

UNITED STATES DISTRICT COURT  
DISTRICT OF MAINE

IMS HEALTH INC., )  
VERISPAN, LLC, and SOURCE HEALTHCARE )  
ANALYTICS, INC., a Subsidiary of )  
WOLTERS KLUWER, HEALTH INC., )  
 )  
Plaintiffs, ) Civil Action No. 07-127-JAW  
 )  
v. )  
 )  
G. STEVEN ROWE, as the )  
Attorney General for the State of Maine )  
 )  
Defendant. )

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BRIEF FOR AARP, COMMUNITY CATALYST, THE NATIONAL  
LEGISLATIVE ASSOCIATION ON PRESCRIPTION DRUG PRICES,  
DR. BETHANY PICKER and DR. DAN SUMMERS  
AS *AMICI CURIAE* IN SUPPORT OF DEFENDANT

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<i>Lorillard Tobacco Co. v. Reilly</i> , 533 U.S. 525 (2001).....	8
<i>Ohralik v. Ohio State Bar Ass'n</i> , 436 U.S. 447 (1978).....	<i>passim</i>
<i>Reno v. Condon</i> , 528 U.S. 141 (2000) .....	5
<i>Thompson v. Western States Medical Center</i> , 535 U.S. 357 (2002).....	8
<i>Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council</i> , 425 U.S. 748 (1976).....	4, 8, 9

### STATUTES

13 U.S.C. §8(c). .....	5
18 U.S.C. §2702.....	5
20 Mo. Code of State Regulations 2220-2.....	5

Cable Communications Policy Act, 47 U.S.C. §551(c)(1). .....	5
Cal. Civ. Code §1798.85(a). .....	5
Driver’s Privacy Protection Act, 18 U.S.C. §§2721-25 .....	5
Fair Credit Reporting Act, 15 U.S.C. §1681 et seq. (2000).....	16
Family Educational Rights and Privacy Act of 1974, 20 U.S.C. §1232g (2000 & Supp. III 2003) .....	16
Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936. ....	5
Me. P.L. 2007, Ch. 460 (amended 22 M.R.S.A. §§1711-E, 8704, and 8713).....	<i>passim</i>
Ohio Rev. Code §4501.27(A). .....	5
Video Privacy Protection Act, 18 U.S.C. §2710-2711. ....	5

**OTHER AUTHORITIES**

American Medical Students Association, Pharm Free Campaign, <a href="http://www.amsa.org/prof/focus.cfm">http://www.amsa.org/prof/focus.cfm</a> .....	15
Jerry Avorn, et al., <i>Scientific Versus Commercial Sources of Influence on the Prescribing Behavior of Physicians</i> , 73 Am. J. Med. 4 (1982). .....	12
Jerry Avorn, <i>Powerful Medicines</i> (rev. 2003).....	11, 14
David Blumenthal, <i>Doctors and Drug Companies</i> , 351 New Eng. J. Med. 1885 (2004). .....	9, 11
Shannon Brownlee & Jeanne Lenzer, Spin Doctored: How Drug Companies Keep Tabs on Physicians, Slate (May 31, 2005), <a href="http://www.slate.com/id/2119712/">www.slate.com/id/2119712/</a> . ....	18
Eric Campbell et al., <i>A National Survey of Physician-Industry Relationships</i> , 356 New Eng. J. Med. 1742, (2007). .....	9
Abigail Caplovitz, <i>Turning Medicine Into Snake Oil: How Pharmaceutical Marketers Put Patients at Risk</i> , NJPIRG Law and Policy Center (2006).....	11

