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The Constitutionality of State Regulation of Prescription Data Mining

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I. Introduction

There is a battle brewing in the federal courts over the rights of states to adopt the same prescription data privacy regulations that now exist in Europe and much of Canada. In those jurisdictions, pharmaceutical companies are not permitted to buy and sell prescription records that identify the prescribing habits of specific health care professionals, but rather can only access aggregate prescription data identified by demographic characteristic or geographic area.¹

Absent similar regulations in the United States, the multibillion-dollar “health information” industry has

¹ See, e.g., Natalie Dunleavy, *Alberta Delivers New Blow to Prescription Data Mining*, 168 CAN. MED. ASS'N J. 1169 (2003) (reporting that Alberta was the second Canadian province after British Columbia to ban the sale of physician-specific prescribing data); Steve Niles, *No Way to Fill in the Blanks*, 25 EUROPEAN INSTITUTIONAL INVESTOR 1 (May 1, 2006) (noting that “in Europe, Canada, and many other parts of the world” prescription data is available only in a “brick”—“a statistical group put together in such a way that you’re not supposed to be able to work out which doctor is writing what”).

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been buying prescription records from pharmacies and other intermediaries to compile massive databases on the prescribing habits of nearly every physician and other licensed prescriber in the country. These databases are mined through sophisticated computer programs for information displaying individual prescribing trends and preferences identifying which doctors are more susceptible to various kinds of sales messages, which are more prone to using new drugs or whether a doctor is “brand loyal” to a certain manufacturer and their gift-bearing sales agents.

New Hampshire, in passing its Prescription Confidentiality Act,² was the first state in the nation to ban the trade in prescriber-identified prescription data for marketing purposes. On April 30, 2007, a federal district court judge ruled that the New Hampshire law violated the First Amendment rights of pharmaceutical corporations to engage in commercial speech (5 PLIR 457, 5/4/07).³ Following that decision, Vermont⁴ and Maine⁵ passed laws that attempted to more narrowly tailor the data restrictions by giving physicians the right to control the subsequent use of prescription records identifying them. These laws have also been challenged in federal court.⁶ The New Hampshire decision has been appealed to the Court of Appeals for the First Circuit,⁷ setting the stage for an appellate decision with far-reaching repercussions.

This article describes two central legal arguments supporting the rights of states to regulate the use and trade of prescription record data mining in the pharmaceutical industry. First, 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

² N.H. REV. STAT. ANN. § 318:47 f (2006).

³ *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163 (D.N.H. 2007).

⁴ VT. STAT. ANN. tit. 18 § 4631 (2007).

⁵ ME. REV. STAT. ANN. tit. 22 § 1711-E (2007).

⁶ *IMS Health Inc. v. Sorrell*, No. 2:07-cv-188 (D. Vt. filed Aug. 29, 2007); *IMS Health Inc. v. Rowe*, 1:07-cv-00127 (D. Me. filed Aug. 29, 2007).

⁷ *IMS Health Inc. v. Ayotte*, No. 07-1945 (1st Cir. appeal docketed June 20, 2007).

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.

Second, 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.

II. The Rise of Prescription Data Mining

Direct marketing of drugs to doctors through sales representatives, now called “detailers,” has been a staple of pharmaceutical marketing practices since the mid-19th century. But it was not until fairly recently that pharmaceutical firms could systematically track individual prescription writing activity to target and assess the efficacy of such marketing on a micro level.

Starting in the late 1980s and increasing through the 1990s, prescription records went digital to serve the needs of electronic claims processing by insurers and pharmacy benefit managers (PBMs).⁸ The technological progression that allowed prescriptions to be electronically transferred to an insurer at the press of the button permitted the same record to be transferred easily to others. A growing industry of “Health Information Organizations” (HIOs) took advantage of this fact, buying up copies of prescription records from pharmacies, insurers, PBMs and others to amass comprehensive databases on the prescribing practices of nearly every physician and other licensed prescriber in the country.¹⁰

Data purchased from pharmacies, insurers, and PBMs often identifies prescribers only by medical li-

cense number or Drug Enforcement Agency tracking number, creating a demand to match these numbers with prescriber identities.¹¹ For this task, HIOs spend over \$40 million a year purchasing access to the American Medical Association’s “physician masterfile,” which links DEA and other identifying numbers to every physician in the country (including the 60 percent who are not AMA members).¹²

The data-mining companies apply sophisticated computer programs to convert the data into charts and statistical summaries for pharmaceutical marketers. The programs can analyze time series data to “pinpoint prescribers who are switching from one medication to another,” display sales trends (e.g. “Increasing Trend, Decreasing Trend, Shift Up, Shift Down, Spike Up, Spike Down”) and classify prescribers’ brand use (e.g. “Brand Switching, Brand Loyalty”).¹³ In its 2005 Form 10K, IMS Health Inc., the largest of the prescription data-mining companies, described its ability to generate reports “precisely tailored for each client,” documenting “the sales of a client’s own products and those of competitors.” IMS further described the use of its products to “measure,” “forecast,” and “target” marketing and sales efforts. It explained:

Our prescription tracking reporting services are designed to monitor prescription activity and to track the movement of pharmaceutical products out of retail channels. Prescription tracking services are used by pharmaceutical companies to facilitate product marketing at the prescriber level. In the United States, our Xponent® service monitors prescription activity from retail pharmacies, longterm care and mail service pharmacies using a patented statistical methodology to project the prescription activity of nearly 1.4 million individual prescribers on a weekly and monthly basis.¹⁴

The rise of data mining occurred coincident with pharmaceutical companies’ fine-tuning their exertion of influence over prescribing processes with massive outlays of gifts, trips and consultancies to prescribers.¹⁵ Data mining radically increased the influence of marketers by allowing them to specifically observe and reward the most profitable prescribing practices while tailoring switching messages to those not using desired products.¹⁶

Doctors are generally opposed to the use of prescription records for marketing purposes, although knowl-

⁸ See Carl Elliott, *The Drug Pushers*, ATLANTIC MONTHLY, April 2006, at 83; Jeremy Greene, *Pharmaceutical Research and the Prescribing Physician*, 146 ANNALS INTERNAL MED. 742 (2007).

