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# Legal Analysis

## The Constitutional Battle Over State Regulation of Data Mining

*The Prescription Project promotes evidence-based prescribing and works to eliminate conflicts of interest in medicine due to pharmaceutical marketing to physicians.*

*It is promoting policy change by working with*

- *State and Federal Policymakers*
- *Academic Medical Centers*
- *Professional Medical Societies*
- *Private Payers*

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## I. Introduction

On Apr. 30, 2007, a New Hampshire District Judge ruled that the First Amendment prevented New Hampshire from implementing a common-sense data privacy law to protect physician privacy and serve the public interest in unbiased prescribing. The New Hampshire law, like those in Europe and some Canadian provinces, banned the trading of prescriber and patient linked prescription data for the purpose of targeting marketing to patients and doctors.<sup>1</sup> Instead, the law required that companies follow the practice in other countries and only compile and use information reporting prescription drug sales in aggregated “bricks” so as to protect the specific prescribing and purchasing practices of individuals from marketing related disclosures.<sup>2</sup>

This article provides a brief explanation of the legal and policy background for state regulation of data mining and “detailing” in the pharmaceutical industry and explains some recent state responses to the New Hampshire decision. Part II provides a brief background on the history and present uses of data mining in pharmaceutical marketing. Part III describes the genesis and requirements of the New Hampshire Act. Part IV analyzes the constitutionality of data mining laws under the First Amendment. Part V explains the recent actions of Vermont and Maine to enact regulations of prescription data mining in the wake of the New Hampshire decision.

## II. Background on Detailing and Data mining

### A. Early marketing to prescribers

Direct marketing of drugs to doctors through sales representatives, now called “detailers,” has been a staple of pharmaceutical marketing practices since the mid-twentieth century.<sup>3</sup> Prior to the 1950s, pharmaceutical sales efforts were more focused on convincing pharmacies to stock medicines than on doctors to prescribe them.<sup>4</sup> With the rapid expansion in new medicine development, and a federal regulatory system requiring prescriptions for many drugs, pharmaceutical marketing efforts shifted toward prescribers.<sup>5</sup>

Coincident with the evolution of prescriber marketing, crude systems to track prescribing habits were established. Sales representatives were often encouraged to categorize doctors as high or low prescribers and more or less susceptible to marketing influence.<sup>6</sup> Some sales representatives went further and paid local pharmacies to give them monthly reports of prescriptions filled.<sup>7</sup> But the watershed event in early prescription tracking was the growth of IBM punch card technology.<sup>8</sup>

By the mid 1950s, several precursors of today’s “Health Information Organizations” (HIOs) were rapidly developing

<sup>1</sup> See, e.g., *R v. Dept. of Health, ex parte Source Informatics Ltd.*, (1999) 4 All E.R.185 (Q.B.); Natalie Dunleavy, *Alberta Delivers New Blow to Prescription Data Mining*, 168 CAN. MED. ASS’N J. 1169 (2003) (reposting that Alberta was the second Canadian province after British Columbia to ban the sale of physician-specific prescribing data).

<sup>2</sup> See Steve Niles, *No Way to Fill in the Blanks*, 25 EUROMONEY 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”).

<sup>3</sup> Carl Elliott, *The Drug Pushers*, ATLANTIC MONTHLY (Apr. 2006), available at [www.theatlantic.com/doc/print/200604/drug-reps](http://www.theatlantic.com/doc/print/200604/drug-reps).

<sup>4</sup> Jeremy Greene, *Pharmaceutical Research and the Prescribing Physician*, 146 ANNALS INTERNAL MED. 742 (2007).

<sup>5</sup> *Id.*; see also JERRY AVORN, POWERFUL MEDICINES; THE BENEFITS, RISKS, AND COSTS OF PRESCRIPTION DRUGS 43 (rev. 2005).

<sup>6</sup> Greene, *supra* note 4, at 743.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

new prescription monitoring systems using IBM's technology.<sup>9</sup> Some organizations purchased pharmacy records for an entire region and collated them to discover which drugs were being most commonly prescribed. Others enlisted groups of physicians to fill out daily prescribing reports for a short period of time that could be compared to others.<sup>10</sup> For the first time, these methods enabled pharmaceutical sales forces to study geographic and national trends in drug usage to guide their tactics; but it was not until fairly recently that pharmaceutical firms could systematically track *individual* prescription writing activity.

