

IN THE
UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF NEW HAMPSHIRE

IMS HEALTH INCORPORATED, a Delaware)
corporation; and VERISPAN, LLC, a Delaware)
limited liability company,)
)
Plaintiffs,)
)
vs.)
)
KELLY A. AYOTTE, as Attorney General of)
the State of New Hampshire,)
)
Defendant.)
_____)

Case No. 06-CV-280-PB

Plaintiffs' Trial Memorandum

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INTRODUCTION

This trial memorandum is submitted by IMS Health Corporation and Verispan LLC in support their request for a declaratory judgment and a preliminary and permanent injunction against enforcement of 2006 N.H. Laws 328, codified as N.H. Rev. Stat. Ann. §§ 318:47-f & 318:47-g & 318-B:12, IV (2006), referred to by plaintiffs as the Prescription Restraint Law. The memo advances the same arguments advanced in the preliminary injunction motion, but also directly addresses the Court's concern about the deference owed to the Legislature, the Attorney General's legal arguments, and facts learned in discovery.¹

The law criminalizes the licensing, sale, use, and transfer of prescriber-identifiable data in prescription records for certain commercial purposes. The law violates the First Amendment as a content-based restriction of non-commercial, lawfully-obtained, truthful speech. It is a direct attempt by the Government to suppress speech because the Government disagrees with how that truthful speech influences doctors.

The Attorney General pejoratively characterizes the plaintiffs efforts to gather information as "data mining" and castigates the sale of the information as serving no interest other than to enrich the plaintiffs and their sources and clients. The First Amendment, she contends, places no limits on the Government's power to ban these "transactions." The fact of

¹ Plaintiffs filed their preliminary injunction motion on July 27, 2006. The Court deferred ruling to on the motion and consolidated the hearing on that motion with the trial on the merits. Since then, the parties have worked together to make their witnesses available for deposition without subpoenas. The Attorney General has five witnesses. She made one available on November 16, three additional witnesses were made available on November 27 and 28, and one witness has not yet been made available. As a consequence, this memorandum, which is filed on November 30, 2006, cannot discuss all of the facts discovered and that will be presented at trial. The arguments here are based, however, on all of the facts known to date. The parties have filed a stipulation regarding the facts that they agree are not in dispute. In addition, plaintiffs have filed a statement of facts which they expect to be able to prove at trial.

the matter is, however, that the plaintiffs are companies dedicated to improving the quality of health care in America and the world through the gathering and reporting of information. They perform the same historic function that newspapers have served throughout the history of the Republic. They search out information that is of great public importance. They analyze and edit that information. They periodically publish the information in a form that will attract subscribers in much the same way that a newspaper attracts subscribers. They charge their subscribers a subscription fee just as do newspaper publishers and they use the profits to grow and improve their publishing business and to reward their investors and employees. They do not discriminate between subscribers. All are welcome. The published information shows professional errors of judgment that can and do cause death. They show trends that tell the subscribers much about the health and lifestyles of the public at large. They suggest ways that the subscribers can better serve the public with new or different products. Subscribers read the plaintiffs' publication and uses the information they learn in much the same way that a newspaper reader uses the news of the day to make decisions about the conduct of his or her life and business.

If the *New Hampshire Union-Leader* were writing a story today about the prescribing practices of doctors and it chose to pay pharmacists for information about doctors for the story, it would be easy to conclude that the Legislature could not, consistent with the First Amendment, gag pharmacists because a manufacturer could buy the newspaper and use it for planning its marketing strategy. Such a law would be an obvious and direct interference with the right of pharmacists to sell truthful, lawfully-obtained information, the right of reporters to gather and report truthful information of public concern, and the right of subscribers, including manufacturers, to read and use the news of the day as they see fit. Such laws may survive only where they serve the most compelling government purposes and where they are the least speech

restrictive means of achieving such compelling purposes. The Prescription Restraint Law is precisely such a law. Indeed, it affects not only the plaintiffs, but every person and entity that gathers and reports about what doctors are prescribing for their patients, including every reporter and newspaper.

This memorandum demonstrates that the Court should subject the law at issue to the strictest scrutiny. It also, however, demonstrates that even if the law is analyzed as a regulation of “commercial speech,” it fails to pass constitutional muster.

Finally, it shows that the law also violates the Commerce Clause by regulating matters that occur entirely outside of New Hampshire when the interests of New Hampshire cannot justify such regulation.

The Court should sever from the Prescription Restraint Law its restrictions on *prescriber*-identifiable data and leave in place its restrictions on *patient*-identifiable data. *See Ayotte v. Planned Parenthood*, 126 S.Ct. 961 (2006).

FACTS UPON WHICH THIS MEMORANDUM IS BASED

The facts upon which this trial memorandum is based are found in the Joint Stipulation of Facts and a separate Statement of Facts plaintiffs contend can be found from the evidence.

ARGUMENT

I.

The Prescription Restraint Law Violates the First Amendment

The law violates the First and Fourteenth Amendments for three separate reasons: (1) the law is subject to and cannot survive strict scrutiny, (2) it cannot survive the intermediate scrutiny applicable to commercial speech, and (3) it is void for vagueness and overbreadth.

A. The Law is Subject to and Cannot Survive Strict Scrutiny

The Court must apply strict scrutiny and the statute plainly cannot survive such scrutiny.

1. Strict Scrutiny Applies Here

Strict scrutiny applies here for two independent reasons: (1) the law regulates the content of noncommercial speech, and (2) the law prohibits the dissemination of lawfully obtained, truthful, non-commercial information of public concern. Furthermore, the statute does not merely regulate commerce nor do the alleged privacy concerns motivating the New Hampshire legislature remove the Prescription Restraint Law from the umbrella of the First Amendment.

a. The Law Regulates the Content of Non-Commercial Speech.

When the government seeks to restrict speech based on its content, the usual presumption of constitutionality afforded legislative enactments is reversed² and the Government bears the burden of rebutting the presumption against invalidity.³ If a statute regulates speech on the basis of content, it must be narrowly tailored to promote a compelling government interest, and if a less restrictive alternative would serve the government's purpose, the legislature must use that alternative.⁴ Moreover, where a regulation strives “to shield the sensibilities of listeners, the general rule is that the right of expression prevails, even where no less restrictive alternative exists. We are expected to protect our own sensibilities ‘simply by averting [our] eyes.’”⁵

The idea that “the line between speech unconditionally guaranteed and speech which may

² *United States v. Playboy Entm't Group, Inc.*, 529 U.S. 803, 817 (2000).

³ *R.A.V. v. St. Paul*, 505 U.S. 377, 382 (1992).

⁴ *Playboy*, 529 U.S. at 804; see also *Reno v. Am. Civil Liberties Union*, 521 U.S. 844, 874 (1997); *Sable Communications of Cal., Inc. v. FCC*, 492 U.S. 115 (1989).

⁵ *Playboy*, 529 U.S. at 813 (quoting *Cohen v. California*, 403 U.S. 15, 21 (1971)). This major First Amendment tenet undermines the New Hampshire legislature's motives and prescribers' arguments regarding abusive marketing practices by pharmaceutical representatives.

legitimately be regulated, suppressed, or punished is finely drawn”⁶ justifies the rules regarding content-based regulations. The line must be finely drawn because: “[e]rror in marking that line exacts an extraordinary cost. It is through speech that our convictions and beliefs are influenced, expressed, and tested[,] . . . that we bring those beliefs to bear on Government and on society[, and] . . . that our personalities are formed and expressed.”⁷

The Attorney General contends that none of these principles have any application here because the statute places limits on the sale of information from a data base, rather than any other form of communication. Memorandum Opposing Preliminary Injunction at 25. The Attorney General bases this argument not on Supreme Court or First Circuit precedent, but rather a UCLA law review⁸ that works hard⁹ to develop a justification for giving legislative bodies a free hand to

⁶ *Speiser v. Randall*, 357 U.S. 513, 525 (1958).

⁷ *Playboy*, 529 U.S. at 817.

⁸ Neil Richards, *Reconciling Data Privacy and the First Amendment*, 52 UCLA L. Rev. 1149 (2005).

⁹ Most scholars disagree that regulation of the content of information in data bases is restricted by First Amendment principles. See, e.g., Fred H. Cate, *First Amendment Ctr., The Privacy Problem: A Broader View of Information Privacy and the Costs and Consequences of Protecting It* (2003), available at, <http://www.firstamendmentcenter.org/PDF/FirstReport.privacyproblem.pdf> (“laws that allow consumers to control the collection and use of information about them interfere not only with the constitutional protection for expression, but also with valuable uses of personal information central to democratic self-governance and protecting public health and safety”) (“privacy laws also run the risk of restricting the greater convenience, lower prices and other benefits that depend on accessible personal information”); A. Michael Froomkin, *The Death of Privacy*, 52 Stan. L. Rev. 1461, 1506 (2000) (“the First Amendment may impose limits on the extent to which legislatures may restrict the collection and sale of personal data in connection with commercial transactions”); Solveig Singleton, *Privacy Versus the First Amendment: A Skeptical Approach*, 11 Fordham Intell. Prop. Media & Entm’t L.J. 97, 125 (2000) (“[t]here is no reason to believe that business transactions take place under a fundamentally different set of default rules. They too are human interactions”); *Freedom of Speech and Information Privacy*, 52 Stan. L. Rev. at 1107 (“[t]he Constitution presumptively prohibits government restrictions on speech and perhaps some government revelation of personal information, but it says nothing about interference with speech or revelation of personal

impose extensive content regulations on information in data bases and to break new constitutional ground in the name of protecting *consumers' privacy* from the advances of technology.¹⁰ Neither the Supreme Court nor the First Circuit ever have accepted such an argument and, in any event, the theory has no place here because that aspect of the law under attack does not protect confidential information about *consumers* purchases of goods or services for their own use, it simply restricts certain uses of information about the prescriptions that highly-regulated professionals give to third parties for their use -- prescriptions that are far from private in the first instance, that historically have been widely-disseminated, and that even under the law at issue itself are expressly allowed to be disseminated for numerous commercial and all non-commercial purposes.

The Supreme Court indeed has recognized that the First Amendment will not afford protection to certain “categories” of speech, but those categories are few, narrowly-defined, and

information by nongovernmental speakers”). Even though the article cites to these additional scholars, the article’s point of view is that the Supreme Court should overrule precedent, contrary to *stare decisis* principles, for policy reasons.

¹⁰ The author of the article, Neil Richards, clerked for Chief Justice William Rehnquist before joining the Washington University Law Faculty in 2003. His theories mirror the views expressed by Chief Justice Rehnquist in various of his dissenting opinions. *See, e.g., Central Hudson*, 447 U.S. at 584 (Rehnquist, J., dissenting) (“the Court errs here in failing to recognizing that the state law is most accurately viewed as an economic regulation and that the speech involved (if it falls within the scope of the First Amendment at all) occupies a significantly more subordinate position in the hierarchy of First Amendment values than the Court gives it today. Finally, the Court in reaching its decision improperly substitutes its own judgment for that of the State . . . the Court adopts as its final part a ‘no more extensive than is necessary’ analysis that will unduly impair a state legislature’s ability to adopt legislation reasonably designed to promote interests that have always been rightly thought to be of great importance to the State”) (emphasis added); *Va. State Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 781 (1976) (Rehnquist, J., dissenting) (“the Court has overruled a legislative determination that such advertising should not be allowed and has done so on behalf of a consumer group which is not directly disadvantaged by the statute in question. This effort to reach a result which the Court obviously desires is a troublesome one”).

justified by compelling governmental interests.¹¹ The Court also has cautioned against the creation of any new categories of speech which may be proscribed simply because the speech falls within that category.¹² Neither information in data bases generally nor prescriber-identifiable data specifically fall within any category of speech that per se may be banned.

