

NO. 08-1248

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

IMS HEALTH INCORPORATED, ET AL.,
Plaintiffs-Appellees,

v.

JANET T. MILLS, as Attorney General for the State of Maine,
Defendant-Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

BRIEF OF DEFENDANT-APPELLANT

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JURISDICTIONAL STATEMENT

The Attorney General of Maine appeals from interlocutory orders of the district court (Woodcock, J.) entered on December 21, 2007 (Order on Plaintiffs' Motion for Preliminary Injunction), January 2, 2008 (Amended Order on Plaintiffs' Motion for Preliminary Injunction), and February 15, 2008 (Order on Motion to Amend Judgment). The lower court granted preliminary injunctive relief to plaintiffs in their action challenging the constitutionality of certain aspects of L.D. 4, An Act to Amend the Prescription Privacy Law (the "Act" or the "Prescription Privacy Law"). *IMS Health, Inc. v. Rowe*, 532 F. Supp. 2d 153, 157 (D. Me. 2008).¹ The Act prohibits the sale or use of prescription drug data for marketing purposes when the prescriber has elected to keep that data from being used in that fashion.

Jurisdiction in the district court is pursuant to 28 U.S.C. §§ 1331 and 1343. Jurisdiction on appeal is pursuant to 28 U.S.C. § 1292(a)(1). Notice of Appeal was timely filed by the Attorney General on February 25, 2008.

STATEMENT OF ISSUES PRESENTED

1. Whether the district court erred in holding that plaintiffs are likely to succeed on the merits of their claim that the Act violates the First Amendment.

¹ The Attorney General of Maine is now Janet T. Mills. The Addendum to this Brief, at A93-A98, contains the Act in its entirety. It also contains the three interlocutory orders that are being appealed.

2. Whether plaintiffs failed to demonstrate a reasonable likelihood of success on the merits of their claim that the Act is constitutionally void for vagueness and is overbroad.

3. Whether plaintiffs failed to demonstrate a reasonable likelihood of success on merits of their claim that the Act violates the dormant Commerce Clause.

4. Whether the district court erred in ruling that plaintiffs will suffer irreparable harm without a preliminary injunction, and that the “balance of equities” and “public interest” prongs of the preliminary injunction test weigh in favor of granting preliminary injunctive relief.

STATEMENT OF THE CASE

In June 2007, after devoting substantial time to investigating the relationship between health care costs, prescription drug marketing, and the safety of Maine people, the Maine Legislature enacted the Prescription Privacy Law. The Act enables prescribers to opt out of the sale or use of their prescribing practices for marketing purposes. The Legislature’s expressly stated purposes in enacting this bill were (A) to limit annual increases in the cost of health care, (B) to improve the public health, and (C) to protect the privacy of patients and prescribers in Maine’s health care system.

The Act's key provision states that:

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.

22 M.R.S. § 1711-E(2-A). Thus, the Act prohibits the sale or use of prescription drug data for marketing purposes when the prescriber has elected to keep that information from being used for those purposes. The Act does not restrict the sale or use of this data for non-marketing purposes, such as health care research.

Maine is one of three states (along with New Hampshire and Vermont) that recently have enacted laws regulating the use of prescription drug data when used for certain marketing or commercial purposes. Only the Maine law features the “opt-out” provision.² New Hampshire’s law is a straight prohibition on the sale or use of such data for commercial purposes, whereas Vermont’s statute has an “opt-in” feature (more restrictive than Maine’s law in that the default in Vermont is a prohibition on the sale or use) and also imposes disclosure requirements on a drug company’s sales representatives.³ These three states have determined that this data

² The Maine Act imposes only a civil penalty for intentional violations, whereas New Hampshire’s law provides for potential criminal penalties.

³ Vermont’s law prohibits pharmacies and other “covered entities” (a defined term that does not include so-called “data miners” such as plaintiffs) from selling or using prescriber-identifiable data for marketing or promoting prescription drugs unless the prescriber consents. 18 V.S.A. § 4631(d). The law also prohibits drug

is being used by the pharmaceutical industry to induce physicians to prescribe expensive, brand-name drugs in place of equally effective, but less costly, generic drugs.

IMS Health, Inc. (“IMS”), Verispan, LLC (“Verispan”), and Source Healthcare Analytics, Inc., which are in the business of harvesting, refining, and selling prescriber-identifiable data to the pharmaceutical industry, commenced this action in the United States District Court for the District of Maine on August 29, 2007. Plaintiffs asked the lower court to preliminarily enjoin enforcement of certain provisions of the Act on the basis that they violate the First Amendment, the dormant Commerce Clause, and the Due Process Clause of the United States Constitution.

The lower court granted the motion for preliminary injunction on December 21, 2007, then amended its injunction *sua sponte* on January 2, 2008, to make a few minor changes. *Rowe*, 532 F. Supp. 2d at 157 n.1 & 183. In preliminarily ruling that plaintiffs had shown a reasonable likelihood of success on the merits of their First Amendment claim, the lower court closely tracked the reasoning of the New Hampshire district court in *IMS Health, Inc. v. Ayotte*, 490 F. Supp. 2d 163 (D.N.H. 2007), *rev’d*, 550 F.3d 42 (1st Cir. 2008), *cert. denied*, 129 S. Ct. 2864 (June 29, 2009). The lower court also held that plaintiffs had shown irreparable

manufacturers and drug marketers from using prescriber-identifiable data for marketing prescription drugs unless the prescriber consents. *Id.*

harm and that the balance of equities supported a preliminary injunction. *Rowe*, 532 F. Supp. 2d at 181-182. The trial court did not reach plaintiffs' other legal theories, although Judge Woodcock did tell the parties at the start of the hearing in November 2007 that he "was not particularly impressed with either the vagueness or overbreadth or commerce clause contentions." (Transcript of Proceedings on Motion for Preliminary Injunction ("Tr.") at 7).

On December 28, 2007, the Attorney General filed a motion to amend the preliminary injunction to allow State of Maine agencies to engage in the non-enforcement activities provided for by the Act. (Docket Item 72). The district court granted the motion. *IMS Health, Inc. v. Rowe*, 532 F. Supp. 2d 183 (D. Me. 2008). Notice of Appeal was timely filed. (Docket Item 82).

The Attorney General's appeal was stayed by this Court pending the final disposition of plaintiffs' challenge to the New Hampshire law that prohibits the sale or use of prescription drug data for certain commercial purposes. On November 18, 2008, this Court reversed the lower court in *Ayotte* and held in New Hampshire's favor. This Court held that (A) the New Hampshire law principally regulated conduct, not speech, and (B) even assuming the law did implicate the First Amendment, it satisfied the Supreme Court's test for regulation of commercial speech. *Ayotte*, 550 F.3d at 45, 54-60. This Court also rejected plaintiffs' other constitutional challenges to New Hampshire's law, ruling that it was not void-for-vagueness or overbroad and did not violate the dormant

Commerce Clause. The Supreme Court denied plaintiffs' petition for a writ of *certiorari* on June 29, 2009. *Id.*, 129 S. Ct. 2864. With the *Ayotte* litigation completed, the Attorney General of Maine presses her appeal of the preliminary injunction entered by the lower court.

STATEMENT OF FACTS

A lucrative market has developed in the last 15 years involving the sale of bulk data that identify the prescribing practices of health care practitioners ("prescriber-identifiable data"). (Joint Appendix ("App.") 402-405). *Ayotte*, 550 F.3d at 45-46; *Rowe*, 532 F. Supp. 2d at 158. Data mining companies such as plaintiffs are willing to pay pharmacies and others large sums of money to acquire this data. (App. 274-276, 283-285). *Rowe*, 532 F. Supp. 2d at 158. These data mining companies then refine the data and combine it with data they obtain from other sources, including the American Medical Association ("AMA"), and sell or license this aggregated data primarily to drug manufacturers. (App. 274-276, 283-285, 407). *Rowe*, 532 F. Supp. 2d at 158.

The drug companies use this data to target prescribers for their marketing, typically without the prescriber even knowing the drug company has this information. *Rowe*, 532 F. Supp. 2d at 159-160. (App. 409-410). According to former Pfizer and Eli Lilly drug company sales representative James Reidy, this

data is “our greatest tool in planning our approach to manipulating doctors.” (App. 642-643).

The data mining industry

Prescriptions are written for approximately 8,000 different drugs in the United States. *Ayotte*, 490 F. Supp. 2d at 165. Approximately 1.4 million licensed practitioners are authorized to write prescriptions in the United States. *Id.*

Generally, patients get their prescriptions filled at retail pharmacies and provide personal information to the pharmacies as part of that process. (App. 283-284).

Retail pharmacies thereby acquire prescriber-identifiable data in the regular course of their business of filling prescriptions.

Without the consent or knowledge of prescribers or patients, pharmacies then sell prescriber-identifiable data to plaintiffs for a hefty fee. *Id.* (App. 407, 819-820, 834-835). The data sold by pharmacies to plaintiffs include the drug name, the form, strength, and dosage of the drug, the quantity dispensed, a patient identifier (gender and year of birth, though the patient’s name is encrypted), and the name and address of the prescriber. (App. 283-284). *Rowe*, 532 F. Supp. 2d at 158. This is data the pharmacies have obtained from health care professionals directly or from patients when their prescriptions are filled. (App. 283-284). *Rowe*, 532 F. Supp. 2d at 158.

Data mining companies combine the data they obtain from pharmacies (and other suppliers) with data they have collected from other sources, including the AMA's "Physician Masterfile." *Ayotte*, 490 F. Supp. 2d at 165. The AMA's Masterfile contains substantial amounts of personal information about the roughly 850,000 physicians in the United States. *Id.* Without the consent of these physicians, the AMA provides this data to plaintiffs in exchange for more than \$40 million annually. (App. 633, 646).

This detailed prescriber-identifiable data would thus show hypothetically, for example, that Dr. Janet Johnson of Bar Harbor, Maine, prescribed Lipitor to Patient #1234, a 52 year-old man who lives in downeast Maine, and who had the prescription filled on June 30, 2008, at the Rite-Aid in Ellsworth, Maine. (Tr. 221-222). Data mining companies can track how often Dr. Johnson prescribed Lipitor and how often she prescribed other cholesterol-reducing drugs. Plaintiffs are also able to track all drugs that have been dispensed to a particular (name-encrypted) person (such as Patient #1234), and identify all the doctors who wrote prescriptions for Patient # 1234. The diagnoses of patients can often be inferred. (Tr. 19).

Plaintiffs then sell or license this combined data primarily to drug manufacturers, again without the prescribers' or the patients' consent, for enormous sums of money. (App. 407, 692-694). *Rowe*, 532 F. Supp. 2d at 158. The drug companies use the data to target prescribers for their marketing. *Rowe*,

532 F. Supp. 2d at 158. Plaintiffs contractually bar the drug companies from further disclosing this data to anyone else— even to the prescribers. (Tr. 53-55). *IMS Health, Inc. v. Sorrell*, 2009 U.S. Dist. LEXIS 35594, at * 39 n.15 (D. Vt. Apr. 23, 2009).⁴

Many prescribers are neither informed nor aware that pharmacies are selling their work product for substantial sums. *See Rowe*, 532 F. Supp. 2d at 161-162. (App. 402-405, 409-411). A survey by the Kaiser Family Foundation in 2001 found that nearly 75% of physicians who were polled disapproved of this practice. (National Survey of Physicians Part II: Doctors and Prescription Drugs. Kaiser Family Foundation, available at <http://www.kff.org/rxdrugs/upload/Highlights-and-Chartpack.pdf>). A poll commissioned by the AMA in 2004 found that two-thirds of the doctors surveyed objected to the release of such data to drug company representatives. (App. 410). In short, many prescribers find the practice of marketing using their prescribing information as intrusive and unhelpful.

The drug industry's vast marketing machine

Drug companies spend billions of dollars annually marketing their drugs to doctors, in part using prescribers' individualized data. *Rowe*, 532 F. Supp. 2d at 59 (\$4 billion in direct-to-physician marketing); *Sorrell*, 2009 U.S. Dist. LEXIS 35594, at *5. The marketing directed at prescribers includes one-on-one sales

⁴ IMS Health and the other plaintiffs have appealed the Vermont decision.

pitches by sale representatives,⁵ providing gifts and free samples, presenting and sponsoring physician meetings and events, and advertising in medical journals. *Ayotte*, 490 F. Supp. 2d at 167-69; *Sorrell*, 2009 U.S. Dist. LEXIS 35594, at *5-6; Puneet Manchanda & Elisabeth Honka, *The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review*, 5 Yale J. Health Pol., L. & Ethics 785, 785-786 (2005) (“Manchanda & Honka”).⁶

Drug companies use drug samples, gifts, free meals and entertainment, and other inducements both to overcome prescribers’ reluctance to meet with detailers and to persuade them to prescribe their drugs. (App. 697, 784-787, 845-846). *Rowe*, 532 F. Supp. 2d at 160-161. Free samples alone are an important tool to promote sales by familiarizing prescribers with a company’s drugs and increasing the likelihood that patients will continue on that drug after the samples are exhausted. (Tr. 61, 281-282; App. 844-847). *Sorrell*, 2009 U.S. Dist. LEXIS 35594, at * 5 n.2.

