment protected speech is erroneous and, if adopted by this court, would have wide ranging effects. Since there is no rational basis test under the First Amendment, courts in this Circuit would be called upon to apply

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[11] *Id.* at 526-27.

[12] N.H. Rev. Stat. Ann. 318:47-f.

[13] *Bartnicki* at 527 n. 10(approving of cases prohibiting use of information from regulated wiretaps "to prepare [business] strategy," "to discipline a subordinate," and "to create a competing product")(citations omitted).

heightened scrutiny to every state and federal law affecting the transfer of speech or text, from confidentiality laws protecting against the sharing of credit histories or social security numbers to the heart of our marketplace laws governing "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."[14] 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.[15]

II. THE STATE HAS COMPELLING INTERESTS IN REGULATING PRESCRIPTION DATA MINING.

Because the New Hampshire Act regulates only the conduct of data mining, not the speech of pharmaceutical marketers, and because the plaintiffs did not challenge the law on equal protection or due process grounds, there is no need for this court to examine New Hampshire's interests in passing the Act. If this court found that the Act did regulate some aspect of protected speech, the most lenient

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[14] *Ohralik*, 436 U.S. at 456.

[15] *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").

possible application of First Amendment scrutiny would be warranted.[16] The District Court erred in applying an especially rigorous scrutiny to New Hampshire's Act and rejecting the many compelling justifications supporting the law.[17]

A. The Act Protects Against Undue Influence.

States have a paramount interest in combating undue influence of pharmaceutical marketers over prescribing decisions. The Supreme Court has made clear that states may regulate – and even ban – commercial speech that is

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[16] Although there is not a clearly articulated rational basis test under the First Amendment, the Supreme Court has instructed that 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 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, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 762 (1985) (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").

[17] *Cf. Trans Union Corp. v. FTC,* 267 F.3d 1138, 1140-41 (D.C. Cir. 2001) (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).

"not provably false, or even wholly false," and that the First Amendment "does not prohibit the State from insuring that the stream of commercial information flows cleanly as well as freely."[18] States may regulate commercial solicitation practices that are "merely deceptive and misleading,"[19] 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."[20]

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."[21]

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

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[18] *Virginia State Bd. of Pharmacy*, 425 U.S. at 771.
[19] *Id.* at 771-72.
[20] *Ohralik*, 436 U.S. at 458 (citations omitted).
[21] See Declaration of Jerry Avorn & Aaron Kesselheim at 6. See also Michael Fischer & Jerry Avorn, *Economic Implications of Evidence-Based Prescribing for Hypertension: Could Better Care Cost Less*, 291 J. Am. Med. Ass'n 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").

receive gifts of significant value, such as meals, branded office supplies, and free drug samples,[22] which create powerful psychological urges to reciprocate.[23] 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.[24]

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.[25] Presumably, the high volume A+ prescribers could expect more valuable and

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

[23] 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).

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

[25] *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).

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.[26] There is also "a large body of evidence from the social sciences that shows that behavior can be influenced by gifts of negligible value,"[27] 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. Doctors, particularly primary care physicians, are overworked and

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[26] *See* Joseph Ross, et al., *Pharmaceutical Company Payments to Physicians*, 297 J. Am. Med Ass'n 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 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.

[27] 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).

overwhelmed by the volume of medical news, creating a system where pharmaceutical marketers become the easiest source of information on new drugs, delivered with lunch directly to the office.[28] When this is combined with a pharmaceutical representative's ability to extol the benefits of their drug in specific, if biased, comparison to the one the physician is currently prescribing, even physicians conscious of the marketing pressure are commonly influenced.[29]

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.[30] An exhaustive data

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[28] Jerry Avorn, *Powerful Medicines*, 220 (rev. 2005).

[29] Jason Dana & George Lowenstein, *A Social Science Perspective on Gifts to Physicians From Industry*, 290 J. Am. Med. Assn. 252 (2003).

[30] *See id.;* Blumenthal, *supra* note 23; 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 27 (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 J. Am. Med. Ass'n. 373 (2000) (reviewing studies); Declaration of Avorn and Kesselheim, at 3-5 (discussing studies demonstrating the "powerful effect [of gifts and detailing] on driving drug utilization").

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."[31] 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 existing formulary drugs."[32]

Studies have also shown that physicians and other health care professionals are not well qualified to filter through misleading and skewed presentations by sales representatives. 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).[33] Further, they generally trust the messages delivered by

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[31] Wazana, *supra* note 29 at 375.

