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W A S H I N G T O N , D C

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House Health and Government Operations Committee  
Health Facilities & Occupations and Government Operations Subcommittees  
Maryland State Legislature  
6 Bladen St.  
Annapolis, MD 21401

Dear Chairmen and Members of the Committee:

It is my pleasure to submit these comments on the practice of prescriber profiling and the sale of physician-specific prescription data.

My name is Meredith Jacob and I am here on behalf of Sean Flynn, the Associate Director of the Program on Information Justice and Intellectual Property (PIJIP) at American University Washington College of Law. PIJIP also serves as counsel to the Prescription Project of Community. These organizations strongly support the passage of legislation to regulate so called “data mining” by the pharmaceutical industry.

My comments include an overview of the practice of data-mining, a review of legislation passed in other states to regulate the practice of prescription data-mining, as well as an analysis of the recent decision of the United State Court of Appeals for the First Circuit upholding the New Hampshire data-mining restriction.

### **The Use and Abuse of Prescription Data Mining**

A multi-billion “health information” industry has been buying prescription records from pharmacies, PBMs 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.

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>1</sup>

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>2</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>3</sup>

Access to prescribing data stoked a massive increase in spending and sales force size for individualized marketing. 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. Over eighty-five percent of pharmaceutical marketing budgets are targeted at doctors.<sup>2</sup>

In the decade after IMS unveiled its flagship prescriber tracking program in 1993,<sup>3</sup> spending on detailing increased by nearly three hundred percent,<sup>4</sup> doubling the number of pharmaceutical sales representatives to over 100,000.<sup>5</sup> There is one pharmaceutical sales representative for every four to five office-based physicians in the nation. 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. The average primary care physician in 2004 interacted with a staggering 28 sales representatives each week.<sup>8</sup>

States are acting to regulate this use of prescription data for several core reasons:

First, prescriptions are part of medical records that document some of the most private and personal activities of people in society. Releasing these records into the public so that marketers can see what drugs people are taking and target marketing to their doctors based on that information invades a core privacy interest that states desire to protect.

Second, there is a large amount of data displaying that drug marketers in the U.S. are exerting undue influence over the prescribing practices in the health profession which is

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<sup>1</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)).

<sup>2</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); EMILY CLAYTON, CALPIRG, *‘TIS ALWAYS THE SEASON FOR GIVING: A WHITE PAPER ON THE PRACTICE AND PROBLEMS OF PHARMACEUTICAL DETAILING* (2004).

<sup>3</sup> See Elliott, *The Drug Pushers*, at 90-91; Liz Kowalczyk, *Drug Companies’ Secret Reports*, BOSTON GLOBE, May 25, 2003, at A1.

<sup>2</sup> Kaiser Family Foundation, *Trends and Indicators in the Changing Health Care Marketplace* exhibit 1.20, <http://www.kff.org/insurance/7031/print-sec1.cfm> (2005)[hereinafter *Trends*].

<sup>3</sup> *IMS America Introduces Xponent, the First and Only True Prescriber Level Prescription Sales Database*, PR Newswire, Feb. 9, 1993, available at Lexis.

<sup>4</sup> *Trends*.

<sup>5</sup> Rayna Herman & Nick Dabruzzo, *2006 Access Report: The State of the Selling Environment*, Pharmaceutical Representative, July 2006, available at <http://www.pharmrep.com/pharmrep/article/articleDetail.jsp?id=353927>; Manchanda, *supra* note 43.

<sup>8</sup> Consumers Union; *Prescription for Change*, Mar. 2006, <http://www.consumersunion.org/pdf/drugreps.pdf>.

contributing to irrational prescribing practices that harm public health and unnecessarily raise the cost of health care;

Third, access to this data is corrupting the medical profession by allowing companies to use advisory board appointments, consultancies and gifts as direct payment for observed prescribing practices;

Finally, doctors themselves are pushing for this legislation in many states because access to individualized data is promoting the use of harassing and vexatious sales practices in which sales representatives attempt to hold doctors “accountable” for gifts and promises as they race toward the massive bonuses companies provide to reps based on their ability to shift prescribing practices.

As I describe further below, all of these purposes provide ample justification for state regulation in this area, regardless of any “free speech” arguments raised by the industry.

