UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

IMS HEALTH CORP., ET AL.,	)	
	)	
PLAINTIFFS	)	
v.	)	CV-07-127-B-W
	)	
G. STEVEN ROWE,	)	
ATTORNEY GENERAL OF THE	)	
STATE OF MAINE,	)	
	)	
DEFENDANT.	)	

AMENDED ORDER ON PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION[1]

Seeking to cure some ills in the healthcare system, the Maine Legislature enacted a law that allows Maine prescribers to shield themselves and prevent others from being influenced by their prescribing history. In doing so, the Law restricts freedom of commercial speech. Since certain provisions violate the protections of the First Amendment, this Court grants, in part, a motion for preliminary injunction and enjoins the enforcement of portions of the Maine law.

I. STATEMENT OF FACTS

On January 1, 2008, L.D. 4, "An Act to Amend the Prescription Privacy Law," will become effective in the state of Maine.[2] The Plaintiffs, three prescription drug information intermediaries (PDIIs), move for a preliminary injunction against the enforcement of the law, claiming it violates the First Amendment.[3]

[1] The Court amends the order on page 41 to reflect the fact that sections five and six of the Law are implementing provisions of the Law, not subsections of 22 M.R.S.A. § 8713.

[2] P.L. 2007, ch. 460, which amends 22 M.R.S.A. §§ 1711-E, 8704, 8713 (2007); because the effective date of the legislation is January 1, 2008, the Plaintiffs requested that, if possible, the Court issue the decision before the turn of the year.

[3] The parties have made creative attempts to gain the high ground by characterization. The Maine Legislature entitled the law "An Act to Amend the Prescription Privacy Law." The Maine Attorney General refers to it as the "Prescription Privacy Law"; the Plaintiffs refer to it as the "Prescription Restraint Law." The Plaintiffs refer to themselves as "health information publishers," a name that evokes an image consistent with their First Amendment

A. **Prescription Drug Information Intermediaries**

In the complex world of American health care, gaps among the traditional roles of physician, pharmacy, and patient in prescribing and filling medication have been filled by niche players who have assumed increasingly significant parts in the delivery of health care.[4] PDIIs fill one of those gaps. As a patient fills a prescription, the pharmacy gains a wealth of information about the transaction, the prescriber, and the patient. This data is not simply useful; it is valuable. When aggregated and analyzed, this information demonstrates the normative prescribing patterns for health care professionals both as a whole and as individuals and is of considerable interest to government agencies, academic institutions, health insurance companies, health maintenance organizations, and other entities. Collectively these groups use the data to regulate, research, reimburse, and monitor prescribing patterns. In addition, these patterns are of particular interest and enormous value to the pharmaceutical companies as a powerful marketing tool, allowing them to focus their energies and money to effectively influence the prescribing practices of prescribers. The pharmaceutical companies are willing to pay huge sums for the information, especially when organized in a useful format.

Enter the PDIIs. These companies pay the pharmacies to transfer this information. As a consequence, upon entering an order, a pharmacy electronically sends to the contracting PDII certain salient information: (1) the medication, (2) the dosage, (3) the prescriber, (4) the year of

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argument; the Attorney General refers to them as "data miners," a term that evokes an image consistent with his regulatory contentions. The Court appreciates the cleverness and power of characterization, but avoids value-laden terms. The Court refers to the new law as "the Law" and, to describe the Plaintiffs, the Court uses the term the Law uses, "prescription drug information intermediary." 22 M.R.S.A. § 1711-E(1)(I).

The Plaintiffs have made additional arguments, including an overbreadth and vagueness contention and a Commerce Clause argument. Because the Court resolves the issue on First Amendment grounds, it does not reach these additional arguments.

The attorneys in this case have represented their clients exceptionally well; the memoranda were illuminating, the evidence was well presented, and the arguments well marshaled by both sides.

[4] Another group of niche players is the pharmacy benefit managers (PBMs). For a description of PBMs and their role in the provision of prescriptive drugs, *see Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 298-99 (1st Cir. 2005); 307 F. Supp. 2d 164, 169 n.1 (D. Me. 2004).

birth of the patient, (5) the patient's gender, and (6) where the prescription was filled. Other information is either not sent or is encrypted. For instance, if the pharmacy obtains the diagnosis, it does not forward it to the PDII; other personal data – such as the patient's name, address, and health insurance information – is encrypted. The net effect is that the PDII does not have access to individual patient information; however, the PDII does obtain information about the individual prescriber which it processes, analyzes, and formats to sell to the pharmaceutical industry.

B. The Pharmaceutical Industry, Drug Detailing, and PDIIs

The pharmaceutical industry is one of the prime movers within the American health care system and its success in ameliorating and even curing numerous medical conditions has been virtually miraculous, transforming many painful and devastating illnesses into livable and treatable conditions. But, its success has come at a price. Pharmaceutical manufacturers routinely spend fortunes to invent and to obtain regulatory approval for a product with a limited useful commercial life. During a drug's period under patent, a pharmaceutical company enjoys the full benefit of its research, but upon expiration, generic drug manufacturers quickly enter the field, and produce the drug more cheaply. Sales by the originator of the once lucrative product invariably plummet. To do business, the pharmaceutical company must convince prescribers to write prescriptions for its newly-patented drugs. To this end, the pharmaceutical industry uses an array of marketing devices, the most obvious being direct to consumer marketing, reflected in ubiquitous advertisements. However, the central focus of this case is direct-to-prescriber marketing, aided by PDII information.

The pharmaceutical industry employs a small army of sales representatives, often referred to as detailers.[5] Dr. Erik Steele, the Chief Medical Officer of Eastern Maine Healthcare, testified that the pharmaceutical industry employs one drug representative for every four to five physicians in the United States.[6] The detailers regularly visit prescribers at their clinics and medical offices to persuade them to prescribe their products. The prescriber-witnesses described periodic visits from detailers, ranging from weekly to monthly, often with the sales representatives bringing along free lunch. During the lunch meetings, the pharmaceutical representatives describe the drug product, provide brochures about its properties, and answer questions. After lunch, detailers will often leave behind trademarked reminders, such as pens, coffee cups, writing pads, and other product-identified material, and they commonly give free samples of selected drugs. The sales force is directed toward pitching patented drugs, since there is no advantage to selling off-patent products. Randolph Frankel, a Vice President at IMS, agreed that pharmaceutical companies annually spend a total of four billion dollars in direct-to-physician marketing, though he did not further break down categories of expenditure.[7]

The detailers come armed with a considerable advantage: they have access to the PDII information and they know the exact prescribing patterns of each prescriber. The PDII information is an extraordinarily valuable marketing tool in that it tells the detailer which prescriber is likely to accept the pitch. Knowing the prescriber's patterns, the detailer can determine whether the prescriber is likely to be an "early adopter," a prescriber, who tends to begin prescribing a new drug relatively soon after it has been patented. Also, they can pitch the

[5] Mr. Frankel, an IMS employee who once worked in the pharmaceutical industry, testified that the term "detailer," used for "pharmaceutical representative," describes a drug company sales force thoroughly familiar with the details of their products.

[6] This figure, although it gives a general sense of the size of the pharmaceutical representative work-force, does not take into account the large number of prescriptions that are written by physician assistants, nurse practitioners, and others authorized to prescribe medication.

[7] Judge Barbadoro mentions this four billion dollar figure in *IMS Health, Inc. v. Ayotte*, 490 F. Supp. 2d 163, 167 (D.N.H. 2007).

product by comparing their preferred drug to the drugs they know the prescriber has routinely prescribed. This information also tells the detailer who is unlikely to accept the pitch. By knowing prescriptive practices, the detailer can avoid trying to sell a doctor on a drug outside his or her narrow sub-specialty or making a case for a brand-new medicine to a doctor who by habit is a "late adopter," one who invariably waits for a new drug to gain general acceptance before prescribing it. In short, the PDII information allows the pharmaceutical companies to target their expenditure of marketing dollars to influence the individual prescribers most likely to be receptive to the message.

C. Disadvantages of Direct to Prescriber Marketing

1. Cost

Critics of the pharmaceutical industry point to several concerns about direct-to-prescriber marketing. A primary complaint is cost. Their argument is that by marketing drugs still under patent, detailers tend to steer prescribers away from cheaper, but equally effective, generic drugs, thereby generating unnecessary costs to an already burdened health care system. Indeed, in enacting the Law, the Maine Legislature found that the pharmaceutical companies use the prescription information "to attempt to influence prescribers to prescribe higher priced drugs, thus increasing the market share and profitability of the manufacturers and driving up the cost of health care." 22 M.R.S.A. § 1711-E(1-A)(C). It also found that "[r]estricting the use of prescriber identifying information will act to decrease drug detailing that targets the prescriber, thus increasing decisions to prescribe lower priced drugs and decisions made on the basis of medical and scientific knowledge and driving down the cost of health care." *Id.* at § 1711-E(1-A)(D). Finally, when describing the purposes of the Law, the Legislature stated that

"[r]estrictions on the use of personally identifying information for marketing purposes will . . . decrease unnecessary marketing costs." *Id.* at § 1711-E(1-B)(B).

2. Sales Methods

The second quarrel is with drug company methods. Drug company representatives inundate prescribers with gifts, running from writing pads, pens, and coffee cups emblazoned with the name of a drug to free lunches. The same is true of free samples. Though the prescribers recognize the value of free samples, particularly for poorer patients, they also sense that the samples are not truly free. The samples often become the drug of choice for patients who later face the dilemma of how to obtain a drug they cannot afford. Further, by prescribing free samples, the prescribers become familiar with the medication and tend to prescribe it more readily for patients who can afford it.