Courts that have directly reviewed the argument that the First Amendment does not restrict the discretion of legislatures to regulate privately held data bases have rejected it. For example, in *U.S. West, Inc. v. FCC*, 182 F.3d 1224, 1228 (10th Cir. 1999), the Tenth Circuit invalidated as an unconstitutional burden on commercial speech an FCC order which restricted telecommunications companies' use, disclosure of, and access to customer proprietary network information ("CPNI"). The Court held that by requiring telecommunications carriers to obtain customer approval when wishing to use, disclose, or permit access to CPNI in a manner not expressly statutorily permitted, the FCC approval process impermissibly restricted speech.¹³ While "[t]he government argue[d] that the FCC's CPNI regulations do not violate or even infringe upon petitioner's First Amendment rights because they only prohibit it from using CPNI to target customers and do not prevent petitioner from communicating with its customer or limit anything that it might say to them," the Tenth Circuit stated that the government's argument was

¹¹ The Court has characterized few interests as sufficiently compelling to justify categorical approval of content-restrictions as consistent with the First Amendment. The generally recognized categories are (1) fighting words "which by their very utterance inflict injury or tend to incite an immediate breach of the peace," *Chaplinsky v. New Hampshire*, 315 U.S. 568, 572 (1942); (2) obscenity, *Miller v. California*, 413 U.S. 15 (1973); and (3) some defamation, *N.Y. Times Co. v. Sullivan*, 376 U.S. 254 (1964).

¹² Because "the First Amendment generally prevents government from proscribing speech," *R.A.V. v. City of St. Paul*, 505 U.S. 377, 382 (1992) (citing *Cantwell v. Connecticut*, 310 U.S. 296, 309-11 (1940)), the Supreme Court has clearly delineated speech which may be proscribed or punished consistent with the First Amendment and frequently hesitates to develop new categories of unprotected speech. *Chaplinsky*, 315 U.S. at 571-72.

¹³ *U.S. West, Inc. v. FCC*, 182 F.3d 1224, 1232 (10th Cir. 1999).

“fundamentally flawed [because] [e]ffective speech has two components: a speaker and an audience. A restriction on *either* of these components is a restriction on speech.”¹⁴

Generally, the Tenth Circuit found that legislatures cannot circumvent the Constitution and argue that a regulation does not touch upon the First Amendment simply because other alternative avenues of communication exist that do not make use of statutorily restricted data or prohibit access to such data. *Cf. Id.* (“a restriction on speech tailored to a particular audience, ‘targeted speech,’ cannot be cured simply by the fact that a speaker can speak to a larger indiscriminate audience, ‘broadcast speech’”). The Tenth Circuit found that the government cannot overcome the restrictions imposed by the First Amendment by merely asserting a broad interest in privacy. “[P]rivacy is not an absolute good because it imposes real costs on society . . . In sum, privacy may only constitute a substantial state interest if the government specifically articulates and properly justifies it.”¹⁵ “Privacy may even threaten physical safety by interfering with the public’s ability to access information needed to protect themselves.” *U.S. West*, 182 F.3d at 1235 n.5 (10th Cir. 1999). *See also* (Dec. Glaser ¶ 17) (“neither physicians nor manufacturers can improve care quality and increase their profitability by remaining ignorant of

¹⁴ *Id.* (citing *Va. State Bd. of Pharm.*, 425 U.S. at 756-57, and noting that the First Amendment protects the communication, whether the speech restriction applies to its source or impinges upon the audience’s reciprocal right to receive the communication); *Martin v. City of Struthers*, 319 U.S. 141, 143 (1943) (noting that the First Amendment “embraces the right to distribute literature and necessarily protects the right to receive it”) (emphasis added).

¹⁵ *U.S. West.*, 182 F.3d at 1234-35 (internal citation omitted) “In the context of a speech restriction imposed to protect privacy by keeping certain information confidential, the government must show that the dissemination of the information desired to be kept private would inflict *specific* and *significant* harm on individuals, such as undue embarrassment or ridicule, intimidation or harassment . . . Although we may feel uncomfortable knowing that our personal information is circulating in the world, we live in an open society where information may usually pass freely. A *general level of discomfort* from knowing that people can readily access information about us does not necessarily rise to the level of a substantial state interest under *Central Hudson* for it is not based on an identified harm.” *Id.* (emphasis added).

prescribing practices. Outmoded and ill-informed prescribing wastes money and results in sub-optimal care; sometimes patients get hurt and die. Moreover those physicians who deliver poor care may face economic extinction. A physician, for example, that continues to prescribe the same drug for the same disease, notwithstanding significant improvements in drugs for treating that disease, will not be able to attract patients or improve profitability”).

The Attorney General also relies on *Ohralik v. Ohio State Bar Association*, 436 U.S. 447 (1978), for the proposition that the First Amendment may be ignored in this case because the law at issue simply regulates commercial transactions. Memorandum at 25. In fact, *Ohralik* reviewed the regulation at issue, a bar rule regulating in-person solicitation for pecuniary gain by lawyers, for validity under First Amendment principles. *Id.* at 457. The Court upheld the rule because of the important interests that it served and the efforts that the state had made to narrowly tailor the rule to serve that interest. *Id.* at 460 (citations omitted). The Court did not dismiss the First Amendment as imposing no restrictions on the discretion of the Bar to regulate commercial transactions.

The Attorney General cites *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 507 (1996) (plurality opinion), as authority for the proposition that the government may regulate commercial transactions without regard to the First Amendment. Memorandum at 26. That case also closely scrutinized the regulation at issue in order to determine whether it violated the restrictions which the First Amendment imposes on government power to regulate speech. The commercial nature of the speech at issue did not make the First Amendment irrelevant. *See 44 Liquormart*, 517 U.S. at 484. The New Hampshire law at issue here strikes at the use and disclosure of the “substance of the information communicated” -- prescriber-identifiable information-- and not the subsequent commercial transactions.

If the New Hampshire law is to be upheld, then, the Court cannot simply dismiss the First Amendment by categorizing the law as regulating a data base to protect privacy or as a regulation of commercial transactions. Instead, the Court first must evaluate whether it is the type of restraint on speech that is valid only if it survives “strict scrutiny.” If the law imposes content-based restrictions on non-commercial speech or it limits the dissemination of lawfully-obtained, truthful, important information such scrutiny is required. The plaintiffs contend that the law is precisely such a regulation and that the strict scrutiny test cannot be met. If the Court finds that the law should not be so classified due to its applicability to “commercial” speech, then it must evaluate its validity under the First Amendment principles that restrict legislative discretion to regulate commercial speech. Casting the First Amendment aside and upholding the law for any rational basis, is not an option.

“As a general rule, laws that by their terms distinguish favored speech from disfavored speech on the basis of the ideas or views expressed are content based.”¹⁶ Here, the Legislature treated prescriber-identifiable data in prescription records as disfavored speech because it opposes the idea or viewpoint that manufacturers should be able to target prescribers for solicitation. The speakers, the pharmacists and similar entities, that sell the information to the plaintiffs and the plaintiffs themselves have a different viewpoint entirely. They believe that prescribing practices can be *improved* through aggregation, analysis, and dissemination of the information. The discovery in the case shows that their viewpoint has much to support it. Whether their viewpoint is right or wrong, however, the government cannot suppress speech merely because it disagrees with that viewpoint. The Attorney General argues that the

¹⁶ *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 642-43 (1994) (“*Turner I*”) (plurality).

information itself does not express a viewpoint. This is similar to arguing that the Legislature could prohibit organizers of the Libertarian Party from disseminating the location of their next meeting because the location of the meeting is not itself the expression of an idea or viewpoint.

In characterizing a regulation, courts also look to its purpose: “[g]overnment regulation of expressive activity is content neutral so long as it is ‘justified *without reference to the content of the regulated speech.*’”¹⁷ The Legislature’s consideration of the Prescription Restraint Law shows that it has attempted to justify the legislation by reference to the content of the speech that it prohibits. Many legislators justified the statute and argued for its passage because it would protect individual prescribers from the pressures of commercial advertising based on information about that prescriber’s prescribing practices, others because they believed that it would protect prescribers from having their “private” prescribing practices disclosed, and some argued that the legislation is needed to reduce the price of prescription drugs because prescriber-identifiable data allows pharmaceutical companies to increase pressure on prescribers to prescribe drugs that are more expensive than generic drugs. Each of these justifications necessarily references the content of the information. Thus, the statute must be regarded as content-based.

The next issue for the Court’s consideration is whether the statute should be classified as having application only to “commercial speech” or whether it extends to “non-commercial speech” as well because the Supreme Court has applied distinct tests for the different types of regulations. The commercial speech test should not be applied here because the Prescription Restraint Law plainly extends beyond the regulation of “commercial speech,” a term that has been defined as “speech which does ‘no more than propose a commercial transaction.’” *Va. Pharmacy Board.*, 425 U.S. at 762 (quoting *Pittsburgh Press Co. v. Human Relations Comm’n*,

¹⁷ *Ward v. Rock Against Racism*, 491 U.S. 781, 791 (1989) (emphasis added).

413 U.S. 376, 385 (1973))¹⁸. Such speech commonly is referred to as advertising. Just because an individual or corporate entity is selling a product or the speaker is making a profit from speaking does not mean that the commercial speech doctrine and the intermediate scrutiny test established in *Central Hudson* apply.¹⁹ “Some of our most valued forms of fully protected speech are uttered for a profit. *See, e. g., New York Times Co. v. Sullivan*, 376 U.S. 254 (1964); *Buckley v. Valeo*, 424 U.S. 1 (1976) (per curiam);” *Bd. of Trustees, State University of New York v. Fox*, 492 U.S. 469, 482 (1989). Major newspapers and books are speech sold for profit and are quintessentially recipients of First Amendment protection.

Professor Volokh, an influential First Amendment scholar, persuasively argues that

¹⁸ In *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410 (1993), the Court noted its exclusive use of the “proposing a commercial transaction” definition. *See also Bd. of Trustees, State University of New York v. Fox*, 492 U.S. 469, 482 (1989) (holding that “propos[ing] a commercial transaction . . . is the test for identifying commercial speech”).