### **State Regulation of Data Mining**

New Hampshire, in passing its Prescription Confidentiality Act,<sup>4</sup> was the first state in the nation to ban the trade in prescriber-identified prescription data for marketing purposes. Following the passage of the New Hampshire Act, Vermont<sup>5</sup> and Maine<sup>6</sup> 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. The law in Vermont is structured so that data-mining restriction is the default and physicians must opt-in if they wish their data to be shared with pharmaceutical companies. In Maine, however, the law has been structured so that physicians must opt-out to prevent their data from being used for marketing purposes. These laws have also been challenged in federal court.<sup>7</sup>

In April 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.<sup>8</sup> This ruling was appealed the United States Court of Appeals for the First Circuit, which overturned the District Court decision and held that the New Hampshire Act was not a violation of the First Amendment. The First Circuit ruling will also apply to Maine, though that decision has not been remanded yet.

### **United State Court of Appeals for the First Circuit Upholds the New Hampshire Prescription Privacy Act.**

The United States Court of Appeals for the First Circuit examined the New Hampshire law and the reversed the decision of the District Court, holding that the New Hampshire Act did

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<sup>4</sup> N.H. REV. STAT. ANN. §318:47 f (2006).

<sup>5</sup> V.T. STAT. ANN tit. 18 §4631 (2007).

<sup>6</sup> ME. REV. STAT. ANN. tit. 22 §1711-E (2007)

<sup>7</sup> 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).

<sup>8</sup> IMS Health, Inc. v. Ayotte, 490 F. Supp. 2d 163 (D.N.H. 2007).

not regulate speech, and that even were it viewed as doing so, it would still be a permissible regulation of commercial speech because of the state interest advanced.<sup>9</sup>

### **I. The First Circuit Holds That Monitoring Prescription Data is Not Speech**

The first area of inquiry for the First Circuit was whether or not the use of prescriber-identifiable data should be classified as speech. Here, the court found that the use of data prohibited by the New Hampshire Act constituted conduct, not speech. The Court reviewed other cases where language-related activities were regulated as conduct, rather than speech, and found that in the case at hand there was “scant societal value” to any informational component of the marketing uses of prescription data.

The Court went on to note that in this situation, information had become a commodity, and could be regulated as such. It recognized that the sale of prescription data did nothing to increase the free flow of information to doctors or patients, or to inform their decision-making in the marketplace. Finally, the Court reviewed precedent establishing that state actions that made speech unprofitable did not restrict speech, and observed that no provision of the New Hampshire Act foreclosed publication or open discussion of prescriber data.

### **II. Even if Prescription Monitoring Were Speech, Regulation is Acceptable to Protect Substantial State Interests.**

Here, the First Circuit asserted that, even were it to find that the regulated conduct *was* speech, the state still had the ability to regulate. First, the Court held that the sale of prescription data was clearly commercial speech, and therefore subject to a lower level of scrutiny. Then it applied the three part commercial speech test, and found that New Hampshire had met its burden to regulate.

The standard that states must meet to impose a valid regulation of commercial speech was evaluated by the Court as follows:

- 1) Does the regulation advance a substantial government interest?  
The Court found that the cost containment goals of the state were a substantial government interest, both in light of the rising cost of healthcare and the large impact that healthcare costs had on the state budget
- 2) Is the government interest directly advanced by the regulation?  
Here the Court recognized a three part synthesis – that detailing increases pharmaceutical costs, the availability of prescriber info increases detailing, and that increased detailing provides no net benefit to patients.
- 3) Is the regulation no more extensive than necessary to serve the state’s interest?  
The Court reviewed the evidence and found that evidence found that New Hampshire had reason to believe that gift bans, academic detailing, and Medicaid formularies were insufficient to serve the needs of cost containment and patient care advanced by the legislation.

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<sup>9</sup> *IMS Health, Inc v. Ayotte*, \_\_\_ F. 3d. \_\_\_, 2008 WL 4911262 (1st Cir. 2008).

## Constitutional State Interests in Regulating Data Mining

While we enthusiastically support the First Circuit's decision that prescriber profiling is not speech, it is also important to note that there is a wide array of state interests that justify the regulation of this practice even were it to be classified as speech.

Allowing pharmaceutical companies to monitor the prescribing practices of physicians permits them to exert an undue influence on prescribing practices that heightens irrational prescribing practices, raises health costs and, ultimately, harms patient health and welfare the protection of which is the most fundamental role of state governments.

### *Regulation of Datamining Prevents Undue Influence in Pharmaceutical Marketing*

States have a paramount interest in combating undue influence of pharmaceutical marketers over prescribing decisions.