These inducements make prescribers more receptive to detailers’ sales pitches. (App. 623-630, 784-787). *Sorrell*, 2009 U.S. Dist. LEXIS 35594, at *35.

As this Court noted recently in *Ayotte*:

⁵ The activity of drug company sales representatives visiting prescribers and their offices is referred to as “detailing.” Sales representatives are sometimes called “detailers.” The Attorney General will refer to them as “sales reps” or “detailers.”

⁶ This Court in *Ayotte* relied upon the Manchanda and Honka article. *Ayotte*, 550 F.3d at 56; *see also id.* at 71-72 (Lipez, J., concurring in part and dissenting in part).

pharmaceutical companies use detailing to promote the sale of brand-name drugs, and those drugs cost significantly more than their generic counterparts. Detailing works: that it succeeds in inducing physicians to prescribe larger quantities of brand-name drugs seems clear (even if the exact magnitude of that effect is not).

Ayotte, 550 F.3d at 56 (footnote omitted). *See also id.* at 89 (Lipez, J., concurring in part and dissenting in part); *Manchanda & Honka* at 809.

Uses of prescriber-identifiable data in detailing

The practice of buying prescription records from pharmacies has allowed detailers to pinpoint the prescribing practices of individual physicians, enabling the drug companies to better target their marketing efforts. *Ayotte*, 490 F. Supp. 2d at 170. Visits by detailers can be specifically tailored to reinforce the prescriber's preference for the manufacturer's product or to influence a switch from another drug to that company's drug. Drug companies also use prescriber-identifiable data to tailor their marketing messages to the individual practitioners and to reward those prescribers who respond. *Id.* Finally, drug companies use prescriber-identifiable data to measure the effectiveness of their customized marketing tactics – including for purposes of determining the compensation and bonuses of detailers. *Id.* at 171.

Detrimental aspects of detailing

Drug detailing can be detrimental. As the Maine Legislature learned when considering this law, one study revealed that 15% of the detailers' promotional

brochures presented data that differed from the published studies on which they were based. (App. 627). The lower court noted another study that concluded that about one-third of the drug companies' marketing material contained information proscribed by the FDA. *Rowe*, 532 F. Supp. 2d at 161.

The flawed nature of drug marketing goes beyond providing inaccurate information. Because the purpose of marketing is to increase sales of that company's product, the information that detailers present to prescribers is not a fair and balanced presentation of the medical literature as a whole concerning the drugs at issue. (App. 627). The record shows that targeted marketing campaigns by the drug industry using prescriber-identifiable data focus on aggressively promoting the widespread use of new drugs as soon as they are available. (App. 412-440, 623-630).

In 2005, Congress held hearings regarding sales of the drug Vioxx. A May 2005 U.S. House of Representative Memorandum summarized the results of a Committee on Government Reform investigation of how Merck marketed Vioxx to physicians. (App. 412-440). For Vioxx alone, the company assigned over 3,000 company representatives across the country to engage in face-to-face discussions with physicians about Vioxx. (App. 418). Merck's detailers – armed with highly detailed information about doctors' prescribing habits -- did not appropriately educate physicians about research that demonstrated Vioxx's cardiovascular risks.

To the contrary, Merck’s highly trained sales force was told not to address the new research findings, but to emphasize outdated and misleading data that indicated Vioxx was safer than alternatives. (App. 414-415). The Legislature was reminded about the Vioxx debacle by Dr. Jerry Avorn, “a renowned expert on the effects of pharmaceutical marketing on drug utilization and behaviors,” *Ayotte*, 490 F. Supp. 2d at 52 n.16. (App. 626-627). The lower court noted the Vioxx problem, as well as statements by a drug company demonstrating the inherently *quid pro quo* nature of detailing – e.g., Novo Nordisk urged its detailers to “hold [doctors] accountable for samples, dinners, programs and past preceptorships that you have provided or paid for and get the business.” *Rowe*, 532 F. Supp. 2d at 161.⁷

AMA creates modified opt-out program to stave off curative legislation

By the early 2000s, some physicians were complaining vehemently about the fact that the drug industry was using prescriber-identifiable data to market

⁷ In a more recent case approved by the Maine Superior Court in 2007, also referenced by the lower court, Purdue Pharma entered into a consent judgment and paid \$19.5 million to settle claims by Maine (among other states) that it had unfairly and deceptively marketed the drug OxyContin. (App. 441-464). Maine alleged, among other things, that (1) Purdue and its sales force aggressively promoted OxyContin to doctors, nurses, and consumers as a first-choice analgesic for treatment of a wide variety of pain symptoms; (2) while expanding the market for OxyContin, Purdue avoided and minimized the known risks of OxyContin abuse, addiction, and diversion; and (3) Purdue failed to adequately warn doctors or consumers of OxyContin’s significant risks and failed to take reasonable steps to guard against OxyContin abuse and diversion, instead striving to “educate” doctors and consumers that concerns over abuse and diversion of OxyContin were misplaced. (App. 465-478).

drugs to them without their consent. (App. 402-405, 409-411). In 2004, several national and state medical societies, led by the American College of Physicians, asked the AMA to prohibit the release of its physician prescribing information. (App. 404). In response to physicians' concerns, the AMA commissioned a poll, which, as noted above, found that two-thirds of the doctors surveyed objected to the release of such data to detailers. (App. 410). The AMA has an obvious vested interest in the status quo, as it receives more than \$40 million annually from the sale or license of the data in its physician databases to plaintiffs and others. (App. 633, 646).

In July 2006, after discussions with the data mining industry, the AMA fashioned a limited "opt-out" program to prevent certain data from being shared directly with detailers. (App. 403-404). The AMA acted with the express goal of heading off legislative efforts to restrict the sale of prescriber-identifiable data for marketing purposes. (App. 402). The AMA program was implemented by amending the agreements between plaintiffs and drug companies to include these limitations. (App. 403-405).

The AMA's program (named the Prescribing Data Restriction Program, or "PDRP") does not stop prescriber-identifiable data from being used for marketing purposes. First, the PDRP does not limit prescriber profiling; it only restricts first-hand access to that data by the detailer and his or her supervisor. There is

otherwise no limit on the use of this data for marketing. (App. 403, 858-859).

Thus, while the detailer who contacts a physician who has chosen to opt-out under the PDRP is not allowed to have the actual data, the detailer's employer is permitted to have this data and use it for marketing purposes. (App. 403, 858-859). That is, the physician will still be targeted by the detailer based on prescriber-identifiable data, but the targeting decision will be made by someone other than the detailer. (App. 402-405). In addition, physicians' assistants, nurse practitioners, and nurse midwives in Maine are not eligible for the PDRP. (App. 402-405; Tr. 444-445). Moreover, roughly two-thirds of the physicians in the United States are not AMA members, even though their personal data are still included in the AMA's Masterfile. (App. 591). Many physicians are not even aware of the PDRP. (App. 591). Finally, the PDRP's sanctions for violations are toothless -- the sanction for even a pattern of repeated abuse is merely the potential loss of data. "Those manufacturers who show a disregard for the program's requirements by maintaining a pattern of abuse may lose access to AMA data, and, if infractions continue, may subsequently lose access to HIO data." (App. 403) (emphases added).⁸

⁸ The PDRP has been criticized for other reasons. *Ayotte*, 550 F.3d at 74; *Sorrell*, 2009 U.S. Dist. LEXIS 35594, at * 42.

Maine's response -- An Act to Amend the Prescription Privacy Law

On June 29, 2007, after a legislative process lasting more than six months, including a public hearing held in March 2007 and five work sessions held by the Joint Committee on Health and Human Services, "An Act to Amend the Prescription Privacy Law" became law. As noted above, Maine is one of three states that have enacted laws since 2006 restricting the use of prescriber-identifiable data for marketing or commercial purposes. Close to 20 other states have considered similar legislation. (Tr. 100-101). Thus, Maine is part of a national movement.

The Act was the product of two bills before the Legislature: L.D. 4 and L.D. 838. Both bills addressed concerns over the confidentiality of prescriber-specific and patient-specific information. (App. 550-564, 590-591). From the outset, the bills were designed to reduce prescription drug costs, to safeguard public health by making prescribing decisions based more on science and medicine, and to protect the confidentiality of prescribers and patients.

The Act's key provision (22 M.R.S. § 1711-E(2-A)) states that:

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 in accordance with subsection 4.

Under the Act, a violation of this provision is a violation of the Maine Unfair Trade Practices Act (“UTPA”). Under the UTPA, each intentional violation is subject to a penalty of no more than \$10,000. 5 M.R.S. § 209.

Thus, the Act provides Maine doctors and other prescribers with a limited right over the prescriptions they write for their patients -- the right to elect to prohibit the covered entities from selling or using, for any marketing purpose, prescription drug data that identify them or their patients.⁹ Notably, the Act does not restrict the use of any prescription drug data for non-marketing purposes, such as health care research.

The information subject to the Act is raw data about Maine prescriptions written by prescribers licensed by Maine. These Maine prescriptions are filled by pharmacies located in Maine or with nexus to Maine -- one of the pharmacies is located exclusively in Maine. (App. 683, 698, 750). These pharmacies then enter this data into computers located in Maine. (App. 816-819, 831-834). These same Maine prescriptions are generally paid for in part by insurance carriers licensed and regulated by Maine. The data gleaned from these prescriptions are then used for marketing drugs to these same Maine prescribers. Thus, as shown below, and

⁹ The election is typically accomplished when prescribers register with their licensing boards, though that is not the exclusive means for opting out. The election is valid until revoked by the prescriber.

contrary to plaintiffs' claim, the Act will not control commerce that takes place wholly outside of the State.

Maine physicians and others advocate in favor of the bills

The two bills were the subject of a public hearing before the Legislature's Joint Committee on Health and Human Services (the "Committee") in March 2007. (App. 526). The legislative record shows that the Committee heard testimony and received documents from a broad range of interested parties, including those opposed to the legislation, such as plaintiff IMS (App. 594-595, 602-607), Rite-Aid (App. 608), and the AMA (App. 672-675).

As plaintiffs concede, a substantial number of physicians supported these bills, as did a national physician organization with thousands of members. (App. 97-100, 278, 287, 292, 597-600, 631-637, 645-650). Dr. Benjamin Schaefer, the chair of a task force of the National Physicians Alliance, which advocates for prohibiting the sale of prescriber-identifiable data nationwide, cited studies that sales reps "gear their presentation towards the beneficial effects of the new drugs and minimize the risks." (App. 646). He said the individualized data are an effective tool used by sales reps to induce doctors to prescribe "new" medicines that are "often not more effective than older, generic drugs; have less of a safety record, and are generally more expensive." (App. 646). Doctors are influenced by drug company sales pitches, he cautioned (as did the studies that he cited to the

Committee), and the drug companies' priorities differ from those of consumers. (App. 645-646).

In addition, Dr. Elizabeth B. Hart, a geriatrician from Mount Vernon, Maine, who treats mostly nursing home residents, told the Committee that it “takes tremendous effort as a physician to resist the constant barrage of aggressive marketing information to which we are subjected by pharmaceutical companies.” (App. 650). She said doctors struggle to base their prescribing decisions “on evidence-based medicine and cost-effective prescribing practices.” (App. 650). To allow drug companies to purchase “what should be confidential information so they can individually target us in more aggressive manners is contrary to every effort to protect confidentiality, to maintain best practices of appropriate prescribing and to limit the escalating costs of prescription medicine,” Dr. Hart told the Committee. (App. 650).

The testimony also informed the Committee about what should be self-evident -- drug company detailers use the data to influence doctors' choice of drugs for their patients. (App. 597-600, 623-627, 632-649). For example, Professor Kevin Outtersson said the Maine bill “strikes at the heart of the problem with drug marketing – the potential conflict of interest present when physicians are unduly influenced by drug detailers offering gifts, sponsorships and medical education trips.” (App. 640). Under the legislation, he said, “drug detailers will no longer be

able to offer incentives to ‘good’ doctors who are high prescribers of their products; nor will they be able to specifically withhold incentives from ‘bad’ doctors who are not prescribing their quotas.” (App. 640).

Experts tell the Committee the Act will reduce costs and improve patient care

Dr. Avorn and Dr. Aaron S. Kesselheim of Brigham and Women’s Hospital in Boston submitted a detailed statement to the Committee, explaining how the marketing of drugs to prescribers has significant economic and clinical consequences for Maine’s health care system. (App. 623-630 & referenced studies). Because physicians’ use of targeted drugs increases significantly after visits by detailers, and because the targeted drugs are generally the high-margin, high-profit patented drugs that the manufacturer has an incentive to promote, effective marketing by drug companies drives drug use toward the most expensive products and strains the health care budgets for individuals, health plans, and state health care programs such as Medicaid, according to Drs. Avorn and Kesselheim. (App. 623, 625-629).

