UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

Appeal No. 07-1945

IMS HEALTH INCORPORATED, a Delaware Corporation; and
VERISPAN, LLC, a Delaware Limited Liability Company

Plaintiffs - Appellees

v.

KELLY A. AYOTTE, New Hampshire Attorney General

Defendant – Appellant

On Appeal from the United States District Court
for the District of New Hampshire

BRIEF OF KELLY A. AYOTTE, ATTORNEY GENERAL OF NEW HAMPSHIRE

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JURISDICTIONAL STATEMENT

This appeal arises from the matter of IMS Health, Inc. v. Kelly A. Ayotte, docket 06-cv-280, originally filed in the U.S. District Court for the District of New Hampshire on July 20, 2006. IMS and Verispan asserted jurisdiction based upon federal question pursuant to 28 U.S.C. § 1331, which provides that a federal district court has "original jurisdiction arising under the Constitution, laws or treaties of the United States." IMS and Verispan also asserted jurisdiction pursuant to 28 U.S.C. §§ 1337 and 1343(a)(3) and (4).

The District Court issued an order in which it granted Appellees' request for declaratory and injunctive relief on April 30, 2007. Judgment was entered on May 7, 2007.

Attorney General Kelly Ayotte appealed from this order and judgment on May 31, 2007. This Court has jurisdiction pursuant to 28 U.S.C. § 1291.

STATEMENT OF ISSUES

I. Whether New Hampshire's Prescription Confidentiality Act, codified at N.H. RSA 318:47-f, N.H. RSA 318:47-g, and N.H. RSA 318-B:12 (2006), restricts speech protected by the First Amendment.

II. Whether New Hampshire's Prescription Confidentiality Act survives First Amendment intermediate scrutiny because it directly advances a substantial state interest and is no more extensive than necessary to serve those interests.

STATEMENT OF CASE

In 2006, the New Hampshire legislature enacted House Bill 1346, which forbids the use, transfer, license, or sale of prescription information containing patient-identifiable and prescriber-identifiable data for certain commercial purposes. The legislature passed the Prescription Confidentiality Act as a measure to control health care costs in New Hampshire, to protect the health and safety of New Hampshire's citizens, and to protect the privacy of doctors and patients who use prescription drugs. House Bill 1346 is codified at N.H. RSA 318:47-f, N.H. RSA 318:47-g and N.H. RSA 318-B:12 (2006) ("the Act"). *See* 2006 N.H. Laws 328. The Act took effect upon its passage.

Appellees IMS Health, Inc. ("IMS Health") and Verispan, LLC ("Verispan") are data mining companies 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 IMS Health and Verispan's customers. A primary category of client is the pharmaceutical industry, which spends a great deal of money acquiring the data for use in marketing activities. Following the passage of the Act, IMS Health and Verispan modified some of their practices so that they could continue to

acquire prescription data and use it for purposes allowed by the law while not using it for purposes prohibited under the Act.

On July 20, 2006 IMS Health and Verispan filed their complaint in Federal District Court in Concord, New Hampshire, claiming that the Act violates the First Amendment, the Commerce Clause, and is void for vagueness. Kelly Ayotte, the Attorney General for New Hampshire, objected to Appellees' request for declaratory and injunctive relief and contended that neither the First Amendment nor the Commerce Clause prevented New Hampshire from enforcing the Act.

After a bench trial, held on January 29-February 1, 2007 and February 5, 2007, the Federal District Court in Concord, New Hampshire (Barbadoro, J.) issued a ruling on April 30, 2007 stating that the Act violates IMS Health and Verispan's First Amendment right to engage in commercial speech, and enjoined its enforcement. The Court made no ruling regarding IMS Health and Verispan's Commerce Clause claim.

This appeal followed.

STATEMENT OF FACTS

Prescriber identifiable data is used for a variety of purposes. It is used to target doctors for office visits by sales representatives (called "detailing"); to know which of the competitor's products to criticize; to determine the effectiveness of a detailer's message; to determine the compensation of the detailer. Because their compensation is directly tied to the effectiveness of their sales message, a pharmaceutical representative (a "detailer") is heavily driven by how much they are able to change the prescribing practices of physicians, which contaminates their role as a teacher. Avorn testimony [140] 33. Prescriber identifiable data is used to tell the detailer which door is open, the message the detailer should use while in the door, and to follow-up on whether that message was effective. *Id*. at [142] 35.

