

IMS v. Ayotte, A.G., State of NH CV-06-280-PB 04/30/07 P

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW HAMPSHIRE

IMS Health Incorporated, et. al.

v.

Case No. 06-cv-280-PB  
Opinion No. 2007 DNH 061 P

Kelly Ayotte, as Attorney General  
of the State of New Hampshire

MEMORANDUM AND ORDER

A lucrative market has developed in recent years for data identifying the prescribing practices of individual health care providers ("prescriber-identifiable data"). Pharmacies acquire prescription data in the ordinary course of business. Data mining companies such as the plaintiffs in this case, IMS Health Incorporated and Verispan, LLC, purchase the prescription data, remove information identifying patients before it leaves the pharmacy, combine what remains with data from other sources, and sell the combined data to interested purchasers. The data miners' biggest clients by far are pharmaceutical companies, which use the data to develop marketing plans targeted to specific prescribers.

The New Hampshire Legislature recently enacted a law that bars pharmacies, insurance companies, and similar entities from transferring or using prescriber-identifiable data for certain commercial purposes. See 2006 N.H. Laws § 328, codified at N.H. Rev. Stat. Ann. §§ 318:47-f, 318:47-g, 318-B:12(IV) (2006) (“Prescription Information Law”). IMS and Verispan have filed this action contending that the new law impermissibly restricts their First Amendment right to free speech.

In this Memorandum and Order, I explain why the new law violates the First Amendment.

## I. **FACTS**<sup>1</sup>

### A. **Prescription Information Collection**

Approximately 1.4 million licensed health care providers are authorized to write prescriptions in the United States for approximately 8,000 different pharmaceutical products in various forms, strengths, and doses. These prescriptions are filled by approximately 54,000 retail pharmacies and other licensed medical

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<sup>1</sup> All factual findings in this Memorandum and Order are based on evidence produced at trial. The facts have been established by a preponderance of the evidence.

facilities throughout the United States.

Retail pharmacies acquire prescription data during the regular course of business. For each prescription filled, a record is kept that includes the name of the patient, information identifying the prescriber, the name, dosage, and quantity of the prescribed drug, and the date the prescription was filled. If the pharmacy is part of a larger organization with multiple retail outlets, each outlet's prescription data is ultimately aggregated with data from other outlets and stored in a central location.

**B. Plaintiffs' Acquisition of Prescription Information**

IMS and Verispan are the world's leading providers of information, research, and analysis to the pharmaceutical and health care industries. IMS, the largest business in the field, purchases prescriber information from approximately 100 different suppliers. Verispan, a company roughly one-tenth the size of IMS, obtains its information from approximately thirty to forty suppliers. Plaintiffs collectively acquire and analyze data from billions of prescription transactions per year throughout the United States.

Plaintiffs purchase prescriber-identifiable data from participating pharmacies and other sources. To comply with state and federal laws protecting patient privacy, participating pharmacies allow plaintiffs to install software on their computers that encrypts any information identifying patients before it is transferred to plaintiffs' computers. After patient information is "de-identified" in this way, a number is assigned to each de-identified patient that permits prescription information to be correlated for each patient but does not allow the patient's identity to be determined. The prescription information is then transferred to the plaintiffs' computers where it is combined with data from other sources and made available to plaintiffs' customers. IMS and Verispan obtain all of their prescription information, including information on prescriptions filled in New Hampshire, from computers that are located outside of New Hampshire.

One way in which plaintiffs add value to prescriber-identifiable data is to combine it with prescriber reference information. This allows plaintiffs to, among other things, match each prescription to the correct prescriber, identify and use the prescriber's correct name, and add address, specialty,

and other professional information about the prescriber to the prescription data. Prescriber reference files are created using information obtained from various sources, including the American Medical Association's ("AMA") Physician Masterfile. The AMA's Masterfile contains demographic, educational, certification, licensure, and specialty information for more than 800,000 active U.S. medical doctors and over 90 percent of osteopathic doctors. Plaintiffs use the patient de-identified prescription data, together with the reference file data, to produce a variety of patient de-identified databases.

The AMA recently adopted a program that gives participating health care providers the power to limit access to their prescribing information ("the Prescribing Data Restriction Program" or "PDRP"). Under the PDRP, pharmaceutical companies are permitted to acquire prescriber-identifiable data for participating providers but they may not share the information with their sales representatives. IMS and Verispan participate in the PDRP and require their customers to abide by its terms.

**C. Uses of Prescription Information by Pharmaceutical Companies**

Plaintiffs' biggest clients by far are pharmaceutical companies. According to IMS's 2005 Annual Report, "[s]ales to

the pharmaceutical industry accounted for substantially all of [IMS's] revenue in 2005, 2004 and 2003." Approximately 95 percent of Verispan's sales of prescriber-identifiable data are to pharmaceutical companies. Plaintiffs also provide prescriber-identifiable information to biotechnology firms, pharmaceutical distributors, government agencies, insurance companies, health care groups, researchers, consulting organizations, the financial community, manufacturers of generic drugs, pharmacy benefit managers, and others. Some of these entities use, license, sell, or transfer the information for advertising, marketing, and promotional purposes, while others use the information for non-commercial purposes.<sup>2</sup>

Pharmaceutical companies commit vast resources to the marketing of prescription drugs. In 2000, the pharmaceutical industry spent approximately \$15.7 billion on marketing, \$4 billion of which was dedicated to direct-to-physician strategies.

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<sup>2</sup> Plaintiffs also make prescriber-identifiable data available at little or no cost for non-marketing purposes to academic researchers, medical researchers, humanitarian organizations, and law enforcement authorities. These entities use the information to track patterns of disease and treatment, conduct research and clinical trials, implement best practices, and engage in economic analyses.

More recent estimates suggest the industry currently spends between \$25 billion and \$30 billion per year on marketing. The large pharmaceutical companies spend roughly 30 percent of their revenues on promotion, marketing, and administration, while spending only approximately 13 percent on research and development.

Pharmaceutical companies market to both consumers and prescribers. Companies rely primarily on print and television advertising to reach consumers and depend more heavily on a variety of direct marketing techniques to reach health care providers. Among the companies' direct marketing practices that are most relevant to this case are their efforts to enlist the support of "thought leaders" in the medical community and their use of "detailing" to persuade individual health care providers to prescribe specific brand-name drugs.

#### **1. Thought Leaders**

Thought leaders are physicians and researchers whose views are accorded special weight in the medical community.

Pharmaceutical companies enlist the support of thought leaders by sponsoring their research, retaining them to serve as consultants and speakers, and entertaining them at dinners and other events.

Although thought leaders rarely, if ever, are paid to endorse particular drugs, their tacit support is deemed by pharmaceutical companies to be highly valuable in persuading others to prescribe their products.