⁹ See 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 95 percent of all drug benefit plans).

¹⁰ See, e.g., *IMS Expands Doctor Marketing Services*, PHARMA MARKETLETTER, Jan. 16, 1992, available at Lexis; Steven Pearlstein, *Pipelines Become Paramount: A Revolution in Distribution Fuels Mergers, Creates Rivalries*, WASH. POST, Aug. 22, 1993, at H1 (reporting that the Medco database of physician prescribing habits was an important asset in the Medco-Merck merger); Jeffery Young, *Information, Please*, FORBES, Oct. 25, 1993, at 222-23 (noting that IMS was facing new competitors in the rapidly expanding field of prescription data mining); *Database Identifies Variations in Prescribing Volumes*, BUSINESS WIRE, Dec. 14, 1993; *National Data Corporation Announces Enhancements to Its Pharmaceutical Micromarketing*, PR NEWSWIRE, May 18, 1998, available at Lexis.

¹¹ See Sheryl Gay Stolberg and Jeff Gerth, *High Tech Stealth Being Used to Sway Doctor Prescriptions*, N.Y. TIMES, Nov. 16, 2000, at A1.

¹² *Id.*

¹³ Paul Kallukaran and Jerry Kagan, *Datamining at IMS Health: How We Turned a Mountain of Data into a Few Information-Rich Molehills*, 24 SAS USERS GROUP INT’L CONF. paper 127 (1999) (on file with author, original removed by SAS at IMS request, source was previously available at www2.sas.com/proceedings/sugi24/Dataware/p127-24.pdf).

¹⁴ IMS Health Inc., Annual Report (Form 10-K), at 23 (Feb. 21, 2006).

¹⁵ See *Advertising, Marketing and Promotional Practices of the Pharmaceutical Industry: Hearing Before the Committee on Labor and Human Resources*, 101st Cong. (1990); EMILY CLAYTON, CALPIRG, *TIS ALWAYS THE SEASON FOR GIVING: A WHITE PAPER ON THE PRACTICE AND PROBLEMS OF PHARMACEUTICAL DETAILING* (2004).

¹⁶ See Elliott, *supra* note 8 at 90-91; Liz Kowalczyk, *Drug Companies’ Secret Reports*, BOSTON GLOBE, May 25, 2003, at A1.

edge of the practice remains limited. A survey conducted in 2001 for the Kaiser Family Foundation revealed that 34 percent of physicians in the United States did not believe that “drug company representatives receive information about how often you prescribe certain drugs,” and that 74 percent agreed that, if true, such use “bothers me” or is “unacceptable.”¹⁷ In 2004, an AMA commissioned poll reported that 25 percent of doctors still did not know that pharmaceutical companies tracked their prescriptions, 66 percent opposed the release of data to pharmaceutical companies, and 77 percent supported the implementation of a mechanism to allow them to “opt out” of data sharing.¹⁸

III. The New Hampshire Legislation

New Hampshire House Bill 1346 was introduced by state Rep. Cindy Rosenwald, whose husband is a cardiologist who had long known that he was being specifically targeted by drug representatives to switch his prescribing habits. It was not until Rep. Rosenwald came home with a 2003 *Boston Globe* article describing prescriber identity data mining¹⁹ that the two understood how drug reps knew that he was not prescribing their products.²⁰

House Bill 1346 proposed “An act requiring certain persons to keep the contents of prescriptions confidential.” As passed by overwhelming margins in each house of the legislature and signed into law by the governor in 2006, the act stated:

Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient’s insurance provider or the agent of either; health care research; or as otherwise provided by law.

The law defined “commercial purpose” as including, but not limited to,

advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.

The act specifically exempted the full range of commercial transfers of prescription data that serve the patient or protect the public health in some way, including

¹⁷ KAISER FAMILY FOUNDATION, NATIONAL SURVEY OF PHYSICIANS, *Highlights and Chartpack*, chart 3 (2002) (conducted March–November 2001).

¹⁸ American Medical Association, *Reports of Board of Trustees of the American Medical Association, 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.

¹⁹ See Kowalczyk, *supra* note 16.

²⁰ See Jake Whitney, *How Drug Reps Know Which Doctor to Target*, *Big (Brother) Pharma*, NEW REPUBLIC ONLINE, ¶ 7 (2006), www.tnr.com/doc.mhtml?i=w060828&s=whitney082906.

for “the dispensing of prescription medications,” “transmission of prescription information between an authorized prescriber and a licensed pharmacy,” transfers of records “in the event a pharmacy ownership is changed or transferred,” “educational communications provided to a patient about the patient’s health condition,” and in the conduct of clinical trials. As the New Hampshire District Court noted, although the statute defines “commercial purpose” broadly, “it expressly excludes from the statute’s scope all conceivable commercial uses of the data except those that are directly associated with advertising and marketing.”²¹

In addition, following the examples of several Canadian provinces and the European Union,²² the law specifically authorized the collection and sale of data in aggregated blocks from which individual physicians cannot be identified.²³

Rep. Rosenwald, the bill’s prime sponsor, described the purposes of the bill as being to protect prescribers’ from “unwarranted intrusion” into their professional privacy, as well as to help restrain drug spending. She explained:

[N]ot only is patient identity inappropriately used for pharmaceutical marketing, but the identity of the prescribers—doctors, nurse practitioners, optometrists and physician assistants—is routinely bought and sold for marketing. Large data mining corporations produce very sophisticated reports that track the individual behavior of our health care professionals. The use of personal identity is both an unwarranted intrusion into professional privacy and, more to the point, it adds to the financial burden of New Hampshire’s health care system by increased pharmaceutical costs for the state, our consumers, and our businesses.²⁴

A large number of doctors and medical organizations spoke in favor of the bill.²⁵ In legislative testimony and public advocacy before and during the New Hampshire deliberations, prescribers raised three primary arguments against prescription data mining for marketing purposes. First, prescribers asserted a privacy interest in their prescription records not being used for commercial purposes without their consent. Second, doctors asserted an interest in policing and reinforcing the integrity of the medical profession that is compromised by physicians being rewarded for prescribing particular drugs. Third, doctors rallied against the public health effects of undue marketing influence which can alter medical decisions toward higher cost treatments that

²¹ *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163, 171 (D.N.H. 2007)

²² See Niles, *supra* note 1.