Even if the prescriber is unmoved by the small gifts and free samples, it remains true that the drug company representatives are competent people trying to make a living.[8] In the words of Family Nurse Practitioner Martha MacDonald, one of the Defendant's experts, there is a saying around her office that drug company salespeople "are people too." The prescribers develop professional relationships with the detailers, making frequent and perpetual rejection more difficult. In sum, for some prescribers, the detailer-prescriber relationship is unseemly.

[8] The prescribers who testified generally dismissed the notion that a free pen or notepad could affect their professional prescribing judgment and the Court agrees that viewed in isolation, it is insulting to suspect that a respected professional would be influenced in a matter of serious medical judgment by a trinket with a drug logo. An exception was Dr. Steele. Though Dr. Steele stressed that he had not prescribed inappropriately, he admitted that he had been subtly influenced by the gifts and this was one of the reasons he elected not to allow the detailers to visit him. There is no suggestion there is a quid pro quo between a notepad and a prescription. Rather, as Dr. Steele's testimony suggested, writing a prescription with a pen and pad emblazoned with the name of a drug, while drinking from a coffee cup with the same name, may subliminally influence the prescriber. Similarly, the accumulation of small gift upon gift over time may have some impact on prescribing practices.

3. Pharmaceutical Company Misconduct

The Attorney General produced evidence that, in an effort to maximize profits, drug companies occasionally engage in overly aggressive marketing tactics. He pointed to Merck's controversial marketing of Vioxx, which provoked congressional concern, and Purdue Pharma's marketing of Oxycontin in Maine and elsewhere, which resulted in a Consent Decree. *Def.'s Mem. of Law in Opp'n to Pls.' Mot. for Prelim. Inj.* at 7-8 (Docket # 39) (*Def.'s Mem.*); *Def.'s Ex.* 4, *Mem. from Rep. Waxman to Democratic Members of the Government Reform Committee*; *Def.'s Ex.* 5, *Consent J., State v. Purdue Pharma, L.P.*, No. CV-07-143 (Me. Super. Ct., Ken. Cty., May 23, 2007). He also pointed to a publicly revealed statement by Vikki Tolbert, a district sales manager with the pharmaceutical company Novo Nordisk, who, in marketing Humalog, a synthetic insulin, urged its detailers to reach its goal of "50 or more scripts per week for each territory" and to "hold [doctors] accountable for samples, dinners, programs and past preceptorships that you have provided or paid for and get the business." *Def.'s Ex.* 14, Gardiner Harris & Robert Pear, *Drug Maker's Efforts to Compete in Lucrative Insulin Market Are Under Scrutiny*, N.Y. Times, Jan. 26, 2006.

4. Inaccurate and Filtered Information

Another complaint is that the detailers rarely tell the whole story and that what they say is on occasion flatly inaccurate. At the hearing, the prescriber-witnesses generally did not claim that the pharmacy representatives misrepresent the properties of the drug; in fact, they acknowledged that what a drug representative says about a drug is strictly regulated by the Food and Drug Administration. But, Dr. Steele referred to a study which concluded that about one-third of pharmaceutical company marketing material contained information proscribed by the FDA. He said there is evidence the FDA is not doing a good job regulating such marketing

materials. Supporting Dr. Steele's point, during its hearing process, the Maine Legislature reviewed studies revealing that detailer information was flawed, sometimes contradicting other verifiable information about the drugs. *Def.'s Mem.* at 7. Even assuming the general accuracy of the marketing material, the glossy brochures and calculated sales pitch give some prescribers an uneasy feeling that the information, though correct, is filtered.

5. Privacy

A fifth concern, for both prescribers and patients, is privacy. Although the prescribers are aware that numerous entities, from government agencies to health insurers, have access to their prescribing history, they are largely unaware that the pharmaceutical representatives also have this information. Thus, when one detailer complained to FNP MacDonald that she had not prescribed any of the new medicine that he had been trying to sell, she exclaimed: "You've been spying on me!"[9] The concern about patient privacy is more illusive. The information to the PDIIs is encrypted and the PDIIs are unable to identify a specific patient. There is no real claim that the PDIIs have violated an individual patient's right of privacy. Nevertheless, the information that is being revealed and compiled emanates from an intensely private encounter between physician and patient and there is an uneasy sense that a third party's access to this information, even in the aggregate, and its use in marketing, encroaches upon the physician-patient relationship, and erodes its confidential nature.

6. Unauthorized and Free Use of Professional Work Product

Dr. Steele was concerned about the pharmaceutical companies' unauthorized and free use of his work product for their financial advantage. He explained that his choice of medication for a patient is the product of his training and skill and, in that sense, it is his intellectual work that a

[9] FNP MacDonald testified that the revelation of detailer knowledge of her prescribing patterns occurred twice. The first time the detailer was young and inexperienced and beat a retreat when she expressed surprise. The second time another detailer said something about a medication she had not prescribed, which provoked the "spying" accusation.

third party is using for financial gain. Further, in doing so, they do not ask his permission, do not pay for this information, and do not pay his employer for it, but they gain a return from his professional time and effort.

7. Waste of Time

A final concern is waste of time. Prescribers are increasingly specialized and for the prescriber who treats only a narrow range of conditions, to sit through a lunch, even a free one, in which the drug company salesperson pitches a product they will never prescribe, is to waste time that could otherwise be devoted to direct patient care.[10]

D. Advantages of Direct to Prescriber Marketing

The PDIIs respond that there are distinct public benefits from direct to physician marketing and that, to the extent the Maine Legislature has identified concerns, the Law does not remedy them.

1. Cost

Any discussion about cost in the current medical system becomes quickly mired in complexity and this case is no exception. The Plaintiffs contend that the broad generalizations that motivated the enactment of the Law must be measured against a more complex and nuanced view of the impact of pharmaceutical marketing.

a. The Branded-Generic Drug Debate

The PDIIs assault one of the Law's premises: that marketing brand-name drugs invariably results in equal care at higher costs. The PDIIs vigorously contend that this premise is simply not true; instead, generic drugs are not always better or more cost effective than branded drugs. The PDIIs explain that generic drugs are not exact duplicates of their branded

[10] For example, FNP MacDonald, who works in an adult family practice office, complained that one detailer tried to push a medication designed for adolescents.

equivalents. Patented and generic drugs share identical molecular structures, but they are rarely exact duplicates, since generic and branded pills vary in size, shape, dye, and filler material. There is also variation among different manufacturers' version of the same generic drug. Similarity among drugs is known as "bioequivalence," a concept that measures how much of the drug becomes available in the bloodstream. Under Federal Drug Administration rules, when compared with its branded sister, a generic drug must meet an availability standard of between 80% and 125% of the branded drug. For many conditions and many patients, variations in bioequivalence between the branded and generic drugs make no therapeutic difference. However, for some medical conditions, the therapeutic window is extremely narrow, and the substitution of a generic drug for a patented drug can have devastating health consequences.

Dr. Andrew Card, the Director of the Massachusetts General Hospital Epilepsy Service, and Dr. Thomas Wharton, a cardiologist, testified about medical conditions they routinely treat that require branded, not generic, drugs. They confirmed that occasionally the improper substitution of generic for branded drugs can cause medical catastrophes and result in costs to the health system far in excess of the savings from the cheaper generic drug. They say that to focus solely on the cost of a pill is to ignore its true cost effectiveness.[11]

b. Marketing of New and More Effective Drugs

The Plaintiffs counter the Maine Legislature's assumption that marketing causes prescribers to order drugs that are more costly, but not more effective, by pointing out that many new drugs are actually worth the higher cost. They presented evidence of break-through drugs, which, though more expensive per pill, were more effective and, therefore, less expensive to the health care system as a whole.

[11] Dr. Steele agreed that occasionally a patient will be better off with a branded drug than with a generic, but he testified that the frequency was rare, perhaps one in fifty patients in his family practice.

Next, the Plaintiffs argue that the detailers often act as a valuable resource for prescribers by alerting and educating them to the availability and properties of new drugs. The detailers are up-to-date about changes in drug guidelines and often supply peer-reviewed articles that discuss the efficacy of the drugs the prescriber is currently prescribing and available alternatives. The Plaintiffs' medical experts gave examples of instances when they became aware of a breakthrough drug through interactions with detailers, and prescribed the new drug with extremely beneficial results. The Plaintiffs presented evidence that the drug companies routinely sponsor lectures by other physicians, provide written guideline information, and distribute product information. The detailer visits often provoke animated discussions among the prescribers about whether and when a drug should be prescribed. The visits also spur the prescribers to educate themselves through research about the best available treatment and thus encourage prescribers to stay abreast of developments in their fields.

2. Sales Methods

The Plaintiffs disagree with the criticism of their sales methods. They point out that none of the prescribers is required to meet with any detailer, and if prescribers prefer not to see a drug representative, their wishes are honored. In essence, drug companies market only prescribers who wish to be marketed.

They acknowledge that drug companies routinely buy lunch and leave small gifts at medical offices, but they make the point that there is never an overt quid pro quo between the gift and the prescriber's decision about what drug to prescribe. Further, they dismiss the notion that the prescribers are so easily bought. Finally, they contend that if the true intent of the Law was to ban pharmaceutical representatives from giving out gifts, the Maine Legislature could

have done so by enacting a statute that actually banned gifts. Here, if the intent was to ban gifts, the Legislature has accomplished this goal by a notably circuitous route.

3. Pharmaceutical Company Misconduct

The Plaintiffs' brief answer to the question of pharmaceutical company misconduct is that "there is no showing that the law at issue . . . would prevent the pharmaceutical companies from engaging in deceptive marketing campaigns as alleged in those cases." *Reply Mem. in Supp. of Pls.' Mot. for Prelim. Inj.* at 3 (Docket # 47).