## **2. Detailing**

Pharmaceutical detailing generally involves the provision of promotional and educational information during face-to-face contact between sales representatives and health care providers. Sales representatives provide prescribers with both written and oral information about particular drugs in an effort to persuade them to prescribe the drugs being detailed. They also offer prescribers free samples that can then be distributed to patients at no charge. Because many prescribers are reluctant to meet with sales representatives, small gifts, free meals, and other inducements are also frequently offered to health care providers and their staffs in an effort to facilitate access and encourage receptivity to the representative's sales pitch.

### **a. Promotional Information**

Pharmaceutical companies strictly control the information that detailers are authorized to present on their behalf.

Although sales representatives generally provide prescribers with accurate information, misstatements and omissions do occur. A 1995 study published in the Journal of the American Medical Association concluded that 11 percent of the in-person statements made to physicians by pharmaceutical sales representatives contradicted information that was readily available to them.<sup>3</sup> Michael G. Ziegler, Pauline Lew, and Brian C. Singer, *The Accuracy of Drug Information From Pharmaceutical Sales Representatives*, 273 JAMA 1296, 1296-98 (1995).

The Federal Food and Drug Administration ("FDA") has broad authority to regulate drug advertisements and promotional labeling. See, e.g., Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331(a), 352 (2000); FDA Prescription Drug Advertising

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<sup>3</sup> For purposes of the study, an inaccurate statement was defined as one that met all three of the following criteria: (i) the statement clearly contradicted prescribing information in the 1993 Physicians' Desk Reference or literature quoted or handed out by the detailer; (ii) a pharmacist and a physician-clinical pharmacologist independently assessed the statement as incorrect; and (iii) a search of reference books, drug company brochures, and MEDLINE files from 1985 through 1993 provided no support for the statement. Seven of twelve pharmaceutical sales representatives in the study made a total of twelve inaccurate statements in their presentations. All twelve inaccurate statements were about the drug being promoted, and all cast that drug in a favorable light. 273 JAMA at 1296-98.

Rule, 21 C.F.R. § 202.1 (1999). Existing regulations prohibit prescription drug advertising and labeling information that is false, misleading, or that lacks a "fair balance between information relating to side effects and contra-indications and information relating to effectiveness . . ." 21 C.F.R. § 202.1(e)(5)-(6). The agency is authorized to take enforcement action against companies that use false and misleading advertising materials. 21 U.S.C. §§ 332-337. This regulatory authority also extends to oral misrepresentations by sales representatives. See, e.g., FDA Priv. Ltr. Warning, available at <http://www.fda.gov/cder/warn/sep2000/dd9199.pdf> (warning to cease false and misleading oral statements by sales representatives).

#### **b. Sampling**

Product sampling is widely used in the marketing of prescription drugs. Published reports estimate that the total annual retail value of sampled drugs exceeds \$11 billion. Product sampling programs permit sales representatives to use sampled drugs as inducements to facilitate access to prescribers. They also promote sales by allowing prescribers to become familiar with the sampled drugs and by increasing the likelihood

that patients will continue to request prescriptions for sampled drugs after their samples have been consumed. Many physicians accept samples because it allows them to provide free medications to patients who might not otherwise be able to afford them.

**c. Gifts, Meals and Other Inducements**

Prescribers are often reluctant to meet with sales representatives. In an effort to overcome this reluctance, sales representatives provide health care providers and their staffs with small gifts, free meals, and other inducements. In addition to facilitating access, such inducements help sales representatives build relationships with prescribers that can make them more receptive to the product information that sales representatives provide.

The Pharmaceutical Research and Manufacturers of America ("PhRMA") has adopted a voluntary "Code on Interactions with Health care Professionals," available at <http://www.phrma.org/files/PhRMA%20Code.pdf>, in an effort to address public concern with gift-giving by sales representatives. The 56-page Code contains aspirational guidelines that are intended to ensure that "[i]nteractions should be focused on informing healthcare

professionals about products, providing scientific and educational information, and supporting medical research and education.” Id. at 5. Although the PhRMA Code permits members to hire health care providers to serve as consultants and speakers, id. at 10-13, it discourages members from otherwise offering inducements directly to health care providers unless either the value of what is provided is insubstantial (less than \$100) and the inducement is primarily for the benefit of patients, or the value of the inducement is minimal and the inducement is directly related to the provider’s practice. Id. at 17. For example, an occasional gift of a stethoscope is acceptable under the Code because it is not deemed to be of substantial value and the gift benefits patients. Id. at 23. In contrast, an unrestricted gift certificate to a local bookstore may not be offered under the Code regardless of its value because it does not benefit patients and is unrelated to the health care professional’s practice. Id. at 33. The Code draws similar distinctions with respect to meals and entertainment. Id. at 28-37.

Pharmaceutical companies are not obligated to follow the PhRMA Code in New Hampshire. Nevertheless, the United States

Department of Health and Human Services, Office of Inspector General ("OIG") has endorsed the Code in guidance it has offered to companies concerning the need for internal compliance programs in the health care industry. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731-01 (proposed May 5, 2003). As the guidance states, "[a]lthough compliance with the PhRMA Code will not protect a manufacturer as a matter of law under the anti-kickback statute, it will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements." Id.<sup>4</sup>

**d. Effectiveness of Detailing**

Detailing is generally used only to market prescription drugs that are entitled to patent protection. After the patents on a brand-name drug expire, competitors can obtain approval to sell generic bioequivalent versions of the drug. Generic drugs are generally substantially less expensive than their brand-name

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<sup>4</sup> The anti-kickback statute, 42 U.S.C. § 1320a-7b(b)(2), makes it a federal crime to pay a health care provider to order something for which payment may be made under a federal health care program.

equivalents, and bioequivalent generic drugs are equally effective for most patients.<sup>5</sup> New Hampshire law authorizes pharmacies to substitute a bioequivalent generic drug for a branded drug unless the prescriber specifies that the brand-name drug is "medically necessary." N.H. Rev. Stat. Ann. § 318-47(d) (2003). Accordingly, sales of brand-name drugs tend to fall substantially after bioequivalent generic drugs become available and detailing is no longer seen as a cost-effective marketing technique.

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<sup>5</sup> In some circumstances, a brand-name drug may be preferable to a bioequivalent generic alternative. This is primarily because generic drugs are not subjected to the same rigorous study and testing as brand-name drugs, may have unknown side effects, and bioequivalent generic alternatives need only demonstrate absorption parameters falling between 80 and 125 percent of those obtained by their branded counterparts. As a result, individual responses to treatment may vary significantly. For example, when patients switch from a brand-name drug to a generic drug, there is a risk that the patient will absorb significantly more or less of the medication than the patient was absorbing from the branded drug. Additionally, because there may be numerous generic producers of a single brand-name drug, with each generic alternative characterized by a different rate of absorption of active ingredients and different side effects, a patient's response to treatment may vary substantially depending on the generic alternative the pharmacist has in stock on a particular day. In treating epilepsy, for example, these variations may result in the patient experiencing seizures that might have been avoided if the absorption rate had remained steady.