²³ The law states:

Nothing in this section shall prohibit the collection, use, transfer, or sale of patient and prescriber de-identified data by zip code, geographic region, or medical specialty for commercial purposes.

²⁴ *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 10 (statement of Rep. Cindy Rosenwald).

²⁵ Supporters of the bill included the New Hampshire Medical Association, the AARP, the National Legislative Association on Prescription Drug Prices, the AFL-CIO, Community Catalyst, and Prescription Policy Choices.

may be clinically no better, or in fact worse, for the patient.²⁶

IV. Data-Mining Regulation and the First Amendment

States that have been leaders in taking affirmative efforts to combat excessive pricing and undue influence in the pharmaceutical industry have come to expect the inevitable litigation that follows the passage of every novel and effective law. The New Hampshire law was characteristic in this regard. Soon after passage, IMS challenged its constitutionality based primarily on the argument that the law unduly restricted the company's right to freedom of speech under the First Amendment.

After a bench trial, the New Hampshire District Court sided with IMS and declared the New Hampshire Act unconstitutional. Judge Paul Barbadoro found that (1) the trading of targeted marketing lists compiled from prescription records is a form of commercial speech protected by the Constitution, and (2) banning the trading and use of prescription data did not adequately advance any legitimate interest of the state. The court specifically found that there was insufficient evidence that data mining contributed significantly to harassing sales practices by pharmaceutical marketers or that its regulation would advance the state's interest in containing health care costs or promoting evidence-based prescribing practices.²⁷ This holding is deeply troubling to public health, prescription access, privacy, and states rights advocates and is headed for a vigorous appeal in the First Circuit.²⁸

Judge Barbadoro's opinion displays two key errors in constitutional reasoning. First, he ventured into new doctrinal ground by finding that the compilation and sale of identity databases for commercial marketing purposes is "speech" rather than traditional economic conduct. Second, he applied an extraordinarily vigorous version of the lenient scrutiny normally reserved for commercial speech cases, second guessing the nearly unanimous legislature as to whether prescription data mining is harmful to state interests.

A. The bounds of commercial speech

The use of the First Amendment to challenge a law regulating the compilation and sale of marketing databases may at first blush seem odd. Certainly the practice lies far from the core interest of the First Amendment "to ensure that debate on public issues will be uninhibited, robust, and wide open."²⁹ If every commercial trade of information was subject to First Amendment scrutiny, the regulatory authority of the states and federal government would be incredibly thin.

The District Court extended First Amendment scrutiny to the New Hampshire Act under the so-called com-

mercial speech doctrine.³⁰ This doctrine emerged in the 1970s when the Supreme Court held, for the first time, that state regulation of commercial advertising was subject to First Amendment scrutiny.³¹ The Court reasoned that commercial advertisements may help consumers make fully informed purchasing decisions and form "intelligent opinions as to how [the economic] system ought to be regulated or altered."³² While recognizing that the legitimate interests of states in regulating commercial advertising is much broader than for other kinds of speech, the Court has struck regulations that completely ban an industry from advertising,³³ restrict the advertisement of prices,³⁴ and ban certain forms of commercial advertising.³⁵

The Supreme Court has never held that every exchange of information between private contracting parties for purely commercial purposes is subject to First Amendment scrutiny. The Court has instructed quite the opposite, noting that such an interpretation would call into question the ability to regulate antitrust, workplace discrimination, corporate fraud, and a large amount of other commercial regulation that necessarily impacts the exchanges of information in corporate life:

Numerous examples could be cited of communications that are regulated without offending the First Amendment, such as 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. Each of these examples illustrates that the State does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of that activity.³⁶

The New Hampshire Act did not restrict corporations from advertising to customers or doctors or otherwise selecting and transmitting sales messages that would fall within any Supreme Court definition of commercial speech. Indeed, the main case cited by the New Hamp-

³⁰ 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").

³¹ See *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976).

³² *Id.* at 765; see also *44 Liquormart Inc. v. Rhode Island*, 517 U.S. 484, 495-96 (1996) (stating that our economy depends to some extent on the ability of commercial entities to communicate "vital information about the market" to the public through "accurate information about the availability of goods and services.").

³³ Cf. *Cent. Hudson Gas & Elec. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557 (1980) (striking down ban on promotional advertising by electric utilities).

³⁴ Cf. *44 Liquormart, Inc.*, 517 U.S. at 495-96 (striking down ban on advertisement of liquor prices).

³⁵ Cf. *Metromedia Inc. v. City of San Diego*, 453 U.S. 490 (1981) (striking down ban on certain outdoor advertising display signs); *City of Cincinnati v. Discovery Network*, 507 U.S. 410 (1993) (striking down ban of commercial handbills on public property); *Edenfield v. Fane*, 507 U.S. 761 (1993) (striking down ban on in-person solicitation by certified public accountants). *But see Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978) (upholding ban on in-person solicitation by lawyers).

³⁶ *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978).

²⁶ See David Grande, *Prescriber Profiling: Time to Call it Quits*, 146 ANNALS INTERNAL MED. 751, 751-52 (2007); see also JERRY AVORN, POWERFUL MEDICINES 202 (rev. 2003); James D. Capozzi and Rosamond Rhodes, *Ethics in Practice: Prescriber Profiles*, 83-A J. BONE & JOINT SURGERY 115 (2001).

²⁷ *IMS v. Ayotte*, 490 F. Supp. 2d 163, 179-80 (D.N.H. 2007).

²⁸ See *State Appeals Prescription Law Rejection*, UNION LEADER (AP), May 4, 2007, at B5, available at Lexis; Joseph Conn, *New Hampshire to Appeal Privacy Decision*, MODERN HEALTHCARE, May 14, 2007, at 32.