Before a detailer even walks into a physician client's office, he or she is armed with very detailed information regarding that physician's prescribing behavior. Physician prescribing data is used by detailers to identify an individual physician's prescribing preferences and how they are trending. Ahari Testimony [10] 64. The detailer can see which drugs a physician is prescribing, what proportion of the physician's prescriptions include the detailer's drug, and trend it out over the course of a year (and use those trends to isolate peaks, troughs and how the physician's prescribing

habits correspond with the detailer's sales visits). *Id*. at [13] 67. Detailers can compare their drug and a specific competitor's drug as prescribed by a particular physician. *Id*. at [14] 68 ("If we're focusing our campaign on one specific drug that we want to diminish their market share, we can make that data, we can compile that data and we can filter it out and make a comparison."). Detailers can decide if the level of sales should remain the status quo, or if there is potential to increase market share by tailoring a sales strategy to find a way to increase the physician's use of the detailer's drug. *Id*.

One detailer described the power of the prescriber specific information provided by data mining companies such as IMS and Verispan as follows:

> But also another advantage of that information is that whenever there is some sort of agreement or buy-in from a client [physician], if I've convinced my client to use Prozac for patient profile X, and I leave him 10 samples to use between now and the next time I come visit his office, . . . without that prescriber information he can just say, oh, yeah, I gave your samples away to those specific patients and I'm very happy with it, and there's no way I can actually verify that he's done so. But with that information, I know when I get an agreement from a physician, whether he's telling me the truth, and if he's not telling me the truth, I know that I can harass him, and in a myriad of different ways, never so bold as to be obnoxious because it's poor business, but I can – I know whether I need to spend time on this person to use more of my product again to make him follow through with his commitments to me, or to simply walk away and say, this is a no win situation financially, and that I'm not going to convince him.

> So it's actually very convincing to be able to help me to design my business tactics with my clients.

Id. at [23] 69.

In response to the pharmaceutical industry's use of prescriber-identifiable data for such marketing purposes, the New Hampshire legislature passed House Bill 1346 as a measure to control health care costs in New Hampshire, to protect the health and safety of New Hampshire's citizens, and to protect the privacy of doctors and patients who use prescription drugs. House Bill 1346 is codified at N.H. RSA 318:47-f, RSA 318:47-g and RSA 318-B:12. *See* 2006 N.H. Laws 328. Addendum at 57. The pertinent language of the Act reads:

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

N.H. RSA 318:47-f.

The Act was strongly supported by the New Hampshire Medical Society ("NHMS"). The primary reasons for supporting the legislation were clinical care and access to unbiased information. Some members of the NHMS also expressed their support for the legislation based on privacy concerns. The NHMS actively supported the legislation before the New Hampshire General Court. Sadowsky Declaration at ¶ 10, Appendix at 47.

By preventing the use of prescriber specific prescription information in detailing physicians, the Act would cause a shift in the message being provided by pharmaceutical representatives. Conversations between detailers and physicians would be less tailored by the detailer and his or her primary interest in the market share of the drug being promoted, and would focus more on the science of the drug. Ahari Testimony at [23-24] 69-70. The State's expert witness, Dr. Avorn, explained the effect of the Act as follows:

> And as I see the statute, it's one small step in the direction of trying to make the discourse between the sales reps and the doctors be about the merits of the drug, and not this kind of underhanded, behind-the-scenes I know what you're prescribing but I'm not going to admit that I know it. But I'm going to tailor my sales pitch to you to undercut the product that I know that you're using. I think that takes us away from the science, and I'd like to see whatever communication happens

> be brought back to the science. And that's why I think the statute is useful.

Avorn Deposition Transcript at [228-29] 43-44.

The use of prescriber specific prescription data for marketing purposes is made possible through "data mining" by companies such as IMS Health and Verispan. Prescriptions are written for approximately 8,000 different pharmaceutical products. Amended Joint Stipulation of Facts ¶ 9 (trial document 88). Prescriptions are dispensed by approximately 54,000 retail pharmacies throughout the United States, as well as other medical facilities licensed to fill prescriptions. *Id.* Retail pharmacies acquire prescription data during the regular course of business, and license, sell, or transfer the data to IMS and Verispan. *Id.* ¶ 11. 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. *Id.* ¶ 13. The patient identifier is unique to an individual patient, and follows that patient, but does not consist of patient identifiable information. *Id.* ¶ 4.