### B. The rise of data mining

The second watershed event in prescriber tracking was also technology driven. Starting in the late 1980s and increasing through the 1990s, prescription records incrementally went digital to serve the needs of electronic claims processing by insurers and pharmacy benefit managers (PBMs).<sup>11</sup> This trend intersected with the growing capacity of computer databases, setting the stage for HIOs to begin to make prescriber-level data available by the late 1980s.<sup>12</sup> In the early 1990s, as digital records and the rise of managed care made it easier to collect and analyze prescription data, IMS and other HIOs marketed products that allowed pharmaceutical manufacturers to track the individual prescribing habits of the majority of doctors.<sup>13</sup> By 1999, HIOs had made the transition from using scattered data sources from pharmacies and physician surveys to using comprehensive data provided by the electronic records of PBMs, national pharmacy chains, and insurers.<sup>14</sup>

Data purchased from pharmacies, insurers, and PBMs often identifies prescribers only by medical license number or Drug Enforcement Agency tracking number, creating a demand to match these numbers with prescriber identities.<sup>15</sup> For this task, the AMA's "physician masterfile" is a particularly valued resource, as it contains detailed practice and biographic information on every physician in the country (including the sixty percent who are not AMA members) linked to DEA, medical license and AMA "medical education numbers" that were assigned to doctors during medical school.<sup>16</sup>

In the late 1990s, as prescription records were nearly universally linked to individual prescribers, the data mining companies applied sophisticated computer programs to convert the data into charts and statistical summaries for 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").<sup>17</sup>

<sup>9</sup> *Id.*

<sup>10</sup> *Id.* at 743-44.

<sup>11</sup> 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% of all drug benefit plans).

<sup>12</sup> See Judith Graham, *IMS Expands in Drug Market Research*, ADVERTISING AGE, Mar. 7, 1988, at 32, available at Lexis.

<sup>13</sup> See, e.g., *IMS Expands Doctor Marketing Services*, PHARMA MARKETLETTER, Jan. 6, 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*, BUS. WIRE, Dec. 14, 1993.

<sup>14</sup> See *National Data Corporation Announces Enhancements to Its Pharmaceutical Micromarketing*, PR NEWSWIRE, May 18, 1998, available at Lexis.

<sup>15</sup> See Sheryl Gay Stolberg & Jeff Gerth, *High Tech Stealth Being Used to Sway Doctor Prescriptions*, N.Y. TIMES, Nov. 16, 2000, at A1.

<sup>16</sup> *Id.*

<sup>17</sup> Paul Kallukaran & 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](http://www2.sas.com/proceedings/sugi24/Dataware/p127-24.pdf))

In its 2005 Form 10K, IMS 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.<sup>18</sup>

Dendrite International similarly touts the benefits of its data mining product as a “comprehensive marketing tool capable of providing physician-level insight to assist in the return on all channels of promotion.”<sup>19</sup> Dendrite’s marketing brochure states, “[n]ow, pharmaceutical manufacturers who partner with Dendrite can gain a level of insight that allows them to predict and influence physician prescribing behavior like never before.”<sup>20</sup>

### C. The uses of prescriber data in pharmaceutical marketing

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.<sup>21</sup> 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.<sup>22</sup>

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>23</sup> Because doctors make the key consumer decisions, literally prescribing the spending choices of patients, over eighty-five percent of pharmaceutical marketing budgets are targeted at doctors.<sup>24</sup>

One of the ways pharmaceutical companies use prescription data is to accurately guide their gift giving to compensate the highest or most influential prescribers for the specific uses of marketed products. While ninety-four percent of all doctors in the country routinely receive gifts of significant value, such as meals, branded office supplies, and free drug samples,<sup>25</sup> 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

<sup>18</sup> IMS Health, Inc., Annual Report (Form 10-K), at 23 (Feb. 21, 2006)

<sup>19</sup> Defendant’s Memorandum of Law in Support of its Objection to Plaintiffs’ Motion for Preliminary Injunction, *IMS v. Ayotte*, No. 06-CV-280-PB, at 13 (D. N.H. filed April 30, 2007). (Memorandum filed September 1, 2006).

<sup>20</sup> *Id.*

<sup>21</sup> See *Advertising, Marketing and Promotional Practices of the Pharmaceutical Industry: Hearing Before the Committee on Labor and Human Resources*, 101<sup>st</sup> Cong. (1990); see also EMILY CLAYTON, CALPIRG, ‘TIS ALWAYS THE SEASON FOR GIVING: A WHITE PAPER ON THE PRACTICE AND PROBLEMS OF PHARMACEUTICAL DETAILING (2004).

<sup>22</sup> See Elliott, *The Drug Pushers*, *supra* note 3 at 7-8; Liz Kowalczyk, *Drug Companies’ Secret Reports*, BOSTON GLOBE, May 25, 2003, at A1.

<sup>23</sup> Puneet Manchanda & Elisabeth Hokna, *Pharmaceutical Innovation and Cost: The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review*, 5 YALE J. HEALTH POL’Y L. & ETHICS 785, 785 (2005).

<sup>24</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).

<sup>25</sup> See Christopher Lee, *Drugmakers, Doctors Get Cozier*, WASH. POST, April 29, 2007, at A03.

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.<sup>26</sup> In effect, the prescribers themselves receive pharmaceutical company commissions.