²⁹ *New York Times v. Sullivan*, 376 U.S. 254, 270 (1964).

shire court in support of its definition of commercial speech held that the speech in question *could* be regulated by the state. In *Dun & Bradstreet Inc. v. Greenmoss Builders Inc.*, the court ruled that a state could regulate information included in a credit report without meeting the heightened evidentiary standards required in speech cases, because the information at issue was “solely in the individual interest of the speaker and its specific business audience.”³⁷

The better interpretation of New Hampshire’s law, and that of other regulations of data mining, is that it regulates the *conduct* of businesses with regard to prescription records in their possession. “[I]t has never been deemed an abridgment of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed.”³⁸

The distinction between speech and conduct using regulated information was emphasized by the Supreme Court in *Bartnicki v. Vopper*.³⁹ In that case, the Court held that it was unconstitutional to penalize a public disclosure of information from a wiretap on a public affairs radio program, but approved of another section of the law that prohibited “use” of the same information “to prepare strategy for contract negotiations,” “to discipline a subordinate,” “to create a competing product,” and for other commercial purposes.⁴⁰ These prohibitions did not implicate the First Amendment, the Court explained, because “the prohibition against the ‘use’ of the contents of an illegal interception” is “a regulation of conduct.”⁴¹

Data-mining laws restrict the commercial trade in prescription data only for certain commercial marketing purposes, and thus are more similar to the ban on use of information “to prepare strategy,” discipline employees, and other uses approved of in *Bartnicki*. Surely if IMS’s next venture was to set up a data-mining operation selling information received through wiretaps of doctor offices to guide pharmaceutical marketing it would be subject to prohibition of “uses” of wiretap information left in place by the Supreme Court, not the prohibition of public disclosures that was stuck down. Yet, Judge Barbadoro found just the opposite, holding that the New Hampshire Act regulated “a form of disclosure.”⁴²

If Judge Barbadoro’s reasoning were allowed to stand, a massive amount of legislation at the state and federal level safeguarding consumer and citizen information from commercial marketing uses would be called into question. Federal and state laws contain numerous regulations that prohibit information provided for one purpose from being used for another commercial purpose without consent. Federal law prohibits in-

formation furnished to the census from being “used to the detriment of any respondent”;⁴³ prohibits release of individually identifiable health information;⁴⁴ prohibits disclosures of “personally identifiable information concerning any consumer” of a video rental establishment⁴⁵ or cable operator;⁴⁶ requires that Internet service providers “not knowingly divulge” subscriber information and communications except for certain public purposes;⁴⁷ and requires states to limit the disclosure of drivers’ personal identifying information without their consent.⁴⁸

Similarly, states prohibit divulging, publishing or receiving Social Security numbers in certain forms;⁴⁹ regulate the use and disclosure of information “obtained in connection with a motor vehicle record”;⁵⁰ require that a news-gathering organization “shall not use or distribute” accident reports “for a commercial purpose other than the news-gathering organization’s publication or broadcasting of the information”;⁵¹ and declare that “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.”⁵² All of these laws are similar in nature to the New Hampshire Act and have long been considered “unproblematic from a First Amendment perspective.”⁵³ The same should hold for laws that ban the secondary uses of prescription information.

⁴³ 13 U.S.C. § 8(c).

⁴⁴ Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936.

⁴⁵ Video Privacy Protection Act, 18 U.S.C. § 2710-2711.

⁴⁶ Cable Communications Policy Act, 47 U.S.C. § 551(c)(1).

⁴⁷ 18 U.S.C.A. § 2702.

⁴⁸ Driver’s Privacy Protection Act, 18 U.S.C. §§ 2721-25. See *Reno v. Condon*, 528 U.S. 141 (2000) (upholding Driver’s Privacy Protection Act as valid regulation of commerce).

⁴⁹ Cal. Civ. Code § 1798.85(a).

⁵⁰ Ohio Rev. Code § 4501.27(A).

⁵¹ Ky. Rev. Stat. § 189.635, see *Amelkin v. McClure*, 330 F.3d 822, 827 (6th Cir. 2003) (holding that § 189.635 “does not restrict or even regulate expression”).

⁵² 20 Mo. Code of State Regulations 2220-2.

⁵³ Neil M. Richards, *Reconciling Data Privacy and the First Amendment*, 52 UCLA L. REV. 1149, 1190 (2005). See also 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, including “communications to offerees, stockholders, and investors now regulated by various state and federal securities laws, including the Securities Act of 1933 and the Securities Exchange Act of 1934; numerous communications among business executives about prices and business practices now regulated by the Sherman Antitrust Act; communications about working conditions and the like now regulated by the National Labor Relations Act; representations about products and services now regulated by the Federal Trade Commission and the Food and Drug Administration; representations about products now regulated by various consumer protection laws, by the Uniform Commercial Code, and by the common law of warranty and contract; statements about willingness to enter into a contract now regulated by the common law of contract; and so on and on”) (citations omitted); 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, 1777-787 (2004) (same).

³⁷ *Dun & Bradstreet, Inc. v. Greenmoss Builders Inc.*, 472 U.S. 749, 762 (1985) (plurality opinion).

³⁸ *Rumsfeld v. Forum for Academic and Institutional Rights Inc.*, ___ U.S. ___, 126 S. Ct. 1297, 1308 (2006) (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949)); *United States v. O’Brien*, 391 U.S. 367, 376 (1968) (“We cannot accept the view that an apparently limitless variety of conduct can be labeled speech whenever the person engaging in the conduct intends thereby to express an idea.”)

³⁹ 532 U.S. 514 (2001).

⁴⁰ *Id.* at 527.

⁴¹ *Id.* at 526-27.

⁴² *Id.* at 528 (citation omitted).