IMS and Verispan collectively acquire, aggregate and analyze prescription data relating to billions of prescription transactions per year throughout the United States. *Id.* ¶ 14. IMS and Verispan sell their products to the pharmaceutical industry for a great deal of money to be used for

marketing patent-protected brand name drugs. After patents or other periods of exclusivity expire, manufacturers can apply to the FDA to sell generic versions, which must be bioequivalent to a brand name drug. *Id.* ¶¶ 21-22. Generic drugs are typically sold at substantial discounts from the branded price, and as a consequence, pharmaceutical companies do not devote any substantial marketing resources to promoting branded drugs for which bioequivalent generics are available. *Id.* ¶¶ 22, 25. Branded drugs are marketed, however, when generic drugs that are designed to treat similar conditions are available, when those generic drugs are not bioequivalent to the branded drug. *Id.* ¶ 26.

Pharmaceutical manufacturers are frequently able to create "new" drugs by slightly modifying an existing drug that may no longer enjoy patent protection. Thus, by modifying the drug, for example by making the new drug a time-release capsule, the drug once again enjoys patent protection. During the time of patent protection, that drug with its particular modification will not be available in a generic form. An example of this practice is Paxil-CR (for generic paroxitine). Sobelson Declaration at ¶ 11, Appendix at 51.

In other cases, certain drugs maintain patent protection by claiming nonequivalency with generics, although their practical use does not support

the claim. Premarin, for example, which for many uses has a generic estrogen substitute, is subject to patent protection. It is not uncommon for a doctor to write a prescription for a name brand drug, on the assumption that the generic equivalent will actually be dispensed at the pharmacy level. If a doctor prescribes Premarin, however, the pharmacy can only fill that prescription with Premarin, even though the generic product would have provided an equally effective treatment option. *Id.* at ¶ 12.

Pharmaceutical companies expend significant resources on direct marketing to prescribers. Amended Joint Stipulation of Facts at ¶ 40. These marketing efforts directed at physicians include office visits by sales representatives ("detailing"); providing samples at no cost; presenting and sponsoring physician meetings and events; and advertisements in medical journals. *Id.* Detailing in particular has a significant effect on physician prescribing behavior. *See* Phil, Honka, *Symposium Pharmaceutical Innovation and Cost: An American Dilemma*, 5 Yale J. Health Pol'y, L. & Ethics 785, 809 (Summer 2005) (Trial Exhibit A9, Appendix at 36). Phil and Honka reported:

> However, from the patient, physician, firm, and policymaker's point of view, it is important to establish that detailing does have a significant effect on physician prescription behavior. Interestingly enough, many studies that have asked physicians this question find that physicians believe that it is likely that prescription behavior can be influenced by detailing. This

> opinion is supported by virtually all the studies that have investigated the effect of detailing (either in isolation or with other marketing instruments) using behavioral data either at the market or the individual physician level. While there seems to be little consensus about the size of the effect, *it is clear that the effect is positive and significant in a statistical sense.*

Id. (emphasis added); *see also* Lawrence, *The High Cost of Prescription Drugs: The Price of Success?*, 4 Yale J. Health Pol'y, L. & Ethics 165, 167 (Winter 2004). Through detailing, drug representatives change prescribing behavior of physicians, resulting in diminished health care for patients, and unnecessary increased expenditures on drugs. Sadowsky Declaration at ¶ 9, Appendix at 47.

More specifically, pharmaceutical detailers use prescriber-identifiable data during sales visits to persuade the prescriber to prescribe a drug. Amended Joint Stipulation of Facts ¶ 41. The data supplied from data mining companies such as IMS and Verispan gives pharmaceutical detailers important personal information about each doctor in their territory. Prescriber information can be used to identify which doctors are suitable targets for a sales message. Once targeted, the doctor, or the doctor's staff, will experience the full sales techniques used by pharmaceutical representatives in their goal of increasing sales of a name brand drug. Sobelson Declaration at ¶ 15, Appendix at 53.