Roberto Cardarelli, et al., <i>A Cross-Sectional Evidence-Based Review of Pharmaceutical Promotional Marketing Brochures and Their Underlying Studies: Is What They Tell Us Important and True?</i> , 7 BMC Fam. Prac. 13 (2006).....	13
Jim Carroll & Tanya Foniri, <i>Infuse Anonymized Patient-Level Information into the Brand-Planning Process to Drive Profitable Growth</i> , IMS, <a href="http://www.imshealth.com/vgn/images/portal/cit_40000873/0/38/78187147Brand%20Planning%20Paper.pdf">http://www.imshealth.com/vgn/images/portal/cit_40000873/0/38/78187147Brand%20Planning%20Paper.pdf</a> (June 1, 2006).....	19
Emily Clayton, CALPIRG, <i>'Tis Always the Season for Giving: A White Paper on the Practice and Problems of Pharmaceutical Detailing</i> (2004). ....	10
Consumers Union; <i>Prescription for Change</i> , March 2006, <a href="http://www.consumersunion.org/pdf/drugreps.pdf">http://www.consumersunion.org/pdf/drugreps.pdf</a> . ....	17
Jane Couetts, <i>Pharmaceutical Group's Head Defends Sale of Medical Data</i> , Globe and Mail (March 28, 1996). ....	14
Susan L. Coyle, <i>Physician-Industry Relations, Part 1: Individual Physicians, Position Paper</i> , 136 Annals of Internal Medicine 396 (March 2002). ....	15
Jason Dana & George Lowenstein, <i>A Social Science Perspective on Gifts to Physicians From Industry</i> , 290 J. Am. Med. Assn. 252 (2003). ....	11
Natalie Dunleavy, <i>Alberta Delivers New Blow to Prescription Data Mining</i> , 168 Can. Med. Assn. J. 1169 (2003).....	2
Carl Elliot, <i>The Drug Pushers</i> , Atlantic Monthly (Apr. 2006), available at <a href="http://www.theatlantic.com/doc/print/200604/drug-reps">www.theatlantic.com/doc/print/200604/drug-reps</a> .....	10, 16, 18
Michael Fischer & Jerry Avorn, <i>Economic Implications of Evidence-Based Prescribing for Hypertension: Could Better Care Cost Less</i> , 291 J. Am. Med. Assn. 1850 (2004). ....	9, 13
Adriane Fugh-Berman & Shahram Ahari, <i>Following the Script: How Drug Reps Make Friends and Influence Doctors</i> , 4 PLoS Med. 0621 (2007). ....	10, 17
Robert Gibbons, et al., <i>A Comparison of Physicians' and Patients' Attitudes Toward Pharmaceutical Industry Gifts</i> , 13 J. Gen. Internal Med. 151 (1998) .....	15

Jeremy Greene, <i>Pharmaceutical Research and the Prescribing Physician</i> , 146 <i>Annals Internal Med.</i> 742 (2007).....	16
Gardiner Harris & Richard Pear, <i>Drug Maker's Efforts to Compete in Lucrative Insulin Market are Under Scrutiny</i> , <i>N.Y. Times</i> , Jan. 28, 2006, at A14.....	18
Gardiner Harris & Richard Pear, <i>Psychiatrists, Children, and Drug Industry's Role</i> , <i>N.Y. Times</i> , May 10, 2007.....	10
Rayna Herman and Nick Dabruzzo, <i>2006 Access Report: The State of the Selling Environment</i> , <i>Pharmaceutical Representative</i> .....	17
<i>IMS America Introduces Xponent, the First and Only True Prescriber Level Prescription Sales Database</i> , <i>PR Newswire</i> , Feb. 9, 1993.....	17
IMS, <i>IMS Announces Integration of Anonymized Patient-Level Data Across Global Portfolio of Offerings</i> , <a href="http://www.imshealth.com/ims/portal/front/articleC/0,2777,6025_3665_79490459,00.html">http://www.imshealth.com/ims/portal/front/articleC/0, 2777,6025_3665_79490459,00.html</a> (Nov. 28, 2006).....	19
Kaiser Family Foundation, <i>Trends and Indicators in the Changing Health Care Marketplace</i> , <a href="http://www.kff.org/insurance/7031/print-sec1.cfm">http://www.kff.org/insurance/7031/print-sec1.cfm</a> (2005).....	17
Dana Katz, et al., <i>All Gifts Large and Small: Toward an Understanding of the Ethics of Pharmaceutical Industry Gift Giving</i> , 3 <i>Am. J. Bioethics</i> 39 (2003) .....	10, 11, 15, 20
Liz Kowalczyk, <i>Drug Companies' Secret Reports</i> , <i>Boston Globe</i> , May 25, 2003, at A1.....	18
<i>Looking Back. Looking Forward; Interview with Irwin Gerson, Chairman Emeritus of Lowe McAdams Healthcare</i> , <i>Medical Marketing &amp; Media</i> April 1998, 70 .....	18
Nicole Lurie, et al., <i>Pharmaceutical Representatives in Academic Medical Centers</i> , 5 <i>J. Gen. Intern. Med.</i> 240 (1990).....	11
S. Suresh Madhavan, et al., <i>The Gift Relationship Between Pharmaceutical Companies and Physicians: An Exploratory Survey of Physicians</i> , 22 <i>J. Clinical Pharmacy &amp; Therapeutics</i> 207 (1997).....	12
Puneet Manchanda & Elisabeth Hokna, <i>Pharmaceutical Innovation and Cost</i> , 5 <i>Yale J. Health Pol'y L. &amp; Ethics</i> 785 (2005).....	11, 17