B. The legitimate interests for regulating data mining

Even if a data-mining law is held to regulate commercial speech, it is clear that there are sufficient justifications for such regulation. Commercial speech is not afforded the same level of protection as political, philosophical or cultural speech. The Supreme Court has recognized legitimate state interests in regulating—and even banning—commercial speech that is “deceptive or misleading,”⁵⁴ exerts an “undue influence,”⁵⁵ or that threatens professional standards.⁵⁶ States are not limited to regulating speech that is false. The Supreme Court has explained:

Obviously much commercial speech is not provable false, or even wholly false, but only deceptive or misleading. We foresee no obstacle to a State’s dealing effectively with this problem. The First Amendment . . . does not prohibit the State from insuring that the stream of commercial information flows cleanly as well as freely.⁵⁷

There is abundant evidence that the pharmaceutical marketing practices today exert undue influence over prescribing and formulary listing decisions that raise health care costs, promote irrational drug selection, threaten the professional integrity of the medical profession and are increasingly harassing and invasive toward health practitioners. Regulating data mining is one moderate step toward addressing these problems, removing the tool that marketers use to target prescribers for individualized marketing campaigns and gift giving.

1. Protecting against undue influence

There are few more important government roles in our health system than combating the undue influence of pharmaceutical marketing in prescribing decisions.

The Supreme Court has held that states have a substantial interest in regulating commercial solicitation 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.”⁵⁸ This is the clear and primary purpose of data-mining legislation.

Pharmaceutical companies have enormous incentives to use their multi-billion dollar marketing budgets to distort and selectively divulge facts about drug benefits and risks. Access to individualized prescribing data multiplies the influence of this already tilted playing field by permitting marketers to tailor their sales pitches to the specific drugs used by the targeted prescriber. The other side normally has little opportunity to respond because “[t]here is virtually no economic incentive for the manufacturers of generic drugs to send sales representatives.”⁵⁹ Thus, the practice of detailing

is highly biased in favor of the newest and most expensive products, regardless of whether they are best for public health concerns.

Data mining is particularly troubling because of its link to influence peddling through gift giving. Pharmaceutical companies use prescription data to accurately guide their gift giving to compensate the highest or most influential prescribers for the specific uses of marketed products. While 94 percent of all doctors in the country routinely receive gifts of significant value, such as meals, branded office supplies, and free drug samples,⁶⁰ prescriber data is used to direct the most lavish gifts and payments to the most loyal and profitable prescribers. High prescribers and thought leaders can receive weekly, even daily, meals for their entire staff, luxury vacations in the guise of educational seminars, and can earn tens and hundreds of thousands of dollars in direct payments each year as speakers, “consultants,” and advisory board members. In effect, the prescribers themselves receive pharmaceutical company commissions.

An e-mail from one pharmaceutical company manager to sales representatives released to the *New York Times* described how prescriber data was used to hold doctors “accountable” for all the gifts they received:

Our goal is 50 or more scripts per week for each territory If you are not achieving this goal, ask yourself if those doctors that you have such great relationships with are being fair to you. Hold them accountable for all of the time, samples, lunches, dinners, programs and past preceptorships that you have provided or paid for and get the business!! You can do it!⁶²

The U.S. House of Representatives Committee on Government Reform’s investigation of Vioxx revealed that Merck gave sales agents monthly reports showing each prescriber’s “market share” of Merck versus competitor product prescriptions. Prescribers were given grades from D to A+ for each product based on how reliably they prescribed a Merck product.⁶³ Presumably, the high volume A+ prescribers could expect more lavish gifts, consultancies, and speaker bureau invitations.

A former pharmaceutical representative from another company explained:

Physicians are ranked on a scale from one to ten based on how many prescriptions they write. Reps lav-

possible reasons for this large divergence between routine practice on the one hand and clinical trial data and evidence-based recommendations on the other. Foremost among these is the vigorous marketing of newer, more costly agents compared with virtually no marketing for older, off-patent drugs. Such marketing affects both physician prescribing choices and patient preferences.”).

⁶⁰ See Christopher Lee, *Drugmakers, Doctors Get Cozier*, WASH. POST, April 29, 2007, at A03.

⁶¹ See Clayton, *supra* note 15 (describing “five and even six figure checks” given to doctors to induce favorable prescribing); Elliott, *supra* note 8, at 7-8.; Stephanie Saul, *Drug Makers Pay for Lunch as They Pitch*, N.Y. TIMES, July 28, 2006, at A1; Whitney, *supra* note 20.

⁶² See Gardiner Harris and Robert Pear, *Drug Maker’s Efforts to Compete in Lucrative Insulin Market are Under Scrutiny*, N.Y. TIMES, January 28, 2006, at A14.

⁶³ See Memorandum from Henry Waxman, 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).

⁵⁴ Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748, 771 (1976).

⁵⁵ Ohralik v. Ohio State Bar Ass’n, 436 U.S. 447, 462 (1978).

⁵⁶ See Edenfield v. Fane, 507 U.S. 761, 767 (1993).

⁵⁷ Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748, 772 (1976).

⁵⁸ Ohralik v. Ohio State Bar Ass’n, 436 U.S. 447, 458 (1978) (citations omitted).

⁵⁹ See Declaration of Avorn and Kesselheim at 6; See also Michael Fischer and Jerry Avorn, *Economic Implications of Evidence-Based Prescribing for Hypertension: Could Better Care Cost Less*, 291 JAMA 1850, 1854 (2004) (“There are many

ish 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.⁶⁴

It is sometimes thought that doctors and other prescribers, being highly educated professionals with training in medical research and scientific analysis, would be relatively immune from unbalanced sales pitches by pharmaceutical companies. Indeed, “the entire infrastructure of science and much of physician education is built on the fundamental notion of eliminating, or at least controlling for, the many and powerful biases inherent in generating and interpreting scientific data.”⁶⁵

Most physicians deny that pharmaceutical marketing, including gift-giving, has any effect on their prescribing practices.⁶⁶ But studies show that health care providers, despite their extensive training and access to medical literature, generally trust the messages delivered by pharmaceutical representatives,⁶⁷ are very poor at detecting false and misleading messages within sales pitches,⁶⁸ and are highly susceptible to psychological urges to reciprocate created by the receipt of gifts.⁶⁹

Numerous studies and investigations have documented a significant, measurable, and increasing corrupting influence of pharmaceutical company marketing in convincing doctors to prescribe more expensive medicines that are no better, and often worse, than alternatives.⁷⁰ An exhaustive data synthesis from over 500 published studies found conclusive evidence that

⁶⁴ Adriane Fugh Berman and Shahram Ahari, *Following the Script: How Drug Reps Make Friends and Influence Doctors*, 4 *PLoS Med.* 0621, 0623 (2007).