Prescribing profile data pinpoints a physician's prescribing history, and his or her current prescribing habits. Prescriber specific information is useful to pharmaceutical detailers to maximize the efficiency of their resources and to maximize sales in their territory. Prescribing data is used to identify which products are currently in favor with physicians in order to develop strategies to change those prescriptions to prescriptions for the detailer's drugs. Ahari Declaration at ¶8-9, Appendix at 57.

Prescriber profiles help identify prescribers who have changed their prescribing habits the most or who prescribe large quantities of drugs the detailer is pushing. The profiles also can provide a comparison of prescribing patterns of the detailer's drug versus a competitor's drug and trends in prescribing habits. *Id.* at ¶16, Appendix at 59.

Prescriber profiles can also provide information about the effectiveness of the sales effort. Prescriber profiles contain details that include the number of patients who are prescribed a specific medicine; how much of one drug is prescribed compared to another similar drug; how a physician's prescribing habits have changed over time, and other similar information. *Id.*

Doctors are ranked from 1-10. This score is often referred to as their "prescribing power" and is commonly used by detailers as a measure of the

doctors' contribution to the local market. Prescriber ranking is used as a tool to develop appropriate strategies for detailing each physician in a detailer's territory. The number of visits physicians receive is typically proportional to that doctor's prescribing power. Significant resources are spent on physicians with prescribing power. Physicians with a trend toward switching from a competitor's drug also receive additional attention. *Id.* at ¶17-18, Appendix at 59-60.

Pharmaceutical manufacturers invest considerable resources in marketing efforts; for example, in 2000, the industry spent around $15.7 billion on marketing, $4 billion of which was dedicated to direct-to-physician strategies. More recent estimates are that the industry currently spends between $25 billion and $30 billion per year on marketing. *Id.*, Appendix at 4. In fact, data from the Securities and Exchange Commission and the federal Department of Health and Human Services indicate that the large pharmaceutical companies spend a higher proportion of their revenues (about 30%) on promotion, marketing, and administration than the proportion (about 13%) spent on research and development. *Id.* In addition to providing verbal descriptions of particular products, detailers give physicians industry-developed sales pamphlets, pens and other supplies, and free samples. Social scientists have shown that these gifts contribute to

many physicians' positive view of sales representatives, and make them more receptive to the information that detailers convey. *Id.*

Detailing is a highly effective marketing strategy for pharmaceutical manufacturers. Researchers investigating four different practices – detailing, medical journal advertisements, direct-to-consumer advertising, and pricing – found detailing to have the most powerful effect on driving drug utilization. Another study showed that meetings with pharmaceutical representatives were associated with changes in physician prescribing practices as well as requests by physicians to add the drugs to their hospitals' formularies. Avorn Declaration, Appendix at 5. Contact with detailers was shown to be the most consistent predictor of physicians' early adoption of new pharmaceutical agents. Overall, many experts agree that there is a "strong, consistent, specific, and independent" association between physicians' behavior and their exposure to detailers. *Id.*

The purpose of all this contact and communication is not to provide an unbiased review of the evidence, but rather to enhance sales of a given company's product, whether or not it is the most appropriate or cost-effective choice. *Id.* Physicians are often unaware of the substantial impact manufacturer promotional activities have on their prescription practices. In a random sample of primary care physicians, while physicians generally

denied that information from commercial channels was an important source of their drug information, their knowledge of drug properties was more consistent with sales information for these drugs than with the medical literature. *Id.*

Because of its powerful effect on physicians' prescribing practices, detailing by pharmaceutical sales representatives has significant economic and clinical consequences for the health care system. Physicians' use of targeted prescriptions increases substantially after visits with sales representatives. This has important effects on the cost of medications. Detailing is generally confined to high-margin, high profit drugs, for which the manufacturer has a substantial incentive to increase sales. Avorn Declaration, Appendix at 6.

There is virtually no economic incentive for the manufacturers of generic drugs to send sales representatives to visit physicians about those products, even though there is clear evidence that these medications can provide therapeutically equivalent and much more affordable and cost-effective treatment in a wide variety of conditions. *Id*. Thus, the work of pharmaceutical sales representatives drives drug use toward the most expensive products, and contributes to the strain on health care budgets for individuals as well as health care programs, especially Medicaid. Health

economists have documented that the promotion of patented drug products lowers price sensitivity, which inhibits price competition and leads to higher prices. *Id*. Appendix at 6-7. Drug samples provided to physicians by detailers have been shown to encourage physicians to prescribe drugs that differed from their preferred drug choice, including more expensive, second-line drugs. *Id*. Appendix at 7.