National Institute for Health Care Management, <i>Prescription Drug Expenditures in 2001: Another Year of Escalating Costs</i> (revised May 6, 2002).	14
National Physicians Alliance, <i>The Sale of Physician Prescribing Data Raises Health Care Costs -- The National Physicians Alliance Calls for a Ban</i> , <a href="http://npalliance.org/images/uploads/IssueBrief-Prescribing_Data_low_res.pdf">http://npalliance.org/images/uploads/IssueBrief-Prescribing_Data_low_res.pdf</a> .	15
Steve Niles, <i>No Way to Fill in the Blanks</i> , Euromoney Institutional Investor, 1 (May 1, 2006).	2
No Free Lunch, <a href="http://www.nofreelunch.org/aboutus.htm">http://www.nofreelunch.org/aboutus.htm</a> .	15
Robert Post, <i>The Constitutional Status of Commercial Speech</i> , 48 UCLA L. Rev. 1 (2000).	5
PricewaterhouseCoopers, HCFA Study of the Pharmaceutical Benefit Management Industry, Contract No. 500-97-0399/0097, at 5 (June 2001).	16
Helen Prosser, Solomon Almond & Tom Walley, <i>Influences on GPs' Decisions to Prescribe New Drugs -- the Importance of Who Says What</i> , 20 Fam. Prac. 61 (2003).	11
Public Citizen, <i>Response to FDA Request for Comments on First Amendment Issues</i> , September 13, 2002, available at <a href="http://www.citizen.org/publications/release.cfm?ID=7199">http://www.citizen.org/publications/release.cfm?ID=7199</a> .	10
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).	18
Neil Richards, <i>Reconciling Data Privacy and the First Amendment</i> , 52 UCLA L. Rev. 1149 (2005).	5
Joseph Ross, et al., <i>Pharmaceutical Company Payments to Physicians</i> , 297 J. Am. Med Ass'n 1216 (2007).	10
Stephanie Saul, <i>Doctors Object as Drug Makers Learn Who's Prescribing What</i> (alternate title, <i>Doctors Object to Gathering of Drug Data</i> ), N.Y. Times, May 4, 2006, at A1.	18
Stephanie Saul, <i>Drug Makers Pay for Lunch as They Pitch</i> , N.Y. Times, July 28, 2006, at A1.	10

Frederick Schauer, <i>Commercial Speech and the Architecture of the First Amendment</i> , 56 U. Cin. L. Rev. 1181 (1988). .....	5
Frederick Schauer, <i>The Boundaries of the First Amendment: A Preliminary Exploration of Constitutional Salience</i> , 117 Harv. L. Rev. 1765 (2004). .....	5
Robert Steinbrook, <i>For Sale: Physicians' Prescribing Data</i> , 354 New Eng. J. Med. 2745 (2006) .....	18
Michael Stienman, et al., <i>Of Principles and Pens: Attitudes and Practices of Medicine Housestaff Towards Pharmaceutical Industry Promotions</i> , 110 Am. J. Med. 551 (2001). .....	12
Sheryl Gay Stolberg & Jeff Gerth, <i>High Tech Stealth Being Used to Sway Doctor Prescriptions</i> , N.Y. Times, Nov. 16, 2000. at A1. ....	18
Henry Waxman, Memorandum from Ranking Minority Member, Committee on Government Reform, on the Marketing of Vioxx to Physicians, to Democratic Members of the Government Reform Committee (May 5, 2005). .....	10, 14
Ashley Wazana, <i>Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?</i> , 283 J. Am. Med. Assn. 373 (2000). .....	11, 12
Jake Whitney, <i>How Drug Reps Know Which Doctor to Target. Big (Brother) Pharma</i> , New Republic Online (2006), <a href="http://www.tnr.com/doc.mhtml?i=w060828&amp;s=whitney082906">www.tnr.com/doc.mhtml?i =w060828&amp;s=whitney082906</a> . .....	10
Michael Ziegler, et al., <i>The Accuracy of Drug Information from Pharmaceutical Sales Representatives</i> , 273 J. Am. Med. Assn. 1296 (1995). .....	12