Drs. Avorn and Kesselheim also informed the Committee that driving doctors toward prescribing the newest and costliest drugs can adversely affect patients’ clinical outcomes. “[B]ecause full understanding of a drug’s side effect profile may not be complete when the drug is first approved for marketing, detailing encourages the prescription of new products that might be riskier to

patients than known agents on the market.” (App. 626). This was evident in the widespread adoption of Vioxx. (App. 626-627).

Another example of a new drug that was dangerously overprescribed, also cited by Dr. Avorn and Dr. Kesselheim, was the cardiac medication nesiritide, which was approved in 2001 for treatment of acute exacerbations of congestive heart failure, “despite the fact that the manufacturer had not adequately studied its side effect profile.” (App. 627). The drug was immediately promoted by its manufacturer, and sales reached \$400 million in 2004, “but its use decreased dramatically in 2005 when it was found to be associated with increased rates of kidney disease and death.” (App. 627).

Drs. Avorn and Kesselheim also told the Committee that the information presented to doctors by detailers is often inaccurate, but that most physicians failed to recognize the inaccuracies and believed that they are immune from marketing influences. (App. 625-627). A 1995 study concluded that 11% of the in-person statements made to physicians by sales reps were scientifically inaccurate. (App. 627). Litigation following the withdrawal of Vioxx from the market “revealed the existence of elaborate sales training campaigns conducted by the manufacturer, Merck, whose main purpose was to divert attention of physicians away from concerns about the possible cardiac risk of that drug.” (App. 627). The two doctors explained that Vioxx “is not a unique situation; because the purpose of

detailing is to increase product sales, the information detailers present to physicians supports this goal, rather than a fair and balanced presentation of the medical literature as a whole.” (App. 627).

Finally, as Drs. Avorn and Kesselheim, among others, explained to the Committee, the use of prescriber-identifiable data has exacerbated these problems. (App. 597-600, 623-627, 632-649). Restricting the sale of this data would help make sure that prescribing decisions are based more on medicine than on marketing, which would result in better health care and reduced health care costs. (App. 597-600, 623-627, 632-649).

Senator Marrache submits amendment to L.D. 4 with opt-out feature

During the roughly 60 days that followed the public hearing, the bills were formally reviewed during five work sessions held by the Committee in April and May 2007. (App. 526-528, 666, 668, 670 & 676). Soon after the first work session, on April 10, 2007, an amendment to L.D. 4 was proposed by Senator Marrache. (App. 671). Her amendment proposed an opt-out feature (L.D. 4 as originally proposed was an outright ban on the sale of prescriber identifiable data). The Maine Medical Association had also advocated for an opt-out program for non-physician prescribers. (App. 535-538).

In enacting the law, after considering the testimony and other evidence presented to it, the Legislature explicitly determined, among other facts, that

“enactment of this section will assist the State to achieve the following compelling state 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.” 22 M.R.S. § 1711-E(1-A). The Legislature further 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.” 22 M.R.S. § 1711-E(1-A)(D). (The Addendum to this Brief, at A93-A98, contains the entire Act).

The Maine Legislature also explicitly set forth its three purposes in enacting the bill:

It is the intent of the Legislature in enacting this section to achieve the following compelling state interests: to improve 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.

22 M.R.S. 1711-E(1-B). On June 29, 2007, Governor Baldacci signed L.D. 4, as amended, into law. The bill became Public Law 2007, Chapter 460, and amended 22 M.R.S. §§ 1711-E, 8704, and 8713.

Evidence adduced at two-day hearing in November 2007

Pursuant to plaintiffs’ request, the lower court convened an evidentiary hearing on plaintiffs’ motion for preliminary injunction in November 2007 – less than three months after plaintiffs had filed their complaint. Both parties submitted

documentary and testimonial evidence, including the legislative record. Evidence adduced on cross-examination of plaintiffs' witnesses, including representatives from pharmacy chains Rite-Aid (which has 82 retail stores in Maine) and CVS-Caremark (17 retail stores in Maine), made clear that the Act is aimed at regulated transactions -- prescribing drugs and filling out prescriptions -- that occur in Maine. (App. 816-819, 831-834). As to the influence of detailers, Dr. Erik Steele of Bangor testified that, before he stopped seeing drug company sales reps, he would regularly prescribe the branded drug Cardizem, rather than less costly and equally effective generic alternatives, because he was unduly influenced (subliminally) by the detailer of Cardizem and the gifts that had been provided to him. (App. 784-787). This practice needlessly drove up health care costs, in his view. (App. 784-787).

Another example Dr. Steele provided is the overprescribing of the patented drug Nexium for acid-reflux. There is an over-the-counter alternative (Prilosec) that is just as effective as Nexium for many or most patients and much less costly to the health care system. (Tr. 277-287; App. 849-851).

Nurse practitioner Margaret Macdonald of Bangor was "shocked" when she first learned that drug companies had bought her prescribing history without her permission. (Tr. 326). Both Dr. Steele and Ms. McDonald believe that it is an intrusion on their privacy and professional confidentiality for drug companies to

buy their information, without their permission, and use it to try to influence what drugs they prescribe for their patients. (Tr. 282-283, 326-327).

Plaintiffs conceded that, for many or most patients, a generic drug is equally effective as other patented drugs. (App. 849-851). They also conceded that detailing by drug companies is more effective at generating sales of the more expensive, patented drugs when detailers use plaintiffs' prescriber-identifiable data. (Tr. 215-216, 427).

STANDARD OF REVIEW

Plaintiffs' burden in the preliminary injunction proceeding below is well-established – they must show that (1) they are likely to succeed on the merits; (2) they would suffer immediate irreparable harm absent injunctive relief; (3) the harm to plaintiffs in the absence of an injunction would exceed that to defendant if the injunction is granted; and (4) the public interest is better served by granting the injunction than by denying it. *New Comm. Wireless Servs., Inc. v. Sprintcom, Inc.*, 287 F.3d 1, 8-9 (1st Cir. 2002); *Pharmaceutical Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 72 (1st Cir. 2001) (reversing entry of preliminary injunction), *aff'd*, 538 U.S. 644, 661-62 (2003). “The *sine qua non* of this four-part inquiry is likelihood of success on the merits: if the moving party cannot demonstrate that he is likely to succeed in his quest, the remaining factors become matters of idle curiosity.” *New Comm. Wireless Servs.*, 287 F.3d at 9; *see also*

Ross-Simons of Warwick, Inc. v. Baccarat, Inc., 102 F.3d 12, 16 (1st Cir. 1996) (“Likelihood of success is the main bearing wall of the four-factor framework.”).

On appeal from an order granting a preliminary injunction, “pure issues of law (e.g., the construction of a statute) are reviewed *de novo*, findings of fact for clear error, and ‘judgment calls’ with considerable deference depending upon the issue.” *Langlois v. Abington Housing Auth.*, 207 F.3d 43, 47 (1st Cir. 2000) (internal citations omitted); *Concannon*, 249 F.3d at 72. Here, the lower court’s merits analysis is reviewed *de novo* because it raises pure issues of constitutional law and mixed questions of law and fact dominated by legal issues. *Ayotte*, 550 F.3d at 48. The lower court’s manipulation of the balance of equities and public interest prongs of the criteria is reviewed for an abuse of discretion. *Langlois*, 207 F.3d at 47.

SUMMARY OF ARGUMENT

Plaintiffs have challenged the Act on three separate constitutional bases. The Act is presumptively valid, *Davies Warehouse Co. v. Bowles*, 321 U.S. 144, 163 (1944), particularly since its purpose is to foster public health. *Hillsborough County v. Automated Med. Lab., Inc.*, 471 U.S. 707 (1985). Because plaintiffs have presented a “facial” challenge, they bear the burden of establishing, by a clear showing, the probability that the mere existence of the statute violates the

Constitution. *See Pharmaceutical Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 661-62 (2003).

This Court's recent decision in *Ayotte* – involving a New Hampshire law that is more restrictive than the Maine Act -- forecloses plaintiffs' First Amendment and void-for-vagueness claims. Under *Ayotte*, the Maine Act does not violate the First Amendment, and it is not unconstitutionally void-for-vagueness. The *Ayotte* decision also significantly undermines plaintiffs' dormant Commerce Clause claim here. The following provides extensive discussion on these issues.

1. The lower court erred by ruling that plaintiffs showed a likelihood of success on the merits of their First Amendment claim. Similar to the New Hampshire statute in *Ayotte*, the Maine Act principally regulates conduct, not speech. Therefore, as this Court held in *Ayotte*, the Act does not implicate the First Amendment. Even assuming *arguendo* the Court were to rule that commercial speech is involved, the Act readily passes the Supreme Court's test for regulation of commercial speech, as this Court also held in *Ayotte* with respect to New Hampshire's more restrictive law.

2. Plaintiffs are unlikely to succeed on their claim that the Act is void-for-vagueness or overbroad. The lower court did not address this claim. The Act sufficiently identifies the conduct that is prohibited, easily satisfying the applicable constitutional standard, particularly since the Act provides for only a civil penalty and requires an intent to violate the Act to trigger a possible civil penalty. The Act

is not subject to the overbreadth doctrine since plaintiffs have made a facial, commercial speech challenge.

3. Plaintiffs' dormant Commerce Clause argument (not addressed by the district court) does not have a reasonable likelihood of success. The prescriber-identifiable data subject to the Act derive from and concern prescribers who are regulated by Maine, and who write prescriptions in Maine primarily for Maine patients. The patients get these prescriptions filled at pharmacies located in Maine and regulated by Maine. The Act simply prohibits certain commercial transactions and conduct by covered entities subject to Maine's jurisdiction, including Maine pharmacies and insurance carriers regulated by Maine. Moreover, plaintiffs have raised a facial challenge to the Act, and cannot show that the Act on its face regulates only commerce that takes place wholly outside of Maine.

4. The court erred in ruling that plaintiffs will suffer irreparable harm without a preliminary injunction, and in ruling that the "balance of equities" and "public interest" prongs of the preliminary injunction test weigh in favor of granting preliminary injunctive relief. Plaintiffs, drug companies, and others can continue to use this data for non-marketing purposes, including research, during the pendency of the suit without a preliminary injunction

I. The lower court erred in ruling that plaintiffs demonstrated a reasonable likelihood of success on the merits of their First Amendment claim.

This Court's 2008 decision in *Ayotte* makes plain that the lower court erred when it held that plaintiffs had demonstrated a reasonable likelihood of success on the merits of their First Amendment claim. In a multi-panel circuit, prior panel decisions closely on point are binding upon newly constituted panels unless there has been supervening authority sufficient to warrant disregarding established precedent. *Zheng v. Holder*, 2009 U.S. App. LEXIS 14142, at *8 (1st Cir. 2009); *United States v. Wogan*, 938 F.2d 1446, 1449 (1st Cir. 1991). *Ayotte* is closely on point as to this issue, and there has been no supervening authority in this case.

A. The Act does not restrict protected speech.

Plaintiffs are engaged in the bulk sale of a commodity for profit. Their interest is in the sale of a product (data) for use in marketing by the drug industry. Their interest is not in free speech that might be protected by the First Amendment.¹⁰ *Ayotte*, 550 F.3d at 52-54.

¹⁰ To the extent plaintiffs argue the Act violates third parties' First Amendment rights, such an argument fails for lack of standing. As this Court held in *Ayotte*, plaintiffs have no standing to assert third parties' First Amendment rights. *Ayotte*, 550 F.3d at 48-50. *See also Wine & Spirits*, 418 F.3d at 49-50. Although there is a narrow exception that applies when some barrier or practical obstacle deters a third party from asserting its rights, *see, e.g., Powers v. Ohio*, 499 U.S. 400, 414-15 (1991) (allowing criminal defendant to assert rights of jurors because they lack financial incentive to undertake the burden of litigation), nothing in the record indicates that pharmacies or the pharmaceutical manufacturers are unable or unlikely to protect their own rights. *See Ayotte*, 550 F.3d at 49-50.

Like the New Hampshire law in *Ayotte*, the Maine Act does not restrict the communication or expression of any ideas, nor does it prohibit the flow of information. Prescriber-identifiable data may be transferred, disclosed, licensed, used, or sold for a myriad of purposes consistent with the Act.

The focus of the Act is a restriction on the use of this data for any “marketing” purpose as defined in the Act, and only on data derived from those prescribers who object to such use. The Act’s restrictions apply only to prevent a particular use of the data. Just like the New Hampshire statute at issue in *Ayotte*, the Maine Act is a regulation of conduct, not speech. Plaintiffs may lawfully obtain, transfer, and sell the data freely so long as the data are not sold or used for a marketing purpose.

The Act does not prevent plaintiffs from communicating *about* commercial transactions, but rather regulates the transactions themselves. Commercial activity alone does not benefit from the protections of the First Amendment’s commercial speech doctrine. *Ayotte*, 550 F.3d at 52-54; *Wine & Spirits Retailers, Inc. v. Rhode Island*, 418 F.3d 36, 49 (1st Cir. 2005).