For example, extensive marketing campaigns were initiated in the 1990s to promote new antihypertensive medications called calcium-channel blockers (CCBs), despite the fact that professional guidelines did not consider them first-choice therapies for the treatment of hypertension. The older drugs were supported by the Joint National Commission on Hypertension. Avorn testimony [58, 59-60] 25, 26-27. As a result of detailing and other marketing efforts, revenues for CCBs grew consistently throughout the decade. Despite the national guidelines toward the older calcium channel blockers, sales of new branded calcium channel blockers supplanted the preferred drugs because of the marketing directed toward the new branded drugs. *Id*. As a result, the pharmaceutical industry can get "a customer for life for a thousand dollar a year drug instead of a $60 dollar a year drug." *Id*. at [58-59] 25-26. This distortion of practice away from the use of drugs recommended in national guidelines was estimated to have

increased health care expenditures by around $3 billion dollars in 1996 alone. Avorn Declaration, Appendix at 7.

The effect of detailing in driving physicians' prescribing practices to the newest, most costly products can also have an important effect on patients' clinical outcomes. First, because full understanding of a drug's side effect profile may not be complete when the drug is first approved for marketing, detailing encourages the prescription of new products that might be riskier to patients than known agents on the market. This was seen in the widespread adoption of Vioxx (rofecoxib), even though it was never shown to be a more powerful analgesic than many older drugs (such as ibuprofen, or Motrin) already on the market. Avorn Declaration, Appendix at 7-8. Some CCBs, in addition to being more expensive than first-line agents for hypertension, were later found to increase the risk of myocardial infarctions by 18%. Avorn Declaration, Appendix at 8.

In another example, the cardiac medication nesiritide (Natrecor) was approved for treatment of acute exacerbations of congestive heart failure in 2001, despite the fact that its side effect profile had not been adequately studied by the manufacturer. *Id.* The product was immediately promoted through a cadre of detailers in individual meetings with cardiologists. Sales of the drug reached $400 million in 2004, but its use decreased dramatically

in 2005 when it was found to be associated with increased rates of kidney disease and death. *Id.* The studies showing these adverse events were largely based on data available to the manufacturer when nesiritide was first approved, but were not featured prominently in its marketing campaigns. *Id.*

The information presented to physicians by detailers has also occasionally been found to be inaccurate. Avorn Declaration, Appendix at 8-9. One study of detailers' promotional brochures found that 15% of the pamphlets presented data that differed from the published studies on which they were based. In another study, 11% of the statements made by pharmaceutical representatives about drugs were scientifically inaccurate, and physicians generally failed to recognize the inaccurate statements. Litigation following the withdrawal of Vioxx has revealed the existence of elaborate sales training campaigns conducted by the manufacturer, Merck, whose main purpose was to divert attention of physicians away from concerns about the possible cardiac risk of that drug. The printed sales materials used by the detailers and presented to the physicians they visited continued to understate the data on the cardiac risk of Vioxx even after the company was in possession of more accurate data. This is not a unique situation; because the purpose of detailing is to increase product sales, the information detailers present to physicians supports this goal, rather than a

fair and balanced presentation of the medical literature as a whole. *Id.*, Appendix at 8-9.

In 2005, Congress held hearings regarding the sales of the drug Vioxx. A May 5, 2005 U.S. House of Representative Memorandum (the "House Memorandum") summarizes the results of a Committee on Government Reform investigation of how the drug Vioxx was marketed to physicians. Appendix at 71. For the drug Vioxx alone, "the company assigned over 3,000 company representatives across the country to engage in face-to-face discussions with physicians about Vioxx." Appendix at 76.

The documents reviewed in the House Memorandum suggest that Merck's sales representatives "did not appropriately educate physicians about research that demonstrated Vioxx's cardiovascular risks. To the contrary, it appears that Merck's highly trained sales force was instructed not to address the new research findings, but to emphasize outdated and misleading data that indicated Vioxx was safer than alternatives." Appendix at 77. Marketing strategies described in the House Memorandum included a discussion of physician prescribing patterns.