An email 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!<sup>27</sup>

The U.S. House of Representatives Committee on Government Reform’s investigation of Vioxx marketing illustrated the uses of prescriber information in detailing. For the drug Vioxx alone, “the company assigned over 3,000 company representatives across the country to engage in face-to-face discussions with physicians about Vioxx.”<sup>28</sup> Merck provided its representatives with highly detailed information on individual doctor’s prescribing habits to target physicians. Representatives were given access to monthly reports on each doctor in their territory which showed each doctor’s “market share” of Merck versus competitor product prescriptions. An important concept was each doctor’s “Merck potential,” which Merck defined as a “dollar estimate of each prescriber’s total prescribing volume that can realistically be converted to Merck prescriptions.”<sup>29</sup> Bonuses for sales representatives were based on individually calculated sales figures, and representatives could see estimates of their bonus rise with increased prescriptions written in their sales territory and could identify low or shifting prescribers.<sup>30</sup>

In a somewhat brazen signal of the link between doctor prescribing performance and the financial rewards they could expect through pharmaceutical company gifting, doctors were given grades from D to A+ for each product based on how reliably they prescribed a Merck product.<sup>31</sup> Presumably, the high volume A+ prescribers could expect more lavish gifts, consultancies and speaker bureau invitations.

Coincident with the rise of prescriber identity data mining, the pharmaceutical industry increased its spending on direct marketing to doctors by over 275 percent,<sup>32</sup> doubled its sales force of detailers,<sup>33</sup> and became the most

<sup>26</sup> See Clayton, *supra* note 21 (describing “five and even six figure checks” given to doctors to induce favorable prescribing); Elliott, *supra* note 3, at 7-8.; 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. Big (Brother) Pharma*, NEW REPUBLIC ONLINE, ¶7 (2006), [www.tnr.com/doc.mhtml?i=w060828&s=whitney082906](http://www.tnr.com/doc.mhtml?i=w060828&s=whitney082906).

<sup>27</sup> See Gardiner Harris & Robert Pear, *Drug Maker’s Efforts to Compete in Lucrative Insulin Market are Under Scrutiny*, N.Y. TIMES, January 28, 2006, at A14.

<sup>28</sup> 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).

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Id.* See Public Citizen, Health Research Group; *Response to FDA Request for Comments on First Amendment Issues (HRG Publication #1638)*, September 13, 2002. (detailing the use of prescription data to reward doctors for prescribing Neurontin for unproven uses).

<sup>32</sup> See KAISER, *supra* note 24, at exhibit 1.20.

<sup>33</sup> See Manchanda & Hokna, *supra* note 23, at 788; Consumer Union, Prescription for Change, *Detailing*, March 2006, <http://www.consumersunion.org/pdf/drugreps.pdf> (citing Rayna Herman & Ashley Mahoney, *Access Report 2005*, PHARMACEUTICAL REP., July 2005).

profitable industry in the world.<sup>34</sup> There were an estimated 101,531 detailers in the U.S. in 2004; more than one for every five office-based physicians in the U.S.<sup>35</sup> In 2004, the average primary care physician interacted with 28 sales representatives each week.<sup>36</sup>

#### D. Building a backlash

For a considerable period, the growing use of prescriber data by pharmaceutical marketers went largely unnoticed by many in the medical profession as well as in the general public. When the collection of physician level prescribing data was mentioned, it was often in the context of a discussion of patient privacy.<sup>37</sup> Gradually reports emerged of prescriber outrage at being informed – either through a slip of tongue or as a tactic to influence<sup>38</sup> – that their prescribing habits were being monitored.

The first prominent news article on prescriber data mining in the U.S. broke in 2000 with a multi-page story in the *New York Times*.<sup>39</sup> In the following months and years, many other articles in national publications documented the growing concern of prescribers about the ethical, privacy and public health implications of releasing detailed prescribing habits to pharmaceutical marketers.<sup>40</sup>

A survey conducted in 2001 for the Kaiser Family Foundation revealed that 34 percent of physicians in the U.S. 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.”<sup>41</sup> 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.<sup>42</sup>

<sup>34</sup> Public Citizen Congress Watch, *Drug Industry Profits: Hefty Pharmaceutical Company Margins Dwarf Other Industries* (June 2003) (reporting that ten largest pharmaceutical companies garner profits equivalent to the other 490 Fortune 500 companies combined).

<sup>35</sup> Consumers Union, *supra* note 33; see also Center for Policy Alternatives, *Prescription Drug Marketing*, <http://www.stateaction.org/issues/issue.cfm/issue/PrescriptionDrugMarketing.xml>.

<sup>36</sup> Consumers Union, *supra* note 33.