Pharmaceutical companies continue to heavily market brand-name drugs as treatments for conditions that can also be treated with generic alternatives that are not bioequivalent. For example, although depression can be treated for many patients with a generic form of Prozac, several pharmaceutical companies also market different brand-name medications as a treatment for depression. Because brand-name medications are often substantially more expensive than non-bioequivalent generic alternatives, those patients who achieve the same benefits from a non-bioequivalent generic medication can save money by substituting the non-bioequivalent generic medication for a branded alternative.

Detailing can be an effective marketing technique for brand-name drugs. It works by, among other things: (i) building name recognition among prescribers for the drug being detailed; (ii) providing information about the drug to prescribers in a form that is designed to be persuasive; and (iii) providing inducements to providers consisting of free samples, small gifts, and meals that facilitate access and foster relationships between the sales representatives and health care providers.

**D. Uses of Prescriber-Identifiable Information in Detailing**

Pharmaceutical companies use prescriber-identifiable data for a variety of purposes. I focus here on the ways in which it is used to target prescribers for detailing, to tailor detailing messages, and to evaluate the effectiveness of detailing practices.

**1. Targeting**

Pharmaceutical companies use prescriber-identifiable data to analyze the prescribing practices of specific health care providers. For example, companies use prescriber-identifiable information when introducing new drugs to identify “early adopters” who have demonstrated by their past prescribing practices that they are disposed to prescribe new medications. They also use prescriber-identifiable data to identify health care providers who have recently changed their prescribing practices with respect to specific drugs, those who are prescribing large quantities of the drugs that the detailer is selling, and those who are prescribing competing drugs. Targeting health care providers in this manner enables pharmaceutical companies to efficiently allocate resources by providing samples to and detailing for those providers who are

most likely to be responsive to detailing for specific products.

## **2. Tailoring**

Pharmaceutical companies use prescriber-identifiable data to tailor their marketing messages to specific health care providers. For example, a sales representative 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. There is no evidence in the record, however, to suggest that pharmaceutical companies use prescriber-identifiable data to facilitate the distribution of false or misleading information.

## **3. Measuring the Effectiveness of Detailing**

Yet another use of prescriber-identifiable data is to measure the effectiveness of detailing. Companies use the data 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. In this way, manufacturers can adjust the marketing message that detailers bring to individual health care providers.

**E. The Statute**

The Prescription Information Law became effective on June 30, 2006 and is codified at N.H. Rev. Stat. Ann. §§ 318:47-f, 318:47-g, 318-B:12(IV) (2006). It expressly prohibits the transmission or use of both patient-identifiable data and prescriber-identifiable data for certain commercial purposes.<sup>6</sup>

The pertinent language of the statute reads:

Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research; or as otherwise provided by law. Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force....

The statute does not regulate the transmission or use of data for non-commercial purposes. Further, although it defines

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<sup>6</sup> Plaintiffs do not challenge the law's restriction on the transmission and use of patient-identifiable data.

“commercial purpose” broadly, it expressly excludes from the statute’s scope all conceivable commercial uses of the data except those that are directly associated with advertising and marketing. Nor does it prohibit pharmaceutical companies from using prescriber-identifiable data in clinical trials.

Violations of the statute are punishable as a misdemeanor if the offender is a natural person and are treated as a felony if the offender is any other person. Violators of the statute are also subject to civil penalties. N.H. Rev. Stat. Ann. § 318:55.

**F. Legislative History**

The Prescription Information Law was introduced on January 4, 2006, as House Bill 1346 by New Hampshire Representative Cindy Rosenwald. On May 11, 2006, following House and Senate hearings, the New Hampshire Legislature passed the amended bill, which the Governor signed into law on June 30, 2006. The law is the first of its kind in the United States.

According to the law’s legislative history, the legislature passed the law to protect patient and physician privacy and to save the State, consumers, and businesses money by reducing health care costs. An Act Requiring Certain Persons To Keep the Contents of Prescriptions Confidential: Hearing on H.B. 1346

Before the S. Comm. on Exec. Departments & Administration, 159th Sess. Gen. Ct. 1 (N.H. 2006) (statement of Rep. Cindy Rosenwald, Member, House of Representatives).

Following passage in the House by a unanimous vote, various representatives spoke in support of the bill at a Senate Committee hearing. According to Representative Rosenwald, the law would accomplish its goals by prohibiting the sale or use of individual patient or prescriber-identifiable information for marketing brand-name prescription drugs. Id. A section of a written attachment to Representative Rosenwald's testimony entitled "What H.B. 1346 will do," states that the law will "hopefully reduce the prescription drug costs for patients, employers & the State Medicaid program." Id. at Attachment 1.

Representative Pamela Price also testified at the hearing and compared the annual costs to Medicaid of a branded calcium channel blocker and a generic calcium channel blocker to purportedly demonstrate state savings that would occur under the law. Id. at 6, Attachment 4 (chart and statement of Rep. Pamela Price, Member, House of Representatives). She claimed that a one-year supply of the branded drug Dynacirc would cost Medicaid \$1,047, while a one-year supply of the generic drug Verapamil

would cost Medicaid only \$162. Id. Because Medicaid insures a hundred thousand patients, she said, the potential cost savings could be substantial. Id.

Representative Price also submitted a short research paper written by Emily Clayton, a health care advocate for the California Public Interest Research Group (CALPIRG). Id. at Attachment 13; Emily Clayton, *Tis Always The Season For Giving: A White Paper on the Practice and Problems of Pharmaceutical Detailing*, CALPIRG, Sept. 2004, available at <http://calpirg.org/reports/TistheSeasonForGiving04.pdf>. In the report, Clayton briefly explained that pharmaceutical companies purchase aggregated prescriber information from data mining companies and then use it "to specifically target their sales pitches when they meet with doctors." Id. at 3.

She described the size and growth of the pharmaceutical marketing industry, the competitiveness of detailing, and the effective use of gifts as inducements. Based on Clayton's review of several other studies that were not a part of the legislative record, she concluded that detailing causes public mistrust of prescriber decisions, increased drug costs, and the provision of incomplete and/or misleading information to prescribers. Id. at

4-5. Next, she outlined the AMA and PhRMA guidelines and the OIG's related guidance, and criticized them as overly narrow, vague, discretionary, and lacking in enforcement mechanisms. To address these problems, she advocated three potential solutions: (i) caps and bans on gifts from pharmaceutical manufacturers to doctors, (ii) disclosure requirements with respect to all gifts from pharmaceutical manufacturers to doctors, and (iii) codification and enforcement of existing guidelines.

A representative of the Department of Health and Human Services ("DHHS") briefly discussed the large commercial market for prescriber-identifiable data, and said that commercial use of this information violates prescribers' "trade secrets." Id. at 9 (statement of Gregory Moore, representative of the DHHS, speaking on behalf of Commissioner John Stephen). According to Moore, the DHHS

believes that these activities ultimately drive up the cost of prescription drugs and the cost of health care in the aggregate. Since no other state has passed legislation like this, it would be hard for us to quantify what that impact might be, but I find it unlikely the drug companies are sending detail[ers] into doctors' offices for the purpose of selling doctors cheaper medication. In fact, I'm confident that, if you're a doctor, that one of the best ways to get a detailer into your office would be if you switched to prescribing a generic drug over a branded

drug.