¹⁹ *See Discovery Network*, 507 U.S. at 420 (“important commercial attributes of various forms of communication do not qualify their entitlement to constitutional protection”); *Rubin*, 514 U.S. at 493, 497 (“I see no basis . . . for upholding a prohibition against the dissemination of truthful, nonmisleading information . . . merely because the message is propounded in a commercial context) (“[a]ny ‘interest’ in restricting the flow of accurate information because of the perceived danger of that knowledge is anathema to the First Amendment”) (Stevens; J., concurring); 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, 1081 (2000) (“[t]he Court’s definition of ‘commercial speech,’ though, isn’t (and can’t be) simply speech that is sold as an article of commerce . . . Likewise, speech can’t be commercial just because it relates to commerce”). *Discovery Network* further emphasized the narrow applicability of the commercial speech definition: “We begin with several propositions that already are settled or beyond serious dispute. It is clear, for example, that speech does not lose its First Amendment protection because money is spent to project it, as in a paid advertisement of one form or another [citations omitted]. Speech likewise is protected even though it is carried in a form that is ‘sold’ for profit [citations omitted] and even though it may involve a solicitation to purchase or otherwise pay or contribute money [citations omitted]. If there is a kind of commercial speech that lacks all First Amendment protection, therefore it must be distinguished by its content. Yet the speech whose content deprives it of protection cannot simply be speech on a commercial subject . . . Purely factual matter of public interest may claim protection. *Bigelow v. Virginia*, 421 U.S. 809, 822 (1975); *Thornhill v. Alabama*, 310 U.S. 88, 102 (1940).” 507 U.S. at 421 (internal quotation marks omitted) (citing *Virginia State Bd. of Pharm.*, 425 U.S. at 761-62).

regulations governing the sale of information are not regulations of mere commercial transactions subject to the commercial speech doctrine, but regulations of constitutionally protected speech subject to the strictest form of judicial scrutiny:

Under the ‘speech that proposes a commercial transaction’ analysis, communication of information about customers by one business to another is not commercial speech. It doesn’t advertise anything, or ask the receiving business to buy anything from the communicating business. It poses no special risk of the speaker misleading or defrauding the listener, beyond those risks presented with fully protected speech generally . . . Some might argue that there’s something inherently un-speech like in corporations communicating to other corporations, but there’s no reason why this would be so.

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).

When pharmacies and other entities license patient-de-identified prescription records to health information companies, neither the licensor nor licensee is proposing a commercial transaction. Moreover, when the health information companies license information to pharmaceutical companies, this also is not proposing a commercial transaction. The information ultimately may be used in proposed commercial transactions, but the affected sales are not themselves proposing sales. The companies that engage in these transactions do not do so solely to serve their economic interests. All of the companies, as shown in the declarations filed in support of this memorandum, are dedicated to improving public health and they have done so for decades. Plaintiffs’ actions do not meet the quintessential definition of commercial speech.

b. The Law Prohibits Dissemination of Lawfully-Obtained Truthful Information of Public Concern

A second, independent reason that the law is subject to strict scrutiny is that it criminalizes the dissemination of lawfully-obtained, truthful information that is of public concern. In *Bartnicki v. Vopper*, 532 U.S. 514 (2001), the Court subjected a content-*neutral* statute before it “to strict scrutiny normally reserved for governmental attempts to censor

different viewpoints or ideas,” 532 U.S. at 544 (Rehnquist, C.J., dissenting), because “state action to punish the publication of truthful information seldom can satisfy constitutional standards.” *Smith v. Daily Mail Publ’g Co.*, 443 U.S. 97, 102 (1979). Thus, this Court should also apply strict scrutiny since the Prescription Restraint Law criminalizes the dissemination of lawfully-obtained truthful information of real public concern. More specifically, the Court repeatedly has held that legislative bodies simply may not prohibit private individuals from communicating lawfully-obtained, truthful information unless the statute not only serves a compelling interest, but an interest of the highest order and is the least restrictive means of serving that interest. *Id.* at 103. The New Hampshire statute here at issue cannot stand if it does not meet this difficult test.²⁰

Pharmacies and similar entities lawfully obtain prescription information given to them by prescribers or by patients. The information at issue -- the prescribing practices of doctors and others authorized to prescribe medication to patients -- while not of a political nature, is certainly a matter of public concern because its review and utilization by third parties such as the plaintiffs, pharmaceutical companies, and others can and does serve important public purposes. Individuals and research organizations use the information to track patterns of disease and treatment, conduct outcomes research, implement best practices, and apply health economic analyses. The databases are essential to effective implementation of prescription drug recall

²⁰ In his article, Professor Eugene Volokh argues that government attempts to control information about individuals are regulations of pure speech subject to First Amendment restrictions: “[b]ut is it constitutional for the government to suppress certain kinds of [truthful] speech in order to protect dignity, prevent disrespectful behavior, prevent emotional distress . . . ? Under current constitutional doctrine, the answer seems to be no.” Volokh, *supra* n. 19 at 1114-17. His view is consistent with Supreme Court precedent that consistently protects the dissemination of truthful information. See *Bartnicki*, 532 U.S. at 529; *Fla. Star v. B.J.F.*, 491 U.S. 524 (1989); *Smith v. Daily Mail Publ’g Co.*, 443 U.S. 97 (1979); *Landmark*, 435 U.S. at 829; *Cox Broad. Corp. v. Cohn*, 420 U.S. 469 (1975).

programs, performance of pharmaceutical marketing studies, efficient pharmaceutical sales and marketing resource allocation, and assessment of drug utilization patterns. Such information collection promotes overall patient health. Furthermore, use of the database information helps to educate doctors about the availability of breakthrough drugs and doctors may subsequently offer their patients safer and more cost-effective drugs than the ones that are currently being prescribed. Suppression of prescriber-identifiable data directly inhibits and hinders research, analysis, and development that advances patient health and welfare. The plaintiffs gather information of public importance and make the information available for purposes other than to propose the sale of a product or service -- *i.e.* for non-commercial purposes. The New Hampshire Legislature cannot criminalize pharmacies' sale of prescriber data that is a matter of public concern consistent with the First Amendment.

Thus, if this Court were to treat the New Hampshire statute as a *Bartnicki*-like content-neutral statute, the statute is still subject to strict scrutiny because it imposes severe criminal punishment on the dissemination of lawfully-obtained, truthful information.²¹ As discussed above, however, the New Hampshire statute is far from content-neutral and therefore can and should be subjected to strict scrutiny on that basis.²²

²¹ Because the statute authorizes pharmacies and similar entities to license, sell, use and transfer prescriber-identifiable data in prescription records for many different purposes, many entities and individuals lawfully can obtain the data and consistent with *Bartnicki*, could not themselves be prohibited from licensing, selling, using or transferring the data to pharmaceutical companies for marketing purposes.

²² If the statute were treated as neither content-based nor criminalizing dissemination of lawfully-obtained, truthful information of real public concern, it would still survive the *O'Brien* test where a content-neutral regulation will be sustained only if "it furthers an important or substantial governmental interest; if the governmental interest is unrelated to the suppression of free expression; and if the incidental restriction on alleged First Amendment freedoms is no greater than is essential to the furtherance of that interest." *Turner I*, 512 U.S. at 662 (quoting *United States v. O'Brien*, 391 U.S. 367, 377 (1968)). For the reasons discussed in Part I.B. *infra*,

2. The Law Cannot Survive Strict Scrutiny

When a statute is subject to strict scrutiny, it may be upheld only where the government shows that the statute serves a compelling interest and that the statute is the least restrictive means of achieving that interest. None of the Legislature's reasons for enacting the law are compelling nor do they outweigh the grave harm that the statute inflicts on public health. Before examining whether the law survives strict scrutiny, it is important to consider the level of deference that the Court should afford the actions of the Legislature.

In conducting strict scrutiny, courts must inquire searchingly and defer little, if at all, to legislative judgments.²³ The judiciary considers and acknowledges the congressional determinations which factor into legislative enactments, but it is ultimately within the province of the judiciary to analyze whether a law violates constitutional guarantees.²⁴ In *Landmark Communications Inc., v. Virginia*, 435 U.S. 829, 843 (1978), the Court refused to defer to a legislative declaration: "Deference to a legislative finding *cannot* limit judicial inquiry when First Amendment rights are at stake." (emphasis added). Legislative declarations do not preclude a party from presenting evidence of the "actual facts" justifying or opposing the constitutional infringement, particularly when "the fundamental rights of free speech and

the statute does not serve an important or substantial government interest and it is hardly an incidental restriction that is essential to the furtherance of the interest that it does serve. Rather, it is a wholesale ban on the communication of certain information that does nothing to achieve the objectives of the statute.

²³ See generally *Sable Commc'ns, Inc. v. FCC*, 492 U.S. 115, 129-30 (1989) (doubting legislative conclusory statements and insufficient evidentiary record); *Landmark Commc'ns Inc., v. Virginia*, 435 U.S. 829, 843 (1978) (noting that state statute lacked "actual facts" and the alleged clear and present danger was only an unsubstantiated legislative declaration);

²⁴ *Sable*, 492 U.S. at 129.

assembly are alleged to have been invaded.” *Id.* at 843-44.²⁵ Therefore, the judiciary’s independence in judicial review is particularly great when considering whether a regulation violates the First Amendment. *Sable Commc’ns, Inc. v. FCC*, 492 U.S. 115, 129 (1989) (citing *Landmark*, 435 U.S. at 843).²⁶ In *Sable*, the federal parties urged the Supreme Court to defer to congressional findings, but the Court highlighted its right to independent judicial review and held that the total ban on indecent commercial telephone communications violated the First Amendment.

When the Court uses a lower level of scrutiny, greater deference sometimes -- but not always -- is afforded to legislative judgments. In *Turner Broad. Systems, Inc. v. FCC*, 520 U.S. 180, 186 (1997) (*Turner II*) and *Turner Broad. Systems, Inc. v. FCC* 512 U.S. 622, 665-66 (1994) (*Turner I*) (plurality opinion), the Supreme Court reviewed a claim that a federal statute requiring cable operators to carry local broadcasters’ programming violates the First Amendment. The Court observed that (1) Congress had acquired considerable expertise in cable regulation over decades, (2) Congress had developed over a three-year period tens of thousands

²⁵ The *Landmark* Court further explained the role of judicial review in First Amendment cases: “A legislature appropriately inquires into and may declare the reasons compelling legislative action but the judicial function commands analysis of whether the specific conduct charged falls within the reach of the statute and if so whether the legislation is consonant with the Constitution. Were it otherwise, the scope of freedom of speech and of the press would be subject to legislative definition and the function of the First Amendment as a check on legislative power would be nullified.” *Landmark Commc’ns*, 435 U.S. at 843-44.

²⁶ See also *Hurley v. Irish-Am., Gay, Lesbian, & Bisexual Group*, 515 U.S. 557, 567-68 (1995) (Souter, J.) (the independent appellate review requirement is an “obligation [that] rests upon [the Court] simply because the reaches of the First Amendment are ultimately defined by the facts it is held to embrace, and we must thus decide for *ourselves* whether a given course of conduct falls on the near or far side of the line of constitutional protection”) (emphasis added); *Globe Newspaper Co. v. Beacon Hill Architectural Comm’n*, 100 F. 3d 175, 181-82 (1st Cir. 1996) (“de novo review of the trial court’s application of a First Amendment standard to the facts before it ensures that the federal courts remain zealous protectors of First Amendment rights”) (internal quotation marks and citations omitted).

of pages of evidence including not only anecdotal testimony, but extensive studies, (3) Congress expressly incorporated findings into the statute ultimately passed, and, perhaps most important, (4) the statute at issue was content neutral, so it did not create as serious a risk that it would be used as a statute that expressly targets speech content. Under these extraordinary and limited circumstances, the Court held: “[i]n reviewing the constitutionality of a statute, ‘courts must accord substantial deference to the predictive judgments of Congress.’ Our sole obligation is ‘to assure that, in formulating its judgments, Congress has drawn reasonable inferences based on substantial evidence.’” *Turner II*, 520 U.S. at 186.