Nearly all direct to prescriber marketing is one sided because only the most expensive and profitable medicines, i.e. branded blockbuster drugs, are marketed through in-person detailing. Access to prescribing data aggravates the negative impacts of this one sided information market by permitting branded medicine marketers to observe and reward favored prescribing behavior. Ninety four percent of all doctors routinely receive gifts of significant value, such as meals, branded office supplies, and free drug samples, which create powerful psychological urges to reciprocate. Prescriber data is used to guide this gift giving, so that the most profitable prescribers receive the highest rewards. The most favored prescribers can receive hundreds of thousands of dollars in payments from drug companies for speaking engagements, research, and sitting on various advisory boards.

The extensive medical and scientific training that health professionals receive does not insulate them from being unduly influenced by pharmaceutical marketers. Doctors, particularly primary care physicians, are overworked and overwhelmed by the volume of medical news, creating a system where pharmaceutical marketers become the easiest source of information on new drugs, delivered with lunch directly to the office. When this is combined with a pharmaceutical representative's ability to extol the benefits of their drug in specific, if biased, comparison to the one the physician is currently prescribing, even physicians conscious of the marketing pressure are commonly influenced.

Numerous studies and investigations have documented a significant, measurable, and increasing influence of direct to physician marketing at convincing doctors to adopt prescribing practices that are contrary to clinical guidelines and the weight of objective scientific evidence. An exhaustive data synthesis from over 500 published studies found conclusive evidence that pharmaceutical detailing guided by access to prescribing data "impact[s] the prescribing practices of residents and physicians in terms of prescribing cost, nonrational prescribing, awareness, preference and rapid prescribing of new drugs, and decreased prescribing of generic drugs."<sup>10</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>11</sup>

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<sup>10</sup> Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 JAMA 373 (2000).

<sup>11</sup> *Id.*

Studies have also shown that physicians and other health care professionals are not well qualified to filter through misleading and skewed presentations by sales representatives. Despite the volume of evidence showing that pharmaceutical marketing is effective at shifting prescribing habits away from the best evidence based practices, most physicians deny that pharmaceutical marketing has any affect on their prescribing practices (while reporting that marketing does affect their colleagues). Further, they generally trust the messages delivered by pharmaceutical representatives, and are very poor at detecting false and misleading messages within sales pitches.<sup>12</sup>

In a recent New York Times article examining the payments to psychiatrists, Dr. Steven Hyman, the provost of Harvard University and former director of the National Institute of Mental Health said intensive marketing and payments in the forms of consultancies could encourage psychiatrists to use drugs in ways that endanger patients' physical health. "There's an irony that psychiatrists ask patients to have insights into themselves, but we don't connect the wires in our own lives about how money is affecting our profession and putting our patients at risk," he said.<sup>13</sup>

#### *Regulation of Datamining Reduces Costs and Promotes Public Health*

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

There are many examples of the successes of our super-charged pharmaceutical marketing system at shifting massive amounts of prescriptions toward newer, more expensive drugs that do not benefit patients. One study, referenced in the New Hampshire legislative history, showed that using highly marketed branded medicines for high blood pressure instead of less expensive generic therapies rated as more effective by national treatment guidelines increased U.S. health costs by \$3 billion in 1996.<sup>14</sup> Another study found that approximately forty percent of Pennsylvania Medicare patients on antihypertensive therapy were being prescribed medications at odds with clinical guidelines at a cost of \$11.6 million per year in that state alone. Extrapolated to national levels, that same study found that marketing-driven non-rational prescribing costs the nation \$1.2 billion for that class of drugs alone. A similar effect can be seen in the incredible marketing push and resultant prescription surge for Vioxx, Celebrex, and other COX 2 inhibitors, despite the lack of any conclusive medical evidence that they were more effective than older pain medications, or that the reduction in gastric side effects were significant for most patients. And in the case

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<sup>12</sup> Michael Ziegler, et al., *The Accuracy of Drug Information from Pharmaceutical Sales Representatives*, 273 JAMA 1296 (1995) (finding that eleven percent of statements by detailers to doctors were inaccurate, but only twenty-six percent of doctors who had heard the inaccurate statements could detect them).

<sup>13</sup> Gardiner Harris, et al., *Psychiatrists, Children and Drug Industry's Role*, N. Y. TIMES, May 10, 2007; See also 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>14</sup> 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).

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.

