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PRESCRIBER INFORMATION AND PRIVACY: THE COSTS OF INNOVATION IN THE HEALTHCARE INDUSTRY

Marc A. McGrath

A battle is being waged in multiple theatres across the U.S.; in court rooms, the media sphere, state governments and the Halls of Congress. As the march of technology accelerates and servers swell, teeming with the infinite data of every second, so too does society's fear of the data and its implementation by various governmental and private actors. Rarely is the counterargument ever made, that this data is a valuable commodity to consumers and citizens; it often only felt but never expressed.

The relationship between privacy and information is a tense one, calls for limitations on data-mining are growing in various unrelated fields. The information age has turned consumer data into a valuable commodity. Consumers receive numerous products for free in exchange for data. Companies like Google and Facebook utilize consumer data for advertising purposes. This commoditization is the same in the healthcare and pharmaceutical industry. Data-mining is revolutionizing the healthcare and pharmaceutical industry. Pharmaceutical companies are heavily investing in these practices to increase sales. Companies such as IMS Health, Inc., a major data-mining firm has made billions of dollars through its efficient use of data aggregation and mining. In response state governments have sought to limit data-mining through narrowly constructed statutes. In response to challenges the Supreme Court ruled against such laws in *Sorrell v. IMS Health, Inc.* In the wake of this decision, state legislatures and private industry are grappling with how best to proceed; states, still looking to limit data-mining and prescriber information with alternative avenues and private industry, how best to exploit and gain from the

Court's decision. Both sides seem certain that their stated goals are paradoxical and mutually exclusive, but this isn't necessarily true.

This paper will demonstrate how industry, governments and consumers can all benefit from Data-mining and prescriber information collection. First, This paper will construct the necessary framework of information by exploring the industry and practices of pharmaceutical companies, data-mining firms and state governments. Next, this paper will briefly sketch both sides of the argument. Then, this paper will use this context to explore the legislative reaction to data-mining practices and the subsequent court challenges. Then this paper will explore the privacy concerns and implications of prescriber information and prescription data, demonstrating that such concerns are legitimate and that a protective regulatory framework is necessary, but that completely limiting data-mining practices does more harm than good. After, this paper will analyze the post-Sorrell framework created by the Supreme Court's decision. Finally, this paper will use this context to demonstrate the industrial, societal and governmental benefits of prescriber information data-mining using specific examples and offering policy considerations and solutions that could alleviate concerns and augment the benefit of data-mining practices for all parties involved.

Data-mining accompanied by smart policy and a strong legal framework will provide countless benefits for all parties involved. If we look past the immediate privacy concerns and consider the innovative ways that this data can be implemented, it will be clear that we have no need to fear data-mining and implementation.

I. Industry Overview: Doctors, Data and Detailing.

The process of data aggregation, mining and detailing involves four major industrial players: The prescribing physician; the pharmacy; the data-mining firm; and the pharmaceutical company. The transfer of data and transaction of money facilitate the engine of this innovative industry. The process has yielded high returns for pharmaceutical companies and data-mining firms.

Pharmaceuticals and “Big Data,” are big business. Pharmaceutical sales generate billions of dollars in revenue each year.¹ Data-aggregating firms such as IMS Health derive a substantial amount of revenue from the sales of mined and aggregated prescriber information to these massive pharmaceutical corporations.² Pharmaceutical companies are increasing their investments in marketing.³⁴

The pharmaceutical industry’s investment in marketing, data-mining and detailing is met by a steady demand of consumers. In the United States alone, Doctors prescribe nearly 4 billion prescriptions, averaging about four prescriptions per person.⁵ The quantity of prescriptions make it evident that pharmaceutical marketing and, in part, detailing has a tremendous effect on prescribers and consumers.

¹ Johnson & Johnson, a large pharmaceutical company has an EBITDA (Earnings before interest, taxes, depreciation and amortizations – essentially cashflow), Johnson & Johnson 3rd Quarter Earnings Report 2012. Available at, <http://files.shareholder.com/downloads/JNJ/2137350681x0x604195/de164f41-f424-4e8a-bfd2-3c5c369909db/CCSEQ312.pdf>. Pfizer, another large pharmaceutical company has an EBITDA of \$5.7 Billion. Pfizer 3rd Quarter 2012 Report. Available at, http://www.pfizer.com/files/investors/presentations/q3performance_110112.pdf.

² Sales to the pharmaceutical industry accounted for “substantially all” of IMS’s revenue from 2003-2005. Marcia M. Boumil, et al, PRESCRIPTION DATA MINING, MEDICAL PRIVACY AND THE FIRST AMENDMENT: THE U.S. SUPREME COURT IN *SORRELL V. IMS HEALTH INC.*, 70 21 Annals Health L. 458

³ Which includes data-mining and detailing

⁴ Pharmaceutical companies spend about \$6.3 billion dollars annually on marketing brand drugs to Prescribers. See, Natasha Singer, A Fight Over How Drugs Are Pitched, N.Y. Times, Apr. 25, 2011, at B1, available at <http://www.nytimes.com/2011/04/25/business/25privacy.html?Pagewanted=all>.

⁵ Janet Lundy, Prescription Drug Trends, Henry J. Kaiser Family Found. 1, 3 (May 2010), <http://www.kff.org/rxdrugs/upload/3057-08.pdf>

The data-mining process begins with the physician. The physician's role in the data-mining and detailing process is both passive and necessary to the large construct. The physician writes a prescription to treat the specific issue that the patient has. The physician also ends the detailing cycle as an audience to the pharmaceutical representative. The patient brings this information to a retail pharmacy. The pharmacy is the first major point of information exchange.

Patients at a pharmacy rarely have a complete picture of what information is being provided to the retail pharmacy. When a patient receives medication, he or she also provides very specific information, both implicit and explicit. Pharmacy's collect the data for each prescription and store the information. This information, in an aggregated form is extremely valuable to data mining companies and pharmaceutical manufacturers.

The next step in the process is the purchase and aggregation of prescriber information. Health information organizations (data-mining companies and data vendors) purchase the information from retail pharmacies.⁶ The information purchased contains such specifics as: name, dosage, and quantity of the drug prescribed; the date and place the prescription was filled; and the patients' age and sex.⁷ The patient's actual name is encrypted,⁸ but every patient is given a unique identification number, thereby allowing health information organizations to link prescriptions and physicians to individual patients and track prescription patterns over time.⁹

⁶ Marcia M. Boumil et. al., Prescription Data Mining, Medical Privacy and the First Amendment: The U.S. Supreme Court in Sorrell v. Ims Health Inc., 21 Annals Health L. 447, 450 (2012)

⁷ *Id.*

⁸ See, http://www.cutbit.com/cutbit/how-encryption-works-in-your-web-browser-video_75e66a641.html to get a better sense of the mechanics of encryption.

⁹ Marcia M. Boumil et. al., 21 Annals Health L. at 450 (2012).