⁶⁵ Susan Coyle, *Physician-Industry Relations, Part 1: Individual Physicians*, Position Paper, 136 *ANNALS INTERNAL MED.* 396, 397 (March 2002).

⁶⁶ See Jerry Avorn, et al., *Scientific Versus Commercial Sources of Influence on the Prescribing Behavior of Physicians*, 73 *AM. J. MED.* 4 (1982); S. Suresh Madhavan, et al., *The Gift Relationship Between Pharmaceutical Companies and Physicians: An Exploratory Survey of Physicians*, 22 *J. CLIN. PHARM. THER.* 207 (1997); Michael Steinman, et al. *Of Principles and Pens: Attitudes and Practices of Medicine Housestaff Towards Pharmaceutical Industry Promotions*, 110 *AM. J. MED.* 551 (2001) (reporting that 61 percent of medical residents believe that their own prescribing practices are unaffected by pharmaceutical marketing, although 84 percent think that marketing affects the practices of their colleagues).

⁶⁷ Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 *JAMA* 373 (2000).

⁶⁸ Michael Ziegler, et al., *The Accuracy of Drug Information from Pharmaceutical Sales Representatives*, 273 *JAMA* 1296 (1995) (finding that 11 percent of statements by detailers to doctors were inaccurate, but only 26 percent of doctors who had heard the inaccurate statements could detect them).

⁶⁹ See David Blumenthal, *Doctors and Drug Companies*, 351 *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).

⁷⁰ See Jason Dana and George Lowenstein, *A Social Science Perspective on Gifts to Physicians From Industry*, 290 *JAMA* 252 (2003) (exploring conflict of interest and bias in the context of gifts to physicians); Dana Katz, Arthur Caplan, Jon Merz, *All Gifts Large and Small: Toward an Understanding of the Ethics of Pharmaceutical Industry Gift Giving*, 3 *AM. J. BIOETHICS* 39 (2003) (summarizing research); Wazana, *supra* note 67 (analyzing 29 studies of the relationship between physi-

interactions with pharmaceutical representatives “impact 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.”⁷¹ 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.”⁷²

Removing the ability of pharmaceutical companies to observe and reward prescribing behavior will not remove all undue influence from the multi-billion dollar effort of pharmaceutical companies to alter prescribing habits toward more profitable products. Indeed, it is one of most moderate measures that can be taken in this area, working to decrease the most abusive marketing practices without regulating the substance of advertising messages or the time, place or manner of sales representative speech.

2. Restraining costs and promoting public health

The general interest of states in reducing undue influence by pharmaceutical marketing is compounded by the enormous costs of such influence to society. These costs are measured not only in dollars, but in the prescribing of drugs that are less effective, and often harmful, to patients.

Nearly a third of the five-fold increase in U.S. spending on drugs over the last decade can be attributed to the increased efficacy of pharmaceutical marketing efforts that shift doctors’ prescribing from existing, effective, and lower cost (often generic) therapies to new and more expensive treatments.⁷³

One study referenced in the New Hampshire legislative history showed, for example, that marketing branded calcium channel blockers for high blood pressure treatment instead of the less expensive generic therapies that are rated as *more effective* by national treatment guidelines increased U.S. health expenditures by \$3 billion in 1996 alone.⁷⁴

In Pennsylvania, a study of Medicare patients on antihypertensive therapy found that 40 percent of patients

and the pharmaceutical industry and finding that the there was a marked relationship between interactions with industry and prescribing practices); Nicole Lurie, Eugene Rich, Deborah Simpson, et al., *Pharmaceutical Representatives in Academic Medical Centers*, 5 *J. GEN. INTERN. MED.* 240 (1990); Abigail Caplovitz, *Turning Medicine Into Snake Oil: How Pharmaceutical Marketers Put Patients at Risk*, NJPIRG Law and Policy Center, 5 (2006) (reviewing studies); Puneet Manchanda and Elisabeth Honka, *Pharmaceutical Innovation and Cost*, 5 *YALE J. HEALTH POL’Y L. & ETHICS* 785, 797-808 (2008) (reviewing studies). See, e.g. Helen Prosser, et al., *Influences on GPs Decisions to Prescribe New Drugs—the Importance of Who Says What*, 20 *FAM. PRAC.* 61 (2003).

⁷¹ Wazana, *supra* note 67 at 375.

⁷² *Id.*

⁷³ National Institute for Health Care Management (NIHCM), *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs*, 2-3 (revised May 6, 2002).

⁷⁴ Roberto Cardarelli, John Licciardone, and Lockwood Taylor, *A cross-sectional evidence-based review of pharmaceutical promotional marketing brochures and their underlying studies: Is what they tell us important and true?* 7 *BMC FAM. PRAC.* 13 (2006). *Cf.* Leg. Hist. at 14 (testimony that the least and most expensive calcium channel blocker on the New Hampshire Medicaid formulary is \$13.50 versus \$87.30 per month respectively).

were on medications other than those recommended by clinical guidelines.⁷⁵ This same study of antihypertensive therapy shows that for this class of medications alone, switching to a nonbranded, nonmarketed medication when medically appropriate could save \$1.2 billion per year.⁷⁶

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 pain relievers than older NSAIDs, or that the reduction in gastric side effects were significant for most patients.⁷⁷ 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.⁷⁸

A significant amount of the increase in irrational prescribing behavior over the last decade is enabled by pharmaceutical marketers knowing that an individual doctor is favoring a less expensive treatment and mounting a campaign in response to convince the doctor to switch treatments.⁷⁹ There can be no doubt that states have an overriding interest in responding to these harmful social trends.