> The documents reveal that Merck provided its representatives with highly detailed information on individual doctor's prescribing habits and that this data was used to target physicians to increase their prescribing of Merck drugs. Merck purchased this prescribing data from an outside company, which obtained the data from pharmacy records of filled

> prescriptions. Based on this data, representatives would be given access to monthly reports on each doctor in their territory. For each doctor, the reports showed the number of filled prescriptions for Merck and competitor products. They also showed each doctor's "market share" by calculating the percentage of Merck versus competitor product prescriptions. An important concept was each doctor's "Merck potential," which Merck defined as a "dollar estimate of each prescriber's total prescribing volume that can realistically be converted to Merck prescriptions."
>
> Based on the data for individual doctors, Merck's software could compile monthly reports on overall sales and market share for each representative's territory. Representatives were told that their bonuses would be based on these overall sales figures, and representatives could see estimates of their bonus along with the data. Thus, representatives could see a direct correlation between the number of prescriptions they convinced doctors to write each month and their bonuses.
>
> Merck also told the sales representatives that doctors would be given grades from D to A+ for each product category depending on how often they prescribed a Merck product and what percentage of their prescriptions were for the Merck product.

Appendix at 83.

Studies demonstrate that the combination of often using over-priced drugs and adopting drugs that are not a wise choice to adopt based on the best available scientific information explains a lot of the difficulty with both paying for drugs and also preventing drug side effects. Avorn testimony [50-51] 23-24.

At trial, the State presented expert testimony from Dr. Jerry Avorn, a Professor of Medicine at Harvard Medical School and Chief of the Division of Pharmaco-epidemiology and Pharmaco-economics in the Department of Medicine at Brigham and Women's Hospital. Avorn testimony at [46-47] 19-20. Pharmaco-epidemiology is the study of the utilization of drugs in large populations, as well as the consequences of that use, whether a benefit or adverse event. *Id*. at [49] 22. Pharmaco-economics is the study of the connection between drug use and economics. *Id*. Dr. Avorn's Division also serves as a resource to the Brigham on appropriate medication use, and helps train its interns and residents in making optimal prescribing decisions. Avorn Declaration, Appendix at 1-2.

In the 1980s, Dr. Avorn pioneered "academic detailing" in which evidence-based information about drugs is provided to doctors through educational outreach programs run by non-commercial sponsors. Avorn Declaration, Appendix at 2. Through his studies, Dr. Avorn has experienced first-hand the power of prescriber-specific prescribing data in targeting behavior-change strategies. Avorn Declaration, Appendix at 10; Avorn testimony at [107-110] 29-32. Based on his first hand experience in using prescriber specific information to change prescribing behavior of physicians, Dr. Avorn described it as "a very powerful tool." As a measure of just how

powerful an effect pharmaceutical detailing has on the prescribing behavior of physicians, Dr. Avorn's studies show that by academic detailing alone, he was able to reduce inappropriate prescribing practices by approximately 14%. Avorn Declaration, Appendix at 10. Dr. Avorn testified that prescriber specific information is "a very effective way of knowing who was prescribing what so that we could try and literally change their behavior." Avorn testimony [76] 28.

Dr. Avorn concluded that New Hampshire's Prescription Confidentiality Act, in particular the provision preventing the sale of prescriber-identifiable prescription data for commercial purposes, is a positive step forward in eliminating wasteful health care spending and promoting public health. Avorn Declaration, Appendix at 9.

STANDARD OF REVIEW

A Court of Appeals assesses the constitutionality of a statute *de novo*. *U.S. v. Hilton*, 167 F.3d 61 (1st Cir. 1999). In First Amendment cases, the Court engages in de novo review of ultimate conclusions of law and mixed questions of law and fact. *Hurley v. Irish-American Gay, Lesbian and Bisexual Group of Boston*, 515 U.S. 557, 567 (1995); *Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 485, 501 (1984).

SUMMARY OF ARGUMENT

New Hampshire's Prescription Confidentiality Act does not regulate speech protected by the First Amendment. The Act does not restrict the communication of any expression or idea, nor does it impede the free flow of information. Under the Act, IMS Health and Verispan can obtain and transfer prescriber-identifiable prescription data freely, so long as the data is not used for a "commercial purpose," as defined in the Act. The Act's restriction on the use of prescriber-identifiable prescription data for commercial purposes is a regulation of non-expressive conduct, which does not abridge freedom of speech under the First Amendment.