This information is then used in conjunction with The American Medical Association's (AMA) "Physician Masterfile"¹⁰ to match data and render individualized prescriber profiles.¹¹

Health information companies then aggregate the information and identify specific patterns and trends, both generally and for specific prescribers.¹² Thus the raw material of information has been narrowed and refined into a very valuable finished product. Health information companies then sell or lease this information product to pharmaceutical companies, whose representatives use it to develop, monitor, and/or adapt their targeted marketing strategies to boost drug sales.¹³ The implementation of this information is done by a process called "Detailing."

Detailing typically consists of pharmaceutical company representatives meeting face-to-face with physicians in an attempt to augment the physician's prescriptive behavior.¹⁴ The Maine legislature defined "detailing" as, "one-to-one contact with a prescriber or employees or agents of a prescriber for the purpose of increasing or reinforcing prescribing of a certain drug by the prescriber."¹⁵ The process of detailing is time-consuming for both physicians and pharmaceutical representatives, so most detailing interactions are used to market pharmaceuticals that generate the most profit.¹⁶ The pharmaceutical industry employs over 90,000 sales representatives, who make weekly or monthly trips to physicians' offices on an annual basis to facilitate this

¹⁰ A complete list of 1.4 million physicians, residents, and medical students in the U.S. *See*, <http://www.ama-assn.org/ama/pub/about-ama/physician-data-resources/physician-masterfile.page>.

¹¹ Marcia M. Boumil et. al., 21 *Annals Health L.* at 450 (2012).

¹² Although prescriber information is generally the information collected and analyzed by health information companies, such companies will also purchase information from insurance companies and other carriers to acquire raw information and data. DePaul J. 344.

¹³ Marcia M. Boumil et. al., 21 *Annals Health L.* at 450 (2012).

¹⁴ Me. Rev. Stat. tit. 22, § 1711-E

¹⁵ *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 46 (1st Cir. 2008).

¹⁶ *IMS Health Inc. v. Mills*, 616 F.3d 7, 14 (1st Cir. 2010).

process.¹⁷ Physicians will meet with twenty-eight or more detailers every week while specialists meet with fourteen per week.¹⁸ To sweeten the meeting, detailers often bring free samples,¹⁹ complimentary gifts and promotional information for the physician.²⁰ Each meeting is vital to the pharmaceutical industry and implicitly the health information companies as well.

The amount of detailing meetings that physician's participate in is evident that such meetings serve a certain purpose to the medical community. Detailing allows for a quick, effective informational presentation²¹ so that physicians can keep up to date on the latest advancements of the pharmaceutical industry. Thus, these meetings can be read to be tacitly beneficial to consumers and patients as well as physicians and the pharmaceutical companies, although such benefits are countered by claims of bias-forming, asymmetrical and limited information which some claim are a detriment to the healthcare industry as well as governments and patient-consumers.

Consumer groups, physicians' organizations and state governments have voiced increasing concern at the proliferation of data by private industry and the effects of detailing on physicians' prescriptive behavior. Critics of data-mining and detailing have claimed that such processes broach privacy rights of consumers and physicians, and that detailing creates prescriptive behavior biases toward brand-name drugs, instigates a compulsion to reciprocate because of gifts and presentations and drives up healthcare costs through over-prescription of high-cost name brand pharmaceuticals.²² These concerns led to the implementation of state laws restricting the

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ Nearly \$1 billion worth annually. *Id.* At 8

²⁰ *Id.*

²¹ Although lacking some objectivity.

²² Marcia M. Boumil et. al., 21 *Annals Health L.* at 451(2012).

practice of data-mining for detailing purposes and eventually the seminal Supreme Court case, *Sorrell v. IMS Health, Inc.* which found these processes constitutionally protected.

II. The March Toward Sorrell: State Legislatures and the Supreme Court Examine the Practice of Data-Mining and Detailing.

An arms race between private industry and state governments began in an attempt to expand and restrict data-mining and detailing respectively. The proliferation and increasing sophistication of data-mining was met by a swath of state legislature attempts at curbing the collection and implementation of data-mining and detailing. Between 2006 and 2007, twenty-six states had either legislated or begun the process to restrict the collection and implementation of prescriber information in the pharmaceutical industry.²³ Combating these legislative efforts were health information organizations, the assertion of first amendment protections and claims that those protections were violated by the newly written statutes. This section will examine the policy considerations and the implications of three statutes that attempted to limit data mining practices. Next, this section will examine the three subsequent challenges to states' legislation. Finally this section will detail the Supreme Court challenge to limits on data mining in *Sorrell v. IMS* as well examine the fallout.

A. State Legislature Attempts at Limiting the Health Information and Pharmaceuticals Industry.

In direct response to the burgeoning industry of data mining, states began to create legislation to limit the data mining of prescriber information. In New Hampshire, Maine and Vermont, state legislatures sought to limit the use an implementation of prescriber information

²³ *Id.* at 454.

using similar procedural mechanisms. Each state advanced three similar goals in legislating against the practice of data-mining and detailing: protection of public health, maintenance of physician privacy, and containment of rising health care costs.²⁴ The theory behind these legislative efforts is that a ban on the commercial use of prescriber information would curb this ‘detrimental’ industry.²⁵ More specifically, protection of public health would benefit by focusing physicians' decision-making on medical and scientific knowledge and by reducing the number of new drugs without well-documented track records being prescribed with the attendant risk of potentially dangerous health effects.²⁶ Cost controls would be affected by limiting the effect of persuasive detailing on physicians, that are argued to lead to the over-prescription of expensive brand drugs.²⁷ Although these legislative efforts would have the effect of curbing the use of prescriber information in a commercial context, none sought to ban such data collection outright, rather these statutes were drafted to restrict commercial use only but allow for other ‘non-commercial’ uses.²⁸ Rather, the statutes would regulate the dissemination of prescriptive information data at its source by preventing pharmacies and other entities from engaging in specific commercial transactions without prescriber permission.²⁹

The three laws utilize different mechanisms to achieve their goals and policies. The New Hampshire law (the most stringent of the three), imposed an absolute ban on utilizing all “records relative to prescription information containing patient-identifiable and prescriber

²⁴ *Id.* At 453. *See*, Vt. Stat. Ann. tit. 18, § 4631(a) (2009); Me. Rev. Stat. Ann. tit. 22, § 1711-E(1-B) (2008).

²⁵ Marcia M. Boumil et. al., 21 *Annals Health L.* at 453 (2012).

²⁶ *Id.* at 453.