3. Maintaining standards in the medical profession

Many physician organizations advocate an end to data mining, along with gift giving and other abusive sales practices, because such practices threaten the ethical standards of the profession and jeopardize their relations with patients.⁸⁰

In *Ohralik*, the Supreme Court explained that “the State bears a special responsibility for maintaining standards among the members of the licensed professions.”⁸¹ The Court held that this interest extends to enforcing ethical standards of the profession, including to “avoid situations where the [professional’s] exercise of judgment on the behalf of the client will be clouded by his own pecuniary interest.”⁸²

There can perhaps be no greater affront to the values governing the medical profession than permitting pharmaceutical companies to give pecuniary rewards to

doctors based on their prescribing habits. Prescription data mining provides the key tool for pharmaceutical companies to literally pay prescribers—with meals, gifts, vacations and high-value low-work “consultancies,” and board appointments—for the use of their products. This incorporation of prescribers into the commission structure of pharmaceutical sales incentives debases the medical profession and, the more the practice becomes public, breaks the chain of trust between doctor and client.⁸³

4. Protecting 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.”⁸⁴ Doctors are pushing many of the reforms in this area in part because a substantial number of them feel harassed by the increasing frequency and aggressiveness of detailing forces fueled by prescription mining.

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.⁸⁵ These laws have been consistently upheld under First Amendment challenge by courts applying extremely deferential standards of review. In 2001, for example, the D.C. Circuit upheld the FTC’s rule prohibiting credit reporting agencies from selling targeted marketing lists based on data they collect. There, the D.C. Circuit refused to examine the intricacies of how the rule operated or what other options were available, holding in summary fashion that the lists were “private speech warranting only qualified constitutional protection” and the government interest in protecting consumer privacy and avoiding harassing sales tactics is substantial.⁸⁶ In the case of medicines, it is doctors who make the purchasing decisions for the ultimate consumers of the product, and their interests in being protected from harassing sales calls deserves the same level of deference as that afforded to other consumers.

Prescribers may be the most marketed-to class of “consumers” in the world, and access to prescribing data has played a key role in its escalation. In 2004, the industry spent \$27 billion on drug marketing, more than any other sector in the United States, on its sales

⁷⁵ See Fischer, *supra* note 59.

⁷⁶ *Id.* See also AVORN, *supra* note 26, at 338 (describing how new, expensive medicines should be critically evaluated for safety and efficacy compared to existing medicines)

⁷⁷ AVORN, *supra* note 26, at 202.

⁷⁸ See Waxman, *supra* note 63.

⁷⁹ See Jane Coutts, *Pharmaceutical Group’s Head Defends Sale of Medical Data*, GLOBE & MAIL (March 28, 1996) (description of medical expert that “[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 B drug.”)

⁸⁰ See Susan L. Coyle, *Physician-Industry Relations, Part 1: Individual Physicians*, Position Paper, 136 ANNALS INTERNAL MED. 396 (March 2002) (statement of the American College of Physicians); National Physicians Alliance, Issue Brief: 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 (“The best way to ensure that physicians retain the trust of patients is to warrant it, by eliminating this commercial intrusion into the doctor-patient relationship. Medical decision-making must remain scientific and objective.”)

⁸¹ *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447, 460 (1978).

⁸² *Id.* at 461.

⁸³ See Robert Gibbons, et al., *A Comparison of Physicians’ and Patients’ Attitudes Toward Pharmaceutical Industry Gifts*, 13 J. GEN. INTERNAL MED. 151, 152 (1998); Dana Katz, et al., *All Gifts Large and Small: Towards an Understanding of the Ethics of Pharmaceutical Gift Giving*, 3 AM. J. BIOETHICS 39, 42 (2003) (“Patients tend to be aware that physicians accept gifts, unaware whether their own physician accepts gifts, and feel that gifts are more influential and less appropriate than do their physicians.”)

⁸⁴ *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163, 179 (D.N.H. 2007). (quoting *Edenfield v. Fane*, 507 U.S. 761, 769 (1993)). See *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447, 458 (1978) (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”).

⁸⁵ See, e.g., Fair Credit Reporting Act, 15 U.S.C. Section 1681 et seq. (2000) (credit reporting information); Family Educational Rights and Privacy Act of 1974, 20 U.S.C. Section 1232g (2000 & Supp. III 2003) (educational information).

⁸⁶ *Trans Union Corp. v. Fed. Trade Comm’n*, 267 F.3d 1138, 1140-41 (D.C. Cir. 2001).

force or media advertising.⁸⁷ Over 85 percent of pharmaceutical marketing budgets are targeted at doctors.⁸⁸ In the decade after IMS unveiled its flagship prescriber tracking program in 1993, the pharmaceutical industry increased its spending on direct marketing to doctors by over 275 percent,⁸⁹ doubled its sales force of detailers,⁹⁰ and became the most profitable industry in the world.⁹¹ There were an estimated 101,531 detailers in the United States in 2004; more than one for every five office-based physicians in the United States.⁹² 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.⁹³ The average primary care physician in 2004 interacted with a staggering 28 sales representatives each week.⁹⁴

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.”⁹⁵ 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’ prescribing volume demands.⁹⁶ At least

part of the increase in the aggressiveness of detailing can be attributed to the availability of prescribing data and its use to not only track prescription writing, but link such writing directly to sales bonuses.⁹⁷

5. Protecting Patient Privacy

While the data-mining companies have not challenged state interests in protecting the privacy of patients in their prescription records, the debate has largely overlooked that this interest cannot be protected by the removal of patient names alone.

Even where patient names are removed, data-mining companies still can, and do, track specific patients’ prescriptions through unique numerical identifiers that carry forward through time.⁹⁸ With knowledge of who that individual patient is receiving prescriptions from, a pharmaceutical company has all the knowledge they need to monitor patient treatment and mount lobbying campaigns at the prescriber to change to a more profitable course of medications. 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 a patient for the pecuniary interest of another through a breach of confidentiality that is nearly impossible to detect.

