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TESTIMONY: THE STATE ROLE IN THE REGULATION OF PRESCRIPTION DATA-MINING

Meredith Jacob*

I. Overview

This model testimony is based off of specific testimony Meredith Jacob has submitted to various state legislatures advocating the passage of “Data-Mining” legislation.

Dear Chairman and Members of the Committee:

I am pleased to submit these comments on the practice of prescriber profiling and the sale of physician-specific prescription data. My comments provide an overview of the practice of prescription data-mining, a review of legislation passed in other states to regulate it, and an analysis of the recent decision of the United State Court of Appeals for the First Circuit upholding the New Hampshire data-mining restriction.

My name is Meredith Jacob and I am a pharmaceutical policy fellow at the Program on Information Justice and Intellectual Property (PIJIP) at American University Washington College of Law. I am here on behalf of the Prescription Project of Community Catalyst, as well as the National Legislative Association on Prescription Drug Prices. PIJIP’s associate director, Sean Flynn, serves as counsel to the Prescription Project of Community Catalyst and to the National Legislative Association on Prescription Drug Prices. These organizations strongly support the passage of legislation to regulate “data-mining” by the pharmaceutical industry.

II. The Use and Abuse of Prescription Data-Mining

The practice of prescription data-mining dates back to the early 1990s, when prescription records went digital and pharmacy benefit managers (PBMs) became widespread. These organizations sought to digitize prescription records so claims could be expedited through an online process, creating the possibility of quickly transferring the records to others. Over the last decade or so, a multi-billion dollar “health information” industry has emerged to buy 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.

The records are then used by pharmaceutical companies to promote incredibly sophisticated marketing efforts to doctors. Pharmaceutical companies use the records to determine which doctors are more susceptible to various kinds of sales messages, which doctors are more prone to using new drugs, whether a doctor is “brand loyal” to a certain manufacturer, and which doctors should be rewarded for their prescribing practices with high paying consultancies, advisory board positions, and scholarships to “educational” seminars. Data-mining has 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.

Access to prescribing data stoked a massive increase in spending and sales force size for individualized marketing. According to the First Circuit’s examination of the record in the New Hampshire case, pharmaceutical companies spend at least $4 billion annually on detailing to doctors.

In the decade after IMS Health Inc., a large Health Information Organization, unveiled its flagship prescriber tracking program in 1993, spending on detailing increased by nearly 300 percent, doubling the number of pharmaceutical sales representatives to over 100,000. There is now one pharmaceutical sales representative for every five 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.

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

- First, prescriptions are part of medical records that document private decisions made in the context of the doctor patient relationship. Permitting commercial use of these records improperly injects marketing influence into the exam room.

* Meredith Jacob is a pharmaceutical policy fellow at the Program on Information Justice and Intellectual Property (PIJIP) and a recent graduate of the Washington College of Law. She would like to thank Sean Flynn for his guidance and for the opportunities that PIJIP has provided her.
Second, there is a large amount of data displaying that drug marketers in the United States are exerting undue influence over the prescribing practices, which is 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.

All of these purposes provide ample justification for state regulation in this area, regardless of any “free speech” arguments raised by the industry.

III. State Regulation of Data-Mining: First Circuit Upholds the New Hampshire Prescription Privacy Act

New Hampshire, in passing its Prescription Confidentiality Act, was the first state in the nation to ban the trade in prescriber-identifiable prescription data for marketing purposes. Following the passage of the New Hampshire Act, Vermont and Maine passed laws that give physicians the right to opt-in or opt-out of sharing their prescription records.

The first-in-the-nation prescription confidentiality law in New Hampshire was recently upheld under a constitutional challenge by the First Circuit Court of Appeals. All three judges on the First Circuit agreed that the law’s core purpose of curbing irrational prescribing of higher priced drugs due to undue influence of marketers was sufficient in itself to justify any encroachment on the companies’ “commercial speech” rights. Two judges held that the law did not actually regulate any speech because prescription records sold as a commodity on commercial markets are subject to traditional economic regulation free of any First Amendment inquiry. The third judge thought that the law did affect the commercial speech of detailers, by prohibiting them from informing their messages with the records, but held nevertheless that the law was adequately justified.