Even if the Act is regarded as regulating constitutionally protected commercial speech, the Act survives intermediate scrutiny because it directly advances substantial state interests and is no more extensive than necessary to serve those interests. The State has a substantial interest in controlling health care costs in New Hampshire, protecting the health and safety of New Hampshire citizens, and protecting the privacy of doctors and patients who use prescription drugs. The Act directly advances these interests by preventing the use of prescriber-identifiable prescription data to influence the prescribing behavior of physicians. The Act's restrictions limit the potential for undue influence by pharmaceutical sales representatives on

the medical profession, and make it more difficult for sales representatives to persuade physicians to prescribe higher cost drugs regardless of whether the more expensive drug will achieve gains in patient outcome. Finally the Act's restrictions are no more extensive than necessary as they are limited to commercial purposes and even allow use of the data for commercial purposes if the data is identified only by zip code, geographic region or medical specialty. The New Hampshire legislature's conclusion that the Act directly advances substantial state interests is reasonable and supported by substantial evidence and should be given substantial deference by this Court.

ARGUMENT

I. NEW HAMPSHIRE'S PRESCRIPTION CONFIDENTIALITY ACT DOES NOT REGULATE "SPEECH" PROTECTED BY THE FIRST AMENDMENT

The First Amendment limits the ability of government to regulate speech, not conduct. "[I]t has never been deemed an abridgment of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed." *Rumsfield v. Forum for Academic and Institutional Rights, Inc.*, 547 U.S. 47, 126 S.Ct. 1297, 1308 (2006) (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949)).

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 non-speech conduct). Because the applicability of the Act's restrictions depends on the intended "use" of the information, it constitutes a regulation of non-speech conduct, not speech.

Nevertheless, the District Court ruled that the Act restricted speech protected by the First Amendment because it restricted the "transfer" of data, which constitutes a form of disclosure. Memorandum and Order, dated April 30, 2007, at 29. While the Act does restrict the "transfer" of prescriber-identifiable data, such transfers are covered by the Act only if the data will be used for a commercial purpose. IMS Health and Verispan can obtain and transfer the data freely, so long as it is not used for a commercial purpose. It is, therefore, the use of the data for commercial purposes that is restricted by the Act, not its disclosure.

The District Court further ruled that the Act restricted speech because it "prevent[ed] pharmaceutical companies from using prescriber-identifiable information both to identify a specific audience for their marketing efforts

and to refine their marketing message." Memorandum and Order, dated April 30, 2007, at 29-30, Addendum at 88-89 (emphasis added). "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). Because the Act does not prevent IMS Health and Verispan from obtaining the information from entities covered by the Act, nor prevent them from disclosing the information to third parties, the Act's restrictions on how IMS Health, Verispan, and others *use* that information once they have received it does not abridge their freedom of speech. *See Bartnicki*, 532 U.S. at 526-27.

The Act is distinguishable from advertising regulations. 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. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 762 (1976) (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 v. Ohio State Bar Assoc., 436 U.S. 447, 455 (1978) (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. Rhode Island*, 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 Act does not prevent IMS Health, Verispan or other covered entities from speaking *about* commercial transactions, but rather regulates the transactions themselves. 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 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 information use rules generally regulate nonexpressive conduct rather than speech." *Richards*, *supra*, at 1194. The Act does not restrict any constitutionally protected speech; therefore, the Plaintiff's challenge to the Act lies outside the scope of the First Amendment.

Furthermore, even if the transfer of prescriber-identifiable prescription information for use in commercial activities 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.

In sum, the Act does not regulate speech protected by the First Amendment. The Act does not restrict the communication of any expression or idea, nor does it impede the free flow of information. Under the Act, IMS Health and Verispan can obtain and transfer prescriber-identifiable prescription data freely, so long as the data is not used for a "commercial purpose," as defined in the Act. Unlike advertising regulations, which

restrict the dissemination of information *about* commercial transactions, the Act regulates the commercial transactions themselves and therefore does not impede First Amendment rights. The Act's restriction on the use of prescriber-identifiable prescription data for commercial purposes is a regulation of nonexpressive conduct, which does