Id. at 8.

In addition, President-elect of the New Hampshire Medical Society, Dr. Seddon Savage, said the law “will deter marketing intended to manipulate the practice of individual physicians that is intended to increase market share for the individual companies, possibly at the expense of appropriate decision-making for the patients.” Id. at 16-17. Janet Monahan, also representing the New Hampshire Medical Society, said that because pharmaceutical companies focus their marketing efforts on their newest, most expensive medicines, successful promotions lead to higher health care costs. Id. at 27, Attachment 13 (discussing Clayton, supra). Bill Hamilton, an advocacy director for AARP said “we did an analysis and we don’t feel [the law] necessarily will increase the cost of drugs.” Id. at 21.

According to testimony offered at this hearing, some detailers use prescriber-identifiable information to put improper pressure on prescribers. One anecdote shared by a nurse practitioner speaking in favor of the Prescription Information Law highlights this alleged problem.

For the past several months, a drug rep has been bringing coffee to our office on Tuesday mornings. We have never asked her to continue doing this since we have a coffee pot, and we routinely make coffee for our staff and our patients. But she does it anyway, which is very nice of her. She calls this "Two for Tuesday." The problem is that every week she also says to me, "If you don't write 2 more prescriptions for my brand today, I'm not going to be able to continue bringing coffee." I prescribe her drug when it is right for my patients. There are many times when it is not right.

We feel pressure from her to prescribe her product even though we have never asked her to bring coffee. This may sound like a small thing, but I feel that since she knows exactly how many prescriptions I write each week for her drug versus the competition, she is expecting a quid pro quo.

Id. at 33, Attachment 15. A similar anecdote, as described in a January 2006 article in The New York Times, was also included in the legislative record. According to the article, a district manager for a pharmaceutical company sent an e-mail to detailers in which she stated that

[o]ur goal is 50 or more scripts per week for each territory. If you are not achieving this goal, ask yourself if those doctors that you have such great relationships with are being fair to you. Hold them accountable for all of the time, samples, lunches, dinners, programs, and past preceptorships<sup>7</sup> that you have provided or paid for and get the business!! You can do it!!

Id. at 27, Attachment 13 (quoting Gardiner Harris & Robert Pear,

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<sup>7</sup> Preceptorships are consulting arrangements with doctors.

*Drug Maker's Efforts to Compete in Lucrative Insulin Market Are Under Scrutiny*, N.Y. TIMES, Jan. 28, 2006).

Others spoke in opposition to the bill. A representative of the New Hampshire Association of Chain Drug Stores expressed concern that the bill struck too broadly and, among other problems, would prevent prescriptions from being transferred from one pharmacy to another. Id. at 11. Representatives of IMS Health and Verispan also spoke in opposition, arguing that the law would do nothing to advance patient privacy, that prescriber privacy could be adequately addressed by the PDRP,<sup>8</sup> and that the legislature should consider other ways to address privacy concerns to avoid losing out on the value of prescriber-identifiable information. Id. at Attachment 10. They suggested that the law would cause unintended harms, including increased health care costs caused by the need for higher drug prices to make up for inefficient marketing, inefficient sampling, and increased compliance and enforcement costs. Id. at 22, Attachment 12.

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<sup>8</sup> As of the time of the hearing, the PDRP was not yet in place.

**G. The Statute's Impact**

IMS and Verispan have substantially altered their business practices to comply with the Prescription Information Law. IMS has entered into agreements with its sources of prescription information to ensure that it will not use the information in ways that violate the law. It removes prescriber-identifiable information from New Hampshire prescriptions and no longer sells prescriber-identifiable data from New Hampshire to third parties. To avoid inadvertent violations, it examines every prescription record it receives and removes all identifying data for prescriptions that originate from a pharmacy or a health care provider with a New Hampshire zip code. Verispan has modified its databases so that it can identify and suppress all prescriber-identifiable data from New Hampshire prescriptions before the information is released to third parties.

**II. ANALYSIS**

Plaintiffs argue that the Prescription Information Law is a content-based restriction on non-commercial speech that is subject to strict scrutiny. They then assert that the law violates the First Amendment because it is not narrowly tailored

to serve compelling state interests. Their fall-back position is that the law is unconstitutional even if it is a commercial speech restriction subject only to intermediate scrutiny because it does not directly advance a substantial governmental interest in a manner that is narrowly tailored to serve that interest.

The Attorney General attacks the plaintiffs' claim at every turn. She first argues that the Prescription Information Law is not subject to the First Amendment because it does not regulate speech. Alternatively, she argues that the law is a commercial speech restriction that is subject only to intermediate scrutiny. She then claims that the law readily passes the intermediate scrutiny test because it has been carefully crafted to directly serve the State's substantial interests in protecting prescriber privacy, promoting public health, and controlling health care costs.<sup>9</sup>

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<sup>9</sup> The Attorney General also contends that plaintiffs lack standing to sue because they are not subject to prosecution under the Prescription Information Law. I am not persuaded by this argument. First, it is at least arguable that plaintiffs could be prosecuted under the law because they acquire prescriber-identifiable data and resell it for commercial purposes and thus are "other similar entit[ies]" that are subject to prosecution under the law. In any event, they are plainly subject to prosecution as conspirators if they conspire with covered entities to violate the law. See N.H. Rev. Stat. Ann. § 629:3

I resolve this dispute by examining each of the Attorney General's arguments in turn. As I explain below, I ultimately conclude that the Prescription Information Law violates the First Amendment because it improperly restricts commercial speech.

**A. Does the Challenged Statute Restrict "Speech"?**

The Attorney General first argues that the Prescription Information Law does not restrict "speech" protected by the First Amendment. This argument takes two forms, neither of which has merit. First, she argues that the First Amendment does not apply to the Prescription Information Law because it targets unprotected factual information rather than constitutionally protected speech. This argument is contradicted by Supreme Court precedent. See, e.g., Fla. Star v. B.J.F., 491 U.S. 524, 540-41 (1989) (rape victim's name); Va. State Bd. of Pharmacy v. Va. Citizens Consumer Counsel, Inc., 425 U.S. 748, 762 (1976) (drug prices); see also Miller v. California, 413 U.S. 15, 34 (1973) (stating that First Amendment protects speech that has scientific

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(1999). More fundamentally, it is undisputed that plaintiffs have incurred substantial costs to comply with the law and face revenue losses if they are unable to acquire and resell prescriber-identifiable data. This kind of economic injury is sufficient to give them standing to sue. See Gen. Motors Corp. v. Tracy, 519 U.S. 278, 286-87 (1997).

value). As the Second Circuit has acknowledged in discussing this precedent, “[e]ven dry information, devoid of advocacy, political relevance, or artistic expression, has been accorded First Amendment protection.” Universal City Studios, Inc. v. Corley, 273 F.3d 429, 446-47 (2d Cir. 2001) (citing Supreme Court cases). Here, the challenged law restricts the transmission of truthful information concerning the prescribing practices of New Hampshire’s health care providers. It is not exempt from First Amendment review merely because it targets factual information rather than viewpoints, beliefs, emotions, or other types of expression.