Because plaintiffs are free to disseminate precisely the same data for any purpose other than marketing, their real complaint is that the Act’s restriction on use may suppress or eliminate the market demand for this data. The Court recently addressed this very issue in *Ayotte* – “plaintiffs’ true complaint, of course, is that in

banning this use of their data, we risk drying up the market for their services.” 550 F.3d at 53. This Court reiterated what it held in previous similar cases: “the First Amendment does not safeguard against changes in commercial regulation that render previously profitable information valueless.” *Id.*

B. Even if commercial speech is implicated by the Act, it does not violate plaintiffs’ First Amendment rights.

Assuming solely for argument’s sake that the Act regulates constitutionally protected speech, it affects only commercial speech, which warrants reduced constitutional protection. *See Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n*, 447 U.S. 557, 563 (1980). Assuming *arguendo* that the Act regulates commercial speech, it easily meets the lower level of scrutiny applicable to commercial speech regulations, as this Court concluded in *Ayotte* with respect to New Hampshire’s more restrictive law. Since Maine’s law applies only when prescribers elect its protections, it is less of an intrusion on any commercial speech rights of plaintiffs than New Hampshire’s outright prohibition.

If commercial speech is neither misleading nor related to unlawful activity, regulation of it survives First Amendment scrutiny if (1) the State asserts a substantial interest to be achieved by the regulation; (2) the regulation directly advances that interest; and (3) the regulation is no more extensive than necessary to serve that interest. *Central Hudson*, 447 U.S. at 564. The Act readily meets these criteria.

As discussed above, the Maine Legislature made extensive findings in the Act. 22 M.R.S. §§ 1711-E(1-A). The Legislature’s findings and predictive judgments are entitled to deference under *Central Hudson* because they are reasonable and supported by substantial evidence. The Supreme Court has made clear that, where First Amendment rights are at stake, although “deference to a legislative finding cannot limit judicial inquiry” altogether, the Court will give Congress’s judgments substantial deference. *Turner Broadcasting System, Inc. v. FCC*, 520 U.S.180, 195 (1997) (“*Turner II*”) (citing *Turner Broadcasting System, Inc. v. FCC*, 512 U.S. 622, 665 (1994) (“*Turner I*”). 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 Congress’s factual predictions with [the Court’s].” *Turner I*, 512 U.S. at 666. Ultimately, “the question is not whether Congress was correct as an objective matter, but whether the legislative conclusion was reasonable and supported by substantial evidence.” *Id.* at 665.

The record shows that the Legislature spent considerable time and effort considering these issues. After a public hearing and five work sessions, the Legislature explicitly found “that enactment of this section will assist the State to achieve the following compelling state 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.” 22 M.R.S. § 1711-

E(1-A). The Legislature also found that “restricting 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.* These findings are reasonable and are supported by substantial evidence, including testimony from Maine physicians and experts on these issues. (App. 597-600, 623-627, 631-650).¹¹

1. The Act furthers three substantial governmental interests.

There are three substantial governmental interests furthered by the Act: (1) limiting annual increases in health care costs, (2) improving public health, and (3) protecting the privacy of patients and prescribers. The Act need to further only one substantial interest to satisfy the first prong of *Central Hudson*

The lower court in this case, this Court in *Ayotte*, and the district court in *Sorrell* all ruled that containing health care costs is a substantial government interest. *Rowe*, 532 F. Supp. 2d at 172; *Ayotte*, 550 F.3d at 55; *Sorrell*, 2009 U.S. Dist. LEXIS 35594, at * 28. This Court should rule likewise.

¹¹ This Committee had extensive experience in the same legislative session dealing with a variety of prescription drug issues. It considered and heard testimony on ten other prescription drug issues, including legislation enacted to prohibit the sale of software containing inappropriate advertising of prescription drugs. (Legislative Digest of Bill Summaries and Enacted Laws, State of Maine, 123rd Legislature, 1st Reg. Sess. at 364 (July 2007)).

The lower court’s merits analysis, which did not track the Act’s three stated purposes,¹² did not directly address whether improving public health was a substantial interest under *Central Hudson*. See *Rowe*, 532 F. Supp. 2d at 170-171. The trial court in *Sorrell* held that it was a substantial interest – indeed, plaintiffs did not “seriously dispute” the issue, according to the court. 2009 U.S. Dist. LEXIS 35594, at ** 28-29. This Court should likewise rule that improving public health is a substantial government interest under *Central Hudson*.¹³

The lower court erred in ruling that the State’s interest in protecting prescribers’ practicing histories from those marketing drugs was “narrow” (presumably meaning it was not substantial). *Rowe*, 532 F. Supp. 2d at 171-72. This Court should rule that protecting prescribers’ rights to prohibit the use of their prescriber-identifiable data for marketing purposes is “substantial” for purposes of *Central Hudson*. This interest is at least as significant as other governmental interests that have been upheld as substantial by the federal courts. See *Missouri ex rel. Nixon v. American Blast Fax, Inc.*, 323 F.3d 649, 655 (8th Cir. 2003) (law

¹² For example, the lower court analyzed whether “Ending the Use of Prescriber Comparisons for Purposes Related to Manufacturer Profitability and Decreasing Unnecessary Marketing Costs” was a substantial interest, and whether the Act directly advanced that interest. *Rowe*, 532 F. Supp. 2d at 171-178. The Attorney General never argued that this was a substantial interest under *Central Hudson*.

¹³ This Court did not rule in *Ayotte* whether promoting public health or protecting prescriber privacy was a “substantial” interest, though Judge Lipez stated his view that promoting public health was a substantial interest. *Ayotte*, 550 F.3d at 84-85 (Lipez, J., concurring in part and dissenting in part).

restricting unsolicited faxes to prevent cost shifting and interference such advertising places on businesses and other recipients held to be substantial government interest) *cert. denied*, 540 U.S. 1104 (2004); *Lanphere & Urbaniak v. Colorado*, 21 F.3d 1508, 1514 (10th Cir.) (law protecting confidentiality of those charged with traffic offenses from dissemination of charging information for commercial purposes held to further substantial interest – although much of information already published in newspapers), *cert. denied*, 513 U.S. 1044 (1994).

2. The Act directly advances the State’s interest in controlling health care costs.

The state “must demonstrate that the harms it recites are real and that [the] restriction will in fact alleviate them to a material degree.” *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993). The regulation must be “in proportion” to the government’s interest. *Central Hudson*, 447 U.S. at 564.

As this Court explained in *Ayotte*, however, “certitude” is not required. 550 F.3d at 55. A state need not go beyond the demands of common sense to show that a statute is likely to directly advance an identified governmental interest. *See, e.g., Burson v. Freeman*, 504 U.S. 191, 211 (1992). States are allowed “to justify speech restrictions by reference to studies and anecdotes” or even to justify them “based solely on history, consensus, and simple common sense.” *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 628 (1995) (internal quotation marks omitted).

As explained above, the Act is designed to contain health care costs. The Maine Legislature's specific findings on this point are entitled to deference because they are reasonable and supported by ample evidence. The record shows that the Act satisfies *Central Hudson*. (App. 597-600, 623, 625-627, 632-637, 639-649, 784-787). Because physicians' use of targeted drugs increases substantially after visits by detailers, and because the targeted drugs are generally the high-margin, high-profit drugs that the manufacturer has a strong incentive to promote, targeted marketing by drug companies drives drug use toward the most expensive products and strains the health care budgets for individuals, health plans, and state health care programs such as Medicaid. (App. 623, 625-627, 632-637, 639-649, 784-787); *Manchanda & Honka* at 809. *See Ayotte*, 550 F.3d at 56 ("The fact that the pharmaceutical industry spends over \$4,000,000 annually on detailing bears loud witness to its efficacy.").

As Drs. Avorn and Kesselheim informed the Legislature, steering doctors toward prescribing the newest drugs also can adversely affect patients' clinical outcomes, driving up costs. (App. 623, 626-627). In short, substantial evidence supports the Legislative determination that detailing increases health care costs. *See Ayotte*, 550 F.3d at 55-56; *Sorrell*, 2009 U.S. Dist. LEXIS 35594, at * 35-36 ("Detailing leads to increased prescriptions for new drugs over generic alternatives which are often more cost-effective").

The evidence (as well as common sense) further shows that detailing is significantly more successful when detailers use prescriber-identifiable data. (App. 597-598, 625-627, 639-649). Even plaintiffs admitted this fact at the evidentiary hearing on their motion for a preliminary injunction. (Tr. 215-216, 426-427). As noted by the district court in *Sorrell* – the fact that drug manufacturers are essentially the only paying customers of the data miners is the strongest evidence of the important role of this data in detailing. “Put simply, if PI data did not help sell new drugs, pharmaceutical companies would not buy it.” *Sorrell*, 2009 U.S. Dist. LEXIS 35594, at ** 35-36. Thus, the Legislature’s determination that prescriber-identifiable data is an effective marketing tool that enables detailers to increase sales of new drugs is conceded by plaintiffs and well-supported in the record. That is why the data mining business exists.

Finally, the record supports the Legislature’s finding that the Act will decrease health care costs in Maine because, if detailers do not have physicians’ prescribing histories, then physicians and other Maine prescribers will less likely be swayed to prescribe unnecessary and more expensive brand-name drugs. (App. 597-600, 623, 626-627, 639-649, 784-787). *See Ayotte*, 550 F.3d at 57-59 (New Hampshire law directly advances cost containment); *id.* at 91-92 (Lipez, J., concurring in part and dissenting in part) (same); *Sorrell*, 2009 U.S. Dist. LEXIS 35594, at ** 34-40 (Vermont law directly advances interest in cost containment).

That is, because the Act will limit the impact of marketing, it will lead to more optimal prescribing practices. The lower court erred in not so ruling.

The lower court's decision – which did not directly address whether the Act would directly advance the State's interest in reducing health care costs -- was influenced by its speculation that if the Act were in effect, some prescribers might be willing to accept payments from plaintiffs or drug companies not to opt out, which might result in plaintiffs' gaining some prescriber data in that fashion. *Rowe*, 532 F. Supp. 2d at 174 n.31, 176 n.35. Whether or not prescribers might be willing to do so, however, is entirely irrelevant to the inquiry before the Court.

The Legislature's reasonable determination that the Act will help reduce health care costs – supported by substantial evidence in the record as well as by common sense – is entitled to deference. *See Ayotte*, 550 F.3d at 59 (Court deferred to New Hampshire legislature on “whether it is sensible to conclude (hypothetically) that net medical outlays will decrease as a result of the withdrawal of prescribing histories from detailers”). This is an area in which States should be given some leeway to seek new ways to combat the social and economic problem of skyrocketing health care costs. *Ayotte*, 550 F.3d at 58. The lower court erred in not according deference to the Legislature's determination on this issue.

3. The Act is no more extensive than necessary to serve the State's interest in cost containment.

Under this third prong, the law must be “in reasonable proportion to the interest served.” *Ayotte*, 550 F.3d at 59. The court also considers whether “there are numerous and obvious alternatives that would restrict less speech and would serve the government’s interest as effectively as the challenged law.” *Mainstream Marketing Servs., Inc. v. Federal Trade Comm’n*, 358 F.3d 1228, 1242 (10th Cir. 2004), *cert. denied*, 543 U.S. 812 (2004).

In *Ayotte*, this Court held that New Hampshire’s law – an outright prohibition on the sale or use of prescriber-identifiable data for certain commercial purposes -- was no more restrictive than necessary to achieve its goal of cost containment. 550 F.3d at 60. As several courts have ruled, opt-out provisions like Maine’s law readily meet this prong of the *Central Hudson* analysis because they restrict only speech that involves unwilling participants. *See, e.g., Mainstream Marketing*, 358 F.3d at 1242-43 (national do-not-call registry was narrowly tailored because it restricts only calls targeted at recipients who have identified themselves as unwilling); *American Blast Fax*, 323 F.3d at 658-89 (upheld law that restricted unsolicited fax advertising; under law, advertisers could send faxes only after obtaining consent from recipients).

Quoting the lower court in *Ayotte*, Judge Woodcock rejected the Attorney General’s argument that the Act was narrowly tailored to reduce health care costs

because, the court stated, detailing is “sometimes” used to benefit public health by promoting what are, at times, arguably more effective drugs. *Rowe*, 532 F. Supp. 2d at 177-178 (quoting *Ayotte*, 490 F. Supp. 2d at 181-182). The court’s logic was explicitly rejected by this Court in *Ayotte*, 550 F.3d at 57-58. The fact that certain branded drugs may produce better results in some cases “is too flimsy a hook on which to hang a conclusion that a decrease in the prescription of brand-name drugs would be unlikely to yield a net diminution in health care costs.” *Id.* at 58.