## STATEMENT OF INTEREST

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 233,000 AARP members live in Maine. 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 is a nonprofit, nonpartisan organization that builds consumer and community participation in the shaping of the U.S. health system to ensure high quality, affordable health care for all. One of its key initiatives is the Prescription Access Litigation Project (PAL), which is a coalition of over 125 state, local and national organizations, including senior citizen groups, consumer advocates, health care advocates, legal services offices, women's health groups, non-profit health plans, labor unions and union benefit funds. PAL's mission is to make prescription drugs more affordable and reform the drug industry using litigation and consumer education.

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 Maine statute were sponsored by NLARx members and have passed in New Hampshire and Vermont.

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physicians are opposed to the dissemination and use of prescription drug records to guide pharmaceutical marketing because such use results in doctors prescribing more expensive treatments and treatments that may not be the best for patients. They oppose pharmaceutical companies' use of prescriber data for detail marketing because it is an unwarranted invasion into the doctor-patient relationship and compromises the integrity of the medical profession.

### **SUMMARY OF ARGUMENT**

Maine recently enacted P.L. 2007, Ch. 460 (the Prescription Privacy Law) authorizing Maine-licensed drug prescribers to protect their prescription information from the license, use, sale, transfer, or exchange for value of prescriber-identifiable data in prescription records for commercial purposes.

Maine is among the first states, along with New Hampshire and Vermont, to pass legislation to regulate prescriber-identified prescription data for marketing purposes. In enacting the legislation, Maine 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.<sup>1</sup>

The collection and sale of complex databases tracking prescribing behaviors of individual 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

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<sup>1</sup> 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. Assn. J. 1169 (2003).

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 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 allowed 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 research 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 Maine 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 Maine's interests in eliminating the most corrupting uses of prescription data at the lowest cost to the state.

Furthermore, under the Maine law prescribers have the option to decide whether they want their prescription information kept confidential. All prescription information will be made available for commercial purposes unless the physicians choose to keep the information private. The choice is left solely to the prescribers.

## 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 Maine Prescription Privacy Law<sup>2</sup> 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 target and compensate the recipients of their marketing, which is not a form of speech protected by the First Amendment.

The commercial speech doctrine extends a lesser degree of First Amendment protection to commercial advertising to the public.<sup>3</sup> It has never been applied by the Supreme Court to protect every 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.”<sup>4</sup>

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<sup>2</sup>Me. P.L. 2007, Ch. 460 (amended 22 M.R.S.A. §§1711-E, 8704, and 8713).

<sup>3</sup> See *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976).

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

Perhaps the closest analogues to the Maine Prescription Privacy Law 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.<sup>5</sup> Such laws have been upheld by courts<sup>6</sup> and approved of by First Amendment scholars as “unproblematic from a First Amendment perspective” because they regulate conduct with business records, not speech.<sup>7</sup>

Plaintiffs incorrectly rely on *IMS v. Ayotte*, 490 F. Supp. 2d 163 (D.N.H. 2007), *appeal docketed*, No. 07-1945 (1st Cir. June 20, 2007), in which a District Court struck down New Hampshire’s Prescription Confidentiality Act on First Amendment grounds. The New Hampshire Prescription Confidentiality Act, like Maine’s Prescription Privacy Law, seeks to

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<sup>5</sup> 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. §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”).

<sup>6</sup> 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”).