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

identifiable data.”³⁰ Thus, prescriber data could only be used in limited circumstances for “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.”³¹ New Hampshire’s legislation banned the use of prescriber data for, “Commercial purpose [which] includes, but is 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.”³² The New Hampshire law had the effect of allowing prescriber data to be used for most anything aside from detailing. Unlike the Maine and Vermont statutes, the New Hampshire statute does not give health care providers the option to either opt in or opt out of the commercial use of their Prescriber information data.³³

The Maine statute is less restrictive than the statute drafted by New Hampshire, but still has the effect of limiting the use of prescriber information for commercial purposes. Maine statute is structured to limit the use of PI data for direct marketing to physicians and other prescribers.³⁴ The major difference between New Hampshire’s complete and total ban of prescriptive information in commercial practices and Maine’s statute is that Maine only limits “prescription drug information that identifies a prescriber who has filed for confidentiality protection.”³⁵ Therefore, Main’s legislature created an ‘opt-out’ mechanism that allows for physicians to shroud their prescriptive behavior by filing for confidentiality protection. Until a prescriber

³⁰ N.H. Rev. Stat. § 318:47-f

³¹ N.H. Rev. Stat. § 318:47-f

³² N.H. Rev. Stat. § 318:47-f

³³ Marcia M. Boumil et. al., 21 *Annals Health L.* at 456 (2012).

³⁴ *Id.* at 455.

³⁵ 22 M.R.S.A. § 1711-E(2-A).

affirmatively indicates a desire to protect his or her identifiable information, the law does not affect the normal course of business between entities receiving prescriber information data, such as pharmacies, and the pharmaceutical manufacturers that purchase the data to inform marketing activities.³⁶

The Vermont law, like the Maine law rests on an option mechanism, allowing for prescribers to choose to allow their data to be used for commercial practices. But where the Maine statute utilizes an ‘opt-out’ mechanism, the Vermont legislature implemented an ‘opt-in’ consent scheme.³⁷ Absent a physician’s consent, prescriber-identifying information may not be sold by pharmacies and similar entities, disclosed by those entities for marketing purposes, or used for marketing by pharmaceutical manufacturers.³⁸ This prohibition is subject to exceptions for prescriber-identifying information to be disseminated and used for a number of purposes, including “pharmacy reimbursement; prescription drug formulary compliance; patient care management; utilization review by a health care professional, the patient's health insurer, or the agent of either; or health care research”³⁹ as well other law enforcement⁴⁰, regulatory⁴¹ and research,⁴² as well as a number of other reasons. While the law appears to create a few narrow exceptions to a blanket ban on prescriber information collect, the effect of the Vermont law, as well as those of New Hampshire and Maine was to limit the narrow practice of data collection of prescriber information for commercial practices.

³⁶ 22 M.R.S.A. § 1711-E.

³⁷ 18 V.S.A. § 4631.

³⁸ *Sorrell v. IMS Health, Inc.*, 131 S.Ct. 2653, 2656 (2011). *See also*, Vt. Stat. Ann., Tit. 18, § 4631(d).

³⁹ 18 V.S.A. § 4631(e)(1).

⁴⁰ *Id.* at (e)(6).

⁴¹ *Id.* at (e)(5).

⁴² *Id.* at (e)(4).

The statutes of New Hampshire, Maine and Vermont all sought to limit commercial use of prescriber information to meet the policy goal of protecting of public health, maintaining physician privacy, and containing rising health care costs. Shortly after the implementation of these statutes, IMS Health and other health information services challenged the constitutionality of these laws on First Amendment grounds.

B. Legal Challenges to State Prescriber Information Laws: Ayotte, Mills, and Sorrell

As quickly as legislation was enacted to limit the pervasive use of prescriber data in commercial practices, so to were challenges to these laws brought in the judicial system. IMS lead the challenges in all three states.⁴³ Verispan, LLC, a small health information vendor, joined IMS Health's challenge to the New Hampshire Law.⁴⁴ Pharmaceutical Research and Manufacturers of America (PhRMA) also brought action against Vermont's statute and was merged with IMS Health's suit.⁴⁵

The statutes represented a direct threat to vital revenue streams for IMS Health, Verispan, LLC and other companies who derived revenue from data-mining and aggregation. In 2006, when New Hampshire passed its law, IMS Health's revenues totaled \$1.96 billion, a twelve-percent increase from the previous year, a large portion of this revenue was from the sale of prescriber data.⁴⁶ IMS Health's biggest clients are pharmaceutical companies, whose use of PI

⁴³ IMS Health, Inc. v. Ayotte; IMS Health, Inc. v. Mills; IMS Health, Inc. v. Sorrell.

⁴⁴ IMS Health, Inc. v. Mills, 616 F.3d 7 (1st Cir. 2010).

⁴⁵ IMS Health, Inc. v. Sorrell, 631 F. Supp. 2d 434, 444 (D. Vt. 2009).

⁴⁶ Marcia M. Boumil et. al., 21 Annals Health L. at 458 (2012).

data would have been curtailed to varying degrees under each statute.⁴⁷ In fact, sales to the pharmaceutical industry accounted for “substantially all” of IMS's revenue from 2003-2005.⁴⁸

The first challenge to a state statute occurred in *IMS Health, Inc. v. Ayotte*. In *Ayotte* the first circuit court of appeals held that New Hampshire’s law limiting Data-Mining and Detailing for commercial reasons was permissible as regulation of conduct and not speech.⁴⁹ The court found New Hampshire’s reasoning and methodology was precise and reasonable in trying to limit a, “novel threat to the cost-effective delivery of health care.”⁵⁰

Two years after the First Circuit upheld New Hampshire’s statute, the first circuit affirmed their reading of prescriber information laws in *IMS Health, Inc. v. Mills*. The first circuit stood its ground in finding that Maine’s prescriber data law was limiting only conduct and not speech.⁵¹ The court also addressed any potential commercial speech concerns, by applying the Central Hudson Test.⁵² The court found that the statute met the Central Hudson Test and was therefore permissible.⁵³ The court found that Maine’s opt-out provision for physicians was similar to a “do not call” option for citizens.⁵⁴

⁴⁷ *Id.*

⁴⁸ *Id.*, (quoting IMS's 2005 Annual Report).

⁴⁹ *Ayotte*, 550 F.3d at 45.

⁵⁰ *Id.*

⁵¹ *Mills*, 616 F.3d at 12-13.

⁵² *Id.*. The Central Hudson Test is a four-part analysis to determine whether a restriction on commercial speech violates the first amendment. The analysis first determines whether the expression is protected by the first amendment, it must be lawful and not misleading. Next, the court looks to whether government interest is substantial. Then, the court looks should determine whether the regulation directly advances the government interest asserted. Finally, the court looks to whether the regulation is more expansive than is necessary to serve the interest. *See CENTRAL HUDSON GAS & ELEC. v. PUBLIC SERV. COMM'N*, 447 U.S. 557 (1980).

⁵³ *Mills*, 616 F.3d at 12-13.

⁵⁴ *Id.* at 21-22.

The last challenge occurred in the Second Circuit Court of Appeals in response to Vermont's legislation banning the use of prescriber information for commercial purposes. After failing to void the laws in the First Circuit, IMS Health Inc. and other similarly situated parties⁵⁵ sought to target Vermont's law in the Second Circuit. The Second Circuit Court of Appeals holding in *IMS Health, Inc. v. Sorrell* initiated the circuit split and ultimately answered in the affirmative the constitutional protections for data-mining and prescriber information in a commercial context.