4. Filtered Information

The Plaintiffs do not deny that the drug companies provide information favorable to their products. However, they observe that the FDA controls what the pharmaceutical representatives can say about the drugs and they must accurately state the drug's side affects. Under FDA oversight, detailers are not allowed to comment on off-label uses for the drugs. If that issue arises, detailers commonly connect the prescriber to a medical officer inside the company so that the discussion takes place peer-to-peer. Finally, once again, the Plaintiffs contend that if the Legislature's concern was the quality of the sales representatives' information, the issue could be addressed more effectively than by limiting the data detailers may use to market the product.

5. Privacy

The Plaintiffs first contest the proposition that the dissemination of prescriber information has any affect on patient privacy. They affirm that patient-identifiable information is encrypted and is not shared with the pharmaceutical companies. The data contains only the year of birth, gender, medication, dose, and location of the pharmacy. This information does not, in their view, present any risk of violating an individual patient's privacy.

The Plaintiffs also dispute the assertion that prescribers have a right of privacy in their own prescribing patterns. They point out that the information is made widely available to insurers, governmental agencies, hospital contracting individuals, compliance officers, quality assurance committees, utilization review officers, and formulary committees. In their view, there is no legal basis for asserting a common law right of privacy, much less a privacy right based on constitutional principles. They acknowledge that it has long been a practice in the pharmaceutical industry not to confront prescribers with their own data, which may contribute to the prescribers' sense that the marketing use of the information amounts to "spying." But, Plaintiffs deny that the undisclosed use of prescription history has impinged upon a constitutionally protected right.

6. Unauthorized and Free Use of Professional Work Product

The Plaintiffs disagree with the idea that the use of prescriptive information amounts to the unauthorized use of a prescriber's work product. They point out that the ability to prescribe medication is not a right, it is a privilege, subject to state licensure. It is highly regulated and prescribers must expect that their prescribing patterns will be repeatedly reviewed, occasionally challenged, and even potentially penalized. In this context, to claim a general right to ownership in prescribing patterns is to assert a novel legal protection to information that is widely available at no charge to countless third parties.

Even Dr. Steele, who proposed the right to reimbursement, had qualms about it. He confessed that he was unsure whether a hospital or clinic would have the right to sell the prescription information of its prescriber-employees. He said that although he thought prescribers or their employers should be approached before the prescribing information is used, he was chary about the prospect of prescribers receiving money from pharmaceutical companies

in exchange for records of their prescribing behavior. Dr. Cole agreed; although he thought it would be wonderful to be paid for his prescribing history, he claimed no expectation of payment for a record of his medical decisions that is by law reviewable by third parties.

7. Waste of Time

The Plaintiffs stand the waste of time argument on its head. The use of prescribing pattern information allows the pharmaceutical industry to focus on those prescribers who are most likely to prescribe their products by identifying early adopters, tailoring the pitch that will be most successful, and evaluating effectiveness. The absence of prescribing information will require the pharmaceutical companies to market more indiscriminately, thereby creating the very problem the Law was enacted to avoid. Finally, the Plaintiffs note that the best evidence is in the attendance: if the prescribers believed the detailers' meetings were a waste of time, they would not show up.

E. The Maine Legislative Response

On June 29, 2007, state of Maine Governor John E. Baldacci signed into law L.D. 4, "An Act to Amend the Prescription Privacy Law." The Law becomes effective on January 1, 2008, and allows Maine prescribers to "opt-out," in other words, to demand confidentiality by preventing pharmaceutical companies from using their individualized prescribing information to market them or others. The Law does not directly affect the PDIIs' ability to purchase pharmacy information or to use that information for purposes other than marketing. If prescribers opt-out, however, the Law forbids carriers, pharmacies, or PDIIs from selling or using their information for marketing:

> Beginning January 1, 2008, a carrier, pharmacy or prescription drug information intermediary may not license, use, sell, transfer or exchange for value, for any marketing purpose, prescription drug information that identifies a prescriber who has filed for confidentiality protection . . . .

P.L. 2007, Ch. 460, § 1711-E(2-A). The Law defines "marketing" to include:

> [A]ny of the following activities undertaken or materials or products made available to prescribers or to their employees or agents related to the transfer of prescription drugs from the producer or seller to the consumer or buyer:
> (1) Advertising, publicizing, promoting or selling a prescription drug;
> (2) Activities undertaken for the purpose of influencing the market share of a prescription drug or the prescribing patterns of a prescriber, a detailing visit or a personal appearance;
> (3) Activities undertaken to evaluate or improve the effectiveness of a professional detailing sales force; or
> (4) A brochure, media advertisement, or announcement, poster or free sample of a prescription drug.

Id. at § 1711-E(1)(F-1). A violation of the Law constitutes a violation of the Maine Unfair Trade Practices Act (MUTPA). *Id.* at § 1711-E(3). Under the MUTPA, if the Attorney General of the state of Maine has "reason to believe that any person is using or is about to use any method, act or practice declared . . . to be unlawful, and that proceedings would be in the public interest, he may bring an action in the name of the State against such person to restrain by temporary or permanent injunction the use of such method, act or practice . . . ." 5 M.R.S.A. § 209. In addition to injunctive relief, the violator is subject to a civil penalty of not more than $10,000 for each violation.[12] *Id.*

F. The PDII Lawsuit

On August 29, 2007, three PDIIs filed a cause of action against Steven Rowe, the Attorney General of the state of Maine, seeking declaratory and injunctive relief against the operation of the Law. *Compl.* (Docket # 1). The Plaintiffs claim that by restricting either commercial or non-commercial speech, the Law violates the First Amendment. *Id.* at Counts I,

[12] The Plaintiffs point out that the statutory language for imposition of the civil penalty is mandatory. 5 M.R.S.A. § 209 ("In addition to a temporary or permanent restraining order, a penalty of not more than $10,000 shall be adjudged for each intentional violation of the Maine Unfair Trade Practices Act established by the Attorney General.") *Compl.* (Docket # 1) (emphasis in original). On the other hand, in dealing with the MUTPA, the Maine Supreme Judicial Court has emphasized the trial court's "considerable discretion to fashion an equitable remedy." *State v. Weinschenk*, 2005 ME 28, ¶ 21, 868 A.2d 200, 207.

II. They also contend that the Law is void for vagueness and overbreadth and that it violates the Commerce Clause. *Id.* at Counts III, IV. The Attorney General responds that the Law passes constitutional muster.

1. The Hearing

The Court held a two-day evidentiary hearing on November 19-20, 2007. The Plaintiffs presented the testimony of Hossam Sadek, Vice President, Sales Force Effectiveness Business Line, IMS Health Incorporated; Dr. Cole; Dr. Wharton; Carol Livingston, Vice President, Customer Operations, Source Health Incorporated; Dr. August Valenti, an Internist with Long Creek Center for Internal Medicine; Dr. Michael Turner, a political economist; Randolf Frankel, Vice President of Corporate Affairs, IMS Health Incorporated; William Wolfe, Vice President of Managed Care for Rite Aid Corporation; and Scott Tierney, CVS Caremark Corporation. The Defendants presented the testimony of Dr. Steele and FNP MacDonald. The parties introduced numerous exhibits and declarations.

II. DISCUSSION

A. The First Amendment

The First Amendment to the United States Constitution provides that "Congress shall make no law . . . abridging the freedom of speech . . . ." U.S. Const. amend. I. The Fourteenth Amendment of the United States Constitution makes the First Amendment applicable to laws enacted by the states. *Id. at* amend. XIV.

B. The Legislative Findings and Response

The Court emphasizes what this case is not about. Through its hearing process, the Maine Legislature identified a serious problem with spiraling health care costs and it enacted legislation to control a significant driver of those costs. This Court does not question the

determination that legislation is necessary and does not lightly declare unconstitutional duly-enacted provisions of the Maine Legislature. The citizens of the state of Maine have the right through their elected representatives and governor to order their affairs and this right is particularly compelling when the state acts to regulate the health and privacy concerns of its citizens.

This Court's sole concern is whether the legislation, as enacted, violates the free speech guarantees of the First Amendment of the United States Constitution. Having concluded that portions of the Law improperly infringe on freedom of speech, the Court has the obligation to strike down those provisions. The Maine Legislature retains the perfect right to enact laws that achieve the very same purposes, so long as they pass constitutional muster.

C. The New Hampshire Law and *IMS Health Incorporated v. Ayotte*

1. Background

In determining whether the Maine Law passes constitutional muster, the Court is fortunate to have the thoughtful guidance of Judge Paul Barbadoro, who earlier this year addressed an analogous New Hampshire statute. In 2006, New Hampshire enacted a blanket proscription against the sale or transfer of prescription information containing patient-identifiable or prescriber-identifiable data for any commercial purpose. N.H. Rev. Stat. Ann. §§ 318.47-f, 318.47-g, 318-B:12(IV) (2006). The major distinction between the New Hampshire and Maine statutes is that, unlike Maine, the New Hampshire law did not provide for an opt-out process. In *IMS Health Incorporated v. Ayotte*, Judge Barbadoro concluded that the New Hampshire statute violated the First Amendment. 490 F. Supp. 2d at 183.[13]

[13] Judge Barbadoro's decision was appealed to the First Circuit, where it is now pending. It has not yet been argued and the parties confirmed that no First Circuit decision is expected before January 1, 2008, the effective date of the Law. The Court suggested to the Maine Attorney General that it made some practical sense to stay enforcement of the Law and await the First Circuit decision in *Ayotte*, since it is likely to resolve a number of critical issues in this

2. *Ayotte* and the Maine Statute

Having reviewed Judge Barbadoro's well-reasoned opinion, the Court concludes that it "should refrain from writing at length to no other end than to hear its own words resonate." *Lawton v. State Mut. Life Assurance Co.*, 101 F.3d 218, 220 (1st Cir. 1996). For the same reasons Judge Barbadoro ably articulated, the Court concludes that the prescription information is commercial speech, that the Maine statute restricts speech, and that, as such, it is subject to intermediate scrutiny.[14] *Ayotte*, 490 F. Supp. 2d at 174-76. The narrow question here is whether the opt-out provision in the Maine Law makes a constitutional difference.