Neither the lower court nor plaintiffs identified any less restrictive alternative that would serve Maine’s interest in cost containment as well as the Act. The lower court erred to the extent it relied on plaintiffs’ alternatives. For example, a ban on gifts to prescribers would target a harm that the Legislature never deemed central to its aims. This and other alternatives identified by these same plaintiffs were rejected in *Ayotte*, 550 F.3d at 59-60, and in *Sorrell*, 2009 U.S. Dist. LEXIS 35594, at * 42.

The Maine Legislature determined that targeted marketing by detailers armed with prescriber-identifiable data results in increased prescriptions for new drugs -- despite the availability of safe and effective cheaper alternatives. The Legislature seeks to limit the overprescription of new drugs in order to lower prescription drug costs and to protect patients from unknown risks and side effects. The Act, which restricts use of this data in marketing only for prescribers who opt

out, is a targeted response to the harm of overprescription caused by detailers' use of this data. The Act provides prescribers with the ability to allow use of their prescribing histories for marketing purposes if they wish. Perfection is not required. The Act is in reasonable proportion to the State's interests. *See Sorrell*, 2009 U.S. Dist. LEXIS 35594, at ** 43-46. *See also Anderson v. Treadwell*, 294 F.3d 453, 457-458, 462 (2d Cir. 2002) (court upheld law permitting homeowners to prohibit real estate licensees from soliciting homeowners for listings).

4. The Act directly advances two other substantial interests and is not more extensive than necessary to serve those interests.

As noted above, the Act also is designed to promote public health and to protect prescriber privacy, both of which are substantial interests under *Central Hudson*. As the record shows, the Act meets the last two prongs of *Central Hudson* as to these other two purposes. The lower court erred in ruling to the contrary. *See Rowe*, 532 F. Supp. 2d at 173-175.

Public health. As shown above, Drs. Avorn and Kesselheim told the Maine Legislature that steering doctors toward prescribing the newest drugs can adversely affect patient health. (App. 623, 626-627). Detailing encourages the prescription of new drugs that might be riskier to patients than already existing drugs because all of a drug's side effects may not be known when the drug is first approved for marketing. (App. 623, 626-627). This was evident in the widespread prescribing

of Vioxx even though it was not shown to be a more effective analgesic than many older drugs already on the market. (App. 626-627).

Another example cited to the Maine Legislature by Dr. Avorn and Dr. Kesselheim was the drug nesiritide, which was approved in 2001 for treatment of congestive heart failure despite the fact that the manufacturer had not adequately studied its side effects. (App. 627). The drug was promoted aggressively by its manufacturer, but its use decreased dramatically when it was found to be associated with increased rates of kidney disease and death. (App. 627).

Accordingly, the Act directly advances the State's interest in promoting public health. The Vermont district court in *Sorrell* ruled likewise as to Vermont's law. 2009 U.S. Dist. LEXIS 35594, at ** 41-42.

The Act is narrowly tailored, as well. It allows prescribers to allow their prescribing histories be used for marketing purposes if they wish. The Act is thus in reasonable proportion to the State's interests. *See Sorrell*, 2009 U.S. Dist. LEXIS 35594, at ** 43-46. The alternatives proffered by plaintiffs – such as a ban on detailers' gifts and increased “academic” counter-detailing -- do not adequately address the Legislature's concerns or are unworkable, as the Court ruled in *Ayotte*, 550 F.3d at 59-60. *See also Sorrell*, 2009 U.S. Dist. LEXIS 35594, at ** 42-43.

Prescriber privacy. The Act also directly advances the Maine Legislature's interest in protecting identifiable prescription drug information from use for

marketing purposes. The Act allows those prescribers who object to such use to “opt out” and prohibit the use of this data for any marketing purpose. The law is plainly designed to provide effective support for its stated purpose.

As several courts have ruled, opt-out provisions readily meet the second prong of *Central Hudson* because they restrict only speech that involves unwilling participants. As the Tenth Circuit explained in *Mainstream Marketing*, “the Supreme Court has repeatedly held that speech restrictions based on private choice . . . are less restrictive than laws that prohibit speech directly.” 358 F.3d at 1242, citing *Rowan v. United States Post Office Dep’t*, 397 U.S. 728, 738 (1970).

Similar to the do-not-mail regulation approved in *Rowan*, the court of appeals in *Mainstream Marketing* ruled that the do-not call registry did not, itself, prohibit any speech. Instead, it merely “permits a citizen to erect a wall that no advertiser may penetrate without his acquiescence.” 358 F.3d at 1242. Thus, in *Mainstream Marketing*, the Tenth Circuit held that the national do-not-call registry was narrowly tailored because it restricts only calls that are targeted at recipients who have identified themselves as unwilling. 358 F.3d at 1242-43.

Plaintiffs have not identified any less restrictive alternative that would serve Maine’s interest in protecting prescriber privacy as well. Alternatives that might reduce costs or restrict unethical and illegal behavior by drug companies do not

address the Legislature's stated goal in protecting this data from being used for marketing purposes when prescribers have elected to keep it confidential.

II. Plaintiffs' void-for-vagueness and overbreadth claims fail.

Plaintiffs allege that various words or phrases in the Act are unclear or ambiguous and that, as a result, the law is unconstitutionally vague and overbroad. The lower court did not address these claims. Since plaintiffs will likely raise them as alternative bases for upholding the preliminary injunction, the Attorney General will address them and asks that the Court address them. This Court summarily rejected the same arguments regarding the New Hampshire law in *Ayotte*. 550 F.3d at 60-63 & n.9. The district court in *Sorrell* likewise rejected these arguments as to the Vermont law. 2009 U.S. Dist. LEXIS 35594, at ** 47-49. In light of these rulings, these same plaintiffs cannot demonstrate a reasonable likelihood of success on the merits of their claim that the Act is void-for-vagueness or overbroad.

A statute is unconstitutionally vague "if its prohibitions are not clearly defined" so that it does not "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited" or does not "provide explicit standards" for those who enforce the law. *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). Standards of vagueness should not be mechanically applied because of the need for "flexibility and reasonable breadth, rather than meticulous specificity."

Grayned, 408 U.S. at 110. As this Court explained in *Ayotte*, the fact that a statute “requires some interpretation does not perforce render it unconstitutionally vague.” *Ayotte*, 550 F.3d at 51. In determining whether a statute is impermissibly vague, the Court looks at the statute as a whole. *United States v. Bohai Trading Co.*, 45 F.3d 577, 580 (1st Cir. 1995). “[P]erfect clarity and precise guidance have never been required even of regulations that restrict expressive activity.” *United States v. Williams*, 128 S. Ct. 1830, 1845 (2008).

“[T]he mere fact that close cases can be envisioned” does not render a statute vague. *Williams*, 128 S. Ct. at 1846. As the Supreme Court pointed out, “[c]lose cases can be imagined under virtually any statute,” but that issue is addressed by the burden of proof requirement, not the vagueness doctrine. *Id.*

Because this is a facial challenge to the Act, plaintiffs must demonstrate that the law being challenged “is impermissibly vague in all of its applications.” *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 497 (1982). That burden means plaintiffs must demonstrate “that the statute is vague in the sense no standard of conduct is specified at all.” *United States v. Nadi*, 996 F.2d 548, 550 (2nd Cir.), *cert. denied*, 510 U.S. 933 (1993).

The Act targets a specific commercial use of a commodity (bulk, processed data) and is therefore an economic regulation. As such, it “is subject to a less strict vagueness test “because its subject matter is often more narrow, and because

businesses, which face economic demands to plan behavior carefully, can be expected to consult relevant legislation in advance of action.” *Village of Hoffman Estates*, 455 U.S. at 498. Even if the Court were to conclude that the Act’s restriction on the transfer of bulk, processed data is a restriction on protected commercial speech, the regulation of commercial speech is not entitled to any heightened vagueness review. *See, e.g., United States v. Stansell*, 847 F.2d 609, 616 (9th Cir. 1988).

The Act is sufficiently specific so that plaintiffs and other entities can govern their conduct to avoid violating it. The Act specifically identifies the entities to whom it applies, and defines these entities with generally understood terms or by their function. The Act prohibits the sale or use of prescription drug information for any “marketing” purpose when the information identifies a prescriber who has filed for confidentiality protection. The Act also defines “marketing.” Any other use (*i.e.*, other than marketing) is not restricted by the Act. *See K-S Pharmacies, Inc. v. American Home Prods. Corp.*, 962 F.2d 728, 731-32 (7th Cir. 1992) (upholding state law regulating wholesale drug prices against void-for-vagueness challenge).

Any confusion by plaintiffs about the Act’s application to health care research is unwarranted. The Act defines “marketing” in terms of specified activities, but then expressly excepts from that definition such activities as health

care research, patient care management, and formulary compliance. The use of exceptions is well understood as a matter of statutory construction; they “operate to restrict the general applicability of legislative language.” 2A Singer, Statutes and Statutory Construction § 47.11, at 245 (6th Ed. 2000).

Plaintiffs below questioned how they could tell whether the data they sold might be used by another for marketing purpose and how to avoid liability from such use. First, liability for any civil penalty under the Act requires a showing of intent. *See* 5 M.R.S. § 209. Second, plaintiffs’ business is based on contractual relationships. They can readily restrict by contract the use of any data they sell to those uses not prohibited by law, as they already do to implement the PDRP and as they do with their suppliers. (Tr. 32, 462-464). *See Sorrell*, 2009 U.S. Dist. LEXIS 35594, at ** 48-49.

Even assuming solely for argument’s sake the Court were to discern any vagueness, the fact that the only penalty under the Act is civil and that liability requires an intentional violation mitigate any constitutional concern. The Supreme Court has “expressed greater tolerance of enactments with civil rather than criminal penalties because the consequences of imprecision are qualitatively less severe.” *Village of Hoffman Estates*, 455 U.S. at 498-99. The Supreme Court also has recognized “that a scienter requirement may mitigate a law’s vagueness,

especially with respect to the adequacy of notice to the complainant that his conduct is proscribed.” *Id.* at 499.

Plaintiffs’ overbreadth argument is likewise without merit. Even assuming *arguendo* the Court were to rule that the Act restricts commercial speech, the overbreadth doctrine does not apply. “A statute whose overbreadth consists of unlawful restriction of commercial speech will not be facially invalidated on that ground – our reasoning being that commercial speech is more hardy, less likely to be ‘chilled,’ and not in need of surrogate litigators.” *Board of Trustees v. Fox*, 492 U.S. 469, 481 (1989) (citations omitted). That is, the overbreadth doctrine does not apply to facial commercial speech challenges. *Sorrell*, 2009 U.S. Dist. LEXIS 35594, at * 47.

III. Plaintiffs failed to demonstrate a reasonable likelihood of success on the merits of their dormant Commerce Clause claim.

As their final argument to the lower court (not addressed by the court), plaintiffs claimed the Act violates the dormant Commerce Clause because it is an impermissible “extraterritorial” regulation.¹⁴ Plaintiffs did not argue that the Act is discriminatory or that it is protectionist state regulation designed to benefit in-state economic interests by burdening out-of-state competitors, which is the harm targeted by the dormant Commerce Clause. *See Grant’s Dairy-Maine, LLC v.*

¹⁴ Plaintiffs did not claim the Act violates the dormant Commerce Clause under a *Pike* balancing analysis. *See Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970).

Comm'r of Maine Dep't of Agric., Food & Rural Resources, 232 F.3d 8, 18 (1st Cir. 2000). Rather, according to plaintiffs, the Act is an unconstitutional “extraterritorial regulation” because it prohibits transactions that allegedly are entered into totally outside Maine between two parties that are allegedly located totally outside Maine. This argument mischaracterizes the transactions and misstates the applicable law.

As the district court in *Sorrell* observed, “[t]he dormant Commerce Clause is not a roving license for federal courts to decide what activities are appropriate for state and local government to undertake. . . .” 2009 U.S. Dist. LEXIS 35594, at ** 53-54 (quoting *United Haulers Ass’n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 343 (2007)). Courts “should be particularly hesitant to interfere with the state’s efforts under the guise of the Commerce Clause,” where, as here, the law at issue involves “a field traditionally subject to state regulation.” *United Haulers*, 550 U.S. at 344.¹⁵

¹⁵ It is open to question whether the “extraterritorial” branch of dormant Commerce Clause doctrine exists at all. Although some litigants have argued that the *Brown-Forman* prohibition on “directly regulating” interstate commerce would invalidate any regulation with extraterritorial effect, the First Circuit has noted that the Supreme Court has not applied *Brown-Forman* in that way. See *Grant’s Dairy-Maine, LLC v. Comm’r of Maine Dep’t of Agric., Food & Rural Resources*, 232 F.3d 8, 19 (1st Cir. 2000).

The Act has no improper “extraterritorial” application. Its prohibition applies to a “carrier,”¹⁶ a “pharmacy,”¹⁷ or a “prescription drug information intermediary,”¹⁸ all defined entities that are located in Maine or have nexus with Maine. These covered entities 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.