<sup>37</sup> See, e.g., John Riley, *Know and Tell: Sharing Medical Data for Fun and Profit*, NEWSDAY, Apr. 2, 1996, at A06 (discussing the broad privacy implications of electronic medical and prescription records and noting that HIOs such as IMS America and Pharmaceutical Marketing Services, can break drug sales down by individual prescribing physician).

<sup>38</sup> See 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 (reporting that “Dr. Brad Wexler . . . was surprised four years ago when pharmaceutical representatives began thanking him for writing prescriptions – the first time he realized that the drug representatives had information he assumed was private”); Elliott, *supra* note 3, at 7 (reporting that with data mining reports “drug reps could detect deception immediately”); *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, Director of Cholesterol Management Center, Catholic Medical Center) (describing sales representative promise of breakfast for staff every week if she would “write me two prescriptions every week,” which the sales representative checked through mining data and returned complaining that “you didn’t write my two prescriptions”).

<sup>39</sup> See Sheryl Gay 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). The story broke about 4 years earlier in Canada.

<sup>40</sup> See Kowalczyk, *supra* note 22; Whitney, *supra* note 26; 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/); Elliott, *supra* note 3; Saul, *supra* note 38; Robert Steinbrook, *For Sale: Physicians’ Prescribing Data*, 354 NEW ENG. J. MED. 2745 (2006)..

<sup>41</sup> KAISER FAMILY FOUNDATION, NATIONAL SURVEY OF PHYSICIANS, *Highlights and Chartpack*, chart 3 (2002) (conducted March-November 2001).

<sup>42</sup> American Medical Association, *Reports of Board of Trustees of the American Medical Association, Use of Physician and Patient*

The AMA poll followed a resolution introduced in 2003 by the American College of Physicians to support a ban on the use of prescribing data for pharmaceutical marketing.<sup>43</sup> The AMA, which receives over \$40 million a year from licensing its physician masterfile to data mining companies,<sup>44</sup> tabled the resolution in its Board of Trustees and instead conducted the poll and eventually (in July 2006) adopted a much criticized Prescribing Data Restriction Program (PDRP).<sup>45</sup>

The PDRP permits doctors to restrict access to the AMA supplied data by street level sales representatives, but continues to sell their data to data mining companies and permits the use of that data by higher level marketing officials that manage and compensate sales representatives.<sup>46</sup> The program has been criticized for requiring renewal by the physician every three years, being inadequately marketed (especially to non-AMA members), and for warning doctors that using it "may result in a reduction of drug samples, CME programs and speaking engagements."<sup>47</sup>

Parallel to efforts in the AMA, physician groups have been active in local medical associations and in state legislatures to curb prescription data mining. In 2002, a resolution was introduced in the California Medical Association's (CMA) House of Delegates calling for the organization to oppose drug company access to prescribing records. The next year, California Assembly Bill 262 was introduced, with the support of the CMA, that would have banned the use of prescribing data for marketing purposes in the state.<sup>48</sup> That bill was eventually killed in the face of active lobbying by IMS and the pharmaceutical industry. But the idea was soon replicated in proposals in other states across the nation.<sup>49</sup> The first such bill to pass a legislature, New Hampshire Prescription Confidentiality Act, was introduced by the wife of a physician and strongly supported by the New Hampshire Medical Society.<sup>50</sup>

### III. The New Hampshire Legislation

New Hampshire House Bill 1346 was introduced by Representative 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 mining<sup>51</sup> that the two understood how drug reps knew that he was not prescribing their

*Prescribing Data in the Pharmaceutical Industry, Resolution 606, I-03, Interim Meeting of the AMA House of Delegates, Dec. 2004.*

<sup>43</sup> See 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.*

<sup>44</sup> Steinbrook, *supra*, note 40, at 2747.

<sup>45</sup> See *id.*

<sup>46</sup> See Robert Musacchio & Robert Hunkler, *More Than a Game of Keep-Away*, PHARMACEUTICAL EXECUTIVE, May 2006. (tracing the growth of the PDRP from a AMA best-practices guideline, to a condition for leasing the physician masterfile).

<sup>47</sup> See Kevin O'Reilly, *AMA Opt-Out Program will Keep Prescribing Data From Drug Reps*, AM. MED. NEWS, May 22/29, 2006, at 1-2 (reporting objections to the AMA program from doctors and bioethicists who feel that the AMA Prescribing Data Restriction Plan does not go far enough to protect the interests of doctors). See also Resolution before the American Medical Association, *AMA's Prescribing Data Restriction Program "Opt-out" Policy*, Resolution 606, Oct. 5, 2006, available at <http://www.ama-assn.org/ama1/pub/upload/mm/475/606.doc> (delineating a resolution put forward by delegates from New England states arguing that the AMA opt-out process was poorly structured and that the AMA literature incorrectly stressed only the possible negative consequences of opting out of marketing use of data).

<sup>48</sup> See Whitney, *supra* note 26.