The aggregate financial costs to society of undue influence by pharmaceutical marketers is enormous. Nearly a third of the five fold increase in U.S. spending on drugs over the last decade can be attributed to pharmaceutical marketing efforts that shift doctors' prescribing from existing, effective, and lower cost (often generic) therapies to new and more expensive treatments. A significant amount of these irrational choices are influenced by pharmaceutical marketers knowing that an individual doctor is favoring the less expensive treatment and mounting a campaign to convince the doctor to switch treatments.

*Regulation of Datamining Maintains Standards in the Medical Profession.*

Many physician organizations advocate an end to prescriber-identified data trading for marketing purposes because the practice threatens the ethical standards of the profession and jeopardizes their relations with patients.

There may be no greater affront to the ethical basis of the medical profession than permitting pharmaceutical companies to give pecuniary rewards to medical professionals based on their prescribing habits. Prescription data mining provides the key tool for pharmaceutical companies to literally pay prescribers with meals, gifts, vacations, high value / low work "consultancies," and board appointments for the use of their products. High prescribers and influential specialists can receive tens and even hundreds of thousands of dollars for consultancies and lectures each year, a cycle that not only rewards high prescribers, but also uses those physicians' prominence to influence other doctors' prescribing choices. This incorporation of prescribers into the commission structure of pharmaceutical sales debases the medical profession and, the more the practice becomes public, breaks the chain of trust between doctor and patient.

*Regulation of Datamining Protects Doctors Against Vexatious Sales Practices*

Doctors are pushing many of the reforms in this area in part because a substantial number feel harassed by the increasing frequency and aggressiveness of detailing forces fueled by the use of prescribing data to track prescription writing and calculate sales bonuses.

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. In the case of medicines, it is doctors who make the purchasing decisions for the ultimate consumers of the product, and therefore they receive the large majority of all marketing efforts.

Although marketing to doctors has long been a key focus of pharmaceutical company marketing budgets, the availability of digitized prescribing data beginning in the early 1990s made the practice more profitable and invasive. In addition to being harassing by its sheer volume, access to prescriber detailing increases the prevalence of coercive marketing practices in individual sales calls. Sales representatives use this data in increasingly obnoxious ways to hold prescribers "accountable" for their marketing messages and gifts,

including by telling prescribers that they are being monitored and that the free lunches and gifts will dwindle if they do not meet the marketers' expectations.

*Regulation of Datamining Protects Patient Privacy.*

There can be no doubt that patients have the strongest possible interest in not having their treatment histories subjected to surveillance and lobbying by pharmaceutical companies. But this interest cannot be protected by the removal of patient names alone.

Patient de-identification is not complete with the removal of names and addresses. The data can still be used to track an individual patient, identified with a unique numerical identifier that carries forward through time. The problem with this is twofold. It weakens the protection of privacy for patients in situations where knowing treatment history and physician identity can allow re-identification of a patient. It also allows pharmaceutical companies to target an individual patient for sales efforts, even name unknown. With access to prescriber identities and "anonymized" patient data, a pharmaceutical company can not only observe a specific treatment event for a particular patient, like the switching of a prescription, but can respond with an individualized marketing campaign at the prescriber to change that patient's treatment. This insertion of the pharmaceutical company into the monitoring and influence of the patient's treatment is an invasion of privacy of the most odious kind: one that directly affects the treatment course of the patient for the pecuniary interest of another through a breach of confidentiality that is nearly impossible to detect.

### **Deceptive Pharmaceutical Industry Arguments**

The pharmaceutical industry misleadingly argues that this type of law limits their ability to target marketing to doctors based on specific prescribing habits, thus diluting the quality of the information they deliver. This is false, as individual physicians are free to tell marketers what type of drugs they prescribe if they desire more specific information from marketers.

The industry argues that laws protecting prescription confidentiality will limit use of prescribing data for research, or for efficiency-promoting health care utilization review. But these purposes are clearly exempted by existing datamining legislation. Researchers testified in the New Hampshire litigation that they prefer to access Medicaid and Medicare treatment data for research purposes because it is more complete and private data is too expensive. Data privacy measures have been in place in Europe and Canada for many years and we do not hear any evidence of problems in those jurisdictions. The companies can still collect identified data, they just cannot use it for marketing purposes and must contractually forbid any other recipient from using it for marketing purposes as well.

### **Conclusion**

Thank you for this opportunity to testify. Please feel free to contact Sean Flynn, associate director of the Program on Information Justice and Intellectual Property with any questions, at 202-274-4157.