<sup>7</sup> 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).

protect prescription privacy by limiting the sale of prescriber-identifiable data for commercial purposes. However, in the New Hampshire case, the court wrongly concluded that the New Hampshire Act regulated speech because it restricted the “transfer” of prescriber identities in prescription records for marketing purposes, which it found was “a form of disclosure”<sup>8</sup> protected by the First Amendment under *Bartnicki v. Vopper*.<sup>9</sup> The District Court misinterpreted *Bartnicki*. In that case, the Supreme Court held that it 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.<sup>10</sup> These prohibitions did not implicate the First Amendment, the Supreme Court explained, because “the prohibition against the ‘use’ of the contents” of a regulated record is “a regulation of conduct,” not speech.<sup>11</sup>

The Maine Prescription Privacy Law allows health care prescribers to limit the use of their identities in prescription records for commercial marketing purposes, specifically, to prepare “advertising, publicizing, promoting or selling a prescription drug” for the purposes “of influencing the market share of a prescription drug or the prescribing patterns of a prescriber, a detailing visit or a personal appearance,” and “activities undertaken to evaluate or improve the effectiveness of a professional detailing sales force.”<sup>12</sup> These are almost identical to the commercial “uses” of regulated records that the Supreme Court, in *Bartnicki*, approved of as not

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<sup>8</sup> *IMS v. Ayotte*, 490 F. Supp. 2d 163, 183 (D.N.H. 2007), *appeal docketed*, No. 07-1945 (1st Cir. June 20, 2007).

<sup>9</sup> 532 U.S. 514 (2001).

<sup>10</sup> *Id.* at 527.

<sup>11</sup> *Id.* at 526-27.

<sup>12</sup> 22 M.R.S.A. § 1711-E, sub-§ 1, as amended by P.L. 2007, Ch. 460, § 1. N.H. Rev. Stat.

implicating the First Amendment.<sup>13</sup> 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.

Similarly, the New Hampshire District Court's ruling that every transfer of information is necessarily a form of First Amendment protected speech is erroneous and, if adopted by this Court, would similarly be an error. Since there is no rational-basis test under the First Amendment, other courts would be called upon to apply 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."<sup>14</sup> 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.<sup>15</sup>

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Ann. 318:47-f.

<sup>13</sup> *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).

<sup>14</sup> *Ohralik*, 436 U.S. at 456.

<sup>15</sup> *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").

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

Because the Maine Prescription Privacy Law 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 Maine's interests in passing the Act.

Even if this court found that the Act did regulate some aspect of protected speech, the most lenient possible application of First Amendment scrutiny would be warranted.<sup>16</sup> Under this lenient application of the law, the Supreme Court has stated that commercial speech may be regulated if the regulation directly advances a legitimate state interest, and the regulation is not more extensive than is necessary to serve that interest.<sup>17</sup>

### **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

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<sup>16</sup> 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 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”).

<sup>17</sup> *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002).

regulate -- and even ban -- commercial speech that is “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.”<sup>18</sup> States may regulate commercial solicitation practices that are “merely deceptive and misleading,”<sup>19</sup> including practices that give marketers an “undue influence” through “one-sided” presentations that “may disserve the individual and societal interest . . . in facilitating informed and reliable decision making.”<sup>20</sup>

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.<sup>21</sup> Access to prescribing data aggravates the negative impact 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,<sup>22</sup> which create powerful psychological urges to reciprocate.<sup>23</sup> Prescriber data is used to guide this gift giving, so that the most profitable prescribers receive the highest rewards. One former sales representative explained:

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<sup>18</sup> *Virginia State Bd. of Pharmacy*, 425 U.S. at 771.

<sup>19</sup> *Id.* at 771-72.

<sup>20</sup> **Error! Bookmark not defined.** *Ohralik*, 436 U.S. at 458 (citations omitted).

<sup>21</sup> See Michael Fischer & Jerry Avorn, *Economic Implications of Evidence-Based Prescribing for Hypertension: Could Better Care Cost Less*, 291 J. Am. Med. Assn. 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”).

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

<sup>23</sup> David Blum**Error! Bookmark not defined.**enthal, *Doctors and Drug Companies*, 351 New

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.<sup>24</sup>

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.<sup>25</sup> Presumably, the high volume A+ prescribers could expect more valuable and frequent gifts from Merck.

The most favored prescribers receive hundreds of thousands of dollars in payments from drug companies for speaking engagements, research, and sitting on various advisory boards.<sup>26</sup>

There is also “a large body of evidence from the social sciences that shows that behavior can be

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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).