<sup>49</sup> See National Conference for State Legislatures, *2007 Prescription Drug State Legislation*, <http://www.ncsl.org/programs/health/drugbill07.htm> (last visited on July 15, 2007) (noting that in 2007 legislator in thirteen states had introduced laws to restrict the trade in prescriber-identifiable prescription information).

<sup>50</sup> See Whitney, *supra* note 26.

<sup>51</sup> See Kowalczyk, *supra* note 22.

products.<sup>52</sup> His outrage, and hers, fueled a legislative campaign that passed the first restriction on prescriber identified prescription data trading in the country.

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 protects the public health in some way, including 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.”<sup>53</sup>

In addition, following the examples of several Canadian provinces and the European Union,<sup>54</sup> the law specifically authorized the collection and sale of data in aggregated blocks from which individual physicians cannot be identified.<sup>55</sup>

Representative 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

<sup>52</sup> See Whitney, *supra* note 26.

<sup>53</sup> IMS v. Ayotte, No. 06-CV-280-PB, 2007 Lexis 31779, at \*21 (D. N.H. April 30, 2007)

<sup>54</sup> See Niles, *supra* note 2.

<sup>55</sup> 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.

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.<sup>56</sup>

A large number of doctors and medical organizations spoke in favor of the bill.<sup>57</sup> 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 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 may be clinically no better, or in fact worse, for the patient.<sup>58</sup>

#### 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 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.<sup>59</sup> 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.<sup>60</sup>

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 whether prescription data mining is harmful to state interests.

<sup>56</sup> *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).

<sup>57</sup> Supporters of the bill included the New Hampshire Medical Association, the AARP, National Legislative Association on Prescription Drug Prices, the AFL-CIO, Community Catalyst, and Prescription Policy Choices..

<sup>58</sup> See AVORN, *supra* note 5, at James D. Capozzi, MD, & Rosamond Rhodes, MD, *Ethics in Practice: Prescriber Profiles*, 83-A Journal of Bone and Joint Surgery 115 (2001).

<sup>59</sup> *IMS v. Ayotte*, No. 06-CV-280-PB, 2007 Lexis 31779, at \*44-45 (D. N.H. April 30, 2007).

<sup>60</sup> 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.

### 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.”<sup>61</sup> 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 commercial speech doctrine.<sup>62</sup> 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.<sup>63</sup> The Court reasoned that commercial advertisements may help consumers make fully informed purchasing decisions as well form “intelligent opinions as to how [the economic] system ought to be regulated or altered.”<sup>64</sup> 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,<sup>65</sup> restrict the advertisement of prices,<sup>66</sup> and ban certain forms of commercial advertising.<sup>67</sup>

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 free exchange 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.<sup>68</sup>

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,

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<sup>61</sup> *New York Times v. Sullivan*, 376 U.S. 254, 270 (1964).

<sup>62</sup> *Cf. Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 591, 589 (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”).

<sup>63</sup> *See Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976).

<sup>64</sup> *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.”).

<sup>65</sup> *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).

<sup>66</sup> *cf. 44 Liquormart, Inc.*, 517 U.S. at 495-96 (striking down ban on advertisement of liquor prices).

<sup>67</sup> *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).

<sup>68</sup> *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447, 456 (1978).

the main case cited by the New Hampshire 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.”<sup>69</sup>

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.”<sup>70</sup>

The distinction between speech and conduct using regulated information was emphasized by the Supreme Court in *Bartnicki v. Vopper*.<sup>71</sup> 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 a section of the same 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.<sup>72</sup> 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.”<sup>73</sup>

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” and discipline employees 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 struck down. Yet, Judge Barbadoro found just the opposite, holding that the New Hampshire Act regulated “a form of disclosure.”<sup>74</sup>

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 information furnished to the Census from being “used to the detriment of any respondent;”<sup>75</sup> prohibits release of individually identifiable health information;<sup>76</sup> prohibits disclosures of “personally identifiable information concerning any consumer” of a video rental establishment<sup>77</sup> or cable operator;<sup>78</sup> requires that internet service providers “not knowingly divulge”

<sup>69</sup> *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 762 (1985) (plurality opinion).

<sup>70</sup> *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.”)

<sup>71</sup> 532 U.S. 514 (2001).

<sup>72</sup> *Id.* at 527.

<sup>73</sup> *Id.* at 526-27.

<sup>74</sup> *Id.* at 528 (citation omitted).

<sup>75</sup> 13 U.S.C. §8(c).

<sup>76</sup> Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936.

<sup>77</sup> Video Privacy Protection Act, 18 U.S.C. §2710-2711.