D. The Maine Law: An Analysis

Before applying the *Central Hudson* criteria, it is necessary to discuss how the statute works. First, the Law does not directly affect the PDIIs' ability to collect prescriber information.

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case. This is apparently what has been done in Vermont, which enacted similar legislation. The Maine Attorney General, however, took the understandable position that he is required to enforce the laws that the people of Maine enact through their Legislature and he declined to await the resolution of a challenge to another state's law before performing the duties of his office.

[14] Judge Barbadoro rejected the argument that the New Hampshire law is subject to strict scrutiny simply because it is a content-based commercial speech restriction. *Ayotte*, 490 F. Supp. 2d at 176 n.11 (citing *Trans Union Corp. v. Fed. Trade Comm'n*, 267 F.3d 1138, 1141-42 (D.C. Cir. 2001), *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410 (1993), and *Consol. Cigar Corp. v. Reilly*, 218 F.3d 30, 41-43 (1st Cir. 2000)).

On June 27, 2007, after *Ayotte*, the First Circuit, in *Association of Community Organizations*, wrote: "Of course, the application of intermediate scrutiny is dependent on whether the challenged regulation is content-neutral . . . . If the ordinance is content-based, strict scrutiny would likely apply." *Ass'n of Cmty. Orgs. for Reform Now v. Town of East Greenwich*, 239 Fed. Appx. 612, 613-14 (1st Cir. 2007); *see Asociacion de Educacion Privada de P.R.., Inc. v. Garcia-Padilla*, 490 F.3d 1, 15 (1st Cir. 2007) ("Regulations that suppress, disadvantage, or impose differential burdens upon speech because of its content are subject to strict scrutiny.").

The Maine Law is manifestly content-based, since it proscribes the use of the same information for one purpose and not for others; the question is whether it is commercial speech and "entitled to lesser protection than other constitutionally guaranteed expression." *City of Cincinnati*, 507 U.S. at 422. In *Association of Community Organizations*, the First Circuit addressed an ordinance that restricted door-to-door solicitations, containing "mixed political speech and solicitation of donations . . . ." *Ass'n of Cmty. Orgs.*, 239 Fed. Appx. at 614-15. By contrast, *Trans Union* concluded that the marketing lists in that case were commercial speech, not subject to strict scrutiny, because the information "is solely of interest to the company and its business customers and relates to no matter of public concern." *Trans Union . v. Fed. Trade Comm'n*, 245 F.3d 809, 818 (D.C. Cir. 2001).

Here, the information – the prescription history of prescribers – is of interest to the PDIIs and the pharmaceutical companies, but it is also a matter of public concern. It may be under this test that the speech here is not purely commercial speech and is subject to strict scrutiny. But, in *Lorillard Tobacco Co. v. Reilly*, the Supreme Court applied the *Central Hudson* intermediate scrutiny test to outdoor advertising for tobacco products. 533 U.S. 525, 554-55 (2001).

There is no need to resolve this thorny question. This Court concludes that the Maine Law fails under the intermediate scrutiny test and therefore, the Law would also fail under the strict scrutiny test.

In fact, the Law recognizes the numerous essential and beneficial purposes for collecting prescribing information for all prescribers and exempts those purposes from its prohibition.[15] Therefore, under the Law, the PDIIs have the continuing right to collect prescriber information, even if the prescriber has opted out, and the PDIIs retain the right to sell that same information to drug companies for purposes other than marketing.[16] Thus, though enacted as a confidentiality law, the Law has no effective confidentiality provision. Exactly the same parties that now have access to the information will continue to have access under the new Law.[17] The Law limits the purposes for which the information can be sold or transferred, not the sale or transfer of the information.

Secondly, the statute does not prevent pharmaceutical representatives from marketing prescribers who have opted out, if they are willing to be marketed.[18] The detailer may still call on willing prescribers, provide them with free lunches, coffee cups, and other inducements, and make the product pitch, emphasizing the benefits of the marketed drug. In marketing all prescribers, whether they have opted-out or not, the detailer is allowed to use data from prescribers who have not opted-out.[19]

Thirdly, although the statute's stated purpose is to decrease the influence of drug company representatives, the statute's prohibitions do not mention the drug companies. The

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[15] "'Marketing' does not include pharmacy reimbursement, formulary compliance, pharmacy file transfers in response to a patient request or as a result of the sale or purchase of a pharmacy, 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, and health care research." P.L. 2007, Ch. 460, § 1711-E(1)(F-1).

[16] For example, if a drug manufacturer wished to know opt-out prescriber data for purposes of focusing its allocation of research dollars, the Law would not prevent the sale of the data, even if the prescriber had opted out.

[17] Technically, the Law does not prevent the pharmaceutical companies from giving the opt-out prescribers' information to its sales force, so long as the sales force does not use the information for marketing.

[18] In fact, as will be discussed, the Law does not directly affect the detailer at all. Rather, the PDIIs are assigned the responsibility to limit the pharmaceutical companies' use of the opt-out prescribers' data.

[19] For example, if an opt-out prescriber allowed detailer visits, the Law does not prevent a detailer from informing the prescriber of the percentage of other prescribers who have prescribed a particular drug for a specific medical condition. If the detailer were to mention the opt-out prescriber's statistics, he would violate the restrictions that the Law mandates the PDIIs impose on their clients to prevent this disclosure.

statute prohibits "a carrier, pharmacy or prescription drug information intermediary" from licensing, using, selling, transferring or exchanging prescription drug information for any marketing purpose that identifies an opt-out physician. P.L. 2007, Ch. 460, § 1711-E(2-A). The Law does not make illegal a drug company's use of opt-out prescriber information for marketing purposes. If a PDII were to violate the Law and supply a drug company with opt-out prescriber information for marketing and if a drug company used the information to market a prescriber, the PDII would be civilly liable, but the pharmaceutical company would not. The Law forbids the PDIIs from selling opt-out data for marketing, but it does not prohibit the pharmaceutical companies from using the data for marketing.

What the law does prevent is the transfer or sale of prescription drug information of opt-out prescribers for marketing. It does not necessarily staunch the flow of opt-out prescriber information to pharmaceutical companies, but it does impose a burden on pharmacies and PDIIs to police their customers. They can still sell the opt-out information, but they cannot do so if their customers, the pharmaceutical companies, are going to use the information for a purpose that the Law prohibits. If the PDIIs successfully police their contracts with the pharmaceutical companies, as the Law contemplates, the pharmaceutical companies will not be able to include opt-out prescriber information in marketing their products. If they do not, then they, not the pharmaceutical companies, are subject to sanction.

E. The Intermediate Scrutiny Standard

Truthful commercial speech that does not promote unlawful activity can be limited only if the restriction "(1) is in support of a substantial government interest; (2) directly advances the governmental interest asserted; and, (3) is not more extensive than is necessary to serve that interest." *El Dia, Inc. v. P.R. Dep't of Consumer Affairs*, 413 F.3d 110, 113 (1st Cir. 2005)

(quoting *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980)).

1. The Government Interest

In its enactment, the Maine Legislature made general findings concerning the government's interests: to improve the public health, to limit annual increases in the cost of health care, and to protect the privacy of patients and prescribers in the health care system of this state. P.L. 2007, Ch. 460, § 1711-E(1-A). Unlike the New Hampshire Legislature, the Maine Legislature set out in detail the purposes behind its enactment: (1) patient privacy; (2) prescriber privacy; (3) decreasing the influence of drug representatives; (4) ending the use of prescriber comparisons for purposes related to manufacturer profitability and decreasing unnecessary marketing costs; and, (5) enhancing the effectiveness of other laws. *Id.* at § 1711-E(1-B).

a. Patient Privacy

The Court readily accepts the Attorney General's view that patient confidentiality is a substantial government interest.

b. Prescriber Privacy

Prescriber privacy is another matter. The Attorney General recognizes that prescribers have no general legal right to maintain secrecy over their prescribing patterns. *Def.'s Mem.* at 12 ("[T]he Act provides Maine doctors and other prescribers with a limited right of confidentiality over the prescriptions they write for their patients . . . ."). The prescribers cannot prevent a host of entities from reviewing their prescribing patterns. The Attorney General's expert witnesses acknowledged that insurance companies, governmental agencies, quality assurance committees,

utilization reviewers, and others have the right and responsibility to assess their prescribing patterns.[20]

The right of privacy the Supreme Court upheld in *Lawrence* extends to "an autonomy of self that includes freedom of thought, belief, expression and certain intimate conduct." *Lawrence v. Texas*, 539 U.S. 558, 562 (2003). Prescribers' prescribing patterns are, however, dissimilar to the traditional areas of privacy and, by contrast, are a matter of public concern.[21] *See Ayotte*, 490 F. Supp. 2d at 179-80. As the Purdue Pharma Consent Decree reflects, the medicine prescribers advise their patients to take can have profound social consequences, and prescribers who misprescribe medication could not assert a prescriber right of privacy to prevent the investigation and cessation of their prescription practices.