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

<sup>25</sup> 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).

<sup>26</sup> See **Error! Bookmark not defined.** 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); **Error! Bookmark not defined.** 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](http://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),

influenced by gifts of negligible value,”<sup>27</sup> 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 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.<sup>28</sup> 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.<sup>29</sup>

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.<sup>30</sup>

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[www.tnr.com/doc.mhtml?i=w060828&s=whitney082906](http://www.tnr.com/doc.mhtml?i=w060828&s=whitney082906).

<sup>27</sup> **Error! Bookmark not defined.** 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).

<sup>28</sup> **Error! Bookmark not defined.** Jerry Avorn, *Powerful Medicines*, 220 (rev. 2005).

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

<sup>30</sup> See **Error! Bookmark not defined.** *id.*; **Error! Bookmark not defined.** Blumenthal, *supra*; **Error! Bookmark not defined.** 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* (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 GPs’ Decision 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.

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.”<sup>31</sup>

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.”<sup>32</sup>

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).<sup>33</sup> Further, they generally trust the messages delivered by pharmaceutical representatives,<sup>34</sup> and are very poor at detecting false and misleading messages within sales

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Am. Med. Assn. 373 (2000) (reviewing studies).

<sup>31</sup> Wazana, *Physicians and the Pharmaceutical Industry*, *supra* at 375 **Error! Bookmark not defined.**

<sup>32</sup> **Error! Bookmark not defined.***Id.*

<sup>33</sup> See **Error! Bookmark not defined.** Jerry Avorn, et al., *Scientific Versus Commercial Sources of Influence on the Prescribing Behavior of Physicians*, 73 Am. J. Med. 4, 4-8 (1982); **Error! Bookmark not defined.** 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); **Error! Bookmark not defined.** 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).

<sup>34</sup> **Error! Bookmark not defined.** Wazana, *supra* at 375.

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The negative impact 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 no 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 Maine and the other 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.

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 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.<sup>36</sup> Another study found that approximately forty percent of Pennsylvania Medicare patients on

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<sup>35</sup>**Error! Bookmark not defined.** Michael Ziegler, et al., *The Accuracy of Drug Information from Pharmaceutical Sales Representatives*, 273 J. Am. Med. Assn. 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).

<sup>36</sup>**Error! Bookmark not defined.** 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

antihypertensive therapy were being prescribed medications at odds with clinical guidelines at a cost of \$1.2 billion per year in that state alone.<sup>37</sup> 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.<sup>38</sup> 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.<sup>39</sup>

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.<sup>40</sup> A significant amount of these irrational decisions 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.<sup>41</sup> There can be no doubt that Maine has an overriding interest in responding to these harmful social trends.

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could not be drawn).

<sup>37</sup> Fischer, *Economic Implications*, *supra* at 1854.

<sup>38</sup> Avorn, *Powerful Medicines*, *supra* at 202.

<sup>39</sup> Waxman, Memorandum, *supra*.

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

<sup>41</sup> See **Error! Bookmark not defined.**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.<sup>42</sup> In *Ohralik*, the Supreme Court explained that “the State bears a special responsibility for maintaining standards among the members of the licensed professions.”<sup>43</sup> 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.”<sup>44</sup>

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 pay prescribers literally -- with meals, gifts, vacations, high-value low-work “consultancies,” and board appointments -- for the use of their products. High prescribers and influential specialists 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

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<sup>42</sup> See **Error! Bookmark not defined.** Susan Coyle, *Physician-Industry Relations, Part I: Individual Physicians, Position Paper*, 136 *Annals of Internal Med.* 396 (March 2002) (statement of the American College of Physicians); **Error! Bookmark not defined.** 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](http://npalliance.org/images/uploads/IssueBrief-Prescribing_Data_low_res.pdf); **Error! Bookmark not defined.** No Free Lunch, <http://www.nofreelunch.org/aboutus.htm>; American Medical Students Ass’n, Pharm Free Campaign, <http://www.amsa.org/prof/focus.cfm>.

<sup>43</sup> **Error! Bookmark not defined.** *Ohralik*, 436 U.S. at 460.