[32] *Id.*

[33] *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 & Theraputics 207 (1997); Michael Stienman, et al. *Of Principles and Pens: Attitudes*

pharmaceutical representatives,[34] and are very poor at detecting false and misleading messages within sales pitches.[35]

The negative impacts of undue influence in prescribing is compounded by the transmission of these marketing-influenced choices through the doctor to the patient where they carry the imprimatur of impartial medical advice. Patients – the ultimate consumers of medicine – have great trust in physicians and little capacity to perceive or evaluate the influence of marketing on the drugs they are prescribed.

B. The Act Restrains Costs and Promotes Public Health.

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

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and Practices if 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).

[34] Wazana, *supra* note 29 at 375.

[35] Michael Ziegler,et al., *The Accuracy of Drug Information from Pharmaceutical Sales Representatives*, 273 J. Am. Med. Ass'n 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).

There are many examples of the successes of our super-charged pharmaceutical marketing system at shifting massive amounts of prescriptions toward newer, more expensive drugs that do not benefit patients. One study, referenced in the New Hampshire legislative history, showed that using highly-marketed branded medicines for high blood pressure instead of less expensive generic therapies rated as *more effective* by national treatment guidelines increased U.S. health costs by $3 billion in 1996.[36] Another study found that approximately forty percent of Pennsylvania Medicare patients on antihypertensive therapy were being prescribed medications at odds with clinical guidelines at a cost of $1.2 billion per year in that state alone.[37] 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.[38] And in the case of Vioxx,

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[36] 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); *cf.* Leg. Hist. at 14 (testimony that the least and most expensive calcium channel blocker on the New Hampshire Medicaid formulary cost $13.50 vs. $87.30 per month respectively).

[37] Fischer, *supra* note 21 at 1854.

[38] Avorn, *supra* note 28 at 202.

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.[39]

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 pharmaceutical marketing efforts that shift doctors' prescribing from existing, effective, and lower cost (often generic) therapies to new and more expensive treatments.[40] A significant amount of these irrational 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.[41] There can be no doubt that states have an overriding interest in responding to these harmful social trends.

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[39] Waxman, *supra* note 25.

[40] National Institute for Health Care Management, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs*, 2-3 (rev. May 6, 2002).

[41] *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 Maintains 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.[42] In *Ohralik*, the Supreme Court explained that "the State bears a special responsibility for maintaining standards among the members of the licensed professions."[43] 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."[44]

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,

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[42] *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.

[43] *Ohralik*, 436 U.S. at 460.

[44] *Id*. at 461.

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.[45] This 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.[46]

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."[47] 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

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[45] *See supra* note 26.

[46] 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 27.

[47] *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.'").

prescribing data to track prescription writing and calculate sales bonuses.

There are a host of federal and state laws that combat harassing and frequent marketing calls on consumers by limiting marketers' access to identifying information.[48] 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,[49] the availability of digitized prescribing data beginning in the early 1990s made the practice more profitable and invasive.[50] 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

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[48] *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* note 5 (citing laws banning the secondary use of consumer data for marketing and other commercial purposes).

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

[50] *See* Elliott, *supra* note 26; 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 phamacies to use of elctronic records).

other sector in the U.S., on its sales force or media advertising.[51] Over eighty-five percent of pharmaceutical marketing budgets are targeted at doctors.[52] In the decade after IMS unveiled its flagship prescriber tracking program in 1993,[53] spending on detailing increased by nearly three hundred percent,[54] doubling the number of pharmaceutical sales representatives to over 100,000.[55] There is one pharmaceutical sales representative for every four to five office based physicians in the nation.[56] 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.[57] The average primary care physician in 2004 interacted with a staggering 28 sales representatives each week.[58]

In addition to being harassing by its sheer volume, access to prescriber

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[51] Manchanda, *supra* note 30.
[52] 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)[herinafter *Trends*].
[53] *IMS America Introduces Xponent, the First and Only True Prescriber Level Prescription Sales Database,* PR Newswire, Feb. 9, 1993, *available at Lexis*.
[54] *Trends*, *supra* note 52.
[55] 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 30.
[56] Herman, *supra* note 55; Manchanda, *supra* note 30.
[57] Fugh-Berman, *supra* note 24 at 624.
[58] Consumers Union; *Prescription for Change*, Mar. 2006, http://www.consumersunion.org/pdf/drugreps.pdf (citing Herman, *supra* note 55).

detailing 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."[59] 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.[60]

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

[60] Gardiner Harris & Richard Pear, *Drug Maker's Efforts to Compete in Lucrative Insulin Market are Under Scritiny*, 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 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 26 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:*

E. The Act Protects Patient Privacy.

The data mining companies have not challenged New Hampshire's interest in protecting the privacy of patients in their prescription records. There can be no doubt that patients have the strongest possible interest in not having their treatment histories subjected to surveillance and lobbying by pharmaceutical companies. But this interest cannot be protected by the removal of patient names alone.