The Attorney General next argues that the Prescription Information Law does not restrict speech because it regulates “uses” of prescriber-identifiable information rather than the disclosure of such information. This argument is based on the mistaken premise that the law restricts only the uses to which prescriber-identifiable data may be put. In fact, the challenged statute provides that prescriber-identifiable information “shall not be licensed, transferred, used or sold” for a prohibited purpose. N.H. Rev. Stat. Ann. § 318:47-f (emphasis added). A transfer of information to a third party is a form of disclosure.

The law is thus a speech restriction because it limits both the use and disclosure of prescriber-identifiable data for commercial purposes. Bartnicki v. Vopper, 532 U.S. 514, 526-27 (2001) (a “prohibition against disclosures is fairly characterized as a regulation of pure speech.”).

The Attorney General’s argument would fail even if the Prescription Information Law did not directly restrict the disclosure of prescriber-identifiable data. A law is not automatically exempt from the First Amendment merely because it regulates protected speech only indirectly. See, e.g., Minneapolis Star & Tribune Co. v. Minn. Comm’n of Revenue, 460 U.S. 575, 585 (1983) (special tax on ink and paper used in production of a publication violates First Amendment). Here, the challenged Law restricts speech by preventing pharmaceutical companies from using prescriber-identifiable information both to identify a specific audience for their marketing efforts and to refine their marketing messages.<sup>10</sup> Such laws are subject to

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<sup>10</sup> Although a plaintiff ordinarily cannot base a claim to relief on the rights of third parties, the Supreme Court has recognized an exception to the general rule when vendors who have suffered their own injuries also assert the rights of their customers. See Craig v. Boren, 429 U.S. 190, 194-95 (1976). This exception applies here and permits plaintiffs to assert the

First Amendment scrutiny because they affect both the speaker's ability to communicate with his intended audience and the audience's right to receive information. U.S. West, Inc. v. Fed. Commc'n Comm'n, 182 F.3d 1224, 1232 (10th Cir. 1999) (regulations restricting use of customer information for marketing purposes regulate speech protected by the First Amendment). Accordingly, I reject the Attorney General's argument that the Prescription Information Law is not subject to the First Amendment.

**B. What Level of Scrutiny Applies?**

Having determined that the Prescription Information Law restricts speech, I must next decide whether to apply strict scrutiny or intermediate scrutiny in evaluating plaintiffs' First Amendment claim. Plaintiffs argue that strict scrutiny applies because the Prescription Information Law is a content-based restriction on non-commercial speech. The Attorney General responds by claiming that intermediate scrutiny is the appropriate standard of review because the challenged provision regulates commercial speech. I agree with the Attorney General.

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First Amendment interests of their pharmaceutical company customers.

Commercial speech regulations ordinarily are subject to intermediate scrutiny. Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 564 (1980). The case law, however, is unclear as to how commercial speech is defined. Sometimes it is deemed to be speech “related solely to the economic interests of the speaker and its audience.” Id. at 561. Other times it is defined more narrowly to encompass only speech that “propose[s] a commercial transaction.” Bd. of Trs. of the State Univ. of N.Y. v. Fox, 492 U.S. 469, 473-74 (1989); see also Eugene Volokh, *Freedom of Speech and Information Privacy: The Troubling Implications Of A Right To Stop People From Speaking About You*, 52 STAN. L. REV. 1049, 1082-83 (2000).

Plaintiffs contend that the Supreme Court repudiated Central Hudson's broader definition of commercial speech in City of Cincinnati v. Discovery Network, Inc., 507 U.S. 410, 423-24 (1993). I reject this argument both because the Supreme Court's holding in Discovery is more limited than plaintiffs suggest, id. at 424, 428, and because the First Circuit continues to apply Central Hudson's broader definition. See Pharm. Care Mngt. Ass'n v. Rowe, 429 F.3d 294, 309 (1st Cir. 2005) (applying test in case that presented a “close question” whether speech at issue was

commercial); El Dia, Inc. v. P.R. Dep't of Consumer Affairs, 413 F.3d 110, 115 (1st Cir. 2005). Accordingly, I will evaluate the Prescription Information Law by using the definition of commercial speech described in Central Hudson.

The Prescription Information Law plainly qualifies as commercial speech under Central Hudson. In understanding why this is so, it is important to bear in mind that the challenged law only restricts the transmission or use of prescriber-identifiable information for certain commercial purposes. It does not prevent anyone from transmitting or using the information for law enforcement purposes, research purposes, educational purposes, compliance review purposes, or for any non-commercial purpose. In short, the law is a commercial speech restriction under Central Hudson because it restricts only speech that is "solely in the individual interest of the speaker and its specific business audience," Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc., 472 U.S. 749, 762 (1985) (plurality opinion); see also Trans Union Corp. v. Fed. Trade Comm'n, 245 F.3d 809, 818 (D.C. Cir. 2001) (applying intermediate scrutiny to ban on sale of targeted marketing lists).

I would reach the same conclusion even under the narrower definition of commercial speech used in Fox. Although the data that the Prescription Information Law directly restricts does not itself propose a commercial transaction, the law's primary purpose is to affect commercial transactions by making it more difficult for pharmaceutical companies to convince health care providers to prescribe brand-name drugs when less expensive and equally effective alternatives are available. The law is thus squarely aimed at speech that proposes a commercial transaction even though it does not explicitly bar such speech. Because the only use of prescriber-identifiable data that the law prohibits is its use in connection with speech that proposes a commercial activity, the Prescription Information Law qualifies as a commercial speech restriction even under Fox's more narrow definition of the term.<sup>11</sup>

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<sup>11</sup> I also reject plaintiffs' alternative argument that strict scrutiny is required because the Prescription Information Law is a content-based commercial speech restriction. "[G]iven the Supreme Court's commercial speech doctrine, which creates a category of speech defined by the content but afforded only qualified protection, the fact that a restriction is content-based cannot alone trigger strict scrutiny." Trans Union Corp. v. Fed. Trade Comm'n, 267 F.3d at 1141-42 (citing City of Cincinnati, 507 U.S. at 410); see also Consol. Cigar Corp. v. Reilly, 218 F.3d 30, 41-43 (1st Cir. 2000) (applying intermediate

## C. Does the Statute Pass Intermediate Scrutiny?

### 1. The Intermediate Scrutiny Test

Truthful commercial speech that does not promote unlawful activity can be limited under Central Hudson only if it "(1) is in support of a substantial government interest, (2) 'directly advances the government interest asserted,' and (3) 'is not more extensive than is necessary to serve that interest.'" El Dia, 413 F.3d at 113 (quoting Cent. Hudson, 447 U.S. at 566). The party seeking to uphold a commercial speech restriction bears the burden of proof with respect to all three elements.<sup>12</sup> Thompson

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scrutiny to regulation of tobacco-related advertising even though the restriction was content-based), *aff'd in pertinent part*, Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001).