<sup>78</sup> Cable Communications Policy Act, 47 U.S.C. §551(c)(1)

subscriber information and communications except for certain public purposes;<sup>79</sup> and requires states to limit the disclosure of drivers' personal identifying information without their consent.<sup>80</sup>

Similarly, states prohibit divulging, publishing or receiving social security numbers in certain forms;<sup>81</sup> regulate the use and disclosure of information "obtained in connection with a motor vehicle record;"<sup>82</sup> 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;"<sup>83</sup> 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."<sup>84</sup> All of these laws are similar in nature to the New Hampshire Act and have long been considered "unproblematic from a First Amendment perspective."<sup>85</sup> The same should hold for laws that ban the secondary uses of prescription information.

### *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,"<sup>86</sup> exerts an "undue influence,"<sup>87</sup> or that threatens professional standards.<sup>88</sup> 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.<sup>89</sup>

<sup>79</sup> 18 U.S.C.A. §2702

<sup>80</sup> 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).

<sup>81</sup> Cal. Civ. Code § 1798.85(a).

<sup>82</sup> Ohio Rev. Code § 4501.27(A).

<sup>83</sup> 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").

<sup>84</sup> 20 Mo. Code of State Regulations 2220-2.

<sup>85</sup> 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).

<sup>86</sup> *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 771 (1976).

<sup>87</sup> *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 462(1978).

<sup>88</sup> See *Edenfield v. Fane*, 507 U.S. 761, 767 (1993).

<sup>89</sup> *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 772 (1976).

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.”<sup>90</sup> 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 target 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.”<sup>91</sup> 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.

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.”<sup>92</sup>

Most physicians deny that pharmaceutical marketing, including gift giving, have any affect on their prescribing practices.<sup>93</sup> Studies also show that health care providers, despite their extensive training and access to medical literature, generally trust the messages delivered by pharmaceutical representatives,<sup>94</sup> and are very poor at detecting false and misleading messages within sales pitches.<sup>95</sup>

<sup>90</sup> *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447, 458 (1978) (citations omitted).

<sup>91</sup> See Declaration of Avorn and Kesselheim at 6. See also Jerry Avorn, *Economic Implications of Evidence-Based Prescribing for Hypertension: Could Better Care Cost Less*, 291 J. AM. MED. ASS’N 1850, 1854 (2004) (“There are many 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.”).

<sup>92</sup> Susan L. Coyle, *Physician-Industry Realitions, Part 1: Individual Physicians, Position Paper*, 136 ANNALS OF INTERNAL MED., 396, 397 (March 2002).

<sup>93</sup> See Jerry Avorn, et al., *Scientific Versus Commercial Sources of Influence on the Prescribing Behavior of Physicians*, 73 AM. J. MED. 4-8 (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 Stienman, et al. *Of Principles and Pens: Attitudes and Practices if Medicine Housestaff Towards Pharmaceutical Industry Promotions*, 110 AM. J. MED. 551 (2001) (reporting that sixty-one percent of medical residents believe that their own prescribing practices are unaffected by pharmaceutical marketing, although eighty four percent think that marketing affects the practices of their colleagues).

<sup>94</sup> Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 J. AM. MED. ASSN. 373 (2000).

<sup>95</sup> M.G. Ziegler, P. Lew and B.C. Singer, *The Accuracy of Drug Information from Pharmacuetical Sales Representatives*, 273 J. AM.

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.<sup>96</sup> An exhaustive data synthesis from over 500 published studies found conclusive evidence that 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.”<sup>97</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>98</sup>

## 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.<sup>99</sup>

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.<sup>100</sup> A significant amount of this shift to less effective and more expensive treatments was enabled by pharmaceutical marketers knowing that an individual doctor is favoring the less expensive treatment and mounting an information campaign in response to convince the doctor to switch treatments.<sup>101</sup>

MED. ASS’N 1296 (1995). (finding that eleven percent of statements by detailers to doctors were inaccurate, but only twenty-six percent of doctors who had heard the inaccurate statements could detect them).

<sup>96</sup> See Jason Dana & George Lowenstein, *A Social Science Perspective on Gifts to Physicians From Industry*, 290 J. AM. MED. ASSN. 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); Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 J. AM. MED. ASSN. 373 (2000) (analyzing twenty-nine studies of the relationship between physicians and the pharmaceutical industry and finding that 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. 240-43 (1990); Declaration of Jerry Avorn, M.D. and Aaron S. Kesselheim, M.D., J.D., pp. 3-5 (discussing studies demonstrating the “powerful effect [of gifts and detailing] on driving drug utilization”); Abigail Caplovitz, *Turning Medicine Into Snake Oil: How Pharmaceutical Marketers Put Patients at Risk*, NJPIRG Law and Policy Center, 5 (2006) (reviewing studies); Manchanda & Hokna, *Pharmaceutical Innovation and Cost*, 5 YALE J. HEALTH POL’Y L. & ETHICS at 797-808 (reviewing studies). See, e.g. Helen Prosser, Solomon Almond & Tom Walley, *Influences on GPs Decisions to Prescribe New Drugs – the Importance of Who Says What*, 20 FAM. PRAC. 61 (2003); David Blumenthal, *Doctors and Drug Companies*, 251 NEW ENG. J. MED. 1885 (2004) (discussing the insidious interplay between the sense of obligation created by even small gifts and the psychological tendency to discount one’s own susceptibility to bias).