IMS Health, Inc. and their constituents challenged Vermont's statute which banned the sale, transmission, or use of prescriber-identifiable data for marketing or promoting a prescription drug without consent.⁵⁶ The appellants claimed that the Vermont law: (1) restricted non-commercial speech and could not withstand strict scrutiny, (2) cannot withstand intermediate scrutiny under *Central Hudson*, and (3) the law violated the dormant Commerce Clause by prohibiting commerce wholly outside of Vermont.⁵⁷ The Second Circuit Court of Appeals held that Vermont's statute, "does not directly advance the substantial state interests asserted by Vermont, and is not narrowly tailored to serve those interests, the statute cannot survive intermediate scrutiny under *Central Hudson*" and subsequently overruled the lower court, holding the statute unconstitutional.⁵⁸

The difference in analysis between the First and Second Circuits stemmed from the differing interpreting methods. The First Circuit read New Hampshire and Maine's statute as

⁵⁵ Verispan, LLC, Source Healthcare Analytics, Inc., a subsidiary of Wolters Kluwer Health, Inc., and Pharmaceutical Research and Manufacturers of America. *See, IMS Health Inc. v. Sorrell*, 630 F.3d 263 (2d Cir. 2010) cert. granted, 131 S. Ct. 857, 178 L. Ed. 2d 623 (U.S. 2011) and aff'd, 131 S. Ct. 2653, 180 L. Ed. 2d 544 (U.S. 2011).

⁵⁶ *IMS Health Inc. v. Sorrell*, 630 F.3d 263, 266 (2d Cir. 2010).

⁵⁷ *Id.*

⁵⁸ *Id.* at 267.

regulating, “conduct because those provisions serve only to restrict the ability of data miners to aggregate, compile, and transfer information destined for narrowly defined commercial ends” rather than speech.⁵⁹ The Second Circuit, in contravention of the first found that Vermont’s statute was a limitation on speech and therefore unconstitutional.⁶⁰ The Second Circuit Court of Appeals was critical of their sister-circuit’s reasoning, writing that the First Circuit had exercised, “freewheeling authority to declare new categories of speech outside the scope of the First Amendment.”⁶¹ With such a disparate reading of similar statutes, the Supreme Court found it necessary to rule on the issue.⁶²

C. The Supreme Court Defends Data-Mining as Speech in Sorrell

The Supreme Court heard both sides of the argument in the lead up to their decision. A great number of amicus curie briefs were filed for both state legislative actions as well as for the pharmaceutical and health information services industries. Much of the arguments from both groups were focused on constitutionality and first amendment grounds.⁶³ At issue was Vermont’s Act 80 and whether the restrictions and narrow exceptions present in the language in the statute unconstitutionally limited free speech.⁶⁴ The Court ultimately determined that Vermont’s law “on its face, Vermont’s law enacts content-and speaker-based restrictions on the sale, disclosure, and use of prescriber-identifying information”⁶⁵ because “The provision first

⁵⁹ Ayotte, 550 F.3d at 53.

⁶⁰ IMS Health Inc. v. Sorrell, 630 F.3d 263, 267 (2d Cir. 2010).

⁶¹ Id. at 272.

⁶² Sorrell v. IMS Health Inc., 131 S. Ct. 857 (2011).

⁶³ See generally, Sorrell v. IMS Health, Inc., amicus curiae briefs.

⁶⁴ Sorrell v. IMS Health Inc., 131 S.Ct. 2653, 2661 (2011).

⁶⁵ Sorrell v. IMS Health, 131 S.Ct. at 2662.

forbids sale subject to exceptions based in large part on the content of a purchaser's speech,"⁶⁶ and , "the provision's second sentence prohibits pharmaceutical manufacturers from using the information for marketing. The statute thus disfavors marketing, that is, speech with a particular content. More than that, the statute disfavors specific speakers, namely pharmaceutical manufacturers."⁶⁷ The Court ultimately concluded that, "§ 4631(d) leaves detailers no means of purchasing, acquiring, or using prescriber-identifying information. The law on its face burdens disfavored speech by disfavored speakers."⁶⁸

The Court began its analysis by looking at the record and the formal legislative findings.⁶⁹ The Court noted that "the law's express purpose and practical effect are to diminish the effectiveness of marketing by manufacturers of brand-name drugs."⁷⁰ Because the law was written to regulate both content and speaker, The Court found that, "heightened judicial scrutiny is warranted."⁷¹

Strict scrutiny is applied when, "regulations reflecting "aversion" to what "disfavored speakers" have to say."⁷² This heightened level of scrutiny requires that the statute support a compelling government interest; the law is narrowly tailored; and the statute employs the least restrictive means for achieving the stated government goal.⁷³ Vermont argued that the statute advanced import public policy, namely that the law would lower the cost of medication for

⁶⁶ Id.

⁶⁷ Id.

⁶⁹ Id. At 2663.

⁷⁰ Id.

⁷¹ Id. At 2664.

⁷² Sorrell v. IMS 131 S.Ct. at 2264, *Quoting*, Turner Broadcasting System, Inc. v. FCC, 512 U.S. 622, 658 (1994).

⁷³ Id.

consumers and promoting public health.⁷⁴ The Court found this argument unpersuasive, stating, “The State seeks to achieve its policy objectives through the indirect means of restraining certain speech by certain speakers—that is, by diminishing detailers’ ability to influence prescription decisions. Those who seek to censor or burden free expression often assert that disfavored speech has adverse effects.”⁷⁵ Thus, Vermont’s legislation was found to be unconstitutional and void.⁷⁶

In the wake of the Supreme Court’s decision in *Sorrell*, industry, academia and states have begun to address the limitations on legal restraints and policy going forward. The *Sorrell* decision has set an importance precedent for the healthcare and pharmaceutical industries as well as consumers and government.

III. Prescription Data and Privacy Concerns

The stakes are high, individual privacy is quickly being eroded by the rising tide of information technology. Our online habits, search and web history, and social activities are being quantified and tracked. This information is being utilized for many positive uses as this paper will demonstrate, but this information is also utilized in processes that compromise privacy and raises concern. This section will discuss some of these privacy issues and concerns and explore how the processes of data-mining and detailing complicate personal privacy for both patients and doctors. Further this section will use real life instances on the detrimental effects of prescription information privacy infringement. Threats to privacy will only become a greater concern as information technology and data analysis advances into other fields. The best way to combat

⁷⁴ *Id.* at 2670.

⁷⁵ *Id.*

⁷⁶ *Id.* at 2672.

such threat is to not legislate or regulate away the technology and usage, but rather to craft legislation that protects privacy without stunting the growth of this vital technology.