It is true, as the Attorney General has argued, that the absence of prior common law or constitutional recognition of prescribers' right of privacy in their prescription history does not mean that the state of Maine cannot recognize a new right and codify it. The Attorney General points to numerous instances where Congress, the Maine Legislature, and other state legislatures

[20] This can be true of pharmaceutical companies as well. For example, the Consent Agreement between the state of Maine and Purdue Pharma required Purdue Pharma to create an OxyContin abuse and diversion detection program and to monitor, among other things, any "sudden, unexplained changes in prescribing or dispensing patterns that are not accounted for by changes in patient numbers or practice type . . . ." *Def.'s Ex.* 5 at 9. The Law does not prevent Purdue Pharma from obtaining this type of statistical information and complying with its agreement with the state of Maine.

[21] In *Whalen v. Roe*, the United States Supreme Court upheld a New York statute which required physicians to provide records for all prescriptions of controlled substances with a potential for abuse. 429 U.S. 589, 604-05 (1977). The debate in *Whalen* concerned the privacy of the patient, not the physician.

The Supreme Court has also ruled on several cases dealing with reporting and recording requirements in the context of abortion rights. What is noteworthy about these cases is that the right of privacy was the patient's, not the provider's. *See Thornburgh v. American College of Obstetricians & Gynecologists*, 476 U.S. 747, 766 (1986) (finding unconstitutional a statute that requires abortion records to be filed that include "information as to method of payment, as to the woman's personal history, and as to the bases for medical judgments," and which "are available . . . to the public for copying."); *Planned Parenthood v. Danforth*, 428 U.S. 52, 80 (1976) (upholding "[r]ecordkeeping and reporting requirements that are reasonably directed to the preservation of maternal health and that properly respect a patient's confidentiality and privacy.").

have created confidentiality rights. *See Def.'s Mem.* at 35. Such legislative judgments are entitled to judicial respect.

Finally, the prescriber right that the Maine Law recognizes is extremely narrow. Presumably, the individual prescribers are generally aware of both their own prescribing patterns and the wide dissemination of this information. The Law only indirectly impacts one-on-one marketing, in that PDIIs are not allowed to sell information from opt-out prescribers for marketing purposes. In this way, the Law attempts to prevent detailers from using or mentioning this data to prescribers, essentially protecting prescribers from truthful information, some of which they already know.[22]

The Law protects this information from well educated professionals, individuals who are otherwise entrusted to make complex and dispassionate medical decisions based on a plethora of information. The prescribers, many of whom are physicians, are by definition highly trained professionals that the State has licensed to prescribe medicine; there is no evidence that by using this information, the detailers intimidate prescribers or that the prescribers are vulnerable victims, who require the law's protection. *See Ayotte*, 490 F. Supp. 2d at 179; *compare Planned Parenthood v. Casey*, 505 U.S. 833, 887-94 (1992) (discussing the impact on pregnant women of a spousal notification provision). Moreover, detailers retain the right during one-on-one sales meetings to present general patterns of prescribing practice; the Law prohibits the sale of opt-out prescribers' information to prevent detailers from incorporating their data into a sales pitch, but it does not restrict detailers' ability to use prescription information from prescribers who choose not to opt-out.

[22] The Law prevents a PDII from selling information from all opt-out prescribers for marketing. If the Law achieves its purpose, the detailer will not be able to use an opt-out prescriber's information in direct marketing to that prescriber, but in addition, the detailer will not be able to use any opt-out prescribers' information in marketing of any kind to any prescriber – opt-out or not.

The pharmaceutical industry applies prescription information to marketing uses other than direct one-on-one solicitations; this information is used to target, tailor, and measure the effectiveness of detailing.[23] *Ayotte*, 490 F. Supp. 2d at 170. The Law seeks to prevent pharmaceutical companies from using the individual prescribers' information to solicit the prescriber, but it also seeks to prevent the inclusion of the opt-out prescribers' data from the statistical pool of all prescribers. The Court concludes, based on the evidence before it, that the state of Maine's interest in protecting the prescribers' prescribing patterns from marketers is narrow.

c. Decreasing the Influence of Drug Representatives[24]

There is substantial evidence that pharmaceutical representatives provide a valuable service to prescribers, informing them of the advantages of newly-patented medications, educating busy practitioners about newly-approved uses for existing medications, and apprising them of the efficacy of commonly-prescribed drugs. At the same time, there are detrimental aspects of drug company sales practices: their tendency to push higher-priced patented drugs, their slick presentations, and their subtle and sometimes direct influence on prescribing decisions. The Court concludes that this legislative choice to inhibit the influence of detailers reflects a substantial government interest.

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[23] Targeting refers to the ability of drug companies to identify early adopters, to focus on prescribers who have recently altered their prescription practices and to find prescribers who prescribe large quantities of the detailer's and others' medicine. *Ayotte*. 490 F. Supp. 2d at 170. Tailoring refers to the use of prescriber information to influence a medication decision; for example, a detailer "might mention during a detailing session that the drug she is detailing does not have a specific side effect that is associated with a competing drug that the health care provider is currently prescribing." *Id.* Measuring the effectiveness of marketing allows the pharmaceutical companies to "identify the ratio of brand-name to generic drugs prescribed, assess the success of or resistance to detailer visits, and measure the effectiveness of larger marketing campaigns" and thus "adjust the marketing message that detailers bring to individual health care providers." *Id.*

[24] Subsumed under this category is the Legislature's statement that the new Law will free prescribers "from pressure to prescribe based on comparisons among them and their peers and aid[] them in making health care decisions based on the best interests of the patient and on medical and scientific evidence about prescription drugs and health care treatments." P.L. 2007, Ch. 460, § 1711-E(1-B).

d. Ending the Use of Prescriber Comparisons for Purposes Related to Manufacturer Profitability and Decreasing Unnecessary Marketing Costs

The Court concurs with the Attorney General that these government interests are substantial.

e. Enhancing the Effectiveness of Other Laws

The State identified a number of laws that it contends the new Law will advance. The Court agrees that enforcing existing laws is a substantial government interest.

2. Directly Advances the Governmental Interest Asserted

a. Patient Confidentiality

The first stated purpose of the Law is to protect patient confidentiality. P.L. 2007, Ch. 460, § 1171-E(1-B)(A) and (B) ("The establishment of a system to protect patient confidentiality is critical to patient trust in the integrity of the health care system of this state."; "Restrictions . . . will protect personal privacy rights . . . ."). Maine already prohibited a prescription drug information intermediary from selling or exchanging for value "prescriptive drug information that identifies directly or indirectly the individual . . . ." 22 M.R.S.A. § 1711-E(2). The new law merely adds "carrier"[25] to the entities captured by the prohibition, expands the scope of prohibited activities,[26] and strikes two statutory qualifiers.[27] To the extent the Law seeks to enhance patient confidentiality by tweaking its statutory definition, the Court does not view the Law as having any constitutional implications and this part of the Law stands unaffected by the

[25] Section 1711-E(1)(A) incorporates the definition of "Carrier" from 24-A M.R.S.A. § 4301-A(3), which broadly defines the term to include insurance companies, HMOs, preferred provider administrators, fraternal benefit societies, nonprofit hospitals or medical service organizations, multiple-employer welfare arrangements, and self-insured employers.

[26] Old section 1711-E(2) prohibited the sale or exchange of the information; the new law prohibits licensing, using, selling, transferring, or exchanging for value the information.

[27] Old section 1711-E(2) prohibited the sale or exchange of the information, "except if expressly permitted under section 1711-C, Title 24, Title 24-A or the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as amended." The new law strikes this language.

pending action. Thus, prior Maine law prohibited a PDII from selling or exchanging patient-identified prescription information and the new law does the same.

One issue is whether the provisions of the Law that the Plaintiffs have challenged affect patient privacy. They do not. Regardless of the opt-out provisions of the new law, personal patient information has been and will continue to be encrypted and there is no evidence that the current practices of the PDIIs and the pharmaceutical companies have had or realistically could have any effect on patient confidentiality.[28] Finally, the new Law does not prevent the pharmacies from transferring exactly the same information to the PDIIs, so long as the information is not ultimately used for marketing. The Attorney General has not effectively argued that this Law achieves its stated purpose of promoting patient confidentiality.

b. Prescriber Privacy

The second stated purpose of the Law is to protect prescriber privacy, but if the Law has an impact on opt-out prescriber privacy, it is oblique. The Law does not restrict the PDIIs from continuing to collect data containing the opt-out prescribers' prescribing patterns. It does not affect the ability of government agencies, academics, insurers, and others from obtaining and analyzing the data. It does not even prevent the sale and transfer of opt-out prescribers' data to pharmaceutical companies for purposes other than marketing. What the Law does effectively prohibit is the sale of the opt-out prescribers' data for a specific use: marketing.

Enacted in the name of prescriber privacy, the Law does not restrict access to the opt-out prescribers' prescription history. In this sense, the Law is not a confidentiality law; it is a use or

[28] At the hearing, the Attorney General made an ingenious attempt to demonstrate that a PDII or pharmaceutical company might be able to identify an individual patient in a particularly rural area of the state of Maine. Nevertheless, given the encrypted nature of the patient identifiers and the limited remaining information, such a possibility is extremely farfetched, would involve extraordinary efforts on the part of the PDII or pharmaceutical company, and would likely violate a host of federal and state laws. There is no evidence that such an attempt has ever been made and the Court views this contention as purely theoretical.

disclosure law, preventing those who retain the right to obtain information from disclosing it to third parties if the third parties are going to use it in a particular way. It is true that to satisfy its legal obligations, a PDII might require a pharmaceutical company to promise not to share the opt-out prescribers' information with its sales force, or a PDII might restrict the information they obtain. The Law does not, however, mandate either result. The Law only marginally advances the governmental interest in prescriber privacy.

c. Decreasing the Influence of Drug Representatives

This category of purposes includes the legislative determination that the Law will protect prescribers "from pressure to prescribe based on comparisons among them and their peers and aid[] them in making health care decisions based on the best interests of the patient and on medical and scientific evidence about prescription drugs and health care treatments." P.L. 2007, Ch. 460, § 1711-E(1-B)(A). Whether limiting the information the pharmaceutical industry uses to market drugs will decrease the influence of the drug representative is questionable.