<sup>97</sup> Wazana, *supra* note 94, at 375.

<sup>98</sup> *Id.*

<sup>99</sup> National Institute for Health Care Management (NIHCM), *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs*, 2-3 (revised May 6, 2002).

<sup>100</sup> Roberto Cardarelli, John Licciardone, 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 PRACT 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 vs. \$87.30 per month respectively).

<sup>101</sup> See Jane Coutts, *Pharmaceutical Group’s Head Defends Sale of Medical Data*, GLOBE & MAIL (March 28, 1996) (describing how

In Pennsylvania, a study of Medicare patients on antihypertensive therapy found that forty percent of patients were on medications other than those recommended by clinical guidelines.<sup>102</sup> This same study of antihypertensive therapy shows that for this class of medications alone, switching to a non-branded, non-marketed medication when medically appropriate could save \$1.2 billion per year.<sup>103</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 pain relievers than older NSAIDs, or that the reduction in gastric side effects were significant for most patients.<sup>104</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>105</sup>

### 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.<sup>106</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>107</sup> 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.”<sup>108</sup>

There can perhaps be no greater affront to these values than permitting pharmaceutical companies to give pecuniary rewards to medical professionals based on their prescribing habits. Prescription data mining provides the key tool for pharmaceutical companies to literally pay prescribers – with meals, gifts, vacations 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.<sup>109</sup>

“[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”.

<sup>102</sup> Michael Fischer and Jerry Avorn, *Implication of Evidence Based Prescribing for Hypertension*, 291 J AM. MED. ASS'N 1850, 1854 (2004).

<sup>103</sup> *Id.* See also AVORN, POWERFUL MEDICINES 202 (rev. 2005).

<sup>104</sup> AVORN, POWERFUL MEDICINES 202 (rev. 2005)

<sup>105</sup> 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).

<sup>106</sup> See Susan L. Coyle, *Physician-Industry Realties, Part 1: Individual Physicians, Position Paper*, 136 ANNALS OF 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](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.”).

<sup>107</sup> *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 460 (1978).

<sup>108</sup> *Id.* at 461.

<sup>109</sup> 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.”).

#### 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.”<sup>110</sup> 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.

Prescribers may be the most marketed-to class of “consumers” in the world. As described above, the rise of data mining was paralleled by a massive increase in detailing. Spending increased by nearly three hundred percent<sup>111</sup> and the number of detailers doubled to one in every 4-5 office based physicians.<sup>112</sup> The average primary care physician interacted with nearly 30 sales representatives each week in 2004.<sup>113</sup>

Doctor complaints about the increasing aggressiveness of detailers have become the stuff of front page news articles in national papers.<sup>114</sup> 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.<sup>115</sup>

There are a host of federal and state laws that combat harassing and frequent marketing calls on consumers by limiting access to identifying information to marketers.<sup>116</sup> In 2001, 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 held 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.<sup>117</sup>

In the case of medicines, it is doctors who make the purchasing decisions for the ultimate consumers of the product, and therefore they receive the large majority of all marketing efforts. Prescribers thus have the same interests as consumers in other settings of being free from harassing sales practices facilitated by the trading in their identities and purchasing habits.

<sup>110</sup> *IMS v. Ayotte*, No. 06-CV-280-PB, 2007 Lexis 31779, at \*44 (D. N.H. April 30, 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”).

<sup>111</sup> See *KAISER*, *supra* note 24, at exhibit 1.20.

<sup>112</sup> 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 & Hokna, *supra*, at 788; Consumers Union, *supra* note 33; see also Center for Policy Alternatives, *Prescription Drug Marketing*, <http://www.stateaction.org/issues.cfm/issue/prescriptiondrugmarketing.xml>; Consumer Union, Prescription for Change, *Detailing*, March 2006, <http://www.consumersunion.org/pdf/drugreps.pdf>

<sup>113</sup> Consumers Union, *supra* note 33.

<sup>114</sup> See *Saul*, *supra* note 38

<sup>115</sup> See Adriane Fugh-Berman and Shahram Ahari, *Following the Script: How Drug Reps Make Friends and Influence People*, PLOS MED.4(4); E150 0621-25.

<sup>116</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); Video Privacy Protection Act of 1988, 18 U.S.C. 2710 (2000) (video rental information); Cable Communications Policy Act of 1984, Pub. L. No. 98-549, 98 Stat. 2779 (subscriber information); Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified in scattered sections of 18 U.S.C., 26 U.S.C., 29 U.S.C., and 42 U.S.C.) (patient medical information).