Patient de-identification is not complete with the removal of names and addresses. The data can still be used to track an individual patient, identified with a unique numerical identifier that carries forward through time.[61] The problem with this is twofold – it weakens the protection of privacy for patients in situations where knowing treatment history and physician identity can allow re-identification of a patient, as well as allowing pharmaceutical companies to target an individual patient for sales efforts, even name unknown. With access to prescriber identities and "anonymized" patient data a pharmaceutical company can not only observe a

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Physicians' Prescribing Data, 354 New Eng. J. Med. 2745 (2006).

[61] *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).

specific treatment event for a particular patient, like the switching of a prescription, but can respond with an individualized marketing campaign at the prescriber to change that patient's treatment. This insertion of the pharmaceutical company into the monitoring and influence of the patient's treatment is an invasion of privacy of the most odious kind – one that directly affects the treatment course of the patient for the pecuniary interest of another through a breach of confidentiality that is nearly impossible to detect.

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

As described above, the New Hampshire Act does not implicate the First Amendment and therefore this court need not investigate the alternative approaches that New Hampshire 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. In addition, none of the alternative policies discussed by the District Court or the data mining companies serve New Hampshire's interests as well as the law it passed.

The American Medical Association's Prescribing Data Restriction Program (PDRP) is a deeply flawed measure to safeguard physician interests in controlling

access to their prescribing data.[62] That program allows doctors to flag the identifying data sold by the AMA to data mining companies to indicate that it should not be used by street level pharmaceutical representatives. However, the AMA continues to include all physician information in the Physician Masterfile that is transferred to data mining companies, relying on pharmaceutical companies to check an updated "opt-out" list and voluntarily keep the prescribing data from their sales representatives. The program does not permit physicians to restrict data access to higher level marketing officials that direct and compensate sales representatives.[63] Thus, the program does not even meet its own narrow interest of protecting physician control over prescribing data.

The PDRP is only targeted at physicians; it does nothing to protect data privacy for nurse practitioners and other non-phyisican prescribers whose behavior is also tracked by pharmaceutical firms. The program has been further criticized for dissuading doctors from using it through a requirement for renewal every three

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[62] *See* Steinbrook, *supra* note 60 at 2745; David Grande, Editorial, *Prescriber Profiling: Time to Call it Quits*, 146 Annals Internal Med. 751 (2007).

[63] *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).

years, inadequate marketing (especially to non-AMA members),[64] and through a warning to doctors that using it "may result in a reduction of drug samples, Continuing Medical Education programs and speaking engagements."[65] Indeed, despite polls suggesting that about two thirds of doctors oppose prescriber identified prescription tracking for marketing purposes,[66] less than 2% of physicians in the country have utilized the AMA's opt-out.[67]

Even if a more expansive opt-out program was created by law, it would only protect the prescribers' interest in controlling whether or not their data is released to marketers. An opt-out program would not meet the full range of New

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[64] *See*, Greene, *supra* note 49 (noting that less than 25 percent of doctors know that the program exists).

[65] 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).

[66] 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)

[67] *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 49 (citing that "7,000 out of roughly 650,000 actively prescribing physicians" had enrolled).

Hampshire's interests in banning the trade in prescriber-identified data entirely, including to set standards in the medical profession, advance evidence based prescribing practices, cut the chain of undue influence in data-fueled pharmaceutical marketing, and to protect patient confidentiality. If New Hampshire determined that prescription data trading is a corrupting influence, then permitting doctors to engage in it at their own will does not serve the state's goals.

Nor is a gift ban or value limit a viable substitute for data trading restrictions. Evidence shows that even the smallest gift creates a reciprocal relationship that effects prescribing practices.[68] 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 efforts 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, is not an effective substitute because no state has the resources to battle biased marketing campaigns of pharmaceutical companies on a dollar for dollar basis. Simply imagine the expenditure of resources it would take to match the 28 visits a week that the average physician receives from a for-profit drug rep. Attempting such a

[68] Katz, *supra* note 27.

program, without using regulatory authority to correct the flaws in the information market that lead to the most gross abuses, would be foolhardy. For this reason, Dr. Jerry Avorn, a primary promoter of counter-detailing programs, supports the New Hampshire legislation.

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 New Hampshire 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 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 in the Appellant's brief, amici respectfully urge that the judgment of the District Court be reversed.

CERTIFICATE OF COMPLIANCE

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1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains XXXX words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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Date:_____ _____

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I, Sean Fiil-Flynn, hereby certify that on September 7, 2007, I served two copies of the forgoing brief on the following parties by way of United States Postal Service First Class Mail, postage prepaid.

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