By far the most effective tool that the prescriber possesses to reduce the influence of detailers is to refuse to see them. During the hearing, there was unanimity among the experts that if prescribers informed the pharmaceutical representatives that they did not wish to be marketed, the detailers honored the request. This was true before the Law was enacted and will continue to be true, regardless of the Law.

The intersection of the Law with the pre-existing practice reveals four categories of providers: (1) those who refuse to see detailers and who will opt-out under the Law; (2) those who refuse to see detailers and who will not opt-out; (3) those who will see detailers and who will not opt-out; and, (4) those who will see detailers and who will opt-out. For direct one-on-one marketing, the Law affects a substratum of prescribers: those willing to be marketed, but

unwilling to allow the pharmaceutical companies to use their own data for marketing.[29] For a prescriber to allow marketing, but deny personal information may seem inconsistent; however, this group may consist of prescribers who are willing to meet with detailers, if only to obtain free samples, yet who are unwilling to allow their personal prescribing patterns to be used for marketing.[30]

The pharmaceutical companies, however, use the data for general marketing and analysis – targeting, tailoring, and measuring effectiveness. Here, there will be an effect, but largely a counterintuitive one. For those prescribers who opt-out, the pharmaceutical companies will lose the data to effectively focus their marketing efforts. The Law does not prevent the pharmaceutical companies from marketing their products and the companies may resort to more general, less tailored marketing, which was the source of prescriber complaint according to FNP MacDonald. It will make the marketing less accurate, since the data will omit the prescribing practices of the cohort which opted out.[31]

Finally, the Law's provisions do not directly address the problem of overly aggressive marketing tactics by drug companies. The law prohibiting unfair trade practices is already on the books in Maine and, in fact, the State has successfully used existing law to correct and curb

[29] The remaining three categories will be unaffected by the Law. Prescribers who refuse to see detailers will not be directly marketed whether they opt-out or not; prescribers who agree to see detailers and do not opt-out will not be affected. It would seem logical that the number of prescribers who opt-out, but are still willing to see detailers would be low, but there is no evidence on this point.

[30] If the prescriber works in a clinic, free samples may well be available anyway. Dr. Steele, who does not meet with detailers, testified that the Family Practice Clinic at the Eastern Maine Medical Center receives free samples. Also, FNP MacDonald testified that she signs for free samples, but she keeps her interaction with the drug representatives to a minimum.

[31] There is no evidence as to whether this will result in declining influence for drug representatives. By its terms, the Law does not prevent pharmaceutical companies or the PDIIs from directly paying prescribers not to opt-out. If a large volume prescriber or an early adopter opted out, the pharmaceutical company would have an incentive to maintain access to the prescriber's data by paying them not to do so. To secure comprehensive, accurate, and unbiased data, the PDIIs might do the same thing for the broader cohort of prescribers. If this took place, the Law, which was concerned with free gifts like coffee cups and writing pads, would have the obverse consequence of encouraging direct payments from pharmaceutical companies and PDIIs to prescribers.

Purdue Pharma's marketing of Oxycontin. More to the point, the Law does not directly apply to pharmaceutical companies. Instead, it subjects the PDIIs to sanctions for what it defines as the drug companies' improper use of prescriber information. A Law that penalizes one person for the misconduct of another cannot be using the most direct approach to achieve its purpose.

d. Ending the Use of Prescriber Comparisons for Purposes Related to Manufacturer Profitability and Decreasing Unnecessary Marketing Costs

The Law seeks to accomplish the goals of ending the use of prescriber comparisons for purposes relating to manufacturer profitability or decreasing unnecessary marketing costs. However, unless all prescribers opt-out (and there is no evidence this will happen), the Law will only successfully limit the number of prescribers whose information is available to the PDIIs and drug companies; it will not end the use of prescriber comparisons. Further, the drug companies use the data to target, tailor, and evaluate their marketing. How requiring a company to market with less specificity decreases its marketing costs is unexplained.

e. Enhancing the Effectiveness of Other Laws

The Legislature lists current laws that it finds will be strengthened by the enactment of this Law: (1) prior authorization and drug utilization review in the MaineCare program under section 3174-M;[32] (2) reporting of a broad array of prescription drug marketing costs under section 2698-A and subsequent reporting by the Department to the Legislature and the Attorney General; (3) prescription drug price disclosure under section 2698-B; (4) generic and therapeutically equivalent substitution of prescription drugs under Title 32, section 13781; and, (5) protection of patient prescription drug information held by health care practitioners under

[32] In *Ayotte*, Judge Barbardoro questioned whether a similar version of this law in New Hampshire conflicted with federal Medicaid law. *Ayotte*, 490 F. Supp. 2d at 183; (citing *Pharm. Research & Mfrs. of Am. v. Meadows*, 304 F.3d 1197, 1201-02 (11th Cir. 2002) (construing 42 U.S.C. § 1396r-8)).

section 1711-C.[33] There is no direct evidence in this record how the Law is intended to promote enforcement of any of these statutes and the Attorney General has not argued the issue.

Based on the evidence in this case, the Court infers that the Law would generally support the legislative policy favoring generic over branded drugs and, in the same sense, it could encourage prescriber use of the drugs on the MaineCare formulary. For some laws, such as the patient confidentiality law, the Court is unconvinced that the challenged portions of the Law would have any impact in promoting enforcement, and for other laws, such as the prescription drug price disclosure provisions, the Court is unable to draw any conclusions based on the evidence.

3. Not More Extensive Than Necessary to Serve The Government Interest

Given the impact the Law has on First Amendment rights, the last criterion requires that the Law be as narrowly tailored as possible to achieve its purposes. Here, the Law substantially fails.

a. Patient Privacy

To the extent the Law attempts to address patient confidentiality, it fails to achieve its purpose. First, the Law is redundant; other state and federal laws, including the earlier version of this Law, already extensively protect patient privacy. Second, the patient information that the Law purports to protect is not protected by the Law; the same patient information that has been

[33] Maine law provides for prior authorization and drug utilization review for the MaineCare program through the establishment by the state Department of Health and Human Services of a formulary using MaineCare's drug utilization review committee. 22 M.R.S.A. § 3174-M(2-A). Maine law requires pharmaceutical companies to file annual reports of the marketing costs for their prescriptive drugs. 22 M.R.S.A. § 2698-A. Maine law mandates that pharmaceutical companies make a quarterly report of their pharmaceutical pricing criteria for each prescription drug dispensed in the state. 22 M.R.S.A. § 2698-B. Under Maine law, every written prescription issued in the state must contain a statement that "[a]ny drug which is the generic and therapeutic equivalent of the drug specified above in this prescription must be dispensed, provided that no check mark ( ) has been handwritten in the box in the lower right-hand corner." 32 M.R.S.A. § 13781 The law thus favors generic drugs over branded drugs and requires the prescriber to act affirmatively to order a branded drug when there is an equivalent generic drug available. Finally, under 22 M.R.S.A. § 1711-C, Maine law has strict rules about patient confidentiality.

shared in the past is still transmitted to the PDIIs, is still made available to a legion of third parties, and is still available to the pharmaceutical companies. Third, the new patient confidentiality provisions of the Law are not under attack and survive this Order. Fourth, once the patient confidentiality provision is excluded, the provisions of the Law that are constitutionally challenged prohibit the sale of prescriber information, not patient-specific information, for marketing purposes.

b. Prescriber Privacy

Although framed as an act to protect prescriber privacy, the Law does not prevent the release of data on the prescribing patterns of Maine prescribers to countless individuals. The Law seeks to prevent PDIIs from allowing drug companies, who otherwise have a legal right to opt-out prescriber information, from marketing those opt-out prescribers with their own data and marketing others with opt-out prescribers' data generally.

c. Decreasing the Influence of Drug Company Representatives

To the extent the Maine Legislature is concerned that drug company representatives are inappropriately influencing Maine prescribers by showering them with gifts in implicit exchange for prescriptions, the Law does not address this concern. The Law does not prevent a detailer from giving gifts, even expensive gifts, to prescribers, whether they opt-out or not. If Maine wishes to restrict drug representatives from giving gifts to prescribers, it could easily do what other states have done: outlaw or restrict such practices.[34] *Ayotte*, 490 F. Supp. 2d at 182 (citing Minn. Stat. Ann. § 151.461 (2007) (prohibiting gifts to prescribers other than free samples of more than $50 in any calendar year), Cal. Health & Safety Code § 119402(d)(1) (2007)

[34] Another possible remedy is to require disclosure of any gifts beyond a certain limit. This is the remedy in the Consent Judgment between the state of Maine and Purdue Pharma. *Def.'s Ex.* 5 (mandating various disclosures of any gift over $25.00 in value).

(requiring each pharmaceutical company to establish a specific annual dollar limit on gifts, promotional materials, or other items or activities)).[35]

The Law allows prescribers to protect themselves from being influenced by their own practice patterns. But, it is notable that, at the same time, the State has licensed these professionals to perform a sophisticated and critical public health function. The State properly requires extensive training and education before it grants prescribers a license to prescribe and entrusts prescribers with significant responsibility on the premise that they possess the intellect and education to perform critical analyses and to exercise scientific judgment.

