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

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Honorable David Catania
Committee on Health
District of Columbia City Council

Dear Councilman Catania:

It is my pleasure to submit these comments on the Safe Rx Act of 2007.

My name is Sean Flynn and I am the Associate Director of the Program on Information Justice and Intellectual Property at American University Washington College of Law. I also serve as counsel to the Prescription Project of Community Catalyst and to the National Legislative Association on Prescription Drug Prices.

My comments will be addressed to Section IV of the bill, regulating the practice of purchasing and tracking prescriber-identified prescription records known as data mining. First, I want to provide some background on recent litigation against state regulation of data mining and the state's interests in these regulations. Then I want to offer some technical advice on how I would recommend altering the language of the bill slightly to make it more clear and effective.

Attached as an appendix to this testimony is an article describing the legal justifications for regulating data mining, parts of which are reproduced in this testimony in abbreviated form.

Litigation Challenging Regulation of Data Mining

There is a battle brewing in the federal courts over the rights of states to adopt the same prescription data privacy regulations that now exist in Europe and much of Canada. In those countries, pharmaceutical companies are not permitted to buy and sell prescription records that identify the prescribing habits of specific health care professionals, but rather can only access aggregate prescription data showing, for example, the number of prescriptions issued for a particular drug in a broad geographic area.

New Hampshire, in passing its Prescription Confidentiality Act, was the first state in the nation to ban the trade in prescriber-identified prescription data for marketing purposes. On April 30, 2007 a Federal District Court Judge in that state ruled that the law violated the First Amendment rights of pharmaceutical corporations to engage in commercial speech. That decision was followed by the passage of laws in Vermont and Maine that attempted to more narrowly tailor the data restrictions by giving physicians the right to control the subsequent

use of prescription records identifying them. These laws have also been challenged in federal court, and the New Hampshire decision has been appealed to the Court of Appeals for the First Circuit.

Defending the Legality of Data Mining Regulation

The New Hampshire District Court that New Hampshire's ban on the marketing related uses of prescription data violated the First Amendment. The Judge 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. It also criticized New Hampshire for not including legislative findings supporting the legislation.

I don't agree with the New Hampshire District Court's decision that trade in prescription data for marketing purposes is protected commercial speech. My views in that regard are canvassed in the enclosed article. More importantly for your purposes, there are compelling justifications for the regulation of data mining that should overwhelm any speech interests of the corporations engaging in this behavior. Judging from the New Hampshire Court's decision, it may be wise to make express legislative findings on what these interests are and include in the record of the bill citations to the research in this area demonstrating these interests.¹

State Interests in Regulating Data Mining

The Act 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

¹ Much of this research is cited in the enclosed article.

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." 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."

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.

The Act 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. 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 \$1.2 billion per year in that state 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 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 are enabled by pharmaceutical marketers knowing that an individual doctor is favoring the less expensive treatment and mounting a campaign in response to convince the doctor to switch treatments.

The Act Maintains Standards in the Medical Profession.

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

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.

The Act 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. Access to prescribing data has stoked a massive increase in spending and sales force size for individualized marketing that has become harassing in its sheer volume. In 2004, the industry spent \$27 billion on drug marketing, more than any other sector in the U.S., on its sales force or media advertising. Over eighty five percent of pharmaceutical marketing budgets are targeted at doctors. In

the decade after IMS unveiled its flagship prescriber tracking program in 1993, spending on detailing increased by nearly three hundred percent, doubling the number of pharmaceutical sales representatives to over 100,000. There is one pharmaceutical sales representative for every four to five office based physicians in the nation. But because low prescribers often do not receive sales attention, it has been estimated that the effective ratio of sales representatives to targeted doctors is closer to one for every 2.5 doctors. The average primary care physician in 2004 interacted with a staggering 28 sales representatives each week.

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.

The Act 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.

Suggestions for Technical Amendments

The term “prescription drug” should be expanded to include “biological medicines or medical devices.”

The current ban on uses for “commercial purposes” is somewhat broad language for what is really a much narrower category. As the New Hampshire court accurately described, what is really being regulated is marketing related purposes. I would therefore use the language “marketing purposes” rather than commercial purposes. The exceptions listed in section 403 could be structured as explicit limitations on the definition of “marketing purpose”

rather than a list of exceptions. E.g. you could use the following language as a substitute for the current definition of “commercial purpose”:

“Marketing purpose” means any activity by a company making or selling pharmaceutical products, biological medicines or medical devices, or such company’s agent, intended to influence prescribing or purchasing choices of its products, including

- (1) advertising, publicizing, promoting or sharing information about a product;
- (2) identifying individuals to receive a message promoting use of a particular product, including an advertisement, brochure, educational material or contact by a sales representative;
- (3) planning the substance of a sales representative visit or communication or the substance of an advertisement, educational or other promotional message or document;
- (4) evaluating or compensating sales representatives;
- (5) identifying individuals to receive any form of gift, consultancy, board appointment or any other item, service, compensation or employment of value;

“Marketing” does not include use of prescription information for purposes unrelated to the commercial promotion of a product, including for pharmacy reimbursement, evaluation for formulary compliance, pharmacy file transfers in response to a patient request or as a result of the sale or purchase of a pharmacy, evaluating patient care management, utilization review by a health care provider or agent of a health care provider or the patient’s health plan or an agent of the patient’s health plan, any non-commercial use, including use by the press, governments or non-profit organizations to serve public purposes, and health care research as defined by 45 CFR 164.501.

Please feel free to contact me with any questions, 202-274-4157.

Sincerely,
/s
Sean M. Flynn