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New York Assembly Committee on Health

Dear Chairman Gottfried and Members of the Committee:

It is my pleasure to submit these comments on Assembly Bill A. 7645, limiting sale of prescribing information by pharmacies or others.

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.

These comments provide background on recent litigation against state regulation of data mining and describe the constitutional interests of states in regulating data mining. It is my firm opinion that data mining regulations, including those recently struck down by district courts in New Hampshire and Maine, are fully within state constitutional authority to enact regulations to protect public health and regulate the medical profession. I believe this opinion will be borne out in an upcoming opinion of the First Circuit Court of Appeals and in any further appellate litigation on this issue.

I do have some technical concerns with the legislation that primarily involve making it more clear and effective. A substitute bill with my preferred language is attached to this testimony. I also attach a longer explication of my legal opinions on the matter, which were recently published a legal publication.

Litigation Challenging Regulation of Data Mining

As you no doubt know, two similar data mining regulations were recently struck down by federal courts in New Hampshire and Maine. The New Hampshire decision was recently heard on appeal by the First Circuit Court of Appeals and participated in that hearing on behalf of public interest groups, including the National Legislative Association on Prescription Drug Prices. The short review of that hearing is this: we think we will prevail in the First Circuit and the New Hampshire law will be upheld in full.

Monitoring Prescription Data is Not Speech

The New Hampshire litigation revolves around the bounds of what the Supreme Court has called "commercial speech." Certain forms of commercial advertising are protected as such

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speech. But this category of protected speech has not been expanded to all uses and exchanges of words between commercial entities.

The First Amendment's commercial speech doctrine is about protecting the rights of companies to speak *to consumers* about their products. It does not protect any right of companies to monitor their consumers to see whether their pitches are successful. In a sense, New York and other states are protecting the right of doctors and patients *not to speak* to the pharmaceutical industry about the details of some of their most intimate purchases without their consent.

There are a host of federal and state laws that restrict marketers from accessing purchasing records and other data on consumers without their consent. Federal law prohibits information furnished to the Census from being "used to the detriment of any respondent;"[1] prohibits release of individually identifiable health information;[2] prohibits disclosures of "personally identifiable information concerning any consumer" of a video rental establishment[3] or cable operator;[4] requires that internet service providers "not knowingly divulge" subscriber information and communications except for certain public purposes;[5] and requires states to limit the disclosure of drivers' personal identifying information without their consent.[6]

Similarly, states prohibit divulging, publishing or receiving social security numbers in certain forms;[7] regulate the use and disclosure of information "obtained in connection with a motor vehicle record;"[8] 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;"[9] 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."[10] All of these laws are similar in nature to the New Hampshire Act and have long been considered "unproblematic from a First Amendment perspective."[11]

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[1] 13 U.S.C. §8(c).
[2] Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936.
[3] Video Privacy Protection Act, 18 U.S.C. §2710-2711.
[4] Cable Communications Policy Act, 47 U.S.C. §551(c)(1)
[5] 18 U.S.C.A. §2702
[6] 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).
[7] Cal. Civ. Code § 1798.85(a).
[8] Ohio Rev. Code § 4501.27(A).
[9] 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").
[10] 20 Mo. Code of State Regulations 2220-2.
[11] 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

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My expectation is that the First Circuit will overturn the New Hampshire decision because the lower court erroneously equated monitoring prescription records with speaking to the public.

Constitutional State Interests in Regulating Data Mining

Even if the First Circuit finds that prescription monitoring is speech, it is clear that there are ample constitutionally recognized interests of states in regulating this practice. The core of the justifications comes down to this:

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.

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 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

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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).

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." [12] 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."[13]

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.

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.

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 $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

[12] Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 JAMA 373 (2000).
[13] *Id.*

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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 between $27 and $54 billion on drug marketing, more than any other sector in the U.S. on sales forces and 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.

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 the legislation. Researchers testified in the 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.

Suggested Edits

I have included as an attachment a proposed substitute for A. 7645. The substitute does the following:

- It adds a fuller set of findings that lay out the constitutional justifications for the bill;
- It provides a fuller and somewhat more specific definition of "marketing purpose." I don't think this new language alters anything substantive in the bill and the current definition is adequate.
- In § 276-b, we propose eliminating the list of covered entities and making the bill generally applicable to any "person" who uses the data for the prohibited purpose.
- We have clarified and simplified the list of permissible purposes to focus on the purpose rather than the type of person.

Conclusion

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

Sincerely,

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