Patient health information privacy is largely directed and protected by HIPAA⁷⁷ and (as amended by) HITECH.⁷⁸ In tandem, these legislative and regulatory efforts require that healthcare information be de-identified before it is used for marketing purposes.⁷⁹ Doctors, pharmacies and even health information companies⁸⁰ are covered entities under HIPAA⁸¹. Under this regime, a covered-entity can claim that information is de-identified only if an individual with appropriate knowledge and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable; or the name,⁸² any and all geographic subdivisions smaller than a State,⁸³ dates, telephone numbers, e-mail addresses, social security numbers, and nearly all other identifying forms.⁸⁴ A covered entity can assign a unique identification number to the record.⁸⁵ These statutory and regulatory protections are seemingly very protective of patient privacy. Critics of Vermont's pre-Sorrell legislation have commented that such protections are more than enough to protect patient privacy interests and that the legislation was redundant.⁸⁶

⁷⁷ 42 U.S.C. § 1320d et seq., 45 C.F.R. Parts 160, 162, and 164.

⁷⁸ Pub. L. No. 111-005 (2009).

⁷⁹ 45 C.F.R. § 164.514(a).

⁸⁰ Under the category of Healthcare Clearinghouse.

⁸¹ 45 C.F.R. § 160.103. *See also*,

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/index.html>.

⁸² *Id.* at (b)(2)(A).

⁸³ *Id.* at (b)(2)(B).

⁸⁴ *Id.* at (b)(2), *generally*.

⁸⁵ *Id.* at (c)

⁸⁶ *Sorrell v. IMS Health Inc.*, 2011 WL 1253930 (U.S.), 5 (U.S.,2011).

Some critics have suggested that patient privacy concerns can be implicated via re-identification of prescription data and that HIPAA privacy standards are out of date.⁸⁷ Although prescriber data is anonymized by retailers prior to being sold to data-mining firms, some fear that this information can be analyzed to re-identify patient identity thus yielding information that could be used to the detriment of that patient.⁸⁸ Proponents of data-mining practices have claimed that patient identification and information cannot be re-identified.⁸⁹ of The Supreme Court in *Sorrell* largely avoided issues of patient privacy, and only addressed privacy in regards to physician privacy.⁹⁰ El Emam and Yakowitz argue in there *Sorrell Amici* Brief that HIPAA and HITECH standards of privacy are more than enough to protect against privacy infringement,⁹¹ but others have argued that these standards are no longer relevant because of the advances in information technology.⁹² Sweeney was able to demonstrate the threat of re-identification by matching demographics in de-identified medical data to a population register to affix patient names to records in the data.⁹³ This work was directly cited in HIPAA legislation.⁹⁴ Sweeney and others are concerned that with the increase in amount of information⁹⁵ and increased capabilities of data-processing that even more information is prone to re-identification.⁹⁶ The debate over privacy protections for patients is contentious, some claim that the current legal regime is more than enough to protect against re-identification and that using this issue as a justification to limit prescriber information and detailing does not logically follow,

⁸⁷ Latanya Sweeney, Patient Privacy Risks in U.S. Supreme Court Case, *available at* <http://dataprivacylab.org/projects/identifiability/pharma2.pdf>.

⁸⁸ *Id.* at 3.

⁸⁹ *Id.* at 3.

⁹⁰ *Sorrell v. IMS Health, Inc.*, 131 S.Ct. at 2667.

⁹¹ *Sorrell v. IMS Health Inc.*, 2011 WL 1253930 (U.S.), (U.S.,2011)

⁹² Sweeney, at 3.

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ Including hospital discharge data, GPS information from phones, etc.

⁹⁶ *Id.* at 4.

while others call for further protections for patient privacy that would further limit uses and the identifying features of prescriber data.

Much of this debate has existed in the abstract, instances of individuals suffering an injury from the use of prescriber information are not seemingly common or recorded, although not unheard of. The case of Walter and Paula Shelton demonstrates the dark side of widely available and accessible prescriber information. The Sheltons were rejected by a health insurance provider after a company representative pulled their drug profiles and questioned them over the telephone about prescriptions from Wal-Mart Stores and Randalls, part of the Safeway grocery chain, for blood-pressure and anti-depressant medications.⁹⁷ The Sheltons claim that the medication was prescribed for off-label uses such as swelling and sleep assistance, but representatives of the health insurance company still denied their application because depression and mental health issues are a red flag for health insurance companies.⁹⁸ Under the current regulatory regime, such identifying information should not be readily available to health insurance companies and other purchasers. While it is unclear exactly how the Sheltons' prescription history was identified, it is clear such identifying information is dangerous and can have negative implications on consumers and those who need healthcare the most.

Any regulation of information and especially prescription data must be secured and unidentifiable. The implications of weak regulation are costly and potentially life threatening. These privacy concerns are addressed by federal regulation, but the strength and effectiveness of these regulations are controversial. Although such data can be used for nefarious reasons, or in

⁹⁷ Chad Terhune, *They Know What's in Your Medicine Cabinet*, BLOOMBERG BUSINESSWEEK, July 22, 2008, available at, <http://www.businessweek.com/stories/2008-07-22/they-know-whats-in-your-medicine-cabinet>.

⁹⁸ *Id.*

practices that induce harm to individuals, this is not by itself to ‘throw out the baby with the bathwater.’ Regulation of prescriber data should prevent re-identification, but should not hamper or limit this innovative aspect of healthcare.

IV. Data-Mining and Legislation in the Wake of Sorrell

The Sorrell decision marked an important evolution in the healthcare and pharmaceutical industry as well as the legal regime that traditionally govern industry. This section will address the possible legal, societal and industry implications of the Supreme Court’s decision. The Sorrell decision has broadened the abilities and uses of data-mining and detailing, but also provides government with a clear roadmap to for legislating data-mining and detailing. Further, alternative forms of regulation are available to both state and federal governments.

The legislative implications are clear, state governments that wish to limit the use of prescriber information and detailing will need to enact stringent laws with few exceptions. First a state writing would need to comport with the Supreme Court’s critical analysis and the Central Hudson Test. A clear state interest in privacy would need to be advanced by the law.⁹⁹ The Supreme Court stated, “The state might have advanced its asserted privacy interest by allowing the information’s sale or disclosure in only a few narrow and well-justified circumstances.”¹⁰⁰ The Maine, New Hampshire and Vermont Statutes all, implicitly or explicitly targeted data-mining used for marketing purposes, but carved out generous exceptions for non-market purposes such as research, law enforcement, and other public policy goals.¹⁰¹ Therefore, any subsequent laws passed after Sorrell would needed to be largely restrictive to most uses of the information aggregated and shaped by health information companies like IMS Health, Inc. Such

⁹⁹ Under the *Central Hudson Test*. See note 52, *supra*.

¹⁰⁰ Sorrell, 131 S.Ct.at 2668.

¹⁰¹ N.H. Rev. Stat. § 318:47-f; 18 V.S.A. § 4631; and 22 M.R.S.A. § 1711-E

restrictive legislation will likely be met by a skeptical court. While such restrictive laws would resolve privacy concerns and provide strong protections against data-mining, they would also curtail the societal, industrial and governmental benefits offered by such data-mining practices. State governments may (and should) be hesitant to draft such restrictive legislation.