<sup>117</sup> *Trans Union Corp. v. Fed. Trade Comm’n*, 267 F.3d 1138, 1140-41 (D.C. Cir. 2001).

## V. State legislative Responses

Since the opinion in *IMS v. Ayotte*, two states moved to enact new regulations of prescription data trading. Each of the states, Maine and Vermont, place a more direct onus on the prescriber to approve of the trading of their data for marketing purposes.<sup>118</sup>

On June 11, 2007, the Vermont governor signed into law a restriction on the sale or transfer of prescriber data unless the health care professional identified in the record affirmatively opts-in to a program authorizing use of his or her prescribing records.<sup>119</sup>

The bill requires the Vermont department of health to “establish a prescriber data-sharing program to allow a prescriber to give consent for his or her identifying information” to be used for marketing purposes by pharmaceutical companies. The department is required to “solicit the prescriber’s consent on licensing applications or renewal forms and shall provide a prescriber a method for revoking his or her consent.” The department must then create a public list of all doctors who have chosen to share their prescription data and pharmaceutical marketers may only use prescriber data for individuals on the list.

The Vermont law further requires pharmaceutical marketers engaging “in any form of prescription drug marketing directly to” a prescriber to divulge government-certified “evidence based” information

describing the specific health benefits or risks of using other pharmaceutical drugs, including drugs available over the counter; which patients would gain from the health benefits or be susceptible to the risks described; the range of prescription drug treatment options; and the cost of the treatment options.<sup>120</sup>

Maine recently signed into law an opt-out model, prohibiting trading “for any marketing purpose, prescription drug information that identifies a prescriber who has filed for confidentiality protection.”<sup>121</sup> Like the Vermont law, the Maine law uses a check off box on licensing or renewal applications. Entities who want to use prescriber data then have the responsibility to check a registry of health care providers who have filed for confidentiality protection and cease to sell or otherwise trade their data.<sup>122</sup>

Massachusetts and the District of Columbia have each announced bills that would license and regulate the practice of detailing. Some of the requirements discussed for inclusion in these bills include professional qualifications for detailers, restrictions on misleading marketing messages not supported by scientific evidence, restrictions on promotion of off-label use, and bans on gift giving. Other states have already moved to require the reporting of gift giving to prescribers, including Vermont, Minnesota and the District of Columbia.

Finally, many states are adopting “academic detailing” programs that fund a group of neutral analysts and detailers to create and promote objective information to doctors about prescribing options.

## VI. Conclusion

The weight of authority suggests that the state’s interest 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 would justify completely banning detailing and gift-giving by pharmaceutical sales representatives. New

<sup>118</sup> See S. 115, 2007 Leg. (Vt. 2007); L.D. 4, 123rd Leg., 1st Reg. Sess. (Me. 2007)

<sup>119</sup> See S. 115, 2007 Leg. (Vt. 2007)

<sup>120</sup> *Id.*

<sup>121</sup> See L.D. 4, 123rd Leg., 1st Reg. Sess. (Me. 2007)

<sup>122</sup> *Id.*

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.

Judge Barbadoro's opinion is currently under appeal in the First Circuit. Several state Attorney Generals, physician professional organizations and public policy organizations have stated their intention to file friend of court briefs in the case supporting the rights of New Hampshire and other states to regulate prescriber data trading in the pharmaceutical industry. In the mean time, state legislatures are continuing to craft policies in this area.

States looking to act in this area in the future should strive to create a fuller record documenting their interests to prevent other courts from blindly following Judge Barbadoro's lead.<sup>123</sup> 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.

States may consider means to stop data trading that may be more narrowly tailored to prescriber interests, for example permitting the information to be released to pharmaceutical companies only if the doctor has explicitly consented to the release. But such programs may not fully serve the state's interest in battling undue influence, promoting cost control and proper utilization and policing professional standards if the substantial share of doctors do not willingly opt out of the pay-for-play pharmaceutical marketing system.

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. Other measures may include licensing and regulating detailers, prohibiting false and misleading detailing, using Medicaid formularies to decrease public purchasing costs, banning or disclosing gifts to prescribers, and creating counter-detailing programs.

In sum, states should keep acting in this area. States and health care advocates should also consider supporting New Hampshire's defense of its landmark regulation in the First Circuit, and, possibly, the Supreme Court.

*The Prescription Project is led by Community Catalyst and the Institute on Medicine as a Profession and funded by the Pew Charitable Trusts. It seeks to eliminate conflicts of interest created by pharmaceutical marketing and to promote evidence-based prescribing through policy change at academic medical centers, professional medical societies and public and private payers.*

*The Program on Information Justice and Intellectual Property (PIJIP) promotes social justice in law governing information dissemination and intellectual property through research, scholarship, public events, advocacy, and provision of legal and consulting services.*

<sup>123</sup> 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, No. 06-CV-280-PB, 2007 Lexis 31779, at \*44