As an initial matter, therefore, as shown by the statutory definitions, only persons or entities located in Maine or subject to Maine’s jurisdiction are subject to the Act. To the extent there is any ambiguity on this issue, the Court should

¹⁶ “Carrier” has the same meaning as in 24-A M.R.S. § 4301-A(3). 22 M.R.S. § 1711-E(1)(A). “Carrier” is defined by 24-A M.R.S. § 4301-A(3)(A) as one of seven different entities that are licensed by the State of Maine, such as “[a]n insurance company licensed in accordance with this Title to provide health insurance.”

¹⁷ “Pharmacy” initially was defined in the Act as a “mail order prescription pharmacy” under former 32 M.R.S. § 13702(13) or a “drug outlet” under former 32 M.R.S. § 13702(10). Laws 2007, ch. 460. The definition of “pharmacy” was amended later in the 2007 legislative session to conform to amendments that were made to the Maine Pharmacy Act during the 2007 legislative session. “Pharmacy” is now defined as “a mail order prescription pharmacy” as defined in 32 M.R.S. § 13702-A(17) or a “pharmacy” as defined in 32 M.R.S. § 13702-A(24). 22 M.R.S. § 1711-E(1)(F-2). *See* Laws 2007, ch. 695 (eff. Apr. 24, 2008). These are entities that have Maine nexus and are subject to Maine regulation.

¹⁸ “Prescription drug information intermediary” means “a person or entity that communicates, facilitates, or participates in the exchange of prescription drug information regarding an individual or a prescriber. Prescription drug information intermediary includes, but is not limited to, a pharmacy benefits manager, a health plan, an administrator and an electronic transmission intermediary and any person or entity employed by or contracted to provide services to that entity.” 22 M.R.S. § 1711-E(1)(I). Only persons and entities located in Maine, or with Maine nexus, are covered by the Act.

construe the Act to apply only to carriers, pharmacies, and prescription drug information intermediaries subject to Maine’s jurisdiction. *See K-S Pharmacies*, 962 F.2d at 730-31 (rejecting extraterritoriality argument, court construed Wisconsin law to apply only to parties subject to Wisconsin jurisdiction). Thus construed, the Act does not apply to parties that are “entirely outside Maine,” as plaintiffs allege.

According to plaintiffs, most (but not all) of their data are acquired from pharmacies – primarily the chain-store pharmacies such as Rite-Aid and CVS, corporations that operate widely in many states, including Maine.¹⁹ The data at issue is information about prescriptions written by prescribers who are licensed by Maine and practice medicine in Maine. These prescriptions are filled almost exclusively by pharmacies located in Maine (or with nexus to Maine) and licensed by Maine. One of these pharmacies is a business that is located exclusively in Maine. (App. 683, 698). These pharmacies enter the prescription drug information into computers located in Maine stores, for the most part. (App. 816-817, 831-832). These same prescriptions are paid for in part by insurance carriers located in Maine and licensed by Maine. The Act will thus regulate entities and

¹⁹ Plaintiffs offered no evidence as to how the rest of their data was acquired and whether those transactions occurred “wholly outside” of Maine. Their facial dormant Commerce Clause challenge fails for that reason, alone.

transactions that are subject to Maine's jurisdiction; it will not control commerce that takes place wholly outside of the State's borders, as plaintiffs allege.

Although some of the covered entities (Rite-Aid and CVS-Caremark) also have part of their business operations in other states, the Supreme Court has never held that a state law impermissibly regulates interstate conduct merely because it has extraterritorial effects. Indeed, contrary examples abound. *See, e.g., Walsh*, 538 U.S. at 668-70; *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 87-88 (1987) (upholding state anti-takeover law despite extraterritorial effects); *Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 125-29 (1978) (upholding law prohibiting vertical ownership in gasoline industry even though law had impact on out-of-state companies); *see also K-S Pharmacies*, 962 F.2d at 731-32 (upholding law that regulated wholesale drug prices despite extraterritorial impact). The Supreme Court "has never suggested that the dormant Commerce Clause requires Balkanization, with each state's law stopping at the border." *Instructional Sys., Inc. v. Computer Curriculum Corp.*, 35 F.3d 813, 825 (3d Cir. 1994) (upholding state law regulating termination of franchise agreements despite extraterritorial impact).

Indeed, Rite-Aid and CVS-Caremark are subject to Maine laws governing the dispensing of prescription drugs in Maine, including the collection and security of prescription records. Title 32, M.R.S., Ch. 117. These pharmacies cannot avoid

these laws by routing an electronic copy of their records to their home offices in another state and then claim that Maine is trying to regulate commerce occurring “wholly outside the State.”

The Supreme Court in *PhRMA v. Walsh* rejected a stronger dormant Commerce Clause claim than this one. 538 U.S. at 668-70. *PhRMA* involved a state law that required any manufacturer selling drugs in Maine through any publicly supported financial assistance program to enter into a rebate agreement with the Commissioner of Human Services. The statute directed the Commissioner to use his or her best efforts to obtain a rebate that would be at least equal to the rebate calculated under the federal program, and the rebates would be distributed to participating pharmacies to compensate them for selling at discounted prices. All the drug manufacturers’ operations were outside of Maine, and their transactions with wholesalers occurred outside of Maine. There, the plaintiff raised the virtually identical extraterritoriality argument to that raised here. *Id.* at 669. All nine Justices rejected the claim. *Id.* at 668-70, 671, 674-75, 683 & 684.

Plaintiffs’ dormant Commerce Clause argument here rests largely on an irrelevant fact -- that the central computers of Rite-Aid and CVS-Caremark are located outside Maine. The electronic prescription data on the computers of Rite-Aid and CVS were entered on their Maine computers and are still accessible by

these Maine computers even after the transfer to plaintiffs of what is, in effect, an electronic copy of that data. (App. 816-818, 831-834). Moreover, records about Maine-licensed prescribers are distinguishable from records about prescribers from other states. Plaintiffs also mischaracterize the location of pharmacies and other covered entities by claiming that they are located entirely outside Maine. Rite-Aid, CVS-Caremark, and Anthem Blue Cross and Blue Shield of Maine are corporations “located” in Maine and licensed by Maine. They are also “located” in other states. Again, one of plaintiffs’ suppliers is a pharmacy business located just in Maine. (App. 683, 698).

Plaintiffs cannot create a viable dormant Commerce Clause issue based on the fact that some of the pharmacies supplying plaintiffs with electronic data are routing a copy of that data through their parent company’s out-of-state computer server on the way to plaintiffs’ out-of-state computers. Likewise, plaintiffs could not create such a claim if these pharmacies made Xerox copies of these prescriptions, brought the copies to Pennsylvania, and sold the copies to plaintiffs there – allegedly creating “commerce occurring wholly outside” of Maine. The district court in *Sorrell* rejected an identical challenge by plaintiffs based on their transactions with Vermont pharmacies. 2009 U.S. Dist. LEXIS 35594, at **57-58.

A fundamental principle in Commerce Clause analysis is that “the [Commerce] Clause protects the interstate *market*, not particular interstate firms,

from prohibitive or burdensome regulations.” *Exxon*, 437 U.S. at 128. The goal of national economic union is not served by such formalisms as the site of the hardware serving the pharmacies’ (or plaintiffs’) information technology operations. *See id.* at 127 (Commerce Clause not concerned about “the particular structure or methods of operation” of the market in question).

Plaintiffs rely on the price-tying cases, such as *Healy v. Beer Inst.*, 491 U.S. 324 (1989), *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935), and *Pharmaceutical Research & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56 (D.C. 2005), *aff’d sub nom. on other grounds, Biotech Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) (“*DC PhRMA*”). Plaintiffs construe the rulings in *Healy*, *Baldwin*, and *DC PhRMA* much too broadly.

Both *Healy* and *Baldwin* were cases where, due to the effect of interlocking and conflicting regulations in neighboring states, price regulations established in one state had the effect of controlling the prices for those goods sold in those neighboring states. Thus, the rulings in those cases involve a state’s extraterritorial regulation of prices. Similarly, in *DC PhRMA*, a law sought to control the prices of patented prescription drugs sold in the District of Columbia by regulating the prices charged by out-of-District wholesalers or distributors. The court held that, as in *Healy* and *Baldwin*, the District of Columbia law would have the practical effect of “establishing a scale of prices for use in other states.” *Id.* at 70.

These cases stand for the proposition that a state law that has the practical effect of establishing prices for goods or services in other states violates the dormant Commerce Clause, but they do not establish the broad rule alleged by plaintiffs. The Maine law does not set the price of any goods in Maine or any other state. The Act simply states that certain types of Maine data may not be sold or used by entities that are subject to Maine’s jurisdiction when the sale or use is for any marketing purpose and the prescriber has elected confidentiality. The Act is not an extraterritorial regulation under *Healy* and *Baldwin*.

Finally, because this is a facial challenge, the Court must look only to the “facial requirements” of the statute and may not speculate about hypothetical or imaginary cases. *Washington State Grange v. Washington State Republican Party*, 128 S. Ct. 1184, 1190 (2007); *see also Field Day, LLC v. County of Suffolk*, 463 F.3d 167, 174 (2nd Cir. 2006) (“A facial challenge to a statute considers only the text of the statute itself, not its application to the particular circumstances of an individual.”). On its face, the Act regulates the actions of regulated entities that do business in Maine, and it restricts certain uses of information obtained from regulated Maine transactions. Speculation about the law’s potential application to out-of-state commerce is irrelevant to a pre-enforcement facial challenge. Moreover, plaintiffs must show that the law *necessarily* regulates out-of-state commerce in all of its applications to sustain their pre-implementation facial

challenge. *See United States v. Salerno*, 481 U.S. 739, 745 (1987); *United States v. Sage*, 92 F.3d 101, 106 (2nd Cir. 1996) (applying *Salerno* standard to facial Commerce Clause challenge). This they cannot do.

IV. The district court erred in ruling that plaintiffs will suffer irreparable harm without a preliminary injunction, and that the “balance of equities” and “public interest” prongs of the preliminary injunction test weigh in favor of granting preliminary injunctive relief.

To prevail on its motion for a preliminary injunction, plaintiffs must prove “immediate and irreparable harm” in the absence of an injunction. *See In re Microsoft Corp. Antitrust Litigation*, 333 F.3d 517, 530 (4th Cir. 2003) (preliminary relief should be denied where harm is “not present or immediate but merely problematic, conditioned on possible future events”) (citations omitted). Plaintiffs did not carry that burden.

Plaintiffs have not suffered irreparable harm. As an initial matter, the Act does not affect their First Amendment rights. Moreover, plaintiffs are national corporations (IMS is multi-national) that annually take in hundreds of millions in revenue (billions for IMS). Less than 1% of plaintiffs’ data comes from Maine prescribers. (App. 702-703). Plaintiffs have provided no concrete evidence that their data will lose its value if some Maine prescribers choose to opt out. The harm to plaintiffs from the Maine Act is nominal. The lower court erred in ruling to the contrary.

Finally, the public interest is best served by giving full effect to the duly enacted laws of the State. The Act will greatly benefit the public by limiting annual increases in the cost of health care, improving public health, and protecting the confidentiality of prescribers. Plaintiffs, the drug industry, and others can continue to use this data for non-marketing purposes, including research, during the pendency of the suit and beyond.

CONCLUSION

For the reasons discussed above, the lower court judgment should be reversed and the preliminary injunction vacated.

Dated: August 19, 2009

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CERTIFICATE OF SERVICE

Pursuant to Fed. R. App. P. 25(d), I, Thomas A. Knowlton, Assistant Attorney General for the State of Maine, hereby certify that, on the 20th day of August 2009, I filed the above brief by causing to be dispatched ten copies of same, along with a computer readable disk containing the same, by First-Class Mail, postage prepaid, to the Clerk of the United States Court of Appeals for the First Circuit.

I further certify that, on the 20th day of August 2009, I served the above brief on the Appellees by causing to be dispatched two copies of the same, by First-Class Mail, postage prepaid, to the following persons:

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CERTIFICATE OF COMPLIANCE WITH RULE 32(a)(7)

I hereby certify that this brief complies with the limitations of Fed. R. App. P. 32(a)(7)(B) because it contains 13,704 words, excluding the parts exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

I hereby certify that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2003 in 14-point Times New Roman font.

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ADDENDUM

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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.)	

ORDER ON PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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.¹ 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.²

¹ 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.

² 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 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

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.³ PDII's 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 PDII's. 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 birth of the patient, (5) the patient's gender, and (6) where the prescription was filled. Other

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.

³ 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).

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 PDII

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.⁴ 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.⁵ 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.⁶

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

⁴ 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.

⁵ 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.

⁶ 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.⁷ 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.

⁷ 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!"⁸ The concern about patient privacy is more illusive. The information to the PDIs is encrypted and the PDIs are unable to identify a specific patient. There is no real claim that the PDIs 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

⁸ 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.⁹

D. Advantages of Direct to Prescriber Marketing

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

⁹ 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.¹⁰

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.