The implications for the pharmaceutical industry are good for business and a concern for policy makers. In the wake of *Sorrell*, there is a growing concern that off-label prescription use will become more prevalent due to the Supreme Court's reading of prescriber information laws. Off-label promotion is the act of marketing or promoting pharmaceutical drugs or treatments for uses other than those that the FDA had approved them for.¹⁰² Commentators have noted that the *Sorrell* ruling, "provides strong support for challenging FDA's efforts to regulate what the government calls the off-label promotion of drugs for medical uses that are not approved by the FDA."¹⁰³ Read broadly, the Court's decision in restricts legislatures from impeding upon pharmaceutical companies and physicians from communicating truthful information and prescriptions regarding FDA approved pharmaceutical products.¹⁰⁴ Current FDA regulation criminalizes pharmaceutical companies' efforts to 'communicate[e] with physicians in an effective and informative manner,' off-label promotions.¹⁰⁵ Thus, under the current FDA regulatory regime, a detailer may not discuss off-label uses of a pharmaceutical drug or treatment with a physician. The Supreme Court's reading of the first amendment, and the protections that it affords to commercial speech will likely render such restrictive regulation void for violation of

¹⁰² Randall S. Stafford., *Regulating Off-Label Drug Use — Rethinking the Role of the FDA*, N. Engl. J. Med. 358, 1427–1429 (2008). Available at, <http://www.nejm.org/doi/full/10.1056/NEJMp0802107>.

¹⁰³ Lisa Blatt, Et. al., DOES SORRELL V. IMS HEALTH MARK THE END OF OFF-LABEL PROMOTION PROSECUTION?, *Pharmaceutical Law & Industry Report* Vol. 0 No. 0., July 15 2011, 3. Available at, http://www.arnoldporter.com/resources/documents/ArnoldPorterLLP_BNAPharmaceuticalLawIndustryReport_7152011.pdf.

¹⁰⁴ LISA BLATT, Et al., *DOES SORRELL V. IMS HEALTH MARK THE END OF OFF-LABEL PROMOTION PROSECUTION*, at 3.

¹⁰⁵ 21 C.F.R. Part 201; see 21 U.S.C. § 352.

the first amendment. The Sorrell decisions' broad protections prevent the FDA from directly (and now) indirectly regulating off-label promotion because such promotions can easily be construed as creation and dissemination of information which are speech for First Amendment purposes.¹⁰⁶ Legislators and regulatory agents such as the FDA will need to augment their laws and regulations to comport with the Sorrell.

The industry will likely benefit from the removal of marketing barriers by the Sorrell decision, but legal and regulatory agencies must alter their current structures or create new legal and regulatory regimes to comply with the Supreme Court's reading of First Amendment protections.

V. Information, Data-Mining and Ad-based Revenue as a Funding Mechanism in the Digital Age Health Care.

Data-mining for marketing purposes is the engine that powers the information age. It is a ubiquitous in nearly every social network and Tech Company, the aggregation and sale of user information to generate revenue. This section will first provide some of the many societal, governmental and consumer benefits that are achieved through the implementation of data-mining provided by health information companies. Next, this section will discuss how prescriber information used for marketing purposes is necessary to achieve these benefits. Ultimately, we as a society should welcome, utilize and craft data, rather than establishing laws and regulation that shore up privacy protections at the cost of future advances and benefits to society, government, consumers and industry.

¹⁰⁶ Sorrell v IMS Health, Inc 131 S. Ct., at 2657.

A. Utility uses of Prescriber Information: The Societal and Consumer Benefits of Data-Mining and Prescriber Information.

Consumers receive a very real and direct benefit from the utilization of prescriptive data. The implementation of prescriber information can be used to locate and prescribe innovative and lifesaving pharmaceutical treatments to patients in need. An example of such lifesaving implementation is demonstrated in the release of Banzel. Banzel was approved by the FDA in 2008 to treat Lennox-Gastaut Syndrome.¹⁰⁷ Lennox-Gastaut Syndrome is a rare and severe form of epilepsy. Seizures usually begin before 4 years of age. Seizure types, which vary among patients, include tonic¹⁰⁸, atonic¹⁰⁹, atypical absence¹¹⁰, and myoclonic¹¹¹.¹¹² There may be periods of frequent seizures mixed with brief, relatively seizure-free periods. Most children with Lennox-Gastaut syndrome experience some degree of impaired intellectual functioning or information processing, along with developmental delays, and behavioral disturbances.¹¹³ The rarity of the disease¹¹⁴ would normally present difficulties in tracking and deploying innovative treatment options. The task of locating and deploying treatment to such a limited number of individuals would be costly and inefficient through traditional means of inquiry and advertisement. Rather, Eisai, the developer of Banzel utilized prescriber information to locate

¹⁰⁷ Banzel Approval History. Available at, <http://www.drugs.com/history/banzel.html>, (last visited November 3, 2012).

¹⁰⁸ stiffening of the body, upward deviation of the eyes, dilation of the pupils, and altered respiratory patterns. See, <http://www.ninds.nih.gov/disorders/lennoxgastautsyndrome/lennoxgastautsyndrome.htm>

¹⁰⁹ brief loss of muscle tone and consciousness, causing abrupt falls. See, <http://www.ninds.nih.gov/disorders/lennoxgastautsyndrome/lennoxgastautsyndrome.htm>.

¹¹⁰ staring spells, See, <http://www.ninds.nih.gov/disorders/lennoxgastautsyndrome/lennoxgastautsyndrome.htm>.

¹¹¹ sudden muscle jerks, See, <http://www.ninds.nih.gov/disorders/lennoxgastautsyndrome/lennoxgastautsyndrome.htm>.

¹¹² <http://www.ninds.nih.gov/disorders/lennoxgastautsyndrome/lennoxgastautsyndrome.htm>

¹¹³ <http://www.ninds.nih.gov/disorders/lennoxgastautsyndrome/lennoxgastautsyndrome.htm>

¹¹⁴ Less than 5% of epilepsy sufferers. Sorrell v. IMS Health, Inc., 2010 WL 5149245 (U.S.), 12.

physicians who had previously prescribed pre-Banzel Lennox Gastaut syndrome treatments.¹¹⁵ Eisai was able to contact and provide information for Banzel to the very small subset of physicians who were treating Lennox Gastaut syndrome.¹¹⁶ One of the few states where Eisai had difficulty locating patients who suffered from Lennox Gastaute syndrome was New Hampshire, where state legislation blocked Eisai's ability to utilize prescriber information to provide treatment.¹¹⁷

Banzel is just one example of the societal benefits of prescriber information. The information can be an extraordinary benefit to consumers who, without such data collection, might not receive proper care and treatment. Banzel is demonstrative of the neutrality of information and how, through proper implementation that information can be used for societal benefit. But more so, Banzel is also a case study in the dangers of over-regulation. New Hampshire's anti-data laws made it very difficult to locate patients who suffered from Lennox Gastaut syndrome. The Supreme Court's *Sorrell* did not completely eliminate the possibility that future state legislation would block the effective use of prescriber information for the benefit of consumers and citizens. As noted above, The Supreme Court did not eliminate limitations on prescriber information and detailing, rather the Court simply required broader limitations on parties who utilized prescriber information as well as narrower exceptions to a broad ban.¹¹⁸ Therefore states that zealously protect physicians privacy interests may attempt to legislate under the endorsed structure, ergo create near-insurmountable barriers to public-benefit use of

¹¹⁵ Id..