<sup>44</sup> **Error! Bookmark not defined.** *d.* at 461.

physicians' prominence to influence other doctors' prescribing choices.<sup>45</sup> 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.<sup>46</sup>

#### **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.”<sup>47</sup> Doctors, the recipients, 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.

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.<sup>48</sup> In the case of medicines, it is doctors who direct the purchasing decisions for the ultimate consumers of the product, and therefore they receive the large majority of all marketing efforts.

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<sup>45</sup> See *supra* note 26.

<sup>46</sup> 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.

<sup>47</sup> *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.’”).

<sup>48</sup> 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).

Although marketing to doctors has long been a key focus of pharmaceutical company marketing budgets,<sup>49</sup> the availability of digitized prescribing data beginning in the early 1990s made the practice more profitable and invasive.<sup>50</sup> 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.<sup>51</sup> Over eighty-five percent of pharmaceutical marketing budgets are targeted at doctors.<sup>52</sup> In the decade after IMS unveiled its flagship prescriber tracking program in 1993,<sup>53</sup> spending on detailing increased by nearly three hundred percent,<sup>54</sup> doubling the number of pharmaceutical sales representatives to over 100,000.<sup>55</sup> There is one pharmaceutical sales representative for every four to five office-based physicians in the nation.<sup>56</sup> 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

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<sup>49</sup> Jeremy Greene, *Pharmaceutical Research and the Prescribing Physician*, 146 *Annals Internal Med.* 742 (2007).

<sup>50</sup> See **EError! Bookmark not defined.**lliott, *The Drug Pushers*, *supra*; **Error! Bookmark not defined.**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).

<sup>51</sup> Manchanda, *supra*.

<sup>52</sup> 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*].

<sup>53</sup> *IMS America Introduces Xponent, the First and Only True Prescriber Level Prescription Sales Database*, PR Newswire, Feb. 9, 1993, available at Lexis.

<sup>54</sup> *Trends*, *supra* note 52.

<sup>55</sup> 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*.

<sup>56</sup> Herman, *supra* note 55; Manchanda, *supra*.

to one for every 2.5 doctors.<sup>57</sup> The average primary care physician in 2004 interacted with a staggering 28 sales representatives each week.<sup>58</sup>

In addition to being harassing by its sheer volume, access to prescriber 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.”<sup>59</sup> Sales representatives use these 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.<sup>60</sup>

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<sup>57</sup> Fugh-Berman, *supra* at 624.

<sup>58</sup> Consumers Union; *Prescription for Change*, Mar. 2006, <http://www.consumersunion.org/pdf/drugreps.pdf> (citing **Error! Bookmark not defined.**Herman, *supra* note 55).

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

<sup>60</sup> 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 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/](http://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: Physicians’ Prescribing Data*, 354 New Eng. J. Med. 2745

### **E. The Act Protects Patient Privacy.**

The data mining companies have not challenged Maine'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.<sup>61</sup> 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 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

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(2006).

<sup>61</sup> 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](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](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6025_3665_79490459,00.html) (Nov. 28, 2006).<sup>12</sup>

treatment course of the patient for the pecuniary interest of another through a breach of confidentiality that is nearly impossible to detect.

### **III. THE MAINE ACT IS SUFFICIENTLY TAILORED TO THE STATE'S COMPELLING INTERESTS.**

As described above, the Maine Prescription Privacy Act does not implicate the First Amendment and therefore this Court need not investigate the alternative approaches that Maine could have considered to meet its purposes. It is worth noting, however, that the Act 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, Maine's Prescription Privacy Law's "opt-out" provision allows each prescriber to decide whether to allow disclosure of his or her prescriber-identified data.

The State is not required to employ the least restrictive means conceivable.<sup>62</sup> The restrictions need only be reasonable and "represent[] not necessarily the single best disposition but one whose scope is in proportion to the interest served."<sup>63</sup>

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, *amici* respectfully urge that the plaintiffs' Motion for a

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<sup>62</sup> *Greater New Orleans Broadcasting Ass'n, Inc. v. U.S.*, 527 U.S. 173, 188 (1999).

Preliminary Injunction be denied and Complaint be dismissed.

Respectfully Submitted,

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<sup>63</sup> *Board of Trustees of State University of New York v. Fox*, 492 U.S. 469, 480 (1989).

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