<sup>12</sup> The Attorney General contends that I must defer to the New Hampshire legislature's predictive judgments in holding her to this burden. When a quality record establishes that the legislature conducted an extensive investigation, acquired considerable expertise in the regulated area, and incorporated express findings into the approved statute, a court must accord substantial deference to the legislature's predictive judgments, even when legislation affects protected speech. See Turner Broad. Sys., Inc. v. Fed. Commc'n Comm, 520 U.S. 180, 186 (1997) ("Turner II"). In contrast, if the legislative record lacks this kind of support, considerably less deference is warranted. See Sable Commc'ns of Cal. v. Fed. Commc'n Comm'n, 492 U.S. 115, 129-30 (1989) (no deference where legislative record "contains no evidence as to how effective or ineffective the . . . regulations were or might prove to be"); Landmark Commc'ns, Inc. v. Virginia, 435 U.S. 829, 843 (1978) (no deference where statute was devoid

v. W. States Med. Ctr., 535 U.S. 357, 373 (2002).

To satisfy the first two elements of the Central Hudson test, the party defending a commercial speech restriction must identify a substantial governmental interest that underlies the restriction. Id. at 367. It then “must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.” Edenfield v. Fane, 507 U.S. 761, 770-71 (1993). A restriction that provides “only ineffective or remote support for the government's purpose” will

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of “actual facts” and contained only “legislative declaration[s]”).

Here, the New Hampshire legislature determined that the Prescription Information Law was necessary to protect prescriber privacy and save money for the State, consumers, and businesses. There is nothing in the record, however, to support a conclusion that the legislature had established expertise in the regulation of prescriber-identifiable data. Moreover, it acted quickly after the bill was introduced, received hearing testimony by numerous individuals who had yet to review proposed amendments, made no express findings either on the record or incorporated into the statute, failed to discuss alternative measures that would not restrict speech, and cited no evidence as to how effective the restriction might prove to be. Principles of federalism and separation of powers counsel respect for the New Hampshire legislature at all times, including here. In light of the particulars of this case, however, I am not free to simply endorse its actions without careful analysis. See Sable, 492 U.S. at 129 (quoting Landmark, 435 U.S. at 843) (“Deference to a legislative finding cannot limit judicial inquiry when First Amendment rights are at stake.”).

not be sustained. Id. at 770 (quoting Cent. Hudson, 447 U.S. at 564). Although empirical data supporting a commercial speech restriction need not be “accompanied by a surfeit of background information,” Fla. Bar v. Went For It, Inc., 515 U.S. 616, 628 (1995), “mere speculation or conjecture” that a speech restriction will cure a purported harm is insufficient to justify it. Edenfield, 507 U.S. at 770.

The test’s third element focuses on the fit between the challenged speech restriction and the governmental interest it is designed to serve. Absolute precision is not required. Instead, a restriction will suffice if the fit is both “reasonable” and “in proportion to the interest served.” Fox, 492 U.S. at 480 (quoting In re R.M.J., 455 U.S. 191, 203 (1982)). Nevertheless, “if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so.” Thompson, 535 U.S. at 371.

## **2. Application**

The Attorney General contends that the Prescription Information Law is a permissible commercial speech restriction because it is narrowly drawn and directly advances the State’s substantial interests in protecting prescriber privacy, promoting

public health, and containing health care costs. Plaintiffs challenge the Attorney General's contention that the State has a substantial interest in protecting prescriber privacy. They also argue that the law cannot be justified as either a public health law or a cost containment measure because the evidence in the record fails to prove that the law will directly serve either interest. Finally, they argue that the law is invalid even if it is effective because its purposes could be achieved as well or better through alternatives that do not restrict protected speech. I address each argument in turn.

**a. Is Protecting Prescriber Privacy a Substantial Governmental Interest?**

In arguing that the State has a substantial interest in protecting prescriber privacy, the Attorney General makes a very narrow claim. She does not argue that prescriber-identifiable data is personal or private information that the State has a substantial interest in helping health care providers shield from public view.<sup>13</sup> Nor does she contend that the data is

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<sup>13</sup> It is not surprising that the Attorney General does not seek to defend the Prescription Information Law as an information privacy measure. First, the challenged provisions target professional information rather than personal information. This distinction is important because most information privacy laws

intellectual property that may be protected from public disclosure as trade secret information. Instead, she claims only

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protect the privacy of personal information. See, e.g., Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified in scattered sections of 18 U.S.C., 26 U.S.C., 29 U.S.C., and 42 U.S.C.) (patient medical information); Fair Credit Reporting Act, 15 U.S.C. § 1681 et seq. (2000) (credit reporting information); Family Educational Rights and Privacy Act of 1974, 20 U.S.C. § 1232g (2000 & Supp. III 2003) (educational information); Video Privacy Protection Act of 1988, 18 U.S.C. 2710 (2000) (video rental information); Cable Communications Policy Act of 1984, Pub. L. No. 98-549, 98 Stat. 2779 (subscriber information). Any argument that the State's interest in protecting business information is equivalent to its interest in protecting personal information would require a substantial extension of existing precedent. See Vega-Rodriguez v. P.R. Tel. Co., 110 F.3d 174, 183 (1st Cir. 1997) (Fourteenth Amendment right to information privacy "has not extended beyond prohibiting profligate disclosure of medical, financial, and other intimately personal data"). Second, health care providers cannot credibly claim that they have a reasonable expectation that their prescribing practices will remain private because prescriber-identifiable data is routinely disclosed to patients, pharmacies, insurance companies, medical review committees, and government agencies. In other words, because health care providers work in a "closely-regulated" industry, they have at best a diminished expectation of privacy with respect to their prescribing practices. New York v. Burger, 482 U.S. 691, 702 (1987) (operators of closely regulated business have diminished expectation of privacy). Finally, it is difficult to see how the law's restriction on the transmission and use of prescriber-identifiable data can be successfully characterized as an information privacy measure because, as the Attorney General concedes, the law does not "attempt to keep prescriber-identifiable data secret or entirely private." Def.'s Trial Memorandum at 20 n.10 (Doc. No. 66).

that the law serves the State's substantial interest in protecting prescriber privacy by "limiting unwarranted intrusions into the decision-making process of prescribing physicians." Def.'s Trial Memorandum at 20 (Doc. No. 66).