¹⁰ 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 effects. 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 PDII's 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 PDII's 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.¹¹ *Id.*

F. The PDII Lawsuit

On August 29, 2007, three PDIIIs 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,

¹¹ 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; Randolph 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 183.¹²

¹² 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.¹³ *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 PDII's ability to collect prescriber information.

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.

¹³ 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 PDII's 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.¹⁴ Therefore, under the Law, the PDII's have the continuing right to collect prescriber information, even if the prescriber has opted out, and the PDII's retain the right to sell that same information to drug companies for purposes other than marketing.¹⁵ 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.¹⁶ 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.¹⁷ 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.¹⁸

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

¹⁴“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).

¹⁵ 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.

¹⁶ 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.

¹⁷ In fact, as will be discussed, the Law does not directly affect the detailer at all. Rather, the PDII's are assigned the responsibility to limit the pharmaceutical companies’ use of the opt-out prescribers’ data.

¹⁸ 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 PDII's 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 PDIIIs 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 PDIIIs 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 PDIIIs 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,

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 PDIIIs 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.²¹

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.

²¹ 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.²² *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 Representatives²³

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.

²² 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.*

²³ 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”²⁴ to the entities captured by the prohibition, expands the scope of prohibited activities,²⁵ and strikes two statutory qualifiers.²⁶ 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

²⁴ 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.

²⁵ 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.

²⁶ 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 PDII's and the pharmaceutical companies have had or realistically could have any effect on patient confidentiality.²⁷ Finally, the new Law does not prevent the pharmacies from transferring exactly the same information to the PDII's, 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 PDII's 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

²⁷ 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.²⁸ 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.²⁹

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.³⁰

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

²⁸ 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.

²⁹ 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.

³⁰ 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 PDIs 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 PDIs 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 PDIs 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 PDIIIs 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 PDIIIs 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;³¹ (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

³¹ 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.³² 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

³² 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." 22 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 PDIIIs, 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 PDIIIs 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.³³ *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)

³³ 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)).³⁴

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.³⁵

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

³⁴ 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.

³⁵ 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.³⁶

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

³⁶If 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 PDII's 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 PDII's 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.³⁷ 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 PDII's' 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 PDII's 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

³⁷ 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 PDIIIs if they fail to comply with its provisions. The Law assumes that the PDIIIs 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 PDIIIs will continue to collect, collate, and transmit all prescriber information to third parties such as governmental agencies and academic researchers.

One alternative for PDIIIs would be to entirely eliminate all opt-out prescribers in Maine from their database. This would vastly simplify the process for the PDIIIs, 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 PDIIIs wholly eliminate opt-out prescribers' data, this data would not be readily available to anyone, including the regulatory agencies.³⁸ 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.³⁹ 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.

³⁸ There may be alternative sources for this data, but the PDIIIs' 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 PDIIIs.

³⁹ 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 PDIIIs 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.⁴⁰

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 PDIs 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

⁴⁰ 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); *Bl(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.⁴¹ The main hardship to the

⁴¹ 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

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*.⁴² 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.⁴³ A number of the Law's provisions remain unaffected by this Order, since they do not implicate the exercise of First Amendment rights:⁴⁴

- (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 22 M.R.S.A. § 8713(5) & (6).

⁴² 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*.

⁴³ 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).

⁴⁴ 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:⁴⁵

- (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 21st day of December, 2007

⁴⁵ The Court DENIES Defendant's Motion to Strike Portions of Declarations. (Docket # 33).

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 INJUNCTION¹

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 PDII's 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 PDII's. 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

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 PDII's

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 PDIs is encrypted and the PDIs are unable to identify a specific patient. There is no real claim that the PDIs 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 effects. 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 PDIIIs 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; Randolph 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 PDII's ability to collect prescriber information.

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 PDII's 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 PDIs have the continuing right to collect prescriber information, even if the prescriber has opted out, and the PDIs 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

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 PDIs 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 PDIs 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 PDIIIs 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 PDIIIs 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 PDIIIs 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 PDII's 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 Representatives²⁴

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.

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 PDII's 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 PDII's, 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 PDII's 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 PDIs 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 PDIs 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 PDIs 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 PDIIIs 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 PDIIIs 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 PDIs, 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 PDIs 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

³⁷If 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 PDII's 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 PDII's 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 PDII's' 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 PDII's 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 PDIIIs if they fail to comply with its provisions. The Law assumes that the PDIIIs 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 PDIIIs will continue to collect, collate, and transmit all prescriber information to third parties such as governmental agencies and academic researchers.

One alternative for PDIIIs would be to entirely eliminate all opt-out prescribers in Maine from their database. This would vastly simplify the process for the PDIIIs, 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 PDIIIs 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 PDIIIs' 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 PDIIIs.

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 PDIIIs 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 PDIs 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); *Bl(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

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.

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

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

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.)	

ORDER ON MOTION TO AMEND JUDGMENT

The Court amends its preliminary injunction to allow the state of Maine agencies to engage in the non-enforcement activities the amendments to the Prescription Privacy Law contemplate.

I. BACKGROUND

On December 21, 2007, the Court issued an Order granting the Plaintiffs' motion for preliminary injunction against certain provisions in L.D. 4, "An Act to Amend the Prescription Privacy Law." *Order on Pls.' Mot. for Prelim. Inj.* (Docket # 71) (*Order*). On December 28, 2007, the Attorney General moved under Rule 59(e) for an amended judgment, asking that the Court lift the injunction as to particular statutory provisions. *Def.'s Mot. to Amend J.* (Docket # 72) (*Def.'s Mot.*). The Plaintiffs objected, *Pls.' Resp. in Opp'n to Mot. to Amend J.* (Docket # 76) (*Pls.' Resp.*), and the Attorney General replied. *Def.'s Mem. in Reply to Pls.' Opp'n* (Docket # 80) (*Def.'s Reply*).

II. THE PARTIES' POSITIONS

A. The Attorney General's Enforcement Only Position

The Attorney General stresses that he is not contesting the merits of the Order, which he intends to appeal, and he is not contesting the portion of the Order that enjoins the Law's enforcement provisions; rather, he contends that the Order went further than necessary by enjoining governmental activities which do not relate to the enforcement of the provisions of the Law that the Court concluded were unconstitutional. He asks that the Court amend the injunction to exclude the following:

1. 22 M.R.S.A. § 1711-E(4) – Confidentiality protection procedures, so long as the application process includes notice of the Court's Order enjoining enforcement of § 1711-E(2-A);
2. 22 M.R.S.A. § 1711-E(5) – Rules – Department of Health and Human Services (DHHS), so long as it does not involve enforcement of § 1711-E(2-A);
3. 22 M.R.S.A. § 8704(4) – Rulemaking – Maine Health Data Organization (MHDO), so long as it does not involve enforcement of § 1711-E(2-A); and,
4. 22 M.R.S.A. § 8713 – regarding the establishment of procedures for the Maine Health Data Organization to accept filings from certain health care providers.

Section 1711-E(4) requires the applicable boards of licensure for prescribers, as part of their application process for licensure and relicensure, to include notices that the prescribers' prescription drug histories are used for marketing purposes and to inform them that they may opt-out by completing a notice to that effect. The licensing boards are then required on a monthly basis to supply lists of opt-out prescribers to the MHDO. On each October 1, beginning in 2007, DHHS assesses annual fees against pharmaceutical companies, 80% of which covers the costs of the MHDO and 20% of which is retained by DHHS. Section 8713 allows the MHDO to

establish procedures to accept prescriber filings from the licensing boards; sections 1711-E(5) and 8704(4) authorize the MHDO and DHHS to promulgate rules to implement the Law.

The Attorney General's main point is that while the narrowest judicial remedy would be to prohibit enforcement of the statute's unconstitutional provisions, the Order extends to "certain non-enforcement activities even though these activities do not affect the constitutional rights of Plaintiffs." *Def.'s Mot.* at 2. The Attorney General argues:

These non-enforcement activities include allowing certain State agencies to continue to permit prescribers to register and provide information to them so as to be listed as having opted out of the disclosure of their prescribing activity, to compile for public information the identities of those prescribers, and to collect fees due by statute from drug manufacturers upon which the State has relied to cover the costs (some of which already has been incurred) of implementing and operating the Law, including the system for prescriber registration, the system for transfer of that registration information among agencies, and the system for compiling and disclosing the identity of those prescribers, if the State desires to proceed in that manner.

Id. The Attorney General continues, arguing that "[t]he Order provides relief beyond that sought by Plaintiffs and affects entities which are not parties to this lawsuit." *Def.'s Reply* at 2.

B. The Plaintiffs' Severability Analysis

The Plaintiffs respond that a severability analysis is appropriate here. Quoting *Town of Windham v. LaPointe*, the Plaintiffs contend that the "legislative provisions are so related in substance and object that it is impossible to determine that the legislation would have been enacted except as an entirety, if one portion offends the Constitution, the whole must fail." *Pls.' Resp.* at 5 n.9; (quoting *Town of Windham*, 308 A.2d 286, 292 (Me. 1973)); see 1 M.R.S.A. § 71(8).

III. DISCUSSION

A. Severability

“Severability is of course a matter of state law.”¹ *Leavitt v. Jane L.*, 518 U.S. 137, 139 (1996); *Rhode Island Med. Soc’y v. Whitehouse*, 239 F.3d 104, 106 (1st Cir. 2001). The absence of a severability clause does not alter the legal analysis. “Rules of statutory . . . construction . . . designed to effect legislative intent, do recognize that partial unconstitutionality of a statute . . . does not necessarily result in tainting the whole legislation, even in the absence of a severability clause.” *Town of Windham*, 308 A.2d at 292. Maine law mandates that the “provisions of the statutes are severable.” 1 M.R.S.A. § 71(8). To determine severability, the Court “considers the legislative purpose or purposes of the statute under consideration” *Opinion of the Justices*, 2004 ME 54, ¶ 23, 850 A.2d 1145, 1152. “When the provisions of a statute ‘are so related in substance and object that it is impossible to determine that the legislation would have been enacted except as an entirety, if one portion offends the Constitution, the whole must fall.’” *Id.* at ¶ 25, 850 A.2d 1152 (quoting *Windham*, 308 A.2d at 292).

Here, the Law expressly delineates its intent. 22 M.R.S.A. § 1711-E(1-A)(A-F), (1-B)(A-C). The Maine Legislature made express findings of the state’s interests in enacting the Law: “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.” *Id.* § 1711-E(1-A). The Legislature also delineated the Law’s purposes: “to protect patient confidentiality” and to “protect personal privacy rights.” *Id.* § 1711-E(1-B)(A)(B). To the extent that the Law’s purposes concern patient privacy, the Law is unaffected by the injunction, since § 2 of the Law was not enjoined.

¹ In this context, severability is not dissimilar from the Court’s obligation “when confronting a constitutional flaw in a statute . . . to limit the solution to the problem.” *Ayotte v. Planned Parenthood of Northern New England*, 546 U.S. 320, 328 (2006). The preference is “to enjoin only the unconstitutional applications of a statute while leaving other applications in force or to sever its problematic portions while leaving the remainder intact.” *Id.* at 328-29 (citations omitted).

The remaining purposes are: (1) to “protect prescribers’ expectations of privacy”; (2) to free prescribers “from pressure to prescribe based on comparisons among them and their peers and aiding 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”; (3) to “decrease the influence of drug representatives”; (4) to “build patient and prescriber confidence in the health care system”; (5) to “end the use of prescriber comparisons for purposes related to manufacturer profitability”; and, (6) to “decrease unnecessary marketing costs.” *Id.* § 1711-E(1-B)(A)(B). The Attorney General urges the Court to allow the state to collect the names of opt-out prescribers, to “compile for public information the identity of those prescribers,” and to “collect fees . . . to cover the costs . . . of implementing and operating the Law,” including new systems necessary to effectuate the Law’s provisions. *Def.’s Mot.* at 2.

If the enforcement provisions of the Law are enjoined, how would the remaining provisions enhance the legislative purposes? Collecting the names of prescribers who would opt-out, if allowed to do so, could assist the Legislature to make its crucial public policy judgments, including whether it has identified an issue that resonates with prescribers. If the number of opt-out prescribers is small, the Legislature could well conclude that it has created a solution in search of a problem. On the other hand, if the number is large, the Legislature could be encouraged to consider alternatives that would pass constitutional muster. The Attorney General qualified its request by emphasizing that it would notify prescribers of the Court’s Order enjoining enforcement. So long as the Attorney General does not propose enforcement rulemaking, there is no reason to enjoin either MHDO or DHHS from promulgating regulations that would allow for the collection of prescriber information under 22 M.R.S.A. §§ 1711-E(5) and 8704(4).