By contrast, the legislature here (1) had no established expertise in the regulation of prescriber-identifiable data, (2) acted quickly after initial introduction of the bill and only after hearing very little anecdotal evidence, (3) did not make any express findings or incorporate them in the statute, and, as shown below, (4) enacted a content-based, rather than content-neutral statute. Under these circumstances, the Court need not and should not afford any significant deference to the Legislature whether it uses strict scrutiny or a lesser level of scrutiny because the record here at issue simply does not command such deference. *See Note, Deference to Legislative Fact Determinations in First Amendment Cases After Turner Broadcasting*, 111 Harv. L. Rev. 2312, 2327 (1997-98) (“[w]hen records fail to meet this threshold, legislative findings should command no special weight because they would fail to meet the only legitimate justification for deference: aiding accurate judicial decisionmaking”). Instead, it should “devote ‘the most exacting scrutiny to [a] regulation[] that suppress[es], disadvantage[s], or impose[s] differential burdens on speech.’”²⁷

²⁷ *Nat’l Amusements, Inc. v. Town of Dedham*, 43 F.3d 731, 736 (1st Cir. 1995) (citing *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622 (1994) (*Turner I*) (plurality opinion) (emphasis

a. The State Lacks a Compelling Interest

The New Hampshire Legislature appears to have enacted the Prescription Restraint Law because (a) it might lead prescribers to make better decisions about the drugs they prescribe to their patients either in terms of the expense or the efficacy of the drugs, and (b) it would protect the “privacy” rights of prescribers. The Court “must searchingly examine the interests that the State seeks to promote . . . and the impediment to those objectives that would flow if its statute is not enforced.” *Gonzalez v. O Centro Espirita Beneficente Uniao do Vegetal*, 126 S.Ct. 1211, 1220 (2006). “Only the gravest abuses, endangering paramount interests,” *Thomas v. Collins*, 323 U.S. 516, 530 (1945), are compelling. Neither of the alleged interests are compelling and the statute cannot be regarded as achieving either objective in a manner that is the least restrictive of speech.²⁸

(1) Optimizing Prescriber Decisions

Although of much the legislative history shows that the legislature’s primary objective in passing the law was to protect doctors from having their prescribing histories scrutinized by drug manufacturers and to shield doctors from pitches by sales representatives based on knowledge of those prescribing histories and that a secondary objective was to save the state’s Medicaid program money, the Attorney General’s defense of the statute now places far greater emphasis on the State’s asserted interest in ensuring that prescribers make optimal decisions concerning

added)). See also Note, *Deference to Legislative Fact Determinations in First Amendment Cases After Turner Broadcasting*, 111 Harv. L. Rev. 2312, 2324 (1997-98) (citing *Reno v. ACLU*, 521 U.S. 844 (1997) (post-*Turner II* strict scrutiny case refusing to defer to legislative findings and suggesting that the *Turner* Court’s insistence on judicial deference was particular to the intermediate scrutiny context)).

²⁸ The Court should be especially cautious about accepting the justifications offered by the New Hampshire legislature as compelling. “It is basic that no showing merely of a rational relationship to some colorable state interest” suffices as a compelling interest. *Sherbert v. Verner*, 374 U.S. 398, 406 (1963).

the drugs that they prescribe for their patients. The defense appears in large measure to be a post-hoc effort to justify the legislation rather than a defense of the actual reasons that the Legislature passed the measure. This is borne out in part by the fact that the Legislature never even consulted with the experts that the Attorney General now employs to try to justify the law by its impact on the decision-making of prescribers. Drs. Jerry Avorn and Aaron Kesselheim were retained by the Attorney General well after the law went into effect on July 1, 2006, and after the plaintiffs filed this lawsuit.²⁹

Optimization of the decisions that doctors make regarding their patients may well be a *desirable* social goal, but it never has been recognized by any court as a compelling or even important *governmental* interest that could justify a restriction on speech. Indeed, the Supreme Court recently “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 v. Western States Medical Center*, 535 U.S. 357, 374 (2002) (invalidating prohibition against advertising of compounded drugs).

This should not be surprising because any legislative effort to *optimize* prescribing

²⁹ The Legislature did have a short research paper by a young, “healthcare advocate,” four years out of college, that cited studies that direct marketing causes doctors to prescribe the newest drugs, even when other cheaper remedies are available. See Emily Clayton: *‘Tis Always the Season for Giving - A White Paper on the Practice and Problems of Detailing*” CALPIRG (2004) The Legislature did not have the underlying studies before it and it failed to consider contrary studies showing that direct marketing has limited impact on prescriber decisions. Natalie Mizik & Robert Jacobson, *Are Physicians ‘Easy Marks’? Quantifying the Effects of Detailing and Sampling on New Prescriptions*, 50 *Management Science* No. 12 at n.30 (Dec. 2004) (concluding that physicians are hard to persuade to prescribe newer products). More important, there was no evidence before the Legislature that supported the notion that the sale of prescriber-identifiable data would have *any* impact on the problem that it perceived to address -- that is, there was no evidence that prescribers would alter their behavior in any way if pharmaceutical sales representatives could *not* obtain information concerning the prescribing practices of prescribers. Clearly, pharmaceutical companies certainly would continue to market their products whether they can obtain prescriber-identifiable data or not.

decisions through control of the flow of information to private decision-makers necessarily is based on the false assumption that a legislative body is capable of determining what decisions are optimal. The depositions taken in the case to date reflect that the determination of what constitutes the optimal treatment of a patient is a complex and difficult matter. Historically, governmental entities have attempted to optimize the decision-making function by placing the decision in the hands of a trained and licensed prescribers. No state in the nation or country in the world has tried to optimize the decision making of prescribers by sheltering them from information. The *compelling interest* that a state does have is protecting the ability of prescribers to obtain information from a multitude of sources, including biased sources, so that they then can use their learned judgment to make the optimal decision for each unique patient. Dr. Avorn testified that no state before New Hampshire has adopted a statute designed to prevent pharmaceutical manufacturers from obtaining information that would allow them to identify the prescribers to whom they would most like to direct their messages. He testified that in the several decades that he himself has sought ways to optimize prescription decisions that he never previously even thought to recommend legislation that would block the flow of information about prescriber practices from biased sources. Instead, he testified, he had advocated methods that would *increase* the flow of non-commercial information to prescribers. He pioneered the concept of government-funded “academic detailing” to ensure that doctors would have, in addition, to information from manufacturers and insurers motivated by conflicting economic interests, dispassionate information provided by a disinterested, evidence-based panel of experts such as himself. He explained that he nevertheless supports the New Hampshire statute now because his efforts to persuade politicians that they should fund academic detailing largely had failed. Both the federal government and all other states have concluded to date that prescriber

decisions are adequately informed by the prescriber's initial and continuing medical education and the enormous flow of information received from manufacturers, insurers, and non-government third parties such as consumer protection groups. The Court cannot conclude that the Legislature's goal of optimizing prescriber decisions is a compelling *governmental* interest.

(2) Shielding Prescribers from
Scrutiny is Not a Compelling Interest

The second articulated justification is that the statute protects prescriber "privacy" by preventing others from accessing information about what drugs a prescriber has prescribed.

(a) Many Other Third Parties Have
Access to Prescriber-Identifiable Information.

As a preliminary matter, the statute obviously does not prevent information about prescribing practices from falling into the hands of many third parties. As noted, numerous uses of the data are expressly *allowed* by the statute for non-commercial and for some commercial purposes. Because other entities have access to prescriber-identifiable information, professional privacy seems a disingenuous state interest.

Nothing in the statute prevents either patients or health care researchers from transferring the information for any purposes whatsoever. Thus, if the objective of the statute is to protect prescriber privacy, it does not do that very well at all. "It is established in . . . strict scrutiny jurisprudence that 'a law cannot be regarded as protecting an interest 'of the highest order' . . . when it leaves appreciable damage to that supposedly vital interest'"³⁰

The suppression of prescriber-identifiable data interferes with obligations of the highest

³⁰ *Church of Lukumi Babalu Aye, Inc. v. Hialeah*, 508 U. S. 520, 547 (1993) (quoting *Florida Star v. B. J. F.*, 491 U. S. 524, 541-542 (1989) (Scalia, J., concurring in part and concurring in judgment)); see also *Gonzalez*, 126 S.Ct. at 1222 (holding law prohibiting use of certain drugs could not survive strict scrutiny due to exceptions to the law).

order; doctors are professionally, ethically, and legally obligated to make decisions that are in patients' best interest based on the most up-to-date scientific and economic information. Influencing doctors who prescribe less effective drugs actually benefits and compliments the medical professions' various duties. Allowing other entities access to prescriber-identifiable information, but not plaintiffs who also promote overall patient welfare, is inconsistent with doctors' important societal roles and undermines the New Hampshire legislature's sincerity in its professional privacy goal.

(b) Professional Privacy Does Not Justify the Suppression of Prescriber-Identifiable Information.

Putting aside the fact that the New Hampshire law does not entirely protect prescriber "privacy," it still cannot be said that the government has a compelling interest in protecting "privacy" of the sort advanced here. *See Organization For a Better Austin v. Keefe*, 402 U.S. 415 (1971) (specifically rejecting that a professional has a "privacy" interest in information about his professional activities that can justify a restriction on publication of that information).

The Court repeatedly has held that "privacy" is not a compelling interest that can justify a restriction on the publication of lawfully-obtained truthful information.³¹ In *Bartnicki*, 532 U.S. at 534, the Court held that "privacy concerns give way when balanced against the interest in publishing matters of public importance." The Court explained:

³¹ *See generally The Florida Star v. B.J.F.*, 491 U.S. 524 (1989) (holding a newspaper could not be punished for publishing a rape victim's identity that it lawfully obtained); *Cox Broad. Corp. v. Cohn*, 420 U.S. 469 (1975) (overturning a civil damage award based on a television station's broadcasting of the name of a rape-murder victim lawfully obtained from courthouse records); *Okla. Publ'g Co. v. Okla. County Dist. Ct.*, 430 U.S. 308 (1977) (reversing an order enjoining the media from publishing the name or photograph of in connection with a juvenile proceeding); *Smith v. Daily Mail Publ'g Co.*, 443 U.S. 97 (1979) (invalidating an indictment of two newspapers for violating a state statute forbidding publication, without written approval of the juvenile court, of the name of any youth charged as a juvenile offender).

As Warren and Brandeis stated in their classic law review article: "The right of privacy does not prohibit any publication of matter which is of public or general interest." *The Right to Privacy*, 4 Harv. L.Rev. 193, 214 (1890). One of the costs associated with participation in public affairs is an attendant loss of privacy.

*Id.*³²

As set forth in the statement of facts, information regarding the prescribing practices of individual prescribers is a matter of great public concern. Prescriber-identifiable data is critical to improving patient health and well-being. Pharmaceutical companies spend millions of dollars searching for pharmaceutical solutions to serious medical problems. As they develop these new solutions, they then spend millions of additional dollars testing those solutions and obtaining regulatory approval. Once they have obtained regulatory approval, they then are faced with the daunting task of introducing the innovative products to the marketplace. The introduction of new products is not easy due to the conservative nature of many prescribers who would prefer to see new products used extensively in the marketplace for many years or even decades before they will prescribe the new product. Prescriber-identifiable data allows pharmaceutical companies to identify those prescribers who are most likely to be treating patients in need of the new products as well as the less conservative prescribers who want their patients to have the benefits of new products as soon as possible. The use of prescriber-identifiable data bolsters more effective marketing practices that influence doctors to prescribe safer and more medically and cost effective drugs.

³² While the Supreme Court did recognize in *Bartnicki* that a First Amendment interest is served by content-neutral protection of the confidentiality of a communications *medium*, such as cell phone communications, no Court has held that any First Amendment interest is served by a content-based restriction on communications by professionals, such as doctors in their professional communications to pharmacies and similar entities. Unlike users of cell phones whose communications might be significantly curtailed if their confidentiality could not be protected, prescribers cannot curtail their communications to patients or pharmacies, even if such communications are not confidential.

Identification of the “right” prescribers allows companies to focus marketing efforts on those prescribers who are most likely to prescribe the new products. Dr. Avorn, the Attorney General’s primary expert witness, acknowledged as much. Companies focus their efforts by having sales representatives who visit those prescribers explain the advantages that new products have over old products and provide samples of the products to prescribers so that patients can try the products without first incurring substantial costs which ensures that the products will be introduced into the market as quickly as possible and persuades conservative prescribers that they should prescribe innovative products when appropriate for their patients. Thus, it is problematic that the New Hampshire Legislature has proscribed the use of prescriber-identifiable data thereby forcing manufacturers to remain ignorant regarding prescriber practices.

If prescriber-identifiable data is not available for marketing purposes, pharmaceutical companies must engage in much more unfocused marketing efforts that exponentially drives up marketing costs and increases the risk that the right message and the right samples will not be delivered to the right prescribers. This significantly slows adoption of innovative products in the marketplace, which ultimately not only *increases* public healthcare costs, but seriously harms public health.³³

In the end, exercise of the right to sell prescription records containing prescriber-identifiable data protects the public health. The information is vitally important to the public, if

³³ The AMA Board of Trustees has noted that pharmaceutical companies believe they “would struggle without the data, resulting in physicians seeing an increase in sales calls, less targeted educational information, and fewer or less relevant drug samples. The public good uses of the data would be severely cut back or eliminated as [health care information organizations] would no longer have a financial incentive to maintain the data.” *Reports of Bd. of Trustees of the Am. Med. Ass’n - 24. Use of Physician and Patient Prescribing Data in the Pharmaceutical Industry* (Resolution 606, I-03) (Interim meeting of the AMA House of Delegates, December 2004) (accessed June 8, 2006, at http://www.ama-assn.org/meetings/public/interim04/bot_reports.pdf.)

not more so, than political information and therefore should receive no less First Amendment protection. *See Va. State Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 763 (1976) (“the particular consumer's interest in the free flow of commercial information . . . may be as keen, if not keener by far, than his interest in the day's most urgent political debate”). Plaintiffs’ need for prescriber-identifiable information is essential: “[b]oth physicians and manufacturers can improve the quality of care to patients everywhere . . . and that one very effective means of achieving this objective is through collection, analysis, and use of information about [] prescribing practices.” (Dec. Glaser ¶ 18).

Constitutional, statutory, and common law “privacy” protections also reject the notion that there is a “privacy” interest to be protected in information of the type that is the subject of this statute.³⁴ In *Whalen v. Roe*, 429 U.S. 589 (1977), the Supreme Court upheld a statute requiring disclosure to the state of every prescription written for certain drugs and rejected physicians’ arguments that such disclosure interfered both with their patients’ privacy rights and with their own right to privately prescribe drugs that they deemed appropriate for their patients free of unwarranted state interference. *Id.* at 604. The Court noted that “a pharmacist, or the patient may voluntarily reveal information on a prescription form.”³⁵ *Id.* at 600. Under the New Hampshire statute, the patient remains free to disclose prescription information to third parties.

In *Vega-Rodriguez v. Puerto Rico Telephone Co.*, 110 F.3d 174, 183 (1st Cir. 1997), the

³⁴ *See Equifax Servs.*, 420 A.2d at 199-200, 208 (acknowledging that protection of consumer privacy is a substantial governmental interest, but that protection of consumer privacy did not fall under constitutional “zones” or “areas” of privacy protected by constitutional law and tort doctrine and thus, could not justify unconstitutional restraints on commercial speech).

³⁵ Courts narrowly interpret privacy. The Supreme Court also rejected the patients’ arguments that their privacy had been invaded. *Whalen v. Roe*, 429 U.S. 589, 600 (1977). *See also Borucki v. Ryan*, 827 F.2d 836, 839 (1st Cir. 1987) (holding that a *patient’s* interest in preventing *government* from disclosing information it obtained about the patient extends only to matters relating to marriage, procreation, contraception, family relationships and child rearing).

First Circuit held that “the [range of] the right of confidentiality . . . has not extended beyond prohibiting profligate disclosure of medical, financial, and other intimately personal data.” Prescriber data does not fall within any of these categories because it discloses nothing about the prescriber’s health, finances, or personal life.³⁶

As previously described, tort law also does not recognize a right of privacy that would protect prescriber-identifiable data in prescription records. New Hampshire courts construe the privacy right against intrusion by seclusion, *see* Restatement (Second) of Torts § 652B,³⁷ as protecting individuals from gathering of information that “relate[s] to something secret, secluded or private pertaining to the plaintiff.” *See Remsburg v. Docusearch, Inc.*, 816 A.2d 1001 (N.H. 2003) (holding that obtaining work address of plaintiff was not invasion of privacy, but obtaining social security number might be). Other courts have held that the intrusion tort only protects an individual’s “interests in concealing intimate personal facts and in preventing intrusion into legitimately private activities, such as phone conversations.”³⁸

Section 652D of the Restatement (Second) of Torts provides a private cause of action for

³⁶ Because plaintiffs do not challenge any aspect of the Prescription Restraint Law that protects patient privacy, the Court need not decide whether those provisions are constitutional. Plaintiffs are of the opinion that the Government has far stronger interests in preventing third parties from accessing information about the drugs patients are prescribed.

³⁷ Section 652B provides: “One who intentionally intrudes, physically or otherwise, upon the solitude or seclusion of another or his private affairs or concerns, is subject to liability to the other for invasion of his privacy, if the intrusion would be highly offensive to a reasonable person.”

³⁸ *See, e.g., Desnick v. Am. Broad. Cos., Inc.*, 44 F.3d 1345, 1353 (7th Cir. 1995) (citing *Haynes v. Alfred A. Knopf, Inc.*, 8 F.3d 1222, 1229 (7th Cir. 1993); *Zinda v. La. Pac. Corp.*, 440 N.W.2d 548, 555 (1989); *Doe v. Methodist Hosp.*, 639 N.E.2d 683, 685 (Ind. App. 1994).

publication of private facts that also would not protect prescriber-data in prescription records.³⁹ As an initial matter, the disclosure contemplated by this tort “generally must be public.” *Lodge v. Shell Oil Co.*, 747 F.2d 16, 20 (1st Cir. 1984). Mere publication to small numbers of persons or entities does not give rise to an action. Restatement (Second) of Torts § 652D comment a. Neither pharmacies nor the plaintiffs publish information about individual prescribers’ practices to the public at large. Instead, they provide it to pharmaceutical companies and researchers with legitimate interests in the information.

Secondarily, “the matter made public must be one which would be offensive and objectionable to a reasonable man of ordinary sensibilities.” *Lodge*, 747 F. 2d at 20 (citing *W. Prosser & W. Keeton, The Law of Torts 856-57* (5th ed. 1984)). The fact that a doctor has prescribed a particular drug could not be regarded as highly offensive to a reasonable doctor of ordinary sensibilities as Dr. Wharton explained in his declaration in this case.

A third reason that section 652D does not protect prescriber information is that prescribing practices of doctors are matters of public concern for all of the reasons set forth above. Information of this nature receives no protection under section 652D. *See Riley v. Harr*, 292 F.3d 282, 298-99 (1st Cir. 2002). If, of course, section 652D were construed more broadly to protect prescribers’ interests, a patient who was dissatisfied with a prescription written by a doctor could be sued by the doctor for complaining to the media about the prescription. No court

³⁹ Section 652D provides: One who gives publicity to a matter concerning the private life of another is subject to liability to the other for invasion of his privacy, if the matter publicized is of a kind that

- (a) would be highly offensive to a reasonable person, and
- (b) is not of legitimate concern to the public.

ever has suggested that a doctor can bring such an action.⁴⁰

Fourth Amendment jurisprudence also counsels that there is no important government interest in prescriber-data in prescription records. *See California Banking Ass'n v. Schultz*, 416 U.S. 21 (1974) (holding that the Fourth Amendment does not protect the privacy of personal information in records maintained by business or government).⁴¹ New Hampshire courts also have held that individuals may not object on privacy grounds to government searches of information in the hands of third parties.⁴²

In addition, the First Circuit has held that those participating in regulated industries have a lower expectation of privacy. For example, the First Circuit held that when a gun dealer chooses to engage in a pervasively regulated business and accepts a federal license, he does so with the knowledge that his business records, firearms, and ammunition will be subject to effective inspection. *United States v. Wilbur*, 545 F.2d 764 (1st Cir. 1976) (holding that government agent properly seized books and records during a compliance check of defendant's licensed firearms business). A doctor who accepts a state medical license also can expect that participation in the highly regulated healthcare industry may lower his privacy expectations.

⁴⁰ Significantly, while New Hampshire law recognizes a doctor-patient privilege, the privilege is solely for the benefit of the patient, not the doctor. RSA 329:26 (2006); *see also In re John C. Fairbanks*, 135 B.R. 717, 722 (Bankr. D. N.H. 1991).

⁴¹ *See also Smith v. Maryland*, 422 U.S. 735 (1979) (holding that customers do not have a legitimate privacy interest in the phone numbers they dial); *United States v. Miller*, 425 U.S. 435 (1976), (holding records of an individual's financial transactions held by his bank as outside the Fourth Amendment's protections); *Couch v. United States*, 409 U.S. 322 (1972) (holding subpoenaing an accountant for records provided by a client for purposes of preparing a tax return implicated neither the Fourth nor Fifth amendment).

⁴² In *New Hampshire v. Gubitosi*, 886 A.2d 1029, 1035 (N.H. 2005), the New Hampshire Supreme Court affirmed a conviction based, in part, on billing records subpoenaed from a cellular telephone company concerning the defendant's cellular telephone calls. Justice Dalianis, concurring, specifically noted the principle that business records disclosed to third parties are not subject to any type of privacy protection.

Accordingly, in New Hampshire, the only confidentiality offered to doctors is through the peer review process. N.H. REV. STAT. § 319:13-b (2006). Furthermore, the FDA has rules in place which strictly control manufacturers' communications. 21 C.F.R. § 203 *et seq.*

Finally, the Canadian Federal Privacy Commissioner considered precisely this issue and concluded:

A prescription is not information about the physician as an individual. It's information about the professional process that led to its issuance. To regard it as personal information would lead to absurdities. If prescribing patterns are information about a physician, then so are identifiable patterns in any work products.

George Radwanski, *The Impact of Canadian Privacy Legislation*, Canadian Corporate Counsel Association National Spring Conference, Ottawa, Ontario (Apr. 23., 2002). Another Canadian commentator framed the issue as follows:

Should an architect have a privacy interest in a list of buildings that he designed? Any suggestion that this information is or should be private is contrary to everyday experience. Architects must seal every professional document they create, a measure that guarantees the plans in question were prepared by a professional and allows for accountability of the architect after the fact.

Christopher Jones, Murray Rankin, and James Rowan, *A Comparative Analysis of Law & Policy on Access to Health Care Provider Data: Do Physicians Have a Right Over the Prescriptions They Write?*, 14 Can. J. Admin. L. & Prac. 225 (2001).

b. The Law is Not the Least Restrictive Means

The Court also cannot conclude that this statute is the least restrictive means of achieving the objective of optimizing prescriber decisions or protecting prescribers from scrutiny.

If companies are in fact persuading prescribers to prescribe drugs that are more expensive than existing remedies that are as safe and as effective, there are meaningful alternative means to achieve the state's legitimate objectives that will not require the suppression of speech at all.

Dr. Avorn, chair of the Harvard Pharmacoepidemiology and Pharmacoeconomics

Department, is a long-time critic of pharmaceutical manufacturers, the FDA, the government, insurers, and doctors. For many years, he has advocated “academic” detailing administered by academics and funded by taxes would be an effective means of counterbalancing the speech of manufacturers. He did a study of the matter in 1982 and has used that study to persuade a number of governments, including the State of Pennsylvania,⁴³ a number of Canadian provinces, and Australia to deal with the “problem” in this way. Dr. Avorn’s approach does nothing to restrict the flow of information at all. It therefore is a less restrictive means of achieving the State’s objective of optimizing prescriber decision making. New Hampshire failed to even attempt such a tried and tested alternative before turning to speech suppression to try to attain its goal.

Asked about whether other alternatives that would not restrict speech such as prohibitions on manufacturers’ gifts to prescribers and laws requiring manufacturers to disclose such gifts, Dr. Avorn testified that he could not even begin to imagine how such alternatives would operate because the opposition to such reforms by both doctors and pharmaceutical companies was so great that they never could be adopted. The lack of political will to adopt a measure that will achieve an objective without restricting speech does not, however, eliminate that alternative from those that a court must consider before it sanctions a law as the *least* restrictive means of achieving a legislative objective. All such alternatives must be considered. The law that is the most politically expedient is not automatically the least restrictive of speech.

Dr. Avorn also conceded in his deposition that he could not know with absolute certainty

⁴³ See Christopher Guadagnino, Ph.D., *Pennsylvania Launches Academic Drug Detailing*, Physician’s News Digest (Dec. 2005) (<http://www.physiciansnews.com/spotlight/1205.html>) (“We have people out in the field who, not unlike detailers for the pharmaceutical manufacturers, are calling on physicians . . . and educating them with respect to prescribing”).

what impact the statute would have on prescription decisions because no studies had been conducted of the impact of a statute prohibiting the sale of prescriber-identifiable data. He acknowledged that manufacturers would continue to market their products even without the information and suggested that the marketing might be just as effective in persuading doctors to make the wrong choices (and some right choices) because doctors would volunteer to sales representatives information about their prescribing practices.

Dr. Avorn testified that he recently completed an article which demonstrated that advertising by manufacturers to prevent rapid adoption of three generic drugs had cost Medicaid programs \$1.5 billion. The article, Aaron S. Kesselheim, Michael A. Fischer, and Jerry Avorn, *Extensions of Intellectual Property Rights and Delayed Adoption of Generic Drugs: Effects On Medicaid Spending*, 25 Health Affairs No. 6 (Nov./Dec. 2006), showed, however, that most of that amount was attributable to what the article claimed to be unwarranted extensions of the life of the patent in the drug and the FDA's conferring of a period of exclusivity for the manufacturer of a drug that challenged a patent extension. As to the remaining differential, Dr. Avorn's youthful co-author, Dr. Aaron Kesselheim, testified that he and Dr. Avorn made no attempt to determine why branded products continued to be prescribed after patent and exclusivity protection expired. They did not look at advertising or detailing of any of the studied drugs. Dr. Kesselheim also acknowledged that he and Dr. Avorn had been unable to obtain reliable information about the discounts that states had negotiated for branded drugs after patent and exclusivity expiration. Instead, they obtained an average discount obtained for all drugs and used that in their estimate. He acknowledged that this may have introduced substantial error in the study and, in any event, that the study did not show that doctors were prescribing more expensive branded drugs rather than less expensive and equally efficacious generic drugs due to

manufacturers use of prescriber identifiable data.

With respect to physicians' interests in not allowing others to see their prescribing practices, the statute is completely ineffective. It does not prevent the plaintiffs from acquiring the prescriber-identifiable data or from licensing the data to the pharmaceutical manufacturers for the purposes allowed by the statute. These purposes include health care research and care management. Separating these uses from the commercial uses that are prohibited is an all but impossible task as was testified to by Dr. Goran Ando, an officer of a pharmaceutical manufacturer, Dr. John Glasser, the chief information officer of Partners Healthcare, a larger prescribers' organization, and Mr. August Dobish, the chief privacy officer of Rite-Aid Corporation.

Further, any prescriber who finds a pharmaceutical company's use of data regarding his or her prescriber data offensive has the option of simply refusing to entertain further marketing and promotion efforts by that company or representative. The right of prescribers -- all of whom are the most sophisticated and educated of consumers -- to "just say no" to sales representatives who confront them with unwelcome data about their own practices also makes the statute unnecessary to protect prescribers from marketing efforts.

B. The Law Also Cannot Survive Intermediate Scrutiny

The Supreme Court has held that commercial speech also is entitled to First Amendment protection against regulation when (1) the speech concerns lawful activity and is not misleading, (2) the regulation does not support a substantial or important government interest, (3) the regulation does not "directly advance the governmental interest asserted," and (4) the regulation is "more extensive than is necessary" to the purpose for which it was enacted. *Central Hudson*, 447 U.S. at 566; *see also El Día, Inc. v. Puerto Rico Dep't of Consumer Affairs*, 413 F.3d 110,

113 (1st Cir. 2005).

As set forth above, the Prescription Restraint Law should not be classified as merely a regulation of commercial speech. Even, however, if the Court so classifies the law, it still should be invalidated because it cannot meet the *Central Hudson* commercial speech test. Furthermore, a court need not defer to a legislature when reviewing a commercial speech regulation because the *Central Hudson* test already accounts for legislative determinations and remains the appropriate standard of review for commercial speech cases.⁴⁴

The Attorney General urges the Court not to evaluate the Prescription Restraint Law under the traditional commercial speech doctrine even if it classifies the law as regulating commercial speech, advocating that the Court instead apply *Valentine v. Chrestensen*, 16 U.S. 52, 54 (1942), an early decision which held that commercial speech is not entitled to any First Amendment protection. The Supreme Court explicitly rejected *Valentine* and expressly guaranteed commercial speech constitutional protection in *Virginia Board of Pharmacy*, 425 U.S. at 761. Furthermore, the Court has consistently applied the *Central Hudson* test to commercial speech cases and the commercial speech area of First Amendment jurisprudence.⁴⁵

Significantly, the Court, of late, has become increasingly protective of commercial

⁴⁴ See *Rubin*, 514 U.S. at 483 n.2 (explicitly refusing to adopt the deferential approach to restrictions on commercial speech involving socially harmful activities urged by the federal government and instead applying the *Central Hudson* test) (“[n]either [*United States v. Edge Broadcasting*], 509 U.S. 418 (1963)], nor *Posadas [de Puerto Rico Associates v. Tourism Co. of P. R.]*, 478 U.S. 328 (1986)], (cases involving the advertising of gambling activities] compels us to craft an exception to the *Central Hudson* standard, for in both of those cases we applied *Central Hudson* analysis).

⁴⁵ See generally *Lorillard Tobacco Co.*, 533 U.S. at 525; *Greater New Orleans Broad. Ass’n, Inc. v. United States*, 527 U.S. 173 (1999); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996); *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995); *Discovery Network*, 507 U.S. at 410; *Fox*, 492 U.S. at 482.

speech rights.⁴⁶ Furthermore, with the *Fox* revision of the *Central Hudson* narrowly tailoring prong and *44 Liquormart's* “special care” mandate for reviewing regulations of truthful and nonmisleading commercial speech, the current version of the *Central Hudson* test approximates strict scrutiny. Given the importance of consumers and audiences receiving information about products and services, the Court may soon abandon *Central Hudson* and apply strict scrutiny to commercial speech regulations:

In *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996), the Supreme Court established a slight modification to the *Central Hudson* framework . . . when a regulation constitutes a blanket prohibition against truthful, nonmisleading speech about a lawful product and the ban serves an interest unrelated to consumer protection, it will be subject to a *heightened form* of First Amendment scrutiny *akin to strict scrutiny*. Under such circumstances, we must review the regulation under *Central Hudson* with “special care, mindful that speech prohibitions of this type rarely survive constitutional review.” Although only four justices subscribed to this view, given Justice Thomas’s concurrence in which he stated that he would abandon *Central Hudson* altogether and apply traditional strict scrutiny under similar circumstances, it is the narrowest majority holding, and we are bound by it.

U.S. West, Inc., 182 F.3d at 1234 n. 5 (internal citations omitted) (emphasis added).⁴⁷

The statute fails *Central Hudson* because it does not directly advance an important governmental interest in a manner that is no broader than necessary.

⁴⁶ See *Lorillard Tobacco Co.*, 533 U.S. at 544 (citing the opinions of the five justices stating or suggesting that commercial speech regulations should be subjected to strict scrutiny).

⁴⁷ See also *Western States*, 535 U.S. at 377 (Thomas, J., concurring) (“I do not believe that such a test [*Central Hudson*] should be applied to a restriction of commercial speech, at least when, as here, the asserted interest in one that is to be achieved through keeping would-be recipients of the speech in the dark”) (citing *44 Liquormart*, 517 U.S. at 523 (1996) (opinion concurring in part and concurring in judgment)) (internal quotation marks omitted); *Discovery Network*, 507 U.S. at 431 (Blackmun, J., concurring) (“the analysis set forth in *Central Hudson* and refined in *Fox* affords insufficient protection for truthful, noncoercive commercial speech concerning lawful activities . . . ‘intermediate scrutiny is appropriate for a restraint on commercial speech designed to protect consumers from misleading or coercive speech, or a regulation related to the time, place, or manner of commercial speech,’ but not for a regulation that suppresses truthful commercial speech to serve some government purpose”).

1. The Law Applies to Speech That is Not Misleading

In accordance with the first prong of the *Central Hudson* test, the speech that is the subject of the Prescription Restraint Law involves a lawful activity and it is not misleading. A pharmacy conveys information regarding the actual prescribing practices of specific prescribers and plaintiffs convey the information to pharmaceutical companies who in turn use the information for a myriad of legitimate purposes. Neither plaintiffs nor pharmacies use the information to promote unlawful activity or to mislead anyone.

While some manufacturers may engage in misleading sales practices,⁴⁸ the statute does not restrict the dissemination of misleading information at all. Instead, it is targeted squarely at the dissemination of accurate information regarding historical prescribing practices.

2. The Law Does Not Serve an Important Government Interest

The second prong of the *Central Hudson* test requires that the regulation serve an important or substantial interest. As noted, above, none of the interests that the Prescription Restraint Law purportedly serve are compelling or important. Even, however, if interests

⁴⁸ Notably, in late October, the Attorney General hired for the flat fee of \$5,000, Shahram Ahari, an Eli Lilly sales representative for a year and a half, to testify concerning how he and others employed by manufacturers used prescriber identifiable data more than six years ago. He testified that the information allowed sales representatives to identify the prescribers to whom they would direct their messages and that the messages that they delivered were always truthful. He testified he resigned as a sales representative in June 2000 because he came to believe that even truthful messages led some prescribers to make less than optimal decisions. He testified he could not, consistent with his own morality, continue to work for Eli Lilly, although he did not tell Eli Lilly this when he resigned. He also testified, however, that when he could not find other employment, that he applied to become a sales representative with Novartis, another manufacturer, but that company rejected his employment application. He explained that his current knowledge of detailing practices is based largely on his recent contact with “Jenna,” an “acquaintance” and current employee of Eli Lilly whose last name, telephone number, and e-mail address he could not recall during his deposition. Today Mr. Ahari is a temporary employee of the University of California at San Francisco. He tries to identify cases of poisonings that may have adverse public health consequences. He expects that employment to terminate in April 2007.

asserted by New Hampshire in the defense of its statute may be so categorized, the statute cannot survive the remaining two parts of the *Central Hudson* test.

3. The Law Does Not Directly Advance an Important Government Interest

Under the third prong of the test, “[t]he limitation on expression must be designed carefully to achieve the State’s goal.” *Central Hudson*, 447 U.S. at 564. “[T]he restriction must *directly* advance the state interest involved; the regulation may not be sustained if it provides only ineffective or remote support for the government’s purpose.” *Id.* (emphasis added). In order to satisfy this requirement, “a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restrictions will in fact alleviate them to a material degree.” *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993). “[M]ere speculation or conjecture” is insufficient to fulfill these requirements. *Id.* at 770.⁴⁹ Furthermore, “[i]f the Government can achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so.” *Thompson v. Western States Medical Center*, 535 U.S. 357, 371 (2002).

Applying these standards, “the Court has declined to uphold regulations that only indirectly advance the state interest involved.” *Central Hudson*, 447 U.S. at 564; *see also Bates v. State Bar of Arizona*, 433 U.S. 350, 363-64 (1977) (overturning an advertising prohibition designed to protect the quality of a lawyer's work); *Va. Bd. of Pharm.*, 425 U.S. at 769) (holding that a ban on price advertising could not be imposed to protect the ethical or performance standards of pharmacists). For example, in *Western States Medical Center*, the Court sustained

⁴⁹ *See also Thompson v. Western States Medical Center*, 535 U.S. 357, 373 (2002) (“we have generally only sustained statutes on the basis of hypothesized justifications when reviewing statutes merely to determine whether they are rationale . . . The *Central Hudson* test is significantly stricter than the rational basis test, however. . . .”(citations omitted).

the challenges of licensed pharmacies who argued that provisions of the Food and Drug Administration Modernization Act (FDAMA) prohibiting the advertising or promotion of compounded drugs failed the third and fourth prongs of *Central Hudson*. 535 U.S. at 377. Despite the government's asserted governmental interests in safety and efficacy of the drug approval process, the Court easily struck down the statute because the government had many available alternatives that were less restrictive of speech and the Court emphasized that "[i]f the First Amendment means anything, it means that regulating speech must be the last--not first--resort." *Id.* at 373. Just as FDAMA attempted to control demand for and utilization of particular drugs by prohibiting speech about the drugs, the New Hampshire legislature similarly justifies its impermissible speech regulation as a means to impede the effectiveness of pharmaceutical detailing. *Id.* at 376. The safety and efficacy concerns at issue in *Western States*, summarily rejected by the Court, are not even present here and the Prescription Restraint Law similarly suppresses beneficial speech: "If the Government's failure to justify its decision to regulate speech were not enough to convince us that the FDAMA's advertising provisions were unconstitutional, the amount of beneficial speech prohibited by the FDAMA would be." *Id.*

In the instant case, the sale by pharmacies and similar entities of prescriber-identifiable data to plaintiffs does not directly affect the price of pharmaceuticals, the marketing practices of pharmaceutical companies, the prescribing practices of physicians, or, in any meaningful way, the privacy of prescribers. At best, the statute has a highly indirect and speculative impact on the government's goals. The statute attempts to prevent prescribers from prescribing drugs that are more expensive than necessary by seeking to prevent pharmacies from communicating information about prescriber practices to third parties. In turn, the prohibition prevents plaintiffs from aggregating and analyzing the information, prevents the information from being conveyed

to the pharmaceutical companies so that they can evaluate the effectiveness of their promotional efforts, and prevents the pharmaceutical companies from electing to use the information in their direct marketing efforts. Yet, there literally is no evidence that any of these communications will lead to prescribers writing prescriptions for drugs that will be more expensive than other equally effective and safe drugs. In actuality, the companies use the information to ensure that prescribers are prescribing the best possible drug for patient welfare.

The statute also does not directly advance the interest of prescribers in protecting their privacy. As noted, exceptions riddle the statute that allow numerous entities to have access to the information the statute seeks to protect. The Supreme Court has held that when a statute “is so pierced by exemptions and inconsistencies[. . .] the Government cannot hope to exonerate it.” *Greater New Orleans Broad. Ass’n, Inc. v. United States*, 527 U.S. 173, 190 (1999); *see also Rubin*, 514 U.S. at 488.

The Prescription Restraint Law does not directly achieve its objectives in derogation constitutional limitations. *See Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995) (the requirement that the regulation at issue achieve its goals directly “is critical; otherwise, ‘a State could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression’”) (quoting *Edenfield*, 507 U.S. at 771).

4. The Law is Broader Than Necessary to Serve an Important Government Interest

In cases addressing the final prong of *Central Hudson*, the Supreme Court has made clear that if the Government can achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so. For example, the prohibition at issue in *Central Hudson* “reache[d] all promotional advertising, regardless of the impact of the touted service on overall energy use.” 447 U.S. at 570. As important as the government’s objectives

were, it “cannot justify suppressing information about electric devices or services that would cause no net increase in total energy use.” *Id.* Here, the State of New Hampshire has banned the licensing, sale, use or transfer of prescriber-identifiable data in prescription records for commercial purposes irrespective of whether the affected transactions would result in unnecessary increases in the prices of pharmaceutical drugs and notwithstanding that prescribers have no reasonable expectation that their prescribing practices will remain private.

Here, the state statute will prevent pharmaceutical companies from identifying prescribers whose historical prescribing practices show that they could benefit their patients by receiving information about innovative new products and free drug samples and will prevent pharmaceutical companies from focusing their marketing efforts on prescribers who are most likely to prescribe innovative drugs for their patients. This, in turn, will slow the entry of innovative drugs into the market and cause overall healthcare costs to go up while denying the benefits of innovative drugs to many. The statute criminalizes a vast amount of speech that in no way relates to the State’s objectives. As such, the statute is broader than necessary.

The Prescription Restraint Law also is broader than necessary because the State has available alternatives to achieve its objectives that would be far less restrictive of speech. *See Rubin*, 514 U.S. 476, 490-491 (invalidating law in part because of the availability of alternatives that “could advance the Government's asserted interest in a manner less intrusive to First Amendment rights” and indicating that the law was “more extensive than necessary”); *see also 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 507 (1996) (plurality opinion) (striking down a prohibition on advertising in part because “alternative forms of regulation that would not involve any restriction on speech would be more likely to achieve the State's goal”).

Here, there are obvious alternatives such as the academic detailing so long advocated by

the state's own expert, Dr. Avorn. Such alternatives would not require any prohibitions on speech and it is far more likely that they would be an effective, direct means of ensuring prescribers are prescribing the appropriate medications for their patients. Although the State complains that some of these alternatives would be expensive, Dr. Avorn himself has opined that the savings from academic detailing "would almost certainly exceed . . . the cost of the research" needed, and that any tax monies to fund academic detailers "would be more than offset by the resulting savings in drug expenditures, not even counting the improvements in quality of care." Jerry Avorn, M.D., *Powerful Medicines - The Benefits, Risks, and Costs of Prescription Drugs* (Alfred A. Knopf 2005).

C. The Prescription Restraint Law is Void for Vagueness & Overbreadth.

Laws are unconstitutionally vague where they fail to provide requisite notice and undermine public confidence that a law is equally enforced. *See City of Chicago v. Morales*, 527 U.S. 41 (1999); *Grayned v. City of Rockford*, 408 U.S. 104, 108-09 (1972); *United States v. Hilton*, 167 F.3d 61, 74-75 (1st Cir.1999). A statute must define an offense with sufficient particularity so that ordinary people can understand what conduct is prohibited and in a manner that does not encourage arbitrary or discriminatory enforcement. *Grayned*, 408 U.S. at 108; *Hilton*, 167 F.3d at 75.

Where a statute criminalizes the content of certain speech, vagueness presents special concerns. *Reno*, 521 U.S. at 871-72. First, vagueness of such a regulation will have an obvious chilling effect on free speech. *See, e.g., Gentile v. State Bar of Nev.*, 501 U.S. 1030, 1048-51 (1991). Second, the "opprobrium and stigma of a criminal conviction . . . may well cause speakers to remain silent rather than communicate even arguably unlawful words, ideas, and images." *Reno*, 521 U.S. at 872. This increased deterrent effect, coupled with the risk of

discriminatory enforcement, poses great First Amendment concerns. *Id.*

The Prescription Restraint Law suffers from undue vagueness in numerous respects. First, sections [1][a] & [b] (references are to the bracketed sections in the statute set forth above) refer to “records relative to prescription information containing patient-identifiable information and prescriber-identifiable.” The statute does not reveal whether “and” is used conjunctively or disjunctively. It also is unclear what would be regarded as “relative to” prescription information.

Sections [1][a] & [b] use the word “identifiable.” The statute does not, however, define this word. The term may refer to (a) information which is readily-identifiable based upon the information provided by the pharmacy (or similar entity), (b) information constituting “identifiable information” pursuant to federal statutes that use the term, or (c) information that has any chance of re-identification when combined with information from any other source (public or private; existing now or in the future).

Section [3] delineates a list of covered entities. New Hampshire law defines “pharmacy”⁵⁰ and “mail order pharmacy,” but terms such as “pharmacy benefits manager”⁵¹ and

⁵⁰ The term “pharmacy” is defined as “the place registered by the board where the profession of pharmacy is practiced and where drugs, chemicals, medicines, prescriptions, or poisons are compounded, dispensed, stored, or retailed.” N.H. Rev. Stat. Ann. § 318:1, XI. The referenced board is the New Hampshire Pharmacy Board. Pharmacies outside of New Hampshire, not registered with the board, also may fill prescriptions written by New Hampshire prescribers. The law is unclear regarding whether it is intended to reach such pharmacies.

⁵¹ The term “pharmacy benefits manager” is not defined by statute, but the New Hampshire Administrative Code provides a definition: “pharmacy benefit manager” is limited to the particular PBM that administers New Hampshire's Medicaid program:

“Pharmacy benefit manager (PBM)” means the representative designated by DHHS to administer the prescription plan for the Title XIX population.

N.H. Code Admin. R. Ann. He-W 570.01(w). If this definition were used, the law would prevent only First Health Services Corporation (FHSC), the single entity that administers the state’s prescription plan for Title XIX population and not other PBMs.

“electronic transmission intermediary” are not. The list of covered entities also concludes with “other similar entity.” This term also is not defined. The plaintiffs and other entities who obtained prescription records are therefore left guessing as to whether the law applies to them.

Section [4] provides that the covered entities may not supply covered data for “commercial purposes,” but it excludes from the definition of “commercial purposes” seven “limited purposes.” The plaintiffs thus may acquire covered data from covered entities and sell the data to third parties for one of these limited purposes. For example, Section [4][e] identifies “health care research” as excluded from the definition of “commercial purpose”. Health care research, however, might allow the purchaser of the covered data to engage in activities that would be profitable to it. In addition, most health care research supports outcomes or practices that are commercially beneficial to someone. The statute does not allow a determination of whether health care research sponsored or conducted by a commercial entity would be regarded as lawful or unlawful. Furthermore, the statute does not indicate how to distinguish restricted “commercial purpose” activities from permitted “limited purposes” activities.

The statute prohibits the transfer of covered data only for certain purposes, but does not state whether it is the purpose of the acquirer of the data, the provider of the data, or both that determines the purpose of the transfer. For example, the purpose of a pharmacy for selling information to the plaintiffs may be simply to make a profit from the sale of the information. The plaintiffs may acquire covered data from a covered entity so that it may analyze and sell the data to third parties. A third party may acquire the data from IMS both for “commercial purposes” as that term is defined and for non-commercial purposes (e.g., “health care research”). The statute does not indicate whose purpose determines how to characterize the purpose of a license, transfer, use or sale of covered data.

Section [4][f] excludes from the term “commercial purpose” the term “as otherwise provided by law.” The statute does not, however, indicate whether any other laws limit the term “commercial purpose” as it is used by this statute other than section [7] of the statute itself. It is also unclear whether the use of covered data to support legal compliance with a statute, regulation, consent decree or other legal requirement would constitute an exclusion that is “otherwise provided by law.”

Section [5] specifically includes various purposes within the term “commercial purpose.” Covered data may be licensed, transferred, used or sold by a covered entity for a purpose such as health care research and also for a purpose such as advertising. For example, data might be sold to the plaintiffs both for health care research and for advertising by a third party. The statute does not indicate whether the license, transfer, use or sale of covered data from covered entities for such dual purposes violates the statute.

Section [6] defines “commercial purpose” as including, but not limited to advertising, marketing, promotion and “any activity that could be used to . . .” to perform the three delineated functions. The statute does not, however, indicate how one may determine whether the data “could be used” for a prohibited commercial purpose.

Section [7] provides that “nothing in this section shall prohibit the collection, use, transfer or sale of patient and prescriber de-identified data by zip code, geographic region or medical specialty for commercial purposes.” This section’s apparent intent is to allow the continued licensing, transfer, use, and sale of covered data by covered entities to companies like the plaintiffs so that they may continue to provide data to third parties concerning which drugs are prescribed in which zip codes and geographic areas and by which types of medical specialists. Thus, for example, the plaintiffs apparently could acquire from a covered entity

covered data showing that Dr. John Smith prescribed Drug X to patient Y. The plaintiffs then could use that data to determine that the prescription had been written by a cardiologist (i.e., a medical specialty) whose office is located in the City of Concord, the County of Merrimack, and the 03301 zip code, and report that data, aggregated with other such data, to third parties without the identities of either the prescribers or the patients. The statute is far from clear in this regard, and plaintiffs and their sources face threats of criminal prosecution and large fines if they engage in this practice.

Such vague and ambiguous statutory language creates a serious threat that it not only will stop the uses of information that the Legislature intends to stop, but also numerous other uses of the information that Legislature does not intend to stop. Many health care organizations are extremely risk averse and will exercise extraordinary care not to run afoul of legislation, such as the New Hampshire law, which imposes not only severe criminal penalties on violators, but also creates civil claims and authorizes class actions and punitive damages for violations.” See *United States v. Lachman*, 387 F.3d 42, 56-59 (1st Cir. 2004); (Dec. Glaser ¶ 22).

II.

The Prescription Restraint Law Violates the Commerce Clause

The Prescription Restraint Law also violates the dormant Commerce Clause by regulating conduct occurring wholly outside of New Hampshire. The dormant Commerce Clause prohibits states from enacting laws that have the practical effect of controlling “commerce that takes place wholly outside of the State's borders.” *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989). If a state statute has an extraterritorial reach, it amounts to a *per se* violation of the Commerce Clause and will be invalidated because “a statute that directly controls commerce occurring outside the boundaries of a State exceeds the inherent limits of the enacting State’s authority . . . regardless

of whether the statute's extraterritorial reach was intended by the legislature." *Id.* A statute has an extraterritorial reach if it "necessarily requires out-of-state commerce to be conducted according to in-state terms." *Cotto Waxo Co. v. Williams*, 46 F.3d 790, 794 (8th Cir. 1995). When evaluating the practical effect of a statute, the court should consider the statute itself and "how the challenged statute may interact with the legitimate regulatory regimes of other states and what effect would arise if not one, but many or every, State adopted similar legislation." *Id.*

Dormant Commerce Clause challenges do not receive the same deference accorded to congressional enactments under the Commerce Clause. Courts must strictly review dormant commerce clause challenges to state laws. If the state statute is facially discriminatory or if a court deems a statute's purpose or effect discriminatory, the law is presumed unconstitutional and a state can only rebut the presumption by demonstrating, under strict scrutiny, that another, non-discriminatory or less restrictive means was not available to serve a compelling state objective.⁵²

In this case, the statute prohibits pharmacy benefits managers, insurance companies, electronic transmission intermediaries, retail, mail order, or Internet pharmacies, or other similar entities, regardless of where they are located, from licensing, transferring, using, or selling any "records relative to prescriber identifiable data." This prohibition is not limited to transfers or uses that occur solely in New Hampshire or even to those that originate in New Hampshire. Instead, the prohibition transcends state lines and directly regulates transactions that occur

⁵² See, e.g., *Hunt v. Washington State Apple Advertising Comm.*, 432 U.S. 333 (1997) (holding that facially neutral law violated the dormant commerce clause); *Kassel v. Consolidated Freightways Corp.*, 450 U.S. 662 (1981) (holding that facially neutral law violated the dormant commerce clause); *City of Philadelphia v. New Jersey*, 437 U.S. 617 (1978) (holding facially discriminatory state law violated the dormant Commerce Clause); *Dean Milk Co. v. City of Madison*, 340 U.S. 349 (1951) (facially neutral state law violated dormant Commerce Clause).

wholly outside of New Hampshire. Plaintiff Verispan, for example, is a company located outside of New Hampshire. Verispan is a Delaware limited liability company with its principal place of business in Yardley, Pennsylvania. Verispan regularly acquires patient-de-identified prescription information from pharmacy benefits managers (PBMs) and other entities that are located outside of New Hampshire. (Fisher ¶ 7). The prescription information that Verispan purchases includes the identity of New Hampshire prescribers and Verispan acquires such prescription information for commercial purposes. Because PBMs are among the entities by the Prescription Restraint Law identifies who may not transfer, license, use or sell prescriber-identifiable data pertaining to New Hampshire prescribers for commercial purposes, Verispan's PBMs suppliers and other entities located outside of New Hampshire may be prohibited from continuing to sell prescription-level data to Verispan if such data originates in New Hampshire.

By prohibiting PBMs from licensing, transferring, using or selling prescriber identifiable data outside of New Hampshire for commercial purposes, the Prescription Restraint Law has the practical effect of regulating speech beyond the boundaries of New Hampshire and such regulation amounts to a *per se* violation of the Commerce Clause. A state may not impermissibly regulate out-of-state speech by tying the speech to a local transaction.⁵³ In this case, the Prescription Restraint Law effectively regulates a whole spectrum of interstate speech by tying a wide-range of out-of-state contact with prescriber information that originates in New Hampshire and then impermissibly restricting both in-state and out-of-state transactions.

In *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935), the Supreme Court confronted and held unconstitutional a similar regulation of an out-of-state transaction triggered by an in-

⁵³ See *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935); *Pharm. Researchers & Mfrs. of Am. v. D.C.*, 406 F. Supp. 2d 56 (D.C. 2005).

state sale. In *Baldwin*, Justice Cardozo reviewed the New York Milk Control Act, which set minimum prices to be paid by milk dealers to milk producers. *Id.* at 519. Although the majority of milk bought in New York was also produced there, approximately 30 percent of New York's milk supply came from out-of-state. *Id.* The act at issue in *Baldwin* contained a provision prohibiting "the sale within the state of milk bought outside unless the price paid to the producers was one that would be lawful upon a like transaction within the state." *Id.* The plaintiff in *Baldwin* was a New York milk dealer that purchased its milk from a Vermont creamery, which, in turn, purchased its milk from producers on neighboring Vermont farms. *Id.* at 518. While the only sale that was prohibited by the New York act was the sale between the dealer and his in-state buyer, the Supreme Court found that the act effectively regulated the out-of-state sale involving the Vermont producers. Pursuant to "the established doctrine . . . that a state may not, in any form or under any guise, directly burden the prosecution of interstate business," *id.* at 522 (quoting *Int'l Text-Book Co. v. Pigg*, 217 U.S. 91 (1910)), the Court struck down the New York Act, reasoning that "New York has no power to project its legislation into Vermont by regulating the price to be paid in that state for milk acquired there." *Id.* at 521.

Similarly in *Pharmaceutical Research and Manufacturers of America v. District of Columbia*, 406 F. Supp. 2d 56 (D.C. 2005), the court invalidated a District of Columbia statute that made it unlawful for any drug manufacturer or its licensee to sell or supply for sale or impose minimum resale requirements for patented prescription drug "that results in" prescription drug being sold in the District for an excessive price. The Act specifically exempted in-state retailers from liability under the statute. The plaintiffs in that case manufactured their patented prescription drugs wholly outside the District of Columbia, did not operate warehouses in the District and sold the "overwhelming bulk" of their patented prescription drugs in out-of-state

transactions to wholesalers or large retail chains that maintained their own warehousing and retail distribution system. *Id.* 406 F.Supp. 2d at 68. Like the manufacturers, none of the wholesalers and large retail chains had their headquarters in the District nor did they operate warehouses in the District. Thus, the overwhelming majority of the manufacturers' sales occurred entirely outside the District of Columbia between out-of-state manufacturers and out-of-state wholesalers.

The manufacturers argued that the D.C. act violated the dormant commerce clause because it effectively regulated transactions that occurred wholly out-of-state, given that the act exempted the point of sale retail seller from its reach, leaving the manufacturer or their licensees as the only parties that could be held liable under the act if any of their patented drugs resulted in a subsequent sale in the District for an excessive price. The government tried to save the statute by arguing that because the liability was not triggered under the act until a retail sale is made "in the District," the Act did not control any out-of-state transaction. *Id.* at 68-69.

The Court rejected the government's argument, finding that because all the manufacturers of patented prescription drugs were found out-of-state and because all of the wholesalers to whom they sell their products are also found out-of-state, it "was impossible to contend that this particular application of the D.C. Act does not effect an impermissible extraterritorial reach" and it did not matter that the statute at issue was triggered by an in-state sale. The court found that there was "no question" that the D.C. act controlled out-of-state conduct. *Id.*

Just as, or even worse than, the statutes at issue in *Baldwin* and *Pharmaceutical*, the Prescription Restraint Law attempts to regulate a whole range of speech that occurs solely outside of the state of New Hampshire by tying the prescription that originates in New Hampshire to the out-of-state speech and then criminalizing the out-of-state speech under the

CONCURRENCE STATEMENT

I hereby certify to the Court that a good faith attempt has been made to obtain concurrence in the relief sought. The moving party has not obtained concurrence.

s/Thomas R. Julin

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served by electronic filing on November 30, 2006, to:

Richard Head
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s/Thomas R. Julin