The case law that the Attorney General relies on to support the State's claimed interest in protecting the decision-making process of prescribers recognizes that the State has a substantial interest in regulating speech that: (i) intrudes upon "the well being, tranquility, and privacy of the home," Carey v. Brown, 447 U.S. 455, 471 (1980); (ii) is "pressed with such frequency or vehemence as to intimidate, vex, or harass the recipient," Edenfield, 507 U.S. at 769; or (iii) involves "willful or knowing affront to or invasion of the tranquility of bereaved or injured individuals," Fla. Bar, 515 U.S. at 630. The present case is far different, however, from other cases in which the state's interest in protecting citizens from improper commercial solicitation has been recognized as substantial. First, although the Attorney General asserts that pharmaceutical companies use prescriber-identifiable data to "pressure" health care providers, she did not even attempt to prove at trial that they use the data to improperly coerce or harass health care

providers.<sup>14</sup> Second, it is obvious that the current case does not involve solicitations that invade the tranquility of the home or that target vulnerable victims. Finally, although the Attorney General asserts that prescriber-identifiable data is used to intrude upon the doctor-patient relationship, she does not claim that the data is being exploited to compromise patient privacy. Instead, she argues only that pharmaceutical companies are using the data to help persuade doctors to make inadvisable prescribing decisions. In short, what the Attorney General claims as a distinct interest in protecting prescriber privacy is

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<sup>14</sup> The Prescription Information Law's legislative history includes two references that arguably support the view that prescriber-identifiable data can be used to coerce health care providers. The first consists of testimony from a nurse practitioner who was told by a sales representative that her once-a-week deliveries of free coffee and donuts would be discontinued unless the practitioner wrote more prescriptions. S. Comm. Hearing on H.B. 1346 at 33, Attachment 15. The second is a newspaper article that describes an email in which a pharmaceutical sales manager exhorted her sales staff to hold their doctors accountable for the samples, gifts, meals, and other inducements they had received. *Id.* at 27, Attachment 13 (quoting *Harris & Pear, supra*). The Attorney General did not follow up on this evidence at trial, and those witnesses who discussed the issue of coercion were not aware of any instances in which health care providers were coerced into writing prescriptions. Thus, I do not find any credible evidence in the record that supports the notion that pharmaceutical companies are routinely using prescriber-identifiable data to coerce health care providers.

nothing more than a restatement of her contentions that the law can be justified because it prevents pharmaceutical companies from using prescriber-identifiable data in ways that undermine public health and increase health care costs. Accordingly, I reject the Attorney General's argument that the law can be justified on the distinct basis that it promotes prescriber privacy.

**b. Does the Prescription Information Law Directly Advance the State's Interests in Promoting Public Health and Containing Health Care Costs?**

The Attorney General contends that the Prescription Information Law is a valid commercial speech restriction because it prevents pharmaceutical companies from using prescriber-identifiable data in ways that undermine public health and increase health care costs. The chain of reasoning that leads to this conclusion begins with the major premise that prescriber-identifiable data allows pharmaceutical companies to target health care providers for marketing and tailor marketing messages in ways that make detailing more persuasive. Next, it assumes that because prescriber-identifiable data makes detailing more persuasive, it inevitably leads to more prescriptions for

brand-name drugs when compared with generic alternatives because only branded drugs are detailed. Finally, it assumes that any increase in the number of prescriptions written for brand-name drugs when compared to generic alternatives harms the public health and increases health care costs because branded drugs often turn out to be more harmful than generic alternatives and almost always are more expensive. Accordingly, a ban on the use of prescriber-identifiable data for marketing purposes promotes public health and contains health care costs by prohibiting pharmaceutical companies from using prescriber-identifiable data to promote the sale of brand-name drugs.

I am unpersuaded by the Attorney General's ultimate conclusion that the Prescription Information Law directly promotes public health and contains health care costs even though I accept her major premise that pharmaceutical companies use prescriber-identifiable data to make detailing more persuasive. Any general claim that the public health is undermined when the effectiveness of detailing for brand-name drugs is increased depends upon the counterintuitive and unproven proposition that, on balance, brand-name drugs are more injurious to the public health than generic alternatives. Moreover, although the

Attorney General specifically claims that the State is entitled to ban the use of prescriber-identifiable data because it is being used to target “early adopters” for the marketing of dangerous new drugs, her argument is unpersuasive because the record does not establish either that early adopters are more likely to be influenced by detailing than other health care providers or that new drugs are generally more injurious to the public health than existing medications. Accordingly, the Attorney General has failed to prove that the Prescription Information Law directly promotes public health.

I am also unconvinced by the Attorney General’s argument that the Prescription Information Law directly promotes the State’s interest in containing health care costs. The Attorney General appears to assume that any health care cost savings that will result from a ban on the use of prescriber-identifiable data can be achieved without compromising patient care. However, this proposition is far from self-evident. Non-bioequivalent generic drugs are not always as effective as brand-name alternatives.<sup>15</sup>

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<sup>15</sup> I refer only to non-bioequivalent generic drugs because the parties agree that a ban on the use of prescriber-identifiable data will not affect a prescriber’s choice between a brand-name drug and a bioequivalent generic alternative. This is

Moreover, even in cases where non-bioequivalent generic drugs will work as well or better than a brand-name alternative for most patients, there may be some patients who will benefit by taking the branded medication. Yet, a ban on the use of prescriber-identifiable data affects both helpful and harmful brand-name prescribing practices in the same way. Because the Attorney General has failed to prove that any reductions in health care costs that may result from a ban on the use of prescriber-identifiable data can be achieved without compromising patient care, I am unable to endorse her argument that the Prescription Information Law can be justified as a cost containment measure.

The Attorney General's argument also suffers from a fundamental flaw that would prevent me from endorsing it even if the assumptions on which it is based were true. Although the Attorney General complains that pharmaceutical companies use prescriber-identifiable data to "manipulate" health care providers, it is important to understand that she does not assert

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because, as the Attorney General acknowledges, pharmaceutical companies generally stop detailing branded drugs when bioequivalent generic drugs become available.

that the data is being used to propagate false or misleading marketing messages. Instead, she argues that pharmaceutical companies manipulate health care providers by using prescriber-identifiable data to enhance the effectiveness of highly persuasive but truthful commercial speech. As the Supreme Court has recently explained, however, “[w]e have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information.” Thompson, 535 U.S. at 374; see also, 44

Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 503 (1996)

(“[B]ans against truthful, non-misleading commercial speech . . . usually rest solely on the offensive assumption that the public will respond ‘irrationally’ to the truth. The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.”) (citation omitted); Va. State Bd. of Pharmacy, 425 U.S. at 770. Health care providers are highly trained professionals who are committed to working in the public interest. They certainly are more able than the general public to evaluate truthful pharmaceutical marketing messages.

Accordingly, the State simply does not have a substantial interest in shielding them from sales techniques that enhance the effectiveness of truthful and non-misleading marketing information. Instead, if the State is concerned that truthful detailing is causing health care providers to make inadvisable prescribing decisions, "the remedy to be applied is more speech, not enforced silence." Whitney v. California, 274 U.S. 357, 377 (1927) (Brandeis, J. concurring).