The first area of inquiry for the First Circuit was whether 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 noted that, in this situation, information had become a commodity, and could be regulated as such. 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.

IV. Creating a Full Record

Although the only circuit court to address the issue unanimously held that states have every right to ban the sale of prescription records to serve public health concerns, the litigation in these cases indicates that legislatures must carefully justify their actions to survive court scrutiny. If anything, the risks of litigation for the next state to act in this area have increased. The pharmaceutical industry is now looking for a circuit split so it can take this issue to the Supreme Court.

The most important thing this Committee can do—other than carefully crafting legislation—is to create a full and persuasive record displaying the reasons for its action in this area. While data-mining legislation should not be subject to First Amendment scrutiny, the Committee should assume that a court may differ on this opinion and that the law will have to meet what courts term “intermediate scrutiny.” This means that the law must directly serve a “substantial government interest” and be reasonably tailored to that interest. There is a wealth of documentary evidence and expert testimony that can be brought to bear on these issues.

Regulation of Data-Mining 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, that is branded blockbuster
drugs, are marketed through in-person detailing. Access to prescribing data aggravates the negative impact of this one-sided information market by permitting branded medicine marketers to observe and reward favored prescribing behavior. 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.

Numerous studies and investigations have documented a significant, measurable, and increasing influence of direct-to-physician marketing by 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 has 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, non-rational prescribing, awareness, preference and rapid prescribing of new drugs, and decreased prescribing of generic drugs.” 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.”

Data-Mining Fueled Marketing Increases Cost Without Benefit to Patients

The aggregate financial costs to society of undue influence by pharmaceutical marketers are enormous. Many examples exist exhibiting the successes of the super-charged pharmaceutical marketing system at shifting massive amounts of prescriptions toward newer, more expensive drugs that do not benefit patients. In 2007, while generic medicines accounted for 65% of prescriptions filled, generics were only responsible for approximately 20% of prescription costs. Reducing the non-medically appropriate overuse of branded pharmaceuticals is essential to controlling health care costs. Another study found that approximately 40% 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.

Increased Prescription Costs Reduce Access to Medicines or Force Patients to Cut Spending on Other Necessities

Increased cost of medications has a direct effect on patient health. In 2007, a review of medical literature found that up to 32% of seniors took less medicine than prescribed in an effort to reduce costs. When data-mining drives the prescription of more expensive alternatives, patients are needlessly forced to make purchasing decisions that can endanger their health.

Data-Mining Accelerates Unsupported, Overly-Broad Adoption of the Newest Drugs

One of the clear effects of data-mining in marketing is that it demonstrably shifts prescribing patterns toward newer drugs. But now there is a growing awareness that the rapid uptake of new drugs may threaten patient health in many areas where older therapies should remain the first line drugs of choice. Newer drugs often have unknown side effects and less developed safety profiles, in comparison to drugs that have been on the market for significant periods of time.

This 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. 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.

Regulation of Data-Mining 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 physicians’ relations with patients by permitting pharmaceutical companies to give pecuniary rewards to medical professionals based on their prescribing habits.

Gift bans and reporting are one good policy tool. But it is difficult and perhaps impossible to ban all payments to doctors by pharmaceutical companies, because some legitimate roles exist for physicians in clinical trials and other consulting roles. By banning sale of prescriber data, we can eliminate payments to physicians based on the drugs they prescribe, rather than work they do.
Regulation of Data-Mining 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. A host of federal and state laws combat harassing and frequent marketing calls on consumers by limiting marketers’ access to identifying information. In the case of medicines, it is the doctors who make the purchasing decisions for the ultimate consumers of the product; therefore, they receive the large majority of all marketing efforts.

In addition to being harassing by its sheer volume, access to prescriber histories 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 Data-Mining Protects Patient Privacy

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 patients’ 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. With access to prescriber identities and “anonymized” patient data, a pharmaceutical company can observe a specific treatment event for a particular patient, like the switching of a prescription, and respond with an individualized marketing campaign at the prescriber to change that 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.

Thank you for this opportunity to testify.