The same is true of filtered information. Trained as professionals, prescribers have access to a broad range of sources to evaluate whether to prescribe a drug for a particular patient. The expert witnesses testified that they are able to refer to a wealth of medical literature, including peer reviewed articles in medical journals and the Prescribers' Letter, which is a subscriber-based service with no connection to any pharmaceutical firm. They also have access to the internet, to educational presentations by peers, and to the advice of their own colleagues.[36]

The Law does not prevent detailers from continuing to present a sales pitch consistent with a favorable view of their product. Instead, the Law singles out for proscription a particular type of information, which is neither slanted nor filtered: the prescribers' own prescribing patterns. Although the Attorney General and his expert, Dr. Steele, presented evidence that some pharmaceutical companies present inaccurate information to prescribers, there is no evidence that the information that the Law seeks to restrict is untrue or inaccurate. If the Maine Legislature

[35] Although it is not clear it will do so, the Law may ultimately encourage direct cash awards to prescribers who would otherwise opt-out, and increase the influence of drug representatives.

[36] The Plaintiffs argue that one solution lies in the availability of more, not less prescribing information. Thus, they contend that the prescribing patterns of individual prescribers should be generally known, so that their professional decision-making is better informed. Their solution, though consistent generally with freedom of speech, is not constitutionally mandated and raises other concerns that the Maine Legislature, through its hearing process and representative role, is uniquely qualified to assess.

intended only to prevent the presentation of inaccurate information, it has done so by prohibiting the presentation of all opt-out information, accurate or not. As with gifts and patient privacy, to the extent the Law was enacted to prevent detailers from presenting biased information, the Law does not reach the problem it has been enacted to address.

d. Ending the Use of Prescriber Comparisons for Purposes Related to Manufacturer Profitability and Decreasing Unnecessary Marketing Costs

In listing the purposes of the Law, the Maine Legislature stated that it was intended to "end the use of prescriber comparisons for purposes related to manufacturer profitability and decrease unnecessary marketing costs." P.L. 2007, ch. 460, § 1711-E(1-B)(C). The Law does not, however, "end the use of prescriber comparisons"; it only restricts the cohort of prescribers whose information may be available to pharmaceutical companies for marketing purposes.[37]

Regarding the cost issue, Judge Barbadoro observed that "[e]ven the harshest critics of pharmaceutical detailing acknowledge that it is sometimes used in ways that benefit public health." *Ayotte*, 490 F. Supp. 2d at 181. This Court agrees. The evidence establishes that "[n]ot all new drugs are harmful and generic drugs are not always as effective for all patients as brand-name alternatives." *Id.* at 181-82. The evidence demonstrated that some branded drugs end up being more cost effective to the system as a whole than their generic or branded counterparts. The Maine Law does not, however, "discriminate between beneficial detailing and harmful detailing." *Id.* at 182. To ban truthful information about opt-out prescribers' prescription patterns is to overreach and restrict more speech than is necessary to address the problem of harmful detailing. In other words, because some detailing is harmful and increases costs, the Law allows the restriction of the use of truthful information that can be applied for beneficial and

[37]If the Maine Legislature intended to end the use of prescriber comparisons, it could have attempted to outlaw their use. In not doing so, however, the Maine Legislature may have been wise. A law that purported to restrict the range of truthful information a company could use to market its products would itself raise First Amendment concerns.

cost effective detailing. As such, the Law restricts commercial speech and "cannot be sustained [because it is] more extensive than necessary to serve the State's claimed interests . . . ." *Id.* at 182.

e. Enhancing the Effectiveness of Other Laws

The surest way to ensure the effectiveness of an existing law is to enforce it. To enact a new law cannot be the most narrowly tailored means of achieving the legislative goal of enforcing the effectiveness of existing law.

F. Deference to Legislative Acts

The parties have skirmished over whether this Court owes deference to the judgment of the Maine Legislature. The Plaintiffs insist that as a content-based regulation on speech, the Law infringes upon the exercise of First Amendment rights and the Court should accord no deference to the Maine Legislature, especially because the legislative record does not contain "substantial evidence" to justify its findings. *Turner Broad. Sys. v. Federal Commc'ns Comm'n*, 520 U.S. 180, 196 (1997). The Attorney General naturally contends that the Court should defer to the will of the people of Maine as reflected in the acts of their legislature and that, contrary to the Plaintiffs' contentions, the Maine Legislature did base its conclusions on "substantial evidence," thereby entitling its enactment to the deference the courts owe to the Legislature's "authority to exercise the legislative power." *Id.*

Judge Barbadoro, addressing the same question, concluded that the New Hampshire Legislature's "predictive judgments" were entitled to respect, but not deference, because there was nothing in the record "to support a conclusion that the legislature had established expertise in the regulation of prescriber-identifiable data." *Ayotte*, 490 F. Supp. 2d at 177 n.12. Under either analysis, at a minimum, this Court is required to accord respect to the enactments of the

state legislature. "Principles of federalism and separation of powers counsel respect for the . . . legislature at all times . . . ." *Id.*

The distinction between judicial deference and judicial respect to a legislature in a First Amendment case is subtle and does not carry the day in this controversy. *Sable Communications* explains that a court's deference extends only to legislative findings and does not "foreclose . . . independent judgment of the facts bearing on an issue of constitutional law . . . ." *Sable Commc'ns of California, Inc. v. Federal Commc'ns Comm'n, Inc.*, 492 U.S. 115, 129 (1989). At the same time, the "obligation to exercise independent judgment when First Amendment rights are implicated is not a license to reweigh the evidence *de novo*, or to replace [legislative] factual predictions with our own. Rather, it is to assure that, in formulating its judgments, [the legislature] has drawn reasonable inferences based on substantial evidence." *Turner*, 512 U.S. at 666.

Here, the resolution of this case does not turn on the close distinction between deference to findings and respect for the enactments of the legislative branch and it is unnecessary, therefore, to parse the language of the legislative findings, to analyze the testimony in hearings before the Maine Legislature, and to make a judicial judgment on the Maine Legislature's "empirical support or . . . sound reasoning on behalf of its measures." *Id.* (quoting *Century Commc'ns Corp. v. Federal Commc'ns Comm'n*, 835 F.2d 292, 304 (D.C. Cir. 1987)). The result, using either standard, is the same.

G. The Statute's Impact

1. The Expense of Compliance

The three PDII plaintiffs are making efforts to comply with the new Maine Law which includes a degree of complexity not present in the New Hampshire law. The Law allows

prescribers to opt-out and, therefore, instead of creating a system whereby all data from all Maine prescribers would be eliminated from the database, the PDIIs are attempting to create software that will allow the inclusion of the prescribers who do not opt-out and the exclusion of those who do. This data will have to be continually updated to make certain it captures new information that the PDIIs will receive from the Maine licensing boards. Mr. Sadak of IMS testified that it currently has thirty people working on a solution that will comply with the Maine Law and he anticipates IMS will spend hundreds of thousands of dollars complying. Carol Livingston of Source Healthcare testified that it has expended about 10,000 hours in its efforts to comply with the new Maine Law.[38] Ms. Livingston also expressed the concern that if Source Healthcare is required to either sell a product with incomplete information or to restrict the use of its product, its customers could view its product as less valuable and demand reduced fees.

2. The Risk of Non-Compliance

The risk of non-compliance is a civil penalty for each intentional violation not to exceed $10,000.00 plus the possible entry of a court order enjoining the PDII from practices that cause non-compliance. 22 M.R.S.A. § 1711-E(3); 5 M.R.S.A. § 209.

3. The PDIIs' Opt-Out Alternative

If incomplete data were limited only to marketing, as the Law intends, the impact of the skewed data would be limited. But, the Law has the potential of generating a more significant consequence: incomplete data for investigative and regulatory purposes. There is no law that compels the PDIIs to collect prescription information from prescribers in the state of Maine. They do so because it is in their financial interest. In turn, they provide the data free of charge to

[38] There is no direct evidence on the efforts of Verispan, LLC, the third plaintiff, to comply with the new Maine Law.

public interest groups, such as academics and governmental authorities, because they are public spirited.

However, the Law creates a substantial risk for PDIIs if they fail to comply with its provisions. The Law assumes that the PDIIs will continue to collect data about opt-out physicians, but would screen that data, so that it is not transferred to pharmaceutical companies for marketing. Yet, at the same time, the Law contemplates that the PDIIs will continue to collect, collate, and transmit all prescriber information to third parties such as governmental agencies and academic researchers.

One alternative for PDIIs would be to entirely eliminate all opt-out prescribers in Maine from their database. This would vastly simplify the process for the PDIIs, since they will otherwise have to retain two types of data – one they can transfer to the pharmaceutical companies without restriction and one they cannot transfer for marketing purposes. The elimination of opt-out prescribers would minimize the risk of a costly mistake. If the PDIIs wholly eliminate opt-out prescribers' data, this data would not be readily available to anyone, including the regulatory agencies.[39] If this happened, the prescription data upon which the government and other third parties rely to track and analyze prescribing patterns would be compromised, since it would omit a significant cohort in Maine.[40] Further, the remaining sources of data would include Medicaid, Medicare, and insurers. These information sources have patient populations with identifiable characteristics and restricted formularies; both factors would further skew the accuracy of the data.

[39] There may be alternative sources for this data, but the PDIIs' value is standardization, speed, and organization; there is no evidence in this record that there are readily available parties that could produce the same information as quickly and efficiently as the PDIIs.

[40] It is speculative which prescribers will opt-out. Nevertheless, prescribers with the potential of being labeled as outliers, such as physicians who prescribe high amounts of Oxycontin or Methadone, would have an added incentive to opt-out, if only to limit the universe of individuals who have access to their prescribing histories. This incentive would be even more acute if the prescribers knew that by opting out, their prescribing patterns would be excluded from the data the PDIIs send government oversight agencies.