**c. Is the Prescription Information Law More Extensive Than Necessary to Serve the State's Substantial Interests?**

Even the harshest critics of pharmaceutical detailing acknowledge that it is sometimes used in ways that benefit public health.<sup>16</sup> Not all new drugs are harmful and generic drugs are not always as effective for all patients as brand-name

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<sup>16</sup> The Attorney General has presented testimony, a written declaration, and published reports of numerous studies conducted by Dr. Jerry Avorn, Professor of Medicine at Harvard Medical School and Chief of the Division of Pharmaco-epidemiology and Pharmaco-economics in the Department of Medicine at Brigham and Women's Hospital. Dr. Avorn is a renowned expert on the effects of pharmaceutical marketing on drug utilization and prescribing behaviors. Although Dr. Avorn is critical of detailing, even he is quick to acknowledge that it has beneficial uses and should not be banned. (Trial Tr. vol. 3 Afternoon Session, 68:13-25, 85:19-23, 87:17-25, Jan. 31, 2007 (Doc. No. 114)).

alternatives. When new drugs work as advertised and branded drugs are superior to non-bioequivalent generic alternatives, detailing serves the state's interest in public health by promoting efficacious treatments. The Prescription Information Law, however, does not discriminate between beneficial detailing and harmful detailing. Instead, it imposes a sweeping ban on the use of prescriber-identifiable information to enhance the effectiveness and efficiency of all detailing. Because this ban restricts commercial speech, it cannot be sustained unless it is no more extensive than necessary to serve the State's claimed interests in promoting public health and containing health care costs.

The record in this case demonstrates that there are a number of ways in which the State can address the concerns that underlie the Prescription Information Law without restricting protected speech. First, if legislators are concerned that pharmaceutical companies are improperly using samples, gifts, meals, and other inducements to promote inadvisable prescribing practices, they can address this perceived problem by following other states that have adopted laws that limit such practices. See, e.g., Minn. Stat. Ann. § 151.461 (2007); Cal. Health and Safety Code §

119402(d)(1) (2007).

Second, if legislators fear that pharmaceutical detailing is simply too effective to go unrebuted, they can require the State to enter the intellectual marketplace in several different ways with competing information that will help health care providers balance and place in context the sales messages that detailers deliver. Among other things, they can require the State to prepare and distribute "best practice" guidelines that educate health care providers as to both the health and cost implications of their prescribing decisions; require the State to develop counter-detailing programs that make health care providers aware of the cost implications of their prescribing decisions, see, e.g., W. Va. Code Ann. § 5-16C-9(5) (2006) (authorizing state to develop counter-detailing programs); or they can require health care providers to regularly participate in continuing medical education programs that are specifically designed to provide practitioners with the best available information concerning the advantages and disadvantages of prescribing generic drugs rather than brand-name drugs.

Finally, if legislators are concerned that pharmaceutical companies are using prescriber-identifiable data to drive up

Medicaid drug costs, they can address the issue directly by properly implementing a Medicaid Pharmacy Program that takes into account the cost-effectiveness of brand-name drugs when compared with non-bioequivalent generic alternatives. New Hampshire's Medicaid Pharmacy Benefit Program requires health care providers to obtain authorization from state officials before prescribing certain drugs for Medicaid patients. See generally, 2004 N.H. Laws, ch. 188 (authorizing the New Hampshire Department of Health and Human Services to establish a preferred drug list and a prior authorization process). The State has also adopted regulations that both authorize the State to take cost considerations into account when deciding which drugs should be subjected to the prior authorization requirement, N.H. Admin. Rules, He-W570.06(F)(3), and permit the State to reject requests to prescribe drugs that are subject to prior authorization, N.H. Admin. Rules, HE-W570.06(I)-P). Accordingly, the State can prevent unnecessary expenditures on brand-name drugs simply by subjecting such drugs to prior authorization and rejecting requests to prescribe them when they are not medically necessary.

Although the parties have not briefed the issue, it is likely that New Hampshire's current Pharmacy Benefit Program

conflicts with federal Medicaid law because it both allows state officials to take a drug's comparative cost into account when deciding whether to subject it to prior authorization and permits the State to reject requests to prescribe drugs subject to prior authorization. See Pharm. Research & Mfrs. of Am. v. Meadows, 304 F.3d 1197, 1201-02 (11th Cir. 2002) (construing 42 U.S.C. 1396r-8). Even if New Hampshire's current program violates federal law, however, legislators could amend the program to both bring it into compliance with federal law and require prescribers to consider the cost implications of prescribing drugs that are subject to prior authorization. One way that this could be done would be to eliminate the State's power to deny prescription requests for non-preferred drugs and replace it with a requirement that health care providers consult with a state pharmacist before prescribing such drugs. Florida has a law that requires consultation, and it has both withstood a court challenge and proved to be highly effective in persuading health care providers to change their prescribing practices. Id. at 1198, 1205 (discussing Fla. Stat. § 409.91195, 409.912).

Dynacirc and Verapamil, two calcium channel blockers that Representative Price cited in support of the Prescription

Information Law, illustrate how the State's Pharmacy Benefit Program could be used to limit unnecessary prescriptions for brand-name drugs. Both drugs are currently treated as preferred drugs under the program, available at <http://www.dhhs.state.nh.us/DHHS/MEDICAIDPROGRAM/LIBRARY/Policy-Guideline/preferred-drug.htm> (follow "NH Medicaid Preferred Drug List-PDL" hyperlink). Thus, both drugs may currently be prescribed without prior authorization. If Dynacirc is substantially more expensive than Verapamil but no more effective for most patients, as Representative Price implied during the legislative hearing on the Prescription Information Law, the State could substantially limit unnecessary prescriptions for Dynacirc under its existing program simply by making it a non-preferred drug and denying unwarranted requests for prior authorization. If the State instead adopted a program such as the one used in Florida, it could require health care providers to consult with a state pharmacist before prescribing Dynacirc for Medicaid patients. Under either approach, the State could significantly reduce Medicaid spending on non-preferred drugs without restricting constitutionally protected speech.

#### IV. CONCLUSION

The Prescription Information Law attempts to address important public policy concerns. Ordinarily, states should be given wide latitude to choose among rational alternatives when they act to benefit the public interest. However, when states adopt speech restrictions as their method, courts must subject their efforts to closer scrutiny. Because the Prescription Information Law restricts constitutionally protected speech without directly serving the State's substantial interests and because alternatives exist that would achieve the State's interests as well or better without restricting speech, the law cannot be enforced to the extent that it purports to restrict the transfer or use of prescriber-identifiable data. Plaintiffs' request for declaratory relief and a permanent injunction are granted.

SO ORDERED.

/s/Paul Barbadoro  
Paul Barbadoro  
United States District Judge

April 30, 2007

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