V. Conclusion

The weight of authority suggests that state interests in maintaining standards in the medical profession, combating escalating drug prices and avoiding undue influence of one-sided in-person solicitation in a licensed profession may justify completely banning detailing and gift-giving by pharmaceutical sales representatives. New Hampshire’s very conservative effort to ban only the marketing-related uses of prescriber identifying prescription records—leaving the companies free to examine geographic and medical specialty sales trends within the same data—is an extremely narrow and eminently justifiable first step to serve a legitimate state interest of the highest order.

States looking to act in this area in the future should strive to create a fuller record documenting their inter-

⁸⁷ Manchanda, *supra* note 70.

⁸⁸ KAISER FAMILY FOUNDATION, TRENDS AND INDICATORS IN THE CHANGING HEALTH CARE MARKETPLACE exhibit 1.20, http://www.kff.org/insurance/7031/print_secl.cfm (2005).

⁸⁹ *See id.*

⁹⁰ *See* Manchanda, *supra* note 70, at 788; Consumer Union, Prescription for Change, *Detailing*, March 2006, <http://www.consumersunion.org/pdf/drugreps.pdf> (citing Rayna Herman and Ashley Mahoney, *Access Report 2005*, PHARMACEUTICAL REP., July 2005).

⁹¹ Public Citizen Congress Watch, *Drug Industry Profits: Hefty Pharmaceutical Company Margins Dwarf Other Industries* (June 2003) (reporting that 10 largest pharmaceutical companies garner profits equivalent to the other 490 Fortune 500 companies combined).

⁹² Rayna Herman and 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 70 at 788; Consumer Union, Prescription for Change, *Detailing*, March 2006, <http://www.consumersunion.org/pdf/drugreps.pdf>; *see also* Center for Policy Alternatives, *Prescription Drug Marketing*, <http://www.stateaction.org/issues.cfm/issue/prescriptiondrugmarketing.xml>.

⁹³ Fugh Berman, *supra* note 64, at 624.

⁹⁴ Consumers Union, *supra* note 90.

⁹⁵ *Looking Back. Looking Forward; Interview with Irwin Gerson, Chairman Emeritus of Lowe McAdams Healthcare*, MEDICAL MARKETING & MEDIA, Apr. 1998, 70, available at Lexis.

⁹⁶ Gardiner Harris and Robert Pear, *Drug Makers Efforts to Compete in Lucrative Insulin Market are Under Scrutiny*, N.Y. TIMES, Jan. 28, 2006, at A14 (quoting an e-mail 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 and Jeanne Lenzer, *Spin Doctored: How Drug Companies Keep Tabs on Physicians*, SLATE (May 31, 2005), <http://www.slate.com/id/2119712/> (same); Elliott, *supra* note 8, at 90-91 (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 and Jeff Gerth, *High Tech Stealth Being Used to Sway Doctor Prescriptions*, N.Y. TIMES, Nov. 16, 2000, at A1 (including statement of outrage [] by former president of American College of Physicians); Liz Kowalczyk, *Drug Companies Secret Reports*, Boston Globe, May 25, 2003, at A1; Robert Steinbrook, *For Sale: Physicians Prescribing Data*, 354 NEW ENG. J. MED. 2745 (2006).

⁹⁷ *See* Elliott, *supra* note 8, at 89 (arguing that with detail prescription data came intensified pressure for pharmaceutical representatives to identify high-prescribing doctors and to relentlessly target those physicians).

⁹⁸ *See* Jim Carroll and 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_40000873/0/78187147Brand%20Planning%20Paper.pdf. (June 1, 2006)

ests to prevent other courts from blindly following Judge Barbadoro's lead.⁹⁹ States may consider bolstering an expectation of privacy in prescription records by including statutory findings and inviting testimony that doctors do not and should not expect that their prescription records will be used for purposes other than to fill and process the prescriptions they order.

Vermont and Maine passed statutes requiring prescriber permission before using prescriber data for marketing purposes. Such laws may be considered more narrowly tailored to prescribers' interest in controlling whether or not their data is released to marketers. But opt-out programs do not meet the full range of state interests in banning the trade in prescriber-identified data, 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 a state determines 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.

States should assess the efficacy of additional measures as part of a full program to combat the ill effects of undue marketing influence and create a fully rational and evidence-based health system. But the many alternative policies that are available to states to combat undue influence in pharmaceutical marketing and dampen spiraling medicine prices are complements, not substitutes, for the regulation of prescription record trading for marketing purposes.

The most trumpeted alternative to state regulation of data mining is the American Medical Association's Prescribing Data Restriction Program (PDRP). 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 represen-

tatives. Thus, the program does not even meet its own narrow interest of protecting physician control over prescribing data.

Gift bans are appropriate programs that aim to lower the undue influence of marketers over prescribers. But most bans in effect or being considered by states include threshold dollar limits (commonly \$25) that limit their effectiveness. Evidence shows that even the smallest gift creates a reciprocal relationship that affects prescribing practices, and those impacts are heightened when the gifts are specifically tailored to reward prescribing behavior. 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 (a/k/a academic detailing), where the state hires trained individuals to provide objective factual information to prescribers, is another key component of a holistic program to combat undue influence in pharmaceutical marketing. But such programs are not an effective substitute for regulations on prescriber data mining because no state has the resources to battle biased and targeted 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 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, professor of medicine at Harvard Medical School and chief of the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital, as well as a primary promoter of counter-detailing programs, supports state restrictions on data mining as well.

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 should be to curb the use of prescriber-identified prescription data to target marketing campaigns and gift giving. All states have a great interest in ensuring that this latest skirmish over the scope of heightened scrutiny under the leaching "commercial speech" doctrine results in a protection, rather than limitation, of traditional state regulatory authority.

⁹⁹ Judge Barbadoro himself called for such a record, stating: "There is nothing in the record, however, to support a conclusion that the legislature had established expertise in the regulation of prescriber-identifiable data. Moreover, it acted quickly after the bill was introduced, received hearing testimony by numerous individuals who had yet to review proposed amendments, made no express findings either on the record or incorporated into the statute, failed to discuss alternative measures that would not restrict speech, and cited no evidence as to how effective the restriction might prove to be." *IMS v. Ayotte*, 490 F. Supp. 2d 163, 179 (D.N.H. 2007).