¹¹⁶ Id. at 11.

¹¹⁷ *Sorrell v. IMS Health, Inc.*, 2011 WL 2647130 (U.S.), 11 (U.S.,2011). *See generally*, Mass. Biotech. Council, *Treatment Delay is Treatment Denied - The Unintended Consequences of State Laws to Ban the Use of Physician Level Data* (2010), available at http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Legislative%20Content/Danger_of_Data_Bans.pdf.

¹¹⁸ Id.

prescriber information. The Banzel case is just one example of direct public benefit from prescriber information, The public and non-industry actors also benefit in other ways as well.

Prescriptive information is also used to monitor the safety and effectiveness of FDA approved pharmaceuticals.¹¹⁹ Usage Trend Mapping is vital to ensuring the safety and usability of prescription drugs. Usage Trend Mapping is done through the implementation of Prescriber Information.¹²⁰ After the information has been thoroughly analyzed it is used to develop best clinical practices. An example of this implementation of prescriber information for public benefit can be demonstrated in the decrease in invasive surgery after the introduction of proton pump inhibitors.¹²¹ Doctors implemented prescriber information to monitor these results and their research ultimately led to fewer invasive procedures, shorter recovery times, and overall reduced costs.¹²²

Data-mining of prescriptive information has also been implemented in FDA practices. RiskMAPs¹²³ are plans that the FDA strongly suggest¹²⁴ pharmaceutical companies develop to monitor and minimize the risk of pharmaceutical drugs.¹²⁵ The stated goal of RiskMAPS are: risk management as an iterative process encompassing the assessment of risks and benefits, the minimization of risks, and the maximization of benefits.¹²⁶ RiskMAP means a strategic safety program designed to meet specific goals and objectives in minimizing known risks of a product

¹¹⁹ Id. at 13.

¹²⁰ Id.

¹²¹ Id. See, Naline M. Guda, M.D. & Nimish Vakil, M.D., Proton Pump Inhibitors and the Time Trends for Esophageal Dilation, 99 Am. J. Gastroenterol. 797 (2004).

¹²² Sorrell v. IMS Health, Inc., 2011 WL 2647130 (U.S.), 13 (U.S.,2011).

¹²³ Risk Minimization Action Plans.

¹²⁴ It is suggestive because there is no legal or regulatory structure to require such plans.

¹²⁵ FDA, *Guidance for Industry Development and Use of Risk Minimization Action Plans*, 3 (March 2003). Available at,

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm071616.pdf>.

¹²⁶ Id.

while preserving its benefits.¹²⁷ A RISKMAP targets one or more safety-related health outcomes or goals and uses one or more tools to achieve those goals.¹²⁸ This process would be extremely difficult to implement without the use of prescriber information because RISKMAPs require the pharmaceutical industry be able to monitor usage and prescriptive trends of individual physicians.¹²⁹ In the post-Sorrell paradigm, where restrictions on prescriber information must be broad, disallowing or the outright barring of prescriber information will make the development of RISKMAPs nearly impossible. Government agencies such as the FDA rely on prescriber information to make more effective and efficient policies, any limitations on use would prove detrimental to the health of individuals.

The FDA is not the only government agency that relies on and is benefitted by the collection, aggregation and analysis of prescriber information. The DEA and other law enforcement organizations are aided in their fight against abuse through prescriber information. Prescriber information allows law enforcement organizations to receive prescriber information for pharmaceuticals that have a high risk of drug abuse. Prescription drug abuse is the fastest growing drug problem in the United States.¹³⁰ With the aid of prescriber information law enforcement organizations are able to target unethical physicians and “pill mills” who overly prescribe medications prone to abuse.¹³¹ With a third of new drug users initially abusing

¹²⁷ Id.

¹²⁸ Id.

¹²⁹ Sorrell v. IMS Health, Inc., 2011 WL 2647130 (U.S.), 13 (U.S., 2011).

¹³⁰ White House, *EPIDEMIC RESPONDING TO AMERICA'S PRESCRIPTION DRUG ABUSE CRISIS*, 1 (2003). Available at, http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/rx_abuse_plan.pdf.

¹³¹ Christian Davenport, *Doctors Who Prescribe Oft-abused Drugs Face Scrutiny*, Wash. Post, Jan. 1, 2011, Available at, <http://www.washingtonpost.com/wp-dyn/content/article/2011/01/01/AR2011010102801.html>

prescription drugs,¹³² prescription drug abuse and the sale of drugs by doctors will only become more of an issue. Prescriber information is necessary to the identification of physicians who over prescribe and endanger the lives of addicts. If state laws are drafted to limit the use of prescriber information, prescription drug abuse will likely be more widespread because the methods, tools and techniques that law enforcement agencies utilize will be limited.

B. Direct Industrial Benefits from Commercial Use of Prescriber Data and Its Indirect Benefit to Consumers.

Sub-section A makes clear that consumers, government and society are directly benefited from the collection, analysis and implementation of prescriber information, but there are also indirect benefits to consumers and society via industry uses. Although these benefits are largely limited to pharmaceutical companies, they produce externalities that are also beneficial to others.

There are extraordinary societal benefits generated by the healthcare and pharmaceutical industries. Pharmaceutical developments have accounted for a 2% increase in average life expectancy.¹³³ For cancer patients specifically, innovative medical and pharmaceutical treatments have increased life expectancy by approximately three years and eighty-six percent of these gains are attributable to innovative treatments.¹³⁴ At the heart of these medical advances are pharmaceutical research and development. Pharmaceutical research companies are

¹³² The Whitehouse, *EPIDEMIC RESPONDING TO AMERICA'S PRESCRIPTION DRUG ABUSE CRISIS*, 1 (2003). Available at, http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/rx_abuse_plan.pdf.

¹³³ Frank R. Lichtenberg, *The Impact of New Drug Launches on Longevity: Evidence from Longitudinal, Disease-Level Data from 52 Countries, 1982-2001*, at 19 (Nat'l Bureau Econ. Res. Working Paper No. 9754, 2003). Available at, http://www.nber.org/papers/w9754.pdf?new_window=1

¹³⁴ Sorrell v. IMS Health, Inc., 2010 WL 5149245 (U.S.), 2. See also, The Determinants of Recent Gains in Cancer Survival: An Analysis of the Surveillance, Epidemiology, and End Results (SEER) Database, 26 J. Clinical Oncology (May 20 Supp.) 6616 (2008)

responsible for nearly all advances in pharmaceutical treatment.¹³⁵ Thus it is beneficial to society and the health of consumers to limit laws and regulation that would stymie or prohibit advances and profitability of the healthcare and pharmaceutical industry. Because detailing and marketing is such a vital part of securing revenue to continue research and acquire smaller research firms, laws and regulation should analyze societal costs to limiting the profitability and sales generation of the pharmaceutical industry. But data-mining and detailing is not only beneficial indirectly, as a means of increasing sales and revenue to continue to fund innovative research, but it can and is used to benefit consumers and government as well.