Finally, the Attorney General requests that the injunction be amended to allow the state to collect the fees authorized by § 1711-E(4)(C). The Attorney General makes the point that in collecting opt-out prescriber information, the state has incurred and will continue to incur costs and that the statute authorizes the collection of fees from drug manufacturers to cover these costs. *Def.'s Mot.* at 2. The Attorney General states that the collection of fees from pharmaceutical companies to establish a system for prescriber registration, for the transfer of registration information among agencies, and for the compilation and disclosure of the identity of those prescribers would not infringe the constitutional concerns that underpin the Court's injunction. *Id.* The Court agrees. If the state wished to survey prescribers who would opt out, if they could, and to establish a system for collecting and collating that information, the imposition of a fee against pharmaceutical companies to fund the survey would pose no issues of constitutional dimension.

B. Parties Bound by the Temporary Injunction

The Attorney General also raises an alternative basis for challenging the scope of the injunction: whether it went too far in reaching state agencies which were not parties to the case. This is a complex question that the Court does not reach, because it has resolved the matter based on a severability analysis.

C. Other Injunction Considerations

Even if the Law had come into effect on January 1, 2008, the state of Maine would not have been able to immediately enforce it, because, among other things, the Law contemplates the promulgation of rules from two state agencies and the gradual collection of opt-out prescriber information compiled through a staggered licensing and relicensing process. It is true that if the state proceeds with the collection of opt-out prescriber information and establishes systems to

share and collate the information, the state could finalize those aspects of the Law that require time to complete while this case is being resolved on appeal. By allowing the state to collect opt-out prescriber information and to establish systems that would make the Law enforceable, the state will be in a much better position to immediately enforce the Law's requirements against the Plaintiffs, if this Court's injunction is not affirmed.

This ordinarily would be of no concern to the Court. However, here, one of the Court's proper considerations in issuing the Order was the impact on the Plaintiffs:

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.

Order at 40. How the Plaintiffs would respond to the ongoing collection of opt-out prescriber information, whether they would expend time and resources to comply with the portions of the law that the Court has declared unconstitutional, and whether the state would act precipitously against the Plaintiffs if the Law is ultimately deemed constitutional remain matters of speculation.

IV. CONCLUSION

The Court GRANTS the Defendant's Motion to Amend Judgment (Docket # 73). The Court's Amended Order on Plaintiffs' Motion for Preliminary Injunction is further amended as follows:

The Court grants the Plaintiffs' motion for a preliminary injunction as to the following statutory provisions:

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 provisions other than § 1711-E(2);
3. 22 M.R.S.A. § 1711-E(5), only to the extent it requires DHHS to promulgate rules enforcing § 1711-E(2-A); and,
4. 22 M.R.S.A. § 8704(4), only to the extent it requires MHDO to promulgate rules enforcing § 1711-E(2-A).

More specifically, the Court amends its Order to clarify that the following provisions remain unaffected by the Court's injunction:

1. 22 M.R.S.A. § 1711-E(4), so long as the application process includes notice of the Court's Order enjoining enforcement of § 1711-E(2-A);
2. 22 M.R.S.A. § 1711-E(5), regarding DHHS rulemaking authority other than rulemaking to enforce § 1711-E(2-A);
3. 22 M.R.S.A. § 8704(4), regarding MHDO rulemaking authority other than rulemaking to enforce § 1711-E(2-A); and,
4. 22 M.R.S.A. § 8713.

SO ORDERED.

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

Dated this 15th day of February, 2008

STATE OF MAINE

JUN 29 '07 460

IN THE YEAR OF OUR LORD
TWO THOUSAND AND SEVEN

BY GOVERNOR PUBLIC LAW

H.P. 5 - L.D. 4

An Act To Amend the Prescription Privacy Law

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §1711-E, as enacted by PL 2005, c. 589, §1, is amended to read:

§1711-E. Confidentiality of prescription drug information

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Carrier" has the same meaning as in Title 24-A, section 4301-A, subsection 3.

A-1. "Administrator" has the same meaning as in Title 24-A, section 1901, subsection 1.

A-2. "Detailing" means one-to-one contact with a prescriber or employees or agents of a prescriber for the purpose of increasing or reinforcing the prescribing of a certain drug by the prescriber.

B. "Electronic transmission intermediary" means an entity that provides the infrastructure that connects the computer systems or other electronic devices used by and between health care practitioners, prescribers, pharmacies, health care facilities and pharmacy benefit managers to, carriers and administrators and agents and contractors of those ~~carriers and agents~~ persons and entities in order to facilitate the secure transmission of an individual's prescription drug order, refill, authorization request, claim, payment or other prescription drug information.

C. "Health care facility" has the same meanings as in section 1711-C, subsection 1, paragraph D.

D. "Health care practitioner" has the same meanings as in section 1711-C, subsection 1, paragraph F.

E. "Health plan" means a health plan providing prescription drug coverage as authorized under the federal Medicare Prescription Drug, Improvement and Modernization Act of 2003, Public Law 108-173.

F. "Individual" means a natural person who is the subject of prescription drug information.

F-1. "Marketing" means any 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.

"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.

F-2. "Pharmacy" means a mail order prescription pharmacy as defined in Title 32, section 13702, subsection 13 or a drug outlet as defined in Title 32, section 13702, subsection 10.

G. "Pharmacy benefits manager" has the same meaning as in section 2699, subsection 1, paragraph F.

G-1. "Prescriber" means a person who is licensed, registered or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice.

H. "Prescription drug information" means information concerning prescription drugs as defined in Title 32, section 13702, subsection 24 and includes prescription drug orders as defined in Title 32, section 13702, subsection 25.

I. "Prescription drug information intermediary" means a person or entity that communicates, facilitates or participates in the exchange of prescription drug information regarding an individual or a prescriber. "Prescription drug information intermediary" includes, but is not limited to, a pharmacy benefits manager, a health plan, an administrator and an electronic transmission intermediary and any person or entity employed by or contracted to provide services to that entity.

I-A. Findings. The Legislature finds that enactment of this section will assist the State to achieve the following compelling state 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.

A. The State has a duty to assist public and private payors and health care practitioners and consumers to maintain an effective and efficient health care system

that is based on sound medical and scientific knowledge and the professional judgment of health care practitioners and that is trusted by the general public.

B. Patients and prescribers have requested that the Legislature provide a mechanism for protecting the confidentiality of identifying prescription drug information from use for marketing purposes. Joining them are payors of all types and the general public demanding from the health care system efficiency, effectiveness and increased access for all persons.

C. Across the nation data companies purchase for marketing purposes computerized prescription drug records from pharmacies and insurers that identify prescribers. These records are sold to prescription drug manufacturers that use personally identifying prescriber 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.

D. Restricting 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.

E. With redirected drug detailing programs, manufacturers of prescription drugs will be able to increase their investments in new and more effective prescription drugs and savings will accrue to payors that can be used for increased access to health care and for other necessary public and private purposes.

F. The provisions of this section are narrowly and carefully tailored to address the findings listed in this subsection, to achieve the State's purposes listed in subsection 1-B and to advance the State's compelling interests.

1-B. Purposes. It is the intent of the Legislature in enacting this section to achieve the following compelling state interests: to improve 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.

A. 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. It will protect prescribers' expectations of privacy, freeing them from pressure to prescribe based on comparisons among them and their peers and aiding 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. It will decrease the influence of drug representatives. This will build patient and prescriber confidence in the health care system.

B. Restrictions on the use of personally identifying information for marketing purposes will protect personal privacy rights, end the use of prescriber comparisons for purposes related to manufacturer profitability and decrease unnecessary marketing costs.

C. The provisions of this section are narrowly and carefully tailored to address the findings listed in subsection 1-A, to achieve the State's purposes listed in this

subsection and in conjunction with the following efforts to advance the State's compelling interests:

- (1) Prior authorization and drug utilization review in the MaineCare program under section 3174-M;
- (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 section 1711-C.

2. Confidentiality of prescription drug information that identifies the individual. A carrier or prescription drug information intermediary may not license, use, sell, transfer or exchange for value, for any marketing purpose, prescription drug information that identifies directly or indirectly the individual 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.

2-A. Confidentiality of prescription drug information that identifies the prescriber. 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 in accordance with subsection 4.

3. Enforcement. A violation of this section subsection 2 or 2-A is a violation of the Maine Unfair Trade Practices Act.

4. Confidentiality protection procedures. The procedures in this subsection apply to the protection of prescription drug information that identifies a prescriber.

A. Beginning October 1, 2007, a board of licensure of a prescriber shall provide as part of the application process for licensure and relicensure confidentiality protection information and procedures as set forth in this paragraph.

(1) The application materials must state that prescription drug information that identifies the prescriber is used for marketing purposes by carriers, pharmacies and prescription drug information intermediaries and that, with regard to that use of information, the confidentiality of the prescriber may be protected under this section in one of 3 ways:

(a) If the licensing procedure is done by regular mail, by signing and submitting to the Maine Health Data Organization the accompanying confidentiality protection form and addressed envelope;

(b) If the licensing procedure includes a check-off box on the application form or electronically, by completing the check-off box and submitting the form to the licensing board; or

(c) If the licensing procedure is done over the Internet and the licensing board has provided an electronic link over the Internet from the application materials, by use of the electronic link to the Maine Health Data Organization website.

(2) The licensing board shall submit to the Maine Health Data Organization on a monthly basis a list of all prescribers who have filed with the licensing board for confidentiality protection.

(3) The confidentiality protection information must inform the prescriber that filing for confidentiality protection is effective until it is revoked by the prescriber.

B. The boards of licensure may adopt rules to implement paragraph A. Rules adopted pursuant to this paragraph are routine technical rules as defined by Title 5, chapter 375, subchapter 2-A.

C. The department shall assess an annual fee payable by October 1st each year beginning in 2007 on manufacturers of prescription drugs whose drugs are dispensed to members of the MaineCare program under chapter 855 and enrollees in the elderly low-cost drug program under section 254-D. Eighty percent of the fees collected under this paragraph must be deposited in a separate account that does not lapse at the end of the fiscal year and must be used to cover the costs of the Maine Health Data Organization pursuant to paragraph A and section 8713. Twenty percent of the assessments must be retained by the department.

5. Rules. The department, after consultation with the Governor's Office of Health Policy and Finance, shall adopt rules to implement this section. Rules adopted pursuant to this subsection are routine technical rules as defined by Title 5, chapter 375, subchapter 2-A.

Sec. 2. 22 MRSA §8704, sub-§4, as amended by PL 1999, c. 127, Pt. B, §8, is further amended to read:

4. Rulemaking. The board shall adopt rules necessary for the proper administration and enforcement of the requirements of this chapter and to carry out the duties of the organization under section 1711-E, subsection 4 and section 8713. All rules must be adopted in accordance with Title 5, chapter 375 and unless otherwise provided are routine technical rules as defined in Title 5, chapter 375, subchapter ~~H-A~~ 2-A.

Sec. 3. 22 MRSA §8704, sub-§7, as amended by PL 2005, c. 565, §5, is further amended to read:

7. Annual report. The board shall prepare and submit an annual report on the operation of the organization and the Maine Health Data Processing Center as authorized in Title 10, section 681, including any activity contracted for by the organization or contracted services provided by the center, with resulting net earnings, to the Governor

and the joint standing committee of the Legislature having jurisdiction over health and human services matters no later than February 1st of each year. The report must include an annual accounting of all revenue received and expenditures incurred in the previous year and all revenue and expenditures planned for the next year. The report must include a list of persons or entities that requested data from the organization in the preceding year with a brief summary of the stated purpose of the request.

As part of its annual report, the organization shall report on filings for confidentiality protection under section 1711-E, subsection 4, the disclosure of the names of prescribers who filed for confidentiality protection, funding through the assessment under section 1711-E, subsection 4, paragraph C and recommendations for legislation to improve operation of section 1711-E, subsection 4.

Sec. 4. 22 MRSA §8713 is enacted to read:

§8713. Confidentiality protection for certain health care practitioners

The organization shall establish procedures to accept filings for confidentiality protection from health care practitioners who file with the organization under section 1711-E, subsection 4 and licensing boards that submit lists of names of practitioners who file for confidentiality protection. The procedures must provide for disclosure, upon request, of the names of practitioners who filed for confidentiality protection. The costs of the organization for performing the functions under this section must be met by funding provided under section 1711-E, subsection 4, paragraph C.

Sec. 5. Transfer to the Maine Health Data Organization. Notwithstanding any other provision of law, the State Controller after consultation with the Commissioner of Health and Human Services and the Director of the Maine Health Data Organization shall transfer funds as determined and available under section 1 of this Act in each of fiscal years 2007-08 and 2008-09 from the Bureau of Medical Services, Other Special Revenue Funds account in the Department of Health and Human Services to the Maine Health Data Organization, Other Special Revenue Funds account for costs incurred as a result of this Act.

Sec. 6. Appropriations and allocations. The following appropriations and allocations are made.

HEALTH AND HUMAN SERVICES, DEPARTMENT OF (FORMERLY DHS)

Bureau of Medical Services 0129

Initiative: Provides a base allocation for the costs of the prescription drug privacy program.

OTHER SPECIAL REVENUE FUNDS	2007-08	2008-09
All Other	\$500	\$500
OTHER SPECIAL REVENUE FUNDS TOTAL	\$500	\$500