4. The Significance of Maine Data

During the hearing, the Attorney General repeatedly made the point through cross-examination that the statistical significance of data from Maine prescribers is minimal. IMS, for example, tracks a total of approximately 1,400,000 prescribers and there are only 7500 prescribers currently prescribing in Maine and an additional 1600 prescribers licensed in Maine who are practicing outside the state. The point was that the true impact of the omission of Maine opt-out prescribers' data from the entire universe of prescribers' data would be minuscule. As far as it goes, the Attorney General's point is well taken: the national impact would be trivial.[41]

But, the potential impact within the state of Maine itself could be significant. With only 7500 active prescribers in the entire state, as the opt-out numbers increase, the chance increases that some sub-disciplines will be entirely unavailable for marketing purposes thereby making the omission more significant. Further, given the small numbers in Maine, the likelihood also increases that the PDIIs will not collect any data on opt-out prescribers.

H. The Criteria for Injunctive Relief

The Court analyzes a request for a preliminary injunction through application of the following four well-established factors:

> (1) the likelihood of success on the merits;
> (2) the potential for irreparable harm [to the movant] if the injunction is denied;
> (3) the balance of relevant impositions, i.e. the hardship to the nonmovant if enjoined as contrasted with the hardship to the movant if no injunction issues; and,
> (4) the effect (if any) of the ruling on the public interest.

Esso Standard Oil Co. v. Monroig-Zayas, 445 F.3d 13, 18 (1st Cir. 2006) (quoting *Bl(a)ck Tea Soc'y v. City of Boston*, 378 F.3d 8, 11 (1st Cir. 2004)). In evaluating a motion for preliminary

[41] Mr. Sadak testified that in addition to Vermont, New Hampshire, and Maine, there are seventeen to twenty other states considering similar legislation. If enough states enacted similar laws, the accumulative impact would be different. What other states will actually do, however, is speculative.

injunction in which the plaintiffs are claiming constitutional infirmity, the court must presume that the challenged act is constitutional. *Davies Warehouse Co. v. Bowles*, 321 U.S. 144, 153 (1944) ("State statutes, like federal ones, are entitled to the presumption of constitutionality until their invalidity is judicially declared."). The Plaintiff must "shoulder[] the burden of overcoming that presumption." *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 661-62 (2003); *Nieves-Marquez v. Puerto Rico*, 353 F.3d 108, 120 (1st Cir. 2003).

1. Likelihood of Success on the Merits

The Court concludes that the Plaintiffs have a reasonable likelihood of success on the merits on their First Amendment claim. The Court does not reach the Plaintiffs' remaining claims.

2. Irreparable Harm

The "loss of First Amendment freedoms for even minimal periods of time, unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 374 (1976); *Asociacion de Educacion Privada de P.R., Inc. v. Garcia-Padilla*, 490 F.3d 1, 21 (1st Cir. 2007); *Bla(a)ck Tea Soc'y*, 378 F.3d at 15 ("A burden on protected speech always causes some degree of irreparable harm.").

3. Balance of Equities

The balance of the equities supports the granting of a preliminary injunction. The Court is required to evaluate what the First Circuit terms the "balance of relevant impositions," an assessment of "the hardship to the nonmovant if enjoined as contrasted with the hardships to the movant if no injunction is granted." *Esso Standard Oil Co*, 445 F.3d at 18 (quoting *Bl(a)ck Tea*, 378 F.3d at 11). In this case, the injunction maintains the status quo.[42] The main hardship to the

[42] In *Crowley*, the First Circuit found that the "traditional function of the preliminary injunction is to preserve the status quo . . . so that the court may retain its ability to render a meaningful decision on the merits." *Crowley v.*

state of Maine is a delay in the application of the new Law. The impact on the Plaintiffs is to require the expenditure of considerable sums of money, to alter computer and software applications, to find and delete the subset of opt-out data and to maintain the accuracy of a changing opt-out list, to renegotiate their contracts with their drug company customers to prevent the drug companies improper use of the opt-out data, and to assume a policing role over their customers to attempt to assure their compliance with a Law that does not apply to them. The balance of equities weighs in favor of the Plaintiffs.

4. Public Interest

The final factor is the public interest. This factor requires the court to "inquire whether there are public interests beyond the private interests of the litigants that would be affected by the issuance or denial of injunctive relief." *Everett J. Prescott, Inc. v. Ross*, 383 F. Supp. 2d 180, 193 (D. Me. 2005). *See also Bl(a)ck Tea*, 378 F.3d at 15 ("[A] determination of the public interest necessarily encompasses the practical effects of granting or denying preliminary injunctive relief."). Here, the public interest in the immediate enforcement of the Law is outweighed by the countervailing public interest in free speech.

III. CONCLUSION

In light of *Ayotte*, the Court returns to its original question: Whether the opt-out provision of the Maine Law makes a difference. The Court concludes it does not. The notion that prescribers have the legal right to restrict access to their own work product is appealing and

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Furniture & Piano Moving, Furniture Store Drivers, etc., 679 F.2d 978, 995 (1st Cir. 1982) (citation omitted). *See also Celebrity, Inc. v. Trina, Inc.*, 264 F.2d 956, 958 (1st Cir. 1959) ("[T]here is traditionally less reluctance to issue a preliminary injunction merely prohibitory in form that is aimed at preserving the status quo . . . ."). The status quo is the "last uncontested status which preceded the pending controversy." *Crowley*, 679 F.2d at 995, (citing *Westinghouse Electric Corp. v. Free Sewing Machine Co.*, 256 F.2d 806, 808 (7th Cir. 1958)). However, "the relevant First Circuit authority does no more than suggest that courts disfavor injunctions that disturb, rather than preserve, the status quo." *United Steelworkers v. Textron, Inc.*, 836 F.2d 6, 10 (1st Cir. 1987). In any event, "the status quo doctrine is one of equity, discretion, and common sense, not woodenly to be followed." *Aoude v. Mobil Oil Corp.*, 862 F.2d 890, 893 (1st Cir. 1988).

the opt-out provision in the Maine Law makes the question closer than the one Judge Barbadoro addressed in *Ayotte*.[43] Nevertheless, at its heart, the Law operates by making illegal the transfer of truthful commercial information for particular uses and disclosures and, as such, the Law must withstand intermediate scrutiny. Tracking the prescribed intermediate scrutiny analysis, the Court concludes that the provisions of the Maine Law that seek to restrict the use and disclosure of commercial information violate the free speech guarantee of the First Amendment.

The Court is required to issue as narrow a ruling as possible.[44] A number of the Law's provisions remain unaffected by this Order, since they do not implicate the exercise of First Amendment rights:[45]

(1) The definitional provisions, 22 M.R.S.A. § 1711-E(1)(A)-(I);

(2) the legislative findings and purposes, 22 M.R.S.A. § 1711-E(1-A) & (1-B);

(3) the patient confidentiality provision, 22 M.R.S.A. § 1711-E(2);

(4) the enforcement provisions of 22 M.R.S.A. § 1711-E(3) insofar as they relate to a violation of 22 M.R.S.A. § 1711-E(2);

(5) the rule-making provisions of 22 M.R.S.A. § 1711-E(5) to the extent the section addresses § 1711-E(2);

(6) the annual report provisions of 22 M.R.S.A. § 8704(7); and,

(7) the funding provisions of P.L. 2007, ch. 460, §§ 5 and 6.

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[43] The opt-out option came up during the oral argument in the New Hampshire case and Judge Barbadoro suggested as much. *See Def.'s Ex*. 9.

[44] None of the parties suggested that the Law presents difficult questions of statutory interpretation that, if presented to a state of Maine court, would save the statute by rendering a definitive and potentially constitutional construction. *Bd. of Airport Comm'rs v. Jews for Jesus, Inc.*, 482 U.S. 569, 575-76 (1989). Neither abstention nor certification applies. *See Sullivan v. City of Augusta*, 2007 U.S. App. LEXIS 29181, at *76-77 (1st Cir. Dec. 14, 2007).

[45] In their Complaint, the Plaintiffs also seek a permanent injunction. They have not, however, moved for the issuance of a permanent injunction. It is the Court's current view that further action should await the First Circuit's ruling on *Ayotte*, since it may resolve many issues critical to this Order and the further disposition of the case. The Court will hold a telephone conference with counsel to discuss the status of the case.

Because the Law amounts to an unconstitutional abridgement of the First Amendment of the United States Constitution, the Court grants the Plaintiff's motion for a preliminary injunction as to the following statutory provisions:[46]

(1) 22 M.R.S.A. § 1711-E(2-A), regarding the confidentiality of prescription drug information that identifies the prescriber;

(2) 22 M.R.S.A. § 1711-E(3), regarding enforcement, but only to the extent it provides for enforcement of violations of provisions other than § 1711-E(2);

(3) 22 M.R.S.A. § 1711-E(4);

(4) 22 M.R.S.A. § 1711-E(5), regarding rule-making authority, but only to the extent it affects provisions other than § 1711-E(2);

(5) 22 M.R.S.A. § 8704(4), regarding rulemaking, but only to the extent it affects provisions other than § 1711-E(2); and,

(6) 22 M.R.S.A. § 8713, regarding confidentiality protection for certain health care practitioners.

SO ORDERED.

/s/ John A. Woodcock, Jr.
JOHN A. WOODCOCK, JR.
UNITED STATES DISTRICT JUDGE

Dated this 2nd day of January, 2008

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[46] The Court DENIES Defendant's Motion to Strike Portions of Declarations. (Docket # 33).

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