Prescriber information can also be beneficial for physicians in practice. Often times, prescriber information and detailing are used to provide (albeit biased) information to physicians who might not ordinarily be up to date on information. In fact, a survey of doctors has concluded that doctors find that pharmaceutical representatives are a great source of information.¹³⁶ Representatives often provide reprints of clinical studies published in peer-reviewed medical literature, as well as other scientific and safety-related information regarding the company's medicines.¹³⁷ With many new drugs entering the market it is difficult for a physician to stay up-to-date on every advancement, detailers – through the use of prescriber information are able to provide doctors with knowledge and information on new treatments that may be beneficial to particular patients they are treating.¹³⁸ Sales representatives are the most time-saving source of

¹³⁵ Sorrell v. IMS Health, Inc., 2010 WL 5149245 (U.S.), 2. *See also*, Cong. Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry 2-3 (1998)* (“1998 CBO Report”).

¹³⁶ *The Facts About Pharmaceutical Marketing & Promotion*, 3-4 (2008), (“Pharmaceutical Marketing”), available at [http:// www.phrma.org/sites/default/files/159/marketing_and_promotion_facts_071108_final.pdf](http://www.phrma.org/sites/default/files/159/marketing_and_promotion_facts_071108_final.pdf)

¹³⁷ Sorrell v. IMS Health, Inc., 2010 WL 5149245 (U.S.), 4.

¹³⁸ Andrew Ching, et al., *The Effects of Detailing on Prescribing Decisions under Quality Uncertainty*, Rotman School of Management, University of Toronto, 4 (April 17 2008). Available at, http://mpr.a.ub.uni-muenchen.de/8324/1/MPRA_paper_8324.pdf.

information because they visit primary care physicians, compile information on clinical studies for them and remind them of drug information.¹³⁹ Doctors also rely on information from medical scholarship, other physicians, insurance companies, and state-funded actors to receive information.¹⁴⁰ A wide array of information sources is only beneficial to both the patient and physician, and ultimately physicians are capable and responsible of using best medical judgment when recommending or prescribing a treatment.¹⁴¹

Data-mining and detailing produce industrial benefits. Pharmaceutical companies require a return on investment and prescriber data is a means of generating more revenue for investment. Further, Data-mining and detailing are used as an indirect source of information to physicians. Data-mining and prescriber information are beneficial to the healthcare of our society. It can help agencies and drug developers track medications to decrease cost and increase safe and effective treatment, as well as assisting law enforcement in combating drug abuse. If government attempts to restrain the use and implementation of prescriber data, it will be at the detriment of not only industry but also consumers that rely on innovative treatment the most.

C. The Necessary Market: Detailing as a Funding Mechanism for Prescriber Information Benefits.

There are numerous benefits generated by the collection, aggregation and analysis of prescriber information. Companies like IMS Health, Inc. and Verispan do more than provide marketing tools for pharmaceutical companies, as Section III A of this paper has demonstrated, prescriber information is utilized to the benefit of consumers and government agencies as well. While non-marketing users benefit from prescriber information, they alone do not establish the

¹³⁹ Andrew Ching, et al., at 4.

¹⁴⁰ Sorrell v. IMS Health, Inc., 2010 WL 5149245 (U.S.), 12.

¹⁴¹ Id.

demand necessary to sustain the industry absent pharmaceutical companies implementation of data for marketing purposes. This section will demonstrate that the benefits derived from data-mining are sustained only through the infusion of money provided by marketing.

Data analysis for marketing purposes is the engine of the information age. Companies such as Google and Facebook collect and analyze user data and provide targeted advertising for purchasers of ad space.¹⁴² Every search query and link clicked on Google, and every product liked or discussed on Facebook, is spun into data and aggregated accordingly. This information is worth billions of dollars to companies looking to advertise with these two giants.¹⁴³ In turn, Google and Facebook use this ad revenue to fund projects that would otherwise be unprofitable, such as a search engine, or a social media site, or any other number of products and services that these two tech giants develop.

The funding mechanism for IMS Health, Inc. and other health information companies is similar, but rather than data-collection and analysis being intra-company, the health information industry is dispersed through many companies and industries. IMS Health, Inc. purchases data from pharmacy retailers, and then aggregates and analyzes the information for trends. After analysis, the information is then compiled into marketable products for clients.¹⁴⁴ When there is a large demand, the price of the data-product will increase accordingly. As the price and sales increases, so too does revenue from the sale of these products. Currently, pharmaceutical companies are the largest consumers of prescriber information and accordingly support the entire

¹⁴² Ryan Singel, *How Google Makes Billions from Tiny Text Ads*, *WIRED*, Oct. 25 2012, <http://www.wired.com/business/2012/10/google-ad-prices/>.

¹⁴³ Somini Sengupta and Eveylen M. Rusli, *Personal Data's Value? Facebook Is Set to Find Out*, *N.Y. Times*, Jan. 21, 2012. Available at, http://www.nytimes.com/2012/02/01/technology/riding-personal-data-facebook-is-going-public.html?pagewanted=all&_r=0.

¹⁴⁴ See, Note 13, *supra*.

industry.¹⁴⁵ While pharmaceutical companies purchase much of this data for marketing purposes, the information is also used to the benefit of consumers, physicians and government as well. The demand and value of these other uses are not marketable to the point of being cost efficient. It can therefore be concluded, that like Google and Facebook, who provide products funded by data analysis for marketing purposes, so too, does society receive benefits implicitly funded by the sale of information to pharmaceutical companies for marketing purposes.

Without large pharmaceutical companies purchasing information for detailing and marketing, it is unlikely that companies like IMS Health, Inc. would be able to provide the necessary level of sophistication and completeness that are obtainable through the current model. While there is a privacy cost to these benefits, the societal benefits far outweigh the ancillary infringement upon doctor's privacy claims.

VI. Conclusion.

Data-mining for marketing purposes is a necessary cost to providing optimal levels of healthcare and consumer safety. Consumers benefit from pharmaceutical tracking, and information development, through drug abuse prevention and from more knowledgeable physicians. The battle over prescriber information's implementation is not over, but future laws should recognize the clear and substantial benefits that data-mining offers and allow for its implementation and funding through marketing. The answer is not always more regulation, but better regulation.

¹⁴⁵ Sorrell v. IMS Health, Inc., 131 S.Ct. 2653, 2663 (2011).