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,	)	
	)	Case No. 06-CV-280-PB
vs.	)	
KELLY A. AYOTTE, as Attorney General of the State of New Hampshire,	)	
Defendant	)	

State's Trial Memorandum

I. INTRODUCTION

A. The Act

House Bill 1346 was passed as a measure to control health care costs in New Hampshire, to protect the health and safety of New Hampshire citizens, and to protect the privacy of doctors and patients who use prescription drugs. House Bill 1346 is codified at RSA 318:47-f, RSA 318:47-g and RSA 318-B:12. *See* 2006 N.H. Laws 328. Contrary to the designation given the bill by the Plaintiffs, it is properly described by its legislative designation as the Prescription Confidentiality Act, hereinafter also referred to as the "Act". *See* HB1346, "An act requiring certain persons to keep the contents of prescriptions confidential." The State incorporates herein its Statement of Facts, filed simultaneously with this Trial Memorandum.

B. The Plaintiffs

The Plaintiffs are data mining companies[1] who collect data from a variety of sources. The information that the Plaintiffs collect is then aggregated with other information, analyzed and made available to Plaintiffs' customers. Plaintiffs attempt to equate their product with that of a newspaper, claiming they "periodically publish the information in a form that will attract subscribers in much the same way that a newspaper attracts subscribers." Plaintiffs' Trial Memo. at 2. This is not, in fact, the nature of their business.

The Plaintiffs sell data. Prescriptions are written for approximately 8,000 different pharmaceutical products. Prescriptions are dispensed by approximately 54,000 retail pharmacies throughout the United States, as well as other medical facilities licensed to fill prescriptions. Retail pharmacies acquire prescription data during the regular course of business, and license, sell, or transfer the data to the Plaintiffs. Stipulation of Facts ¶¶ 8, 10. The prescription data includes the name of the pharmaceutical product, the form, strength and dosage of the product, the quantity dispensed, a patient identifier and the name and address of the prescriber. Stipulation of Facts ¶ 12. The patient identifier is unique to an individual patient, and follows that patient, but does not consist of patient

[1] Plaintiffs object to the use of the term "data mining". Plaintiffs' trial memo at 1-2. Yet, this is a term of art used by the Plaintiffs themselves. In a paper prepared by Paul Kallukaran and Jerry Kagan of co-Plaintiff IMS Health (Leg. History at 47-54), IMS's representatives explained the advantage of IMS's data mining analysis. In their conclusion, the authors wrote:

> Using a classical subjective approach to the examination and analysis of 600,000 time series would take weeks of work. By using a *data-mining solution*, IMS can pinpoint prescribers who are switching from one medication to another. A sales person can use this model to target doctors who have switched from the drug they are selling and to devise a specific message to counter that switching behavior.

Leg. History at 53 (emphasis added).

identifiable information. Stipulation of Facts ¶ 4, Fisher Depo. at 19-21 (Mr. Fisher is Vice President of Product Management for Verispan).

The Plaintiffs have products that are sold to the pharmaceutical industry for a great deal of money. Plaintiff Verispan, for example, has gross revenues of "a little bit less than nine figures per year." Fisher Depo. at 32. "[W]e collect the information, we stage that information, we put it in usable form and we provide and sell that information for profit to mainly health care concerns." *Id.* at 8. Verispan's primary category of client is the pharmaceutical industry (approximately 80%). *Id.* IMS has global gross revenues of approximately $1.8 billion. Hassam Sadek Depo. at 98. IMS claims it does not categorize revenues or determine how much it receives from each customer. *Id*. at 10.[2]

C. The State's Interests

House Bill 1346 was passed as a measure to control health care costs in New Hampshire, to protect the health and safety of New Hampshire citizens, and to protect the privacy of doctors and patients who use prescription drugs.

The State has an interest in health care costs directly in its role as Medicaid payor, and in controlling the cost of health care to its citizens. The legislative process is well suited to determine the best way to control health care costs. "Congress has enacted this legislation as a vehicle to better control expenditures of the federal government in connection with the Medicare and Medicaid Programs.... [I]t can hardly [be] said that a

[2] Mr. Sadek was V.P. of the sales force effectiveness business line for IMS. He was unable to state whether the pharmaceutical industry is IMS's largest or smallest client. Sadek Depo. at 10 (Q: What is your -- in term of categories what is your largest client of the ones that you've listed? A. They -- they're all our customers, we don't really categorize our revenues or how much we get from every customer"). IMS's 2005 Annual Report, however, breaks down its products as follows: 48% sales force effectiveness to pharmaceutical clients; 29% portfolio optimization, 23% launch, brand management and other services. Appendix at 101. The 2005 Annual Report states "[s]ales to the pharmaceutical industry accounted for substantially all of our revenue in 2005, 2004 and 2003." Appendix at 105.
References to the Appendix in this Trial Memorandum are to the State's Appendix, filed with its Objection to Preliminary Injunction.

statutory scheme designed to achieve better cost control in the field of health care is outside the competency of the federal government." *Assn. for Amer. Physicians and Surgeons v. Weinberger,* 395 F. Supp. 125, 140 (N.D. Ill. 1975). States fulfill a similar role when such costs involve its citizens, and where the state itself is incurring the health care costs.

In addition, health and safety is a key role for the State in protecting citizens of the State. "It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power. The state's discretion in that field extends naturally to the regulation of all professions concerned with health." *Barsky v. Bd of Regents of University of St. of N. Y.,* 347 U.S. 442, 449 (1954). The Prescription Confidentiality Act fulfills this role by ensuring that prescribing decisions are based on the best interests of the patient and not a pharmaceutical manufacturer.

Finally, the State has an interest in protecting the privacy of its citizens, both physicians and patients. "[W]e have frequently recognized that individual States have broad latitude in experimenting with possible solutions to problems of vital local concern." *Whalen v. Roe*, 429 U.S. 589, 597 (1977). Patients and physicians have a right to privacy regarding how prescriber-identifiable information is used after prescriptions are transferred to a pharmacy or similar entity. RSA 318:47-f provides that "Records relative to prescription information containing … prescriber-identifiable data shall not be licensed, transferred, used, or sold … for any commercial purpose [with exceptions]." The statute defines "commercial purpose" to include "advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical

product, *influence or evaluate the prescribing behavior of an individual health care professional,* or evaluate the effectiveness of a professional pharmaceutical detailing sales force." RSA 318:47-f (2006) (emphasis added).

The Plaintiffs take raw data, aggregate and analyze it, then sell their product to the pharmaceutical industry. The pharmaceutical industry takes this data, now including individual prescribers' prescription details and history, to market their drugs to individual physicians. In doing so, they are interfering with the patient-physician relationship. New Hampshire's patients have a reasonable right to expect that their relationship with the physician is private, and a pharmaceutical detailer is not manipulating the physician's prescribing behavior. A physician's decision regarding medication is unlike any other form of purchase. A physician "prescribes" the drug for his or her patient based upon a clinical diagnosis. The patient can fill the prescription, but cannot change it without the physician's authorization. Given the level of data available to detailers, they have become an invisible intruder in the physician's examination room, manipulating the prescribing decisions of physicians based on profit motives, not on the medical needs of the patient.

II. ARGUMENT

A. The Decision of the New Hampshire Legislature Is Given Substantial Deference

The U.S. Supreme Court has held that where First Amendment rights are at stake, the Court will give Congress's predictive judgments substantial deference, but such

"deference to a legislative finding cannot limit judicial inquiry" altogether.[3] *Turner Broadcasting System, Inc. v. FCC*, 520 U.S. 180, 195 (1997) ("*Turner II*") (citing *Turner Broadcasting System, Inc. v. FCC*, 512 U.S. 622, 665 (1994) ("*Turner I*")). *See also Columbia Broadcasting System, Inc. v. Democratic Natl. Comm.*, 412 U.S. 94, 103 (1973); *Sable Comm. of Cal., Inc. v. FCC*, 492 U.S. 115, 129 (1989).

The "obligation to exercise independent judgment when First Amendment rights are implicated is not a license to reweigh the evidence *de novo*, or to replace Congress's factual predictions with [the Court's]." *Turner I* , 512 U.S. at 666. Ultimately, "the question is not whether Congress was correct as an objective matter, but whether the legislative conclusion was reasonable and supported by substantial evidence." *Id*. at 665. *See also Free Speech Coalition v. Gonzales,* 406 F. Supp. 2d 1196, 1207 (D.Colo. 2005) ("Such a common sense conclusion is certainly within the realm of congressional authority.") (*citing Florida Bar v. Went For It, Inc.,* 515 U.S. 618, 628, (1995) (noting that the Court has allowed the government "to justify restrictions based solely on history, consensus, and simple common sense"); *City of Los Angeles v. Alameda Books, Inc.,* 535 U.S. 426, 438 (2002)("a municipality may rely on any evidence that is 'reasonably believed to be relevant' for demonstrating a connection between speech and a substantial,

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[3] The State inserts this standard on the basis that the Plaintiffs raise a 1st Amendment challenge. As noted in Section II.B, *infra*, the State argues that the First Amendment is not implicated by the Act. When the 1st Amendment is not implicated, the Supreme Court has used even broader broad language to describe the importance of granting deference to legislative bodies.

> A state legislature, in the enactment of laws, has the widest possible latitude within the limits of the Constitution. In the nature of the case it cannot record a complete catalogue of the considerations which move its members to enact laws. In the absence of such a record courts cannot assume that its action is capricious, or that, with its informed acquaintance with local conditions to which the legislation is to be applied, it was not aware of facts which afford reasonable basis for its action. Only by faithful adherence to this guiding principle of judicial review of legislation is it possible to preserve to the legislative branch its rightful independence and its ability to function.

Carmichael v. Southern Coal & Coke Co., 301 U.S. 495, 510 (1937).

independent government interest").; *Assn of Am. Physicians and Surgeons* 395 F. Supp., 141 ("In upholding the constitutionality of the legislation on its face, this Court does not reach the validity of the statute as it will be applied. Nor does this Court pass upon the wisdom of this particular piece of legislation. Whether the implementation and application of this statute may result in an unwieldy bureaucracy of monstrous proportions is a policy question for the consideration of the legislative rather than the judicial branch of the government."

The Court wrote in *Turner II*

> In 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." As noted in the first appeal, substantiality is to be measured in this context by a standard more deferential than we accord to judgments of an administrative agency. We owe Congress' findings deference in part because the institution "is far better equipped than the judiciary to 'amass and evaluate the vast amounts of data' bearing upon" legislative questions. This is not the sum of the matter, however. We owe Congress' findings an additional measure of deference out of respect for its authority to exercise the legislative power. *Even in the realm of First Amendment questions where Congress must base its conclusions upon substantial evidence, deference must be accorded to its findings as to the harm to be avoided and to the remedial measures adopted for that end, lest we infringe on traditional legislative authority to make predictive judgments when enacting nationwide regulatory policy.*

Turner II, 520 U.S. at 196 (emphasis added, citations omitted).

The "reasonable and supported by substantial evidence" standard stated in *Turner II* does not mean the law is not supported by the evidence if the Court disagrees with the ultimate conclusion of the legislative body. "[W]e inquire 'not whether Congress, as an objective matter, was correct', ... but rather 'whether the legislative conclusion was reasonable and supported by substantial evidence in the record before Congress.'" *Time*

Warner Entertainment Co., L.P. v. U.S., 211 F.3d 1313, 1322 (D.C. Cir. 2000) (*citing Turner II*).

The decision to act upon the constitutionality of an act of Congress

> is not a matter to be taken lightly by this, or any other court. In approaching such a task, it is essential to first ascertain what deference the court must afford the acts of Congress generally. Every act of Congress is entitled to a "strong presumption of validity and constitutionality" [and] ... should be invalidated "only for the most compelling constitutional reasons." In *Westside Comm. Bd. of Educ. v. Mergens,* the Supreme Court said, "given the deference due 'the duly enacted and carefully considered decision of a coequal and representative branch of our Government," a court is not [to] lightly "second-guess such legislative judgments." 496 U.S. 226, 251 (1990). A more precise question is what deference the court must afford the findings of Congress in justifying a legislative enactment that triggers a challenge under the First Amendment. In [*Turner II*], the Supreme Court enunciated the standard. In reviewing the constitutionality of a statute, "courts must accord substantial deference to the predictive judgments of Congress." [*Turner I*].

U.S. v. Pearl, 89 F.Supp.2d 1237, 1239-40 (D.Utah 2000)(citations partially omitted) (vacated in part on other grounds, *U.S. v. Pearl*, 324 F.3d 1210 (10th Cir. 2003)).

Futhermore, the Act is designed not only to protect the privacy of physicians and their patients, and to reduce health care costs, but it is also designed to protect the health and safety of New Hampshire's citizens. *See* State's Factual Summary. "It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power. The state's discretion in that field extends naturally to the regulation of all professions concerned with health." *Barsky*, 347 U.S. at 449.

The Act was established to protect the health and safety of New Hampshire's citizens from the inappropriate marketing of pharmaceuticals to physicians, to reduce health care costs in the State of New Hampshire, and to protect the privacy of patients and prescribers. The Court, under the *Turner* decisions, should accord the predictive

judgment of the New Hampshire General Court substantial deference. The General Court has concluded that prescriber specific information is used by pharmaceutical detailers for inappropriate marketing to physicians. Pharmaceutical marketing in this manner has led to inappropriate prescribing behavior, influenced not only by objective science and medical judgment, but by marketing techniques employed by detailers. Because such prescribing decisions are not based entirely on science or medical necessity, the legislature has concluded, in part, that patient health and safety have been compromised. Similarly, where equally effective, less expensive, drugs are not being prescribed due to the marketing efforts of pharmaceutical companies, the State, and its citizens, are subjected to increased health care costs. Finally, the legislature has found that releasing prescriber specific information to pharmaceutical companies for marketing purposes interferes with the privacy integral to the doctor-patient relationship.

Not only does the Court accord substantial deference to the predictive effect of the Act, and not only did the legislature have before it substantial evidence to support this conclusion (*see* State's Factual Summary), there is substantial evidence that prescriber specific information does, in fact, lead to inappropriate prescribing behavior. This is amply supported by the legislative record, and the testimony of the witnesses in their declarations and deposition testimony.

B. The Prescription Confidentiality Act Does Not Violate the First Amendment

1. The Prescription Confidentiality Act does not regulate "speech" protected by the First Amendment.

The First Amendment has never been interpreted as protecting every utterance. *Roth v. U.S.*, 354 U.S. 476, 483 (1957). The First Amendment was adopted to foster the spread of ideas: "The protection given speech and press was fashioned to assure

unfettered interchange of ideas for the bringing about of political and social changes desired by the people." *Id.* at 484. On the other hand, speech that is "so far removed from any exposition of ideas, and from truth, science, morality, and arts in general, in its diffusion of liberal sentiments on the administration of Government" lacks First Amendment protection. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976).

"[T]he fact that the First Amendment applies to expression using language does not necessarily mean that anything spoken or written in a language is expressive, and therefore within its protection." Katherine A. Moerke, *Free Speech to a Machine? Encryption Software Source Code is not Constitutionally Protected "Speech" Under the First Amendment* 84 Minn. L. Rev. 1007, 1030 (2000); *see also Frohwerk v. United States*, 249 U.S. 204, 206 (1919) ("[T]he First Amendment while prohibiting legislation against free speech as such cannot have been, and obviously was not, intended to give immunity for every possible use of language."). What determines whether something is protected by the First Amendment freedom of speech is whether it expresses ideas. *See Roth*, 354 U.S. at 484; *Va. Citizens Consumer Council*, 425 U.S. at 762. Despite the fact that prescriber-identifiable prescription data is written in a language, its sale as a commodity does not involve the communication or expression of ideas, and therefore falls outside the scope of the First Amendment. "Regulating how two parties to a commercial transaction act with respect to information received during that transaction no more offends the Constitution than does government regulation of other aspects of the commercial relationship." Neil M. Richards, *Reconciling Data Privacy and the First Amendment* 52 UCLA L. Rev. 1149, 1153 (2005).

New Hampshire's Prescription Confidentiality Act does not restrict the communication or expression of any ideas, nor does it impede the free flow of information. Prescriber-identifiable prescription data remains accessible under the Act and can be licensed, transferred, used or sold for a myriad of purposes. The Act's restrictions only apply if the data will be used for a "commercial purpose," as defined in the Act. It is, therefore, the use of the information for a particular purpose that determines the Act's regulatory effect. The Supreme Court has drawn a sharp distinction between regulating the *use* of information and regulating the *disclosure* of information. *See Bartnicki v. Vopper*, 532 U.S. 514, 526-27 (2001) (reasoning that while the disclosure of information illegally intercepted under the Wiretap Act could constitute speech, the prohibition against the "use" of the contents of an illegal interception is a regulation of nonspeech conduct). Because the applicability of the Act's restrictions depends on the intended "use" of the information, it constitutes a regulation of nonspeech conduct, not speech.

This interpretation of the Act as a regulation of nonexpressive conduct, rather than speech, is reinforced by the Plaintiffs' own arguments. The Plaintiffs themselves focus almost entirely on how the prescription information is *used*, describing how information available from the Plaintiffs is used by academic researchers, medical researchers, humanitarian organizations, law enforcement, and pharmaceutical companies. The Plaintiffs state that "IMS Health has entered into agreements with its sources of prescription data that state that IMS Health will not *use* the prescription data for purposes that are prohibited under the act," and that "Verispan also is in the process of modifying its practices so that it may continue to acquire data and *use* it for purposes allowed by the

law and will not *use* it for purposes that are not permitted by the law." Plaintiffs' Statement of Facts in Support of Trial Memorandum at 1 (emphasis added). In their Complaint, the Plaintiffs state that they will suffer serious and irreparable injury "if [they] cannot *use* the information other than for purposes identified as permissible in the [Act]." Plaintiffs' Complaint at ¶¶ 45-46. It is evident from the Plaintiffs' Complaint and Trial Memorandum that their true objection to the Act is the restrictions it places on the use of prescriber-identifiable prescription data, not any infringement on their right to engage in free speech.

The threshold question to be considered in any First Amendment claim is what "speech" is being restricted? The Plaintiffs fail to demonstrate that *any* speech is being restricted by New Hampshire's Prescription Confidentiality Act. The Plaintiffs claim that the prescriber-identifiable prescription data itself constitutes the constitutionally protected "speech" being regulated by the Act. The Plaintiffs acknowledge, however, that numerous uses of the data are expressly *allowed* by the statute for non-commercial purposes and for some commercial purposes. Therefore, the Act does not prevent the Plaintiffs from obtaining the information from entities covered by the Act, nor does it prevent the Plaintiffs from disclosing the information to third parties.[4] A restriction on how the Plaintiffs *use* that information once they have received it does not abridge their freedom of speech. *See Bartnicki*, 532 U.S. at 526-27.

In sum, the Act is not a regulation of speech, but rather a regulation of information use. "[T]he conduct of using information . . . can be regulated through generally applicable laws without implicating the First Amendment in most cases, because

[4] The Plaintiffs' argument that they are entitled to the same protections as newspaper publishers fails to take into account the fact that the Act does not prevent the Plaintiffs from disclosing the information for noncommercial purposes.

information use rules generally regulate nonexpressive conduct rather than speech." *Richards*, *supra*, at 1194. The Plaintiffs have failed to identify any constitutionally protected speech restricted by the Act; therefore, their claim lies outside the scope of the First Amendment.

Furthermore, even if prescriber-identifiable prescription information can be deemed "speech," there are "[n]umerous examples . . . of communications that are regulated without offending the First Amendment, such as the exchange of information about securities, corporate proxy statements, the exchange of price and production information among competitors, and employers' threats of retaliation for the labor activities of employees." *Ohralik v. Ohio State Bar Assn.*, 436 U.S. 447, 456 (1978) (citations omitted); *see also* Frederick Schauer, *The Boundaries of the First Amendment: A Preliminary Exploration of Constitutional Salience* 117 Harv. L. Rev. 1765, 1777-1784 (2004) (discussing numerous areas of speech for which the First Amendment generally does not even show up in the analysis, including securities regulation, proxy solicitation, antitrust law, labor law, copyright law, law of sexual harassment, trademarks, law of fraud, regulation of professionals, law of evidence, large segments of tort law, and areas of criminal law such as conspiracy and criminal solicitation). Similar to these areas of law, regulation of prescriber-identifiable prescription data which does no more than restrict the future use of the information does not present a First Amendment issue at all, even if the transactions at issue involve "speech" in the ordinary sense of the term.

The advertising cases cited by the Plaintiffs in their Trial Memorandum lend no support to their argument that the Act abridges their First Amendment freedom of speech. While an advertisement constitutes "speech" within the scope of the First Amendment

because it expresses a message by "propos[ing] a commercial transaction," *see Va. Citizens Consumer Council*, 425 U.S. at 762 (holding statutory ban on advertising prescription drug prices violated the First and Fourteenth Amendments), the actual transaction which follows is not the expression of a message, commercial or otherwise, and therefore does not fall within the First Amendment's protection, *see Ohralik*, 436 U.S. at 455 (recognizing that "*expression[s]* concerning purely commercial transactions ha[ve] come within the ambit of the [First] Amendment's protection") (emphasis added). Regulating commercial transactions themselves does not implicate the First Amendment. *See 44 Liquormart, Inc. v. R.I.*, 517 U.S. 484, 499 (1996) (recognizing the State's power to regulate commercial transactions as a justification to regulate commercial speech linked to those transactions: "The entire commercial speech doctrine, after all, represents an accommodation between the right to speak and hear expressions *about* goods and services and the right of government to regulate the sales *of* such goods and services.") (emphasis in original) (citation omitted).

The Plaintiffs themselves admit that the Act does not prevent them from speaking *about* commercial transactions, but rather regulates the transactions themselves. *See* Plaintiffs' Trial Memo at 13 ("When pharmacies and other entities license patient-de-identified prescription records to health information companies, neither the licensor nor the 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 Plaintiffs' argument that the Act is therefore subject to strict scrutiny fails

to recognize that it is the expressive nature of proposing a commercial transaction that brings such speech within the ambit of First Amendment protection. *See Central Hudson Gas & Elec. Corp. v.. Public Serv. Commn. of N.Y.*, 447 U.S. 557, 563 (1980) ("The First Amendment's concern for commercial speech is based on the informational function of advertising."). Commercial activity alone does not benefit from the protections of the First Amendment's commercial speech doctrine. *See* Robert Post, *The Constitutional Status of Commercial Speech* 48 UCLA L. Rev. 1, 21 (2000) ("Commercial speech doctrine is thus not merely about the boundary that separates commercial speech from public discourse, but also about the boundary that separates the category of 'commercial speech' from the surrounding sea of commercial communications that do not benefit from the protections of the doctrine.").

In sum, the Plaintiffs have failed to identify any constitutionally protected speech restricted by the Act. The fact that patient and prescriber-identifiable prescription data is written in a language does not mean it falls within the protection of the First Amendment. Regulations affecting only the use and transfer of data as a commodity do not implicate the First Amendment because no expression or communication is being restricted. Unlike advertising regulations, which restrict the dissemination of messages *about* commercial transactions, the Act regulates the commercial transactions themselves and therefore does not impede First Amendment rights. Patient and prescriber-identifiable prescription data standing alone is not constitutionally protected "speech" under the First Amendment.

2. Even if the Prescription Confidentiality Act is regarded as regulating constitutionally protected "speech," it only affects commercial speech, which warrants reduced constitutional protection.

The Plaintiffs assert that the only test for identifying commercial speech is whether the expression at issue "propose[s] a commercial transaction." Plaintiffs' Trial Memo. at 11 (quoting *Va. Citizens Consumer Council*, 425 U.S. at 762). The Plaintiffs argue that their actions do not meet this definition of commercial speech because neither licensor nor licensee is proposing a commercial transaction when prescriber-identifiable data is licensed from one company to another. Plaintiffs' Trial Memo. at 13.

Although the United States Supreme Court first defined the category of commercial speech as "speech which does no more than propose a commercial transaction," *Va. Citizens Consumer Council*, 425 U.S. at 762, in later opinions the Court has "also suggested that such lesser protection was appropriate for a somewhat larger category of commercial speech – 'that is, expression related solely to the economic interests of the speaker and its audience.'" *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 422 (1993) (quoting *Central Hudson*, 447 U.S. at 561); *see also El Dia, Inc. v. Puerto Rico Dept. of Consumer Affairs*, 413 F.3d 110, 115 (1st Cir. 2005) (defining commercial speech as "expression related solely to the economic interests of the speaker and its audience"). The Supreme Court has recognized "the difficulty of drawing bright lines that will clearly cabin commercial speech in a distinct category." *Discovery Network*, 507 U.S. at 419. Contrary to the Plaintiffs' assertions, the Supreme Court has not adopted an all-purpose test to distinguish commercial from noncommercial speech under

the First Amendment.[5]

To the extent the Prescription Confidentiality Act regulates constitutionally protected "speech," it clearly affects only commercial speech, which warrants reduced constitutional protection. *See Central Hudson*, 447 U.S. at 563 (The Constitution "accords lesser protection to commercial speech than to other constitutionally guaranteed expression."). The Act is expressly limited to patient and prescriber-identifiable prescription data that is licensed, transferred, used or sold for any *commercial* purpose. "Commercial purpose" is defined by the Act as:

i. advertising,
ii. marketing
iii. promotion, or
iv. any activity that could be used to
    a. influence sales or market share of a pharmaceutical product;
    b. influence or evaluate the prescribing behavior of an individual health care professional, or
    c. evaluate the effectiveness of a professional pharmaceutical detailing sales force.

RSA 318:47-f section [5][a].[6] All of these uses relate solely to the economic interests of the pharmacies and other entities that sell prescriber-identifiable prescription data for

[5] The Plaintiffs cite *Discovery Network* in support of their claim that the "proposing a commercial transaction" definition is the exclusive definition for commercial speech. Although the Supreme Court in that case described such speech as "core" commercial speech, it did not expressly reject the broader definition. *Id.* In fact, in a decision released the very next month, the Supreme Court noted that "ambiguities may exist at the margins of the category of commercial speech," *Edenfield v. Fane*, 507 U.S. 761, 765 (1993), demonstrating the Court's reluctance to reduce the doctrine to any simple rule or determinate criteria. *See also Kasky v. Nike, Inc.*, 27 Cal. 4th 939, 960, 45 P.3d 243 (Cal. 2002) ("The United States Supreme Court has not adopted an all-purpose test to distinguish commercial from noncommercial speech under the First Amendment . . . . [C]ategorizing a particular statement as commercial or noncommercial speech requires consideration of three elements: the speaker, the intended audience, and the content of the message."); Post, *Commercial Speech*, 48 UCLA L. Rev. at 18 (noting that the "Court has in its commercial speech doctrine persistently gestured toward the "common sense" distinction between commercial speech and speech at the First Amendment's core. The evaluations of "commonsense" are complex, contextual, and ultimately inarticulate; the Court's appeal to common sense acknowledges that the achievement of constitutional purposes cannot be reduced to any simple rule or determinate criteria. The judgments of common sense ultimately revolve around questions of social meaning; they turn on whether the utterance of a particular speaker should be understood as an effort to engage public opinion or instead simply sell products.") (quotations, citations, and footnotes omitted).

profit, and the pharmaceutical companies that use that information for marketing purposes. Any additional uses of the information by such groups as academic researchers, medical researchers, humanitarian organizations and law enforcement do not meet the definition of "commercial purpose" and are therefore not restricted by the Act.

The plain and unambiguous language of the Act limits its coverage to *commercial* uses of the information; therefore, even if the Act is regarded as regulating constitutionally protected "speech," it only affects commercial speech which warrants reduced constitutional protection. *See Mainstream Marketing Serv., Inc. v. FTC*, 358 F.3d 1228, 1236-37 (10th Cir. 2004) (applying intermediate scrutiny to national do-not-call registry's restrictions that apply only to telemarketing calls made by or on behalf of sellers of goods or services); *Trans Union Corp. v. FTC*, 245 F.3d 809, 818 (D.C. Cir. 2001), *reh'g denied*, 267 F.3d 1138 (D.C. Cir. 2001), *cert. denied*, 536 U.S. 915 (2002) (holding ban on sale of target marketing lists from consumer reporting agency to target marketers warranted "reduced constitutional protection" because the lists were solely of interest to the consumer reporting agency and its business customers who used the lists to market customers)[7]; *U.S. West, Inc. v. FCC*, 182 F.3d 1224, 1232-33 (10th Cir. 1999) (holding FCC regulations that required telecommunications companies to obtain affirmative approval from customer before company could use customer's "customer proprietary network information" for marketing purposes restricted commercial speech only and were therefore subject to intermediate scrutiny).[8]

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[6] References to sections in [ ] are to the line-by-line breakdown in the parties Stipulation of Facts.

[7] The *Trans Union* court did not determine whether the target marketing lists were speech, but rather assumed that the First Amendment applies. 245 F.3d at 818. That case does not, therefore, conflict with the arguments set forth in section II,B,1, *supra*, that the restrictions in the Act raise no First Amendment issue.

The Plaintiffs make the unsupported claim that

> the Attorney General urges the Court not to evaluate the Prescription [Confidentiality Act] under the traditional commercial speech doctrine . . . , 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.

Plaintiffs' Trial Memo. at 34. The Plaintiffs do not, and can not, provide any cite to support this assertion, since nowhere in the Defendant's Memorandum of Law in Support of its Objection to Plaintiff's Motion for Preliminary Injunction did the Defendant even cite to *Valentine*. To the contrary, the Defendant expressly applied the *Central Hudson* test in her Memorandum of Law. *See* Defendant's Memorandum of Law at 29-30. In fact, it is the Plaintiffs, not the Defendant, who now suggest the application of a different standard. *See* Plaintiffs' Trial Memo. at 34-35 (opining that "the Court may soon abandon *Central Hudson* and apply strict scrutiny to commercial speech regulations."). Despite the Plaintiffs' hopes that *Central Hudson* will be abandoned, it remains good law and intermediate scrutiny is the appropriate test for commercial speech regulations.

The Act easily survives the lower level of judicial scrutiny applicable to commercial speech regulations. If commercial speech[9] is neither misleading nor related to unlawful activity, State regulation of that communication survives First Amendment scrutiny if (1)

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[8] Although the Tenth Circuit did directly address the threshold question for application of the First Amendment and hold that the regulations restricted "speech" by preventing target marketing, that case is distinguishable from the instant case. The regulations at issue in *U.S. West* placed restrictions on companies that were actually engaged in marketing their products to customers, and thus it could be argued that this direct regulation of marketing restricted commercial speech. In contrast, the Prescriber Confidentiality Act is specifically limited to pharmacy benefits managers, the insurance industry, electronic transmission intermediaries, retail, mail order, or internet pharmacies, or other similar entities. RSA 318:47-f section [3]. These entities simply sell prescriber-identifiable prescription data to other parties and do not use the information themselves for marketing or advertising purposes. Unlike the regulations at issue in *U.S. West*, the Act does not regulate companies who are actually engaged in marketing their products to consumers. Nothing in the Act regulates the advertising, marketing, or promotion by pharmaceutical companies of their drugs; therefore, the First Amendment is not implicated.

[9] As discussed, *supra* at section II.B.1, the State disputes that the Act places any restrictions on constitutionally protected speech.

the State asserts a substantial interest to be achieved by the regulation; (2) the restriction directly advances the state interest involved; and (3) the governmental interest cannot be served by a more limited restriction on commercial speech. *Central Hudson*, 447 U.S. at 564. The Act meets all these criteria.

First, the State has a substantial interest in lowering health care costs and limiting unwarranted intrusions into the decision making process of prescribing physicians.[10] These harms which the Act targets need not be proven by "empirical data" or "a surfeit of background information." *See Florida Bar v. Went For It, Inc.*, 515 U.S. 618 (1995) (noting that the Court has "permitted litigants to justify speech restrictions by reference to studies and anecdotes pertaining to different locales altogether, . . . or even . . . to justify restrictions based solely on history, consensus, and 'simple common sense.'"). As described in the State's Factual Summary, pharmaceutical companies' use of prescriber-identifiable prescription data for target marketing purposes influences the prescribing practices of New Hampshire physicians in ways that serve the interests of the pharmaceutical companies and not necessarily the clinical needs of patients. This marketing activity adds to the financial burden of New Hampshire's health care system by increasing pharmaceutical costs for the state, consumers, and businesses. Where equally effective and less costly generic medication is available, the use of prescriber-identifiable prescription data by pharmaceutical companies to pressure physicians to

[10] The Plaintiffs' characterization of the State's interests as "price controls," and "shielding prescribers from scrutiny," is mistaken. The Act places no restrictions on pharmaceutical pricing, nor does it attempt to keep prescriber-identifiable prescription data secret or entirely private. The focus of the Act is not on pricing, or on shielding the information from view, but rather on the use of that information by pharmaceutical companies to improperly influence physicians' medical decisions, directly resulting in raising health care costs and intrusions into the doctor/patient relationship.

change their prescriptions intrudes on the prescribing practices of New Hampshire's physicians and unnecessarily raises health care costs.

Second, the Act directly advances these State interests by preventing the use of prescriber-identifiable prescription data to influence the prescribing behavior of physicians. By prohibiting the license, transfer, use, or sale of prescriber-identifiable prescription data for commercial purposes, the Act prevents pharmaceutical companies from using that information to pressure physicians into changing their prescriptions from less costly medications to name brand drugs for reasons unrelated to the clinical needs of patients. Dr. Seddon Savage spoke in favor of the bill, stating in part, "[the Act] will deter marketing intended to manipulate the practice of individual physicians that is intended to increase market share for the individual companies, possibly at the expense of appropriate decision making for the patients." Leg. History at 24-25. Like the disclosure requirements at issue in *Pharmaceutical Care Mgt Assoc. v. Rowe*, 429 F.3d 294 (1st Cir. 2005), which sought to help control prescription drug costs by placing health benefit providers on a level playing field with drug manufactures, New Hampshire's Prescription Confidentiality Act is similarly

> designed to create incentives within the market for the abandonment of certain practices that are likely to unnecessarily increase cost without providing any corresponding benefit to the individual whose prescription is being filled and that appear to be designed merely to improve a drug manufacturer's market share.

Id. at 310. Contrary to the Plaintiffs' claims, the Act does directly affect the marketing practices of pharmaceutical companies by preventing them from using prescriber-identifiable prescription data by pharmaceutical detailers to modify physician prescribing behavior toward a more expensive drug, without achieving gains in patient outcome.

Finally, the Act's restrictions are not more extensive than necessary to serve the State's interests. This requirement does not require the government to adopt the least restrictive means, but instead requires only a "reasonable fit" between the government's purpose and the means chosen to achieve it. *Bd of Trustees, State U. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989). The prohibitions in the Act are narrowly limited to ensure that any alleged restriction on commercial speech[11] is reasonably tailored to achieve the objectives of the Act. The Act's restrictions only apply to the license, transfer, use, or sale of patient and prescriber-identifiable prescription data for *commercial* purposes, as defined in the Act, and not the myriad of beneficial uses the Plaintiffs spend pages discussing in their Trial Memorandum. Under the Act, the Plaintiffs can continue to collect prescriber-identifiable prescription data, aggregate and analyze that data, and disseminate the information to academic researchers, medical researchers, humanitarian organizations, law enforcement, and even pharmaceutical companies. Almost all of the activities listed by the Plaintiffs as uses for which the data is put remain permissible under the Act. *See* State's Factual Summary. The Plaintiffs can even sell the information to pharmaceutical companies for commercial purposes, so long as the data is identified only by zip code, geographic region or medical specialty. RSA 318:47-f section [7].

In challenging the Act as overly restrictive, the Plaintiffs suggest that academic detailing would be an effective means of counterbalancing the detailing by pharmaceutical companies.

[11] As discussed in Section II.B.1, *supra*, it is the State's position that the Act does not restrict speech within the scope of the First Amendment. The Act does not regulate speech at all, but rather commercial transactions or activities. By merely denying access to information used by companies to target their marketing, the Act places no restrictions whatsoever on the actual advertisements (the commercial speech); therefore, the rational basis test is the appropriate standard of review. *C.f. Pharmaceutical Care*, 429 F.3d at 316 (applying rational basis test to disclosure requirements aimed at helping control prescription drug costs).

This presupposes that the problem of physicians substituting more expensive drugs for equally effective and cheaper substitutes arises from a lack of knowledge on the part of physicians. The legislative history of the Act does not support this proposition. Rather, the history demonstrates a valid concern that access to prescriber-identifiable prescription data encourages use of that information by pharmaceutical companies to pressure physicians to change their prescriptions for reasons other than the clinical needs of patients. Simply providing physicians with more information about generic drugs, without addressing the problems created by the pressure being put on New Hampshire physicians by commercial entities having access to their prescription data, would be insufficient to address the State's substantial interest in lowering health care costs and limiting unwarranted intrusions into the decision making process of prescribing physicians.

Furthermore, the Plaintiffs' suggestion of "counter-detailing" as it is called, would require the State to raise and expend the billions of dollars necessary to effectively counter the pharmaceutical industry's army of representatives who target physicians on a daily basis. With the pharmaceutical industry's outlay of $7.8 billion (*supra*, Section I.E), New Hampshire would be unable to compete. Indeed, such a solution would simply treat the symptom; New Hampshire's Prescription Confidentiality Act is an effort to treat the disease itself.

Because the Act directly advances substantial state interests and is no more extensive than is necessary to serve those interests, the Act survives First Amendment scrutiny.

3. The Plaintiffs' assertion that strict scrutiny applies is completely without merit.

The Plaintiffs' assertion that the Act regulates non-commercial speech and is subject to strict scrutiny warrants little response. In support of this claim, the Plaintiffs argue that (1) the Act constitutes a content-based regulation on *non-commercial* speech, and (2) it prohibits the dissemination of lawfully-obtained, truthful, *non-commercial* speech of public concern. The Plaintiffs' claim that the Act regulates anything other than *commercial* activity, particularly given the express wording of the Act limiting its restrictions to "commercial purposes," strains common sense. To the extent the Plaintiffs discuss non-commercial uses of prescriber-identifiable data by themselves and other entities, the Act does not restrict those activities.

Nevertheless, the Plaintiffs argue that the Act is subject to strict scrutiny because it is targeted at the content of the "speech"[12] it seeks to regulate, namely, patient and prescriber-identifiable prescription data. The District of Columbia Court of Appeals rejected a similar argument made by a consumer reporting agency in the business of selling target marketing lists to target marketers when it challenged a statute which allowed the sale of information for some purposes, but not others. *Trans Union,* 267 F.3d at 1141-42 (holding any restriction on speech resulting from ban on sale of lists was subject to intermediate scrutiny even though it made content-based distinctions). The Court of Appeals noted that "given the Supreme Court's commercial speech doctrine, which creates a category of speech defined by content but afforded only qualified protection, the fact that a restriction is content-based cannot alone trigger strict scrutiny." *Id.* Because the Act is a regulation of commercial activity, it necessarily focuses on the

[12] As discussed in section II.B.1, *supra*, the State disputes that any speech protected by the First Amendment is regulated by the Act.

content of the information being regulated. *See Metromedia, Inc. v. City of San Diego*, 453 U.S. 490, 504 n. 11 (1981) ("If commercial speech is to be distinguished, it must be distinguished by its content."). The Act is expressly limited to commercial activity, and is therefore subject to a lesser degree of scrutiny. *See Discovery Network*, 507 U.S. at 416, 429-30 (applying intermediate scrutiny to determine constitutionality of Cincinnati rule drawing content-based distinctions by banning handbill racks, but not newspaper racks, on public property); *Mainstream Marketing*, 358 F.3d at 1236-37 (applying intermediate scrutiny to national do-not-call registry's telemarketing restrictions that drew a line "between commercial and non-commercial speech on the basis of content").

As for the Plaintiffs' argument that the Act prohibits the dissemination of lawfully obtained, truthful, non-commercial information of public concern, they are simply incorrect. Accepting for purposes of argument the Plaintiffs' characterization of prescriber-identifiable prescription data as "information of public concern," this very information can be used for numerous purposes, both non-commercial and commercial. None of the important public purposes described by the Plaintiff are restricted by the Act.[13] Therefore, even if one overlooks the fact that the Act is expressly limited to *commercial* activity, the Act continues to allow the dissemination of prescriber-

[13] Moreover, even if the Act did restrict the dissemination of non-commercial information of public concern, the cases the Supreme Court has decided in this area have involved application of statutes to newspaper publishers and reporters. There is a vast difference between silencing the media whose sole purpose is communicating information to the *public*, and prohibiting the dissemination of information from one private company to another private company for economic gain. "Because the extension of First Amendment protection to commercial speech is justified principally by the value to *consumers* of the information such speech provides," *Zauderer v. Office of Disc Counsel of the Sup. Ct of Ohio*, 471 U.S. 626, 651 (1985) (citing *Va Citizens Consumer Council, Inc.*, 425 U.S. 748) (emphasis added), the Plaintiffs' purported constitutionally protected interest in obtaining and disseminating prescriber-identifiable data solely for its own economic benefit and the economic interests of other commercial entities is minimal.

identifiable prescription data for public purposes, and the Plaintiffs' argument that strict scrutiny applies fails.

Finally, even if strict scrutiny were to apply, the Act survives for all of the reasons discussed above in relation to intermediate scrutiny. The State's interest in lowering health care costs and limiting unwarranted intrusions into the decision making process of prescribing physicians are compelling, and the Act's limited restrictions on the use of prescriber-identifiable prescription data for commercial purposes are the least restrictive means of achieving those objectives.[14]

C. The Plaintiffs Have Not Shown That the Act Is Void For Vagueness Or Overbreadth.

The Plaintiffs claim that the Act is constitutionally infirm due to vagueness or overbreadth.[15] Plaintiffs' Trial Memo. at 44. This claim is in error. An act is void for vagueness when it is so unclear that a person of normal intelligence would not be able to discern from a reading of the act how to avoid an inadvertent violation. *U.S. v. Bohai Trading Co., Inc.,* 45 F.3d 577, 580 (1st Cir. 1995) (citing *U.S. v. Harriss,* 347 U.S. 612, 617 (1954)). Also, if a statute regulates speech, it will be judged to be void due to vagueness when the language of the statute is so unclear that, in order to avoid possible

[14] The Plaintiffs' argument that the AMA's Prescribing Data Restriction Program is a less restrictive means of achieving the objectives of the Act fails. As discussed in the State's Factual Summary, the PDRP is insufficient to achieve the goals of the Act. Moreover, because the Act only impacts commercial speech (if it impacts any speech at all), intermediate scrutiny applies, and "[s]o long as the means chosen are not substantially broader than necessary to achieve the government's interest, . . . [a] regulation [is] not . . . invalid simply because a court concludes that the government's interest could be adequately served by some less-speech-restrictive alternative." *Trans Union*, 267 F.3d at 1143 (quoting *Turner II,* 520 U.S. at 218) (opt-in scheme satisfied intermediate scrutiny even though it limited more speech than the opt-out scheme preferred by plaintiff). Furthermore, Senator Kenney specifically discussed the inadequacy of the AMA opt out in his comments on the Senate floor. *See* State's Factual Summary at 8-9.

[15] While the Plaintiffs claim the Act is overbroad, they make no specified allegation regarding which provisions, if any, are overbroad, or why. Accordingly, the State will concentrate on the Plaintiffs' claims of unconstitutional vagueness.

prosecution, there is a high likelihood that people will "steer too far clear" of the prohibited speech, and that protected speech is chilled. *Ridley v. Mass. Bay Transp. Auth.,* 390 F.3d 65, 94 (1st Cir. 2004) (citing *Children of the Rosary v. City of Phoenix,* 154 F.3d 972, 983 (9th Cir. 1998)).[16] Another factor when determining whether a statute is impermissibly vague is whether it is open to arbitrary or inconsistent enforcement. *Kolender v. Lawson,* 461 U.S. 352, 357 (1983) ("[T]he void-for-vagueness doctrine requires that a penal statute define the criminal offense with sufficient definiteness that ordinary people can understand what conduct is prohibited and in a manner that does not encourage arbitrary and discriminatory enforcement.") (citations omitted). The Act fits none of these descriptions.

In determining whether a law is impermissibly vague, the Court will look at the statute as a whole rather than word by word or phrase by phrase. *Bohai,* 45 F.3d at 580. ("[S]tatutes are not enacted on a piecemeal basis and . . . should not be read that way."). Rather than follow this rule, the Plaintiffs deconstruct the statute and proceed to identify individual words and phrases they claim render the Act impermissibly vague. Plaintiffs' Trial Memo. at 42-45. Yet, even under their piecemeal analysis, the Plaintiffs identify no legal authority that supports any of their claims that any of the terms identified, either in and of itself or as applied in the Act, is so vague as to render the Act unconstitutional.

The first sentence of the Act states "Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other

[16] As noted previously, however, the State maintains that the Act merely regulates non-speech conduct, and in no way limits protected speech.

similar entity for any commercial purpose except for [specified limited purposes]." In this single sentence, the Plaintiffs identify the following terms as rendering the Act impermissibly vague: "and," Plaintiff's Trial Memo. at 42; "relative to," *id.*; "identifiable," *id.,* "Pharmacy Benefits Manager," *id.*; "other similar entity," *id*. at Page 43; and "commercial purpose" *id.* All these words and terms are either common words that are generally understood by average people ("relative to," "identifiable," "other similar entity"), terms of art ("Pharmacy Benefits Manager"), or defined in the statute itself ("commercial purpose"). As discussed below, only the arguably inaccurate use of the word "and" causes any possibility of misunderstanding the Act, and this is not fatal. Otherwise, these words, in and of themselves, are commonly understood and not vague. Nor does their inclusion render the Act as a whole impermissibly vague or ambiguous.

Taken as a whole, the challenged passage specifies in understandable terms how certain enumerated entities may use prescription records containing patient-identifiable and prescriber-identifiable data in commercial transactions.

Even using the Plaintiffs' myopic view, however, the Act passes constitutional muster. The statute begins by identifying the entities to which the restrictions apply. These are set out in terminology that is both commonly understood and which is well known to those in the trade. Therefore, the Plaintiffs' claim that this passage is vague is not supported by any legal authority and is without merit.

At Page 43 of their Trial Memorandum, the Plaintiffs state that the term "pharmacy benefits manager" is undefined, but such a definition is not necessary as the term is well known to those in the trade. A term which is so well known that it is routinely referred to

by its acronym is not a term which needs a specific definition in a statute in order for the statute to avoid being stricken for vagueness.

The Plaintiffs go on to bemoan the lack of precision in the term "other similar entity," yet again, when read as a whole, there is no impermissible ambiguity. The entities to which this law applies are PBMs, insurance companies, electronic transmission intermediaries, pharmacies (either retail, mail order or who operate via the Internet), and other similar companies. If the entity that intends to license, transfer, use or sell covered information is, or is similar to, a PBM, insurance company, electronic transmission intermediary or pharmacy, it will be covered. Otherwise, the Act will not apply to that entity. Again, the Plaintiffs' claim that the use of these terms without being specifically defined by statute renders the statute impermissibly vague is entirely unsupported by legal authority, and is without merit.

Similarly, the Plaintiffs state that it is unclear whether "and" in the first sentence should be conjunctive or disjunctive. Plaintiffs' Trial Memo. at 42. At most, a literal reading of "and" renders the Act ambiguous regarding the information that is covered, leaving the Act ripe for judicial interpretation. The mere fact that a statute may benefit from judicial interpretation does not, in and of itself, mean the statute is impermissibly vague. *Ridley,* 390 F.3d at 93. *See also Planned Parenthood of Cent. and Northern Ariz. v. Ariz.,* 718 F.2d 938, 948 (9th Cir. 1986) ("Potential for [disagreements over the precise meaning of a statute] cannot be enough to render the statute void for vagueness"). This ambiguity, rather than rendering the Act impermissibly vague, may be rectified with a judicial construction by the Court.

There is a long history of the confusion with the application of "and" and "or" in statutory drafting. Norman J. Singer, *Sutherland Statutory Construction* § 21:14 (West, 6th ed. 2002). If the literal meaning of these words renders a statute inoperable or renders the meaning questionable, there is room for interpretation by the Court. *Id.* ("[W]here the word 'and' is used inadvertently and the intent or purpose of the statute seems clearly to require the word 'or,' this is an example of a drafting error which may properly be rectified by a judicial construction."). As the ambiguity pointed out by the Plaintiffs surrounding the use of the word "and" results from exactly the sort of drafting error identified above, that ambiguity may be removed by a judicial interpretation of the Act. Thus, rather than indicating that the Act is void for vagueness, the drafting error merely creates an ambiguity requiring judicial clarification.

When clarifying the Act, the Court must look at the intent of the legislature. *Carlisle v. Frisbie Memorial Hosp.,* 152 N.H. 762, 773 (2005) ("If a statute is ambiguous, however, we consider legislative history to aid our analysis. Our goal is to apply statutes in light of the legislature's intent in enacting them, and in light of the policy sought to be advanced by the entire statutory scheme."). The legislative history indicates that the legislature intended the Act to independently cover both patient-identifiable information and prescriber-identifiable data. *See* Testimony of Rep. Rosenwald before Senate Committee on Executive Departments and Administration, April 19, 2006. Legis. History page 9 ("This legislation will accomplish [its] goals by prohibiting the sale or use of individual patient *or* prescriber identity") (emphasis added). This Court should conclude that the legislature meant the "and" to be an "or," and construe the Act accordingly.

Further underscoring the conclusion that the legislature meant "and" to mean "or" is that a literal interpretation of the Act renders it inoperative. A covered entity would be able to avoid the prohibitions set out in the Act by simply removing either patient-identifiable or prescriber-identifiable data from the records it intends to sell. Since patient-identifiable information is regularly removed pursuant to, among others, the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") statute, a literal reading of the Act would render it entirely ineffective. Thus, a judicial interpretation which would give meaning to the Act is necessary. *Colautti v. Franklin,* 439 U.S. 379, 392 (1979) (stating that it is elementary that a statute should be interpreted so as not to render it inoperative). *See also U.S. v. Menasche,* 348 U.S. 528, 538-539 (1955) ("It is our duty to give effect, if possible to every clause and word of a statute.").

Taking all this into consideration, two conclusions are inescapable: first, that "and" must be interpreted to mean "or;" and second, the use of "and" rather than "or" merely renders the Act ambiguous, not unconstitutionally vague. The recommended interpretation removes the ambiguity and gives full meaning to the statute.

The Plaintiffs go on to state, without specifying any legal basis therefor, that the restriction on the use of covered information for "commercial purposes" is impermissibly vague. Plaintiffs' Trial Memo. at 43. The Plaintiffs state that the sale, licensing, use, or transfer of covered data for an allowable purpose, *e.g.,* health care research, could ostensibly be a prohibited commercial purpose provided that the researcher is paid a profit for his or her research, or because the result of the research would most likely be commercially beneficial to someone. *Id.* However, the exceptions specified in the Act serve to remove any such ambiguity. Furthermore, the Plaintiffs' definition of

"commercial purpose" is inconsistent with that set out in the Act, which defines "commercial purpose" as follows:

> Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing force.

RSA 318-47-f, Section [5][a].

Under New Hampshire law, the use of the phrase "including but not limited to" preceding a specified list of actions serves to limit the statute to those types of actions specified. *Roberts v. Gen. Motors Corp.,* 138 N.H. 532, 538 (1994). Therefore, for the purposes of the Act, "commercial purpose" relates only to acts *of the type* listed in the definition. With this in mind, reading the Act as a whole, a reasonable person of average intelligence would find that the Act defines with reasonable specificity what is considered to be the commercial sale, use, licensing or transfer of the covered data. Furthermore, the Act goes on to explicitly allow the sale, use, licensing or transfer of covered data when the covered data will be used for specifically identified purposes. Thus, the Act gives adequate guidance to allow that person to avoid prosecution.

The Plaintiffs also claim that "otherwise provided by law" renders the statute impermissibly vague. Plaintiffs' Trial Memo. at 44. The Plaintiffs seem to believe that in order to use such a common statutory provision, the legislature needs to enumerate all statutory and regulatory provisions that would limit the defined term "commercial purpose" or otherwise risk the striking of the statute for vagueness. The Plaintiffs provide no legal basis for this claim.

Finally, the Plaintiffs point to Section [7] as an example of what they see as the ambiguity of the statute. Ironically, in their hypothetical, the Plaintiffs explain with some precision exactly how the passage in question would serve to operate, but then go on to state that "the statute is far from clear in this regard." *Id.* at 44 - 45. So, the Plaintiffs show by their understanding of the statutory provisions they themselves question that this section of the Act is understandable by those who would wish to remain in compliance.

Read as a whole, the Act provides fair notice for those who wish to remain compliant, and is not so vague as to be likely to chill any protected speech. At most, the Plaintiffs have identified at least one portion of the Act which may require judicial interpretation, but as noted above, the First Circuit has stated that such a requirement does not indicate a fatal vagueness. Furthermore, the Plaintiffs make no claim that the Act is so vague as to allow for arbitrary or inconsistent enforcement.

Finally, the Plaintiffs state that the statute is overbroad, but they point to no specific provision or provisions which they claim render the statute overbroad. Historically, courts are reluctant to invalidate a statute for overbreadth absent specific and substantial instances where the statute sweeps too far. *See N.Y. v. Ferber,* 458 U.S. 747, 769 (1982). ("We have recognized the overbreadth doctrine is strong medicine and have employed it with hesitation, and then only as a last resort.") (internal citations and quotations omitted). *See also Osborne v. Ohio,* 495 U.S. 103, 112 (1990). (A statute will not be judged as overbroad unless the overbreadth is "real, but substantial as well . . ."). Here, the Plaintiffs have failed to identify a single incidence of overbreadth. Accordingly, this Court should deny their claim that the Act is overbroad. The Plaintiffs' claim that the

Act is either void for vagueness or overbreadth is not supported by the law, and is without merit.

D. The Plaintiffs Have Not Shown That The Act Violates The Commerce Clause.

Article 1 § 8 Cl. 3 of the U.S. Constitution[17] grants Congress the power to regulate commerce among the states. When a state statute is said to violate the dormant Commerce Clause of the Constitution, courts use a two step analysis.[18] A statute that reaches outside the borders of the state and controls commerce in another state will be held to *per se* violate the Commerce Clause. *Healy v. Beer Inst.,* 491 U.S. 324, 337 (1989) ("Generally speaking, the Commerce Clause protects against inconsistent legislation arising from the projection of one State's regulatory regime into the jurisdiction of another State. And, specifically, the Commerce Clause dictates that no State may force an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another.").

On the other hand, when a state statute does not have an extraterritorial reach, the Courts will apply a balancing test to determine whether the benefits of the statute outweigh any effect on interstate commerce. The Supreme Court has held that certain types of legislation affect interstate commerce so severely that the state bears a heavy burden in its attempt to prevail in a dormant Commerce Clause challenge. A state statute that discriminates against out-of-state commerce or that protects in-state commerce from

[17] "Congress shall have the power . . . to regulate commerce with foreign nations, and among the several states, and within the Indian tribes."

[18] Because the Commerce Clause provides Congress the power to regulate commerce with foreign nations and among the states, when a state law regulates commerce in a way that conflicts with an act of Congress, that state law is in violation of the Commerce Clause. The term "dormant" or "negative" Commerce Clause, in contrast, is used when a state regulation affects interstate commerce and Congress has failed to regulate. *See* Lawrence H. Tribe, *American Constitutional Law*, 2d Ed. 1988 § 6.2 (describing the doctrine as arising from "negative judicial inferences from a Constitutional grant of Congressional power").

out-of-state competition is such a statute. *City of Philadelphia v. N.J.,* 437 U.S. 617, 626-627 (1978) ("Whatever New Jersey's ultimate purpose, it may not be accomplished by discriminating against articles of commerce coming from outside the State unless there is some reason, apart from their origin, to treat them differently."). *See also Hunt v. Wash. St. Apple Advert. Comm.,* 432 U.S. 333, 353 (1997) ("When discrimination against commerce . . . is demonstrated, the burden falls on the State to justify it, both in terms of the local benefits flowing from the statute and the unavailability of nondiscriminatory alternatives adequate to preserve the local interests at stake.").

However, a nondiscriminatory state statute that only incidentally affects interstate commerce requires that the state merely be able to show that the benefits of the law in question outweigh the burdens on interstate commerce. *Pike v. Bruce Church, Inc.,* 397 U.S. 137, 142 (1970) ("Where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits.").

In their Trial Memorandum, the plaintiffs do not claim that the Act is discriminatory or incidentally affects interstate commerce. Rather, the plaintiffs claim the Prescription Confidentiality Act has an extraterritorial reach, and is thus *per se* in violation of the Commerce Clause. Plaintiffs' Trial Memo. at 45. This is error for three reasons. First, the Plaintiffs misconstrue the Commerce Clause when they claim that the Commerce Clause limits a state's ability to regulate out-of-state speech. Second, the Act does not have the geographic reach described by the Plaintiffs. Finally, the Plaintiffs misconstrue

the rule established by the Supreme Court relative to the regulation of out-of-state commerce.

While the Commerce Clause grants Congress the power to regulate interstate commerce, there is a remainder of power in the states to make laws that may affect interstate commerce. *Southern Pacific Co. v. Ariz., ex rel. Sullivan*, 325 U.S. 761 (1945). Furthermore, a fundamental principle in Commerce Clause analysis is that "the [Commerce] Clause protects the interstate *market*, not particular interstate firms from prohibitive or burdensome regulations." *Philip Morris, Inc. v. Reilly*, 2001 WL 1215365 at *16 (1st Cir. 2001) (emphasis added).

To begin, the Commerce Clause, by its plain language, relates to the regulation of *commerce*, not speech.[19] Thus, in pages 47 and 49 of their Trial Memorandum, where the Plaintiffs state that New Hampshire's law violates the Commerce Clause because it "attempts to regulate . . . *speech* that occurs solely outside of the State of New Hampshire," the Plaintiffs propose a novel interpretation of the Commerce Clause. By interchanging "speech" and "commerce," the plaintiffs seem to suggest that commercial activity should receive the same level of Constitutional protection as does protected speech. This Court should reject their proposal that this Court rewrite the Commerce Clause to relate to speech rather than commerce.

Second, the Act does not regulate commerce that takes place entirely outside New Hampshire because the Prescription Confidentiality Act has no such reach. The Plaintiffs argue that the General Court failed to limit the geographic scope of the Act, and that as a result, the Act has an extraterritorial reach and is thus invalid. Plaintiffs' Trial Memo. at

[19] As noted in Section II.B.1, *supra*, the State's position is that the Act merely regulates non-speech conduct and has no impact on protected speech of any kind.

50. In other words, the plaintiffs propose that this Court find, in the absence of any expressed legislative intent, that the New Hampshire legislature meant for the Act to have a global reach. There is no legal foundation for this Court to reach that conclusion.

Generally, legislation is presumed to relate only to activity that takes place domestically. For example, it is well established that federal legislation is presumed to have only a domestic effect. *Foley Bros. v. Filardo,* 336 U.S. 281, 285 (1949) ("The canon of construction which teaches that legislation of Congress, unless a contrary intent appears, is meant to apply only within the territorial jurisdiction of the United States, is a valid approach whereby *unexpressed congressional intent may be ascertained*.") (internal citations omitted) (emphasis added).

This principle has also been applied to state legislatures. For example, when a plaintiff who lived and worked in Georgia claimed that he had been subject to age discrimination and filed a complaint against his employer, a Pennsylvania company, under the Pennsylvania Human Relations Act ("PHRA"), the District Court said that the PHRA did not reach activities that took place outside of Pennsylvania. *Taylor v. Rodale, Inc.,* 2004 WL 1196145, at *2 (E.D. Pa. May 27, 2004). The Court reasoned that since federal courts have long recognized a presumption against extraterritorial application of federal statutes, the same should apply to state legislation. *Id.* ("This presumption reflects a standard of comity toward other countries . . . when the conduct at issue occurs outside the United States. The same consideration would seem to preclude us from extending the reach of the PHRA . . . in the absence of clear legislative intent to the contrary."). Since the Prescription Confidentiality Act bears no language indicating that the New Hampshire legislature intended that the Act would reach activities that take

place outside its jurisdiction, it is proper to presume that the unexpressed intent of the legislature is to limit the Act's effectiveness to transactions that take place inside New Hampshire.

Further, the legislature is presumed to know the law. *Barksdale v. Town of Epsom,* 136 N.H. 511, 516 (1992). Thus, it is presumed to understand the limits of its jurisdiction. The Act omits language limiting - or extending - its geographic reach. This should result in the conclusion that the legislature intended the Act not to reach beyond the State's borders. The omission is presumed to be due to the legislature's inherent understanding of the limits of its authority. *Kennett's Petition,* 24 N.H. 139, 140 (1851) ("The omission of a proviso restricting [the statute's] application . . . may well be attributed to the settled and well known construction given by the courts, which confines the operation of . . . statutes . . ."). Thus, the omission from the Act of the words "within this State" or some other limiting language should not lead to the conclusion that the Act is meant to have an extraterritorial reach and therefore result in its automatic invalidation on constitutional grounds.[20]

Where a statute is written in such a way that it may be subject to two constructions, one which results in the statute being unconstitutional and another which renders the statute constitutional, the Court must invoke the construction that renders the statute constitutional. This principle has long been established. In 1861, for example the Supreme Court held that when a statute would be unconstitutional if applied to one party

[20] The Act also states that a violation constitutes an unfair or deceptive act or practice in the course of trade or commerce as described in RSA 358-A, the Consumer Protection Act ("CPA"). It is worth noting that the CPA specifically relates only to such acts or practices that take place "within this state." RSA 358-A:2. Plaintiffs ask the Court to reach the improbable conclusion that the legislature intended that the geographic reach of the Act relative to the availability of different remedies would not be harmonious, and that criminal liability pursuant to RSA 318:55 would have no geographic limitations, whereas civil liability under the CPA would be confined to acts performed in New Hampshire.

but constitutional when applied to another, the Court must construe the statute so as to render it constitutional.

> The rule of construction universally adopted is, that when a statute may constitutionally operate upon certain persons, or in certain cases, and was not evidently intended to conflict with the constitution, it is not to be held unconstitutional merely because there may be persons to whom, or cases in which it cannot constitutionally apply; but it is to be deemed constitutional, and to be construed not to apply to the latter persons or cases, on the ground that courts are bound to presume that the legislature did not intend to violate the constitution.

In re Opinion of the Justices, 41 N.H. 553, 555 (1861).

Thus, it is impermissible to interpret a statute so as to render the statute unconstitutional where an interpretation which would save the statute is reasonable. *U.S. ex rel Atty. Gen. v. Del. & Hudson Co.,* 213 U.S. 366, 408 (1909) ("[W]here a statute is susceptible of two constructions, by one of which . . . constitutional questions arise and by the other of which such questions are avoided, our duty is to adopt the latter.").

This principle still stands. While a federal court will not "rewrite a state law to conform it to constitutional requirements," the Court will uphold the statute if it is "readily susceptible to a . . . construction that would make it constitutional." *Va. v. Am. Booksellers Assn., Inc., et. al.,* 484 U.S. 393, 397 (1988). *See also Odle v. Decatur County, Tenn.,* 421 F.3d 386, 396 (6th Cir. 2005) ("It is true that we must adopt a limiting construction to save the ordinance from invalidation if it is 'readily susceptible' to such a construction."). Properly construed, the Act is not *per se* in violation of the Commerce Clause because it does not control commerce that takes place wholly outside of the State's borders..

Third, by removing the Court's statements in *Healy,* 491 U.S. 324 (1989), and *Baldwin v. G.A.F. Seelig, Inc.,* 294 U.S. 511 (1935), from the context of the cases in

which they were contained, the Plaintiffs propose that the rulings in *Healy* and *Seelig* are broader than they actually are. Both *Healy* and *Seelig* were cases where, due to the effect of interlocking and conflicting regulations in neighboring states, price regulations established in one state had the secondary effect of actually controlling the prices for those goods sold in those neighboring states. Thus, the rulings in *Seelig* and *Healey* relate to a state's extraterritorial regulation of prices.

To explain, at issue in *Seelig* was the New York Milk Control Act, which banned the in-state sale of milk purchased from out-of-state producers at a price lower than in-state producers were allowed to sell their milk. 294 U.S. at 519. Because of the New York law, any out-of-state milk producer who wanted to sell to a New York distributor would need to conform its price to the minimum New York price. Thus, by giving the out-of-state milk producers the choice of either complying with the New York law or losing the New York State market, the New York law had the effect of controlling the price of milk in other states. *Id.* at 528.

Similarly, in *Healy,* the Connecticut Liquor Control Act required beer distributors to sell their product to Connecticut wholesalers at a price no higher than it sold its products in neighboring states. 491 U.S. at 326. Connecticut's law allowed distributors to change their prices only on a monthly basis. *Id.* at 329. Consequently, distributors could only change their prices in neighboring states on a monthly basis without possibly violating Connecticut law. *Id.* As a result, distributors selling into neighboring states could not respond to local market conditions, have a special sale, or otherwise modify their prices. *Id.* at 339. Thus, due to interlocking and interrelating state statutes in the states that

bordered it, Connecticut's law had the effect of controlling the prices for which beer could be sold to wholesalers in neighboring states. *Id.* at 338-339.

Similarly, in *Pharm. Research and Mfrs. of Am. v. District of Columbia,* 406 F. Supp. 2d 56 (D.C. 2005), a law which was found to violate the Commerce Clause sought to control the prices of patented prescription drugs sold in the District of Columbia by regulating the prices charged by out-of-District wholesalers or distributors. The district court held that, like the New York Milk Control Act and the Connecticut Liquor Control Act, the D.C. law was "a statutory scheme" that would have the practical effect of "establishing a scale of prices for use in other states." *Id.* at 70. Thus, the D.C. act was found to violate the dormant Commerce Clause.

These cases stand for the proposition that a state law that has the practical effect of controlling prices for goods or services being offered in other states violates the dormant Commerce Clause, and do not establish a rule that is as broad as that proposed by the plaintiffs.[21] In contrast, the Prescription Confidentiality Act has no direct effect on prices of any goods in this or any state. The Act simply states that certain types of information may not be transferred or used for certain explicitly defined purposes. The Act does not affect the price of drugs.

In addition, in their Trial Memorandum, the plaintiffs misstate the standard of review for dormant commerce clause complaints where they state that the Court must "strictly

[21] Another line of cases exists in which the term affecting commerce taking place outside the state's borders figures prominently, but those cases indicate a Commerce Clause violation when the state regulations burden an instrumentality of interstate commerce. *See, e.g. Southern Pacific,* 325 U.S. 761 (State regulation on number of cars allowed on a train projects state law beyond its borders and burdens interstate commerce), and *Bibb v. Navajo Freight Lines, Inc.,* 359 U.S. 520 (1959) (State requirement that all trucks be equipped with certain configuration of mudflaps projects state law beyond its borders and burdens instrumentality of interstate commerce). However, there is no allegation that the Prescription Confidentiality Act burdens any instrumentality of interstate commerce.

review" dormant commerce clause challenges to state laws.[22] Plaintiffs' Trial Memo. at 46. In fact, strict scrutiny is a term which is generally not applicable to dormant Commerce Clause analysis. A reading of the cases cited by the plaintiffs turns up no reference to "strict scrutiny." Instead, the cases cited by the plaintiff merely illustrate the analysis, as described above, used by the Court when analyzing whether a discriminatory state law affecting interstate commerce violates the Commerce Clause.

The Act is not discriminatory. The Act is even-handed on its face and in its application, and provides no benefit or preferential treatment for any New Hampshire business at the expense of out-of-state businesses.

If this Court determines that the Act does affect interstate commerce, it should apply the *Pike* balancing test. In doing so, the Court should consider the strong interest of the State in enacting the statute. Protecting health and the welfare of consumers are two of the State's primary roles. *Hunt* 432 U.S. at 350 (State has a "residuum" of power to regulate interstate commerce in matters related to health and consumer protection). The State's interest, therefore, is strong, and the weight of the state's interest should be heavy in the scale. Here, the New Hampshire legislature has sought to protect consumers and physicians from the invasion of the privacy of the doctor-patient relationship, and the interference with the physician's clinical judgment regarding which medications are best suited to the patient's needs.

As noted earlier, the legislature found that the trade in physician-identified prescription data was having a detrimental influence on the provision of and payment for health care by causing physicians to prescribe based on factors unrelated to the clinical

[22] The first full paragraph on page 46 of the Plaintiffs' Trial Memorandum relates to deference to legislative authority. However, deference is usually afforded the legislature regarding its factual determinations and the predictive effects of the proposed legislation. Thus, this reference is somewhat puzzling.

benefits to the patient, and by unnecessarily increasing health care costs. The Prescription Confidentiality Act is designed specifically to combat these ills. Therefore, the benefits to the people of New Hampshire outweigh any incidental affect on interstate commerce caused by the Act.

Because this action by the New Hampshire legislature is strictly a matter of patient health and safety and consumer protection, and because the Prescription Confidentiality Act has, at most only an incidental affect on interstate commerce, if the Court finds that the Commerce Clause is implicated, the Court should apply the *Pike* test and conclude that the Act is not prohibited by the Commerce Clause.

For all the above reasons, the Plaintiffs have not shown that the Act is barred by the Commerce Clause.

III. CONCLUSION

For all of the reasons stated in this Memorandum, the State's Summary of Facts, and such argument that may be presented to the Court, the State respectfully requests that this Court rule that the Act is constitutional, and enter judgment in favor of the State.

Respectfully submitted,

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Certification of Service

I hereby certify that a copy of the foregoing document was filed electronically and served electronically by operation of the Court's electronic filing system or by mail on anyone unable to accept electronic filing. Jeffrey C. Spear, Esquire, James Bassett, Esquire, Patricia Acosta, Esquire and Thomas R. Julin, Esquire have appeared as counsel of record for plaintiffs IMS Health Incorporated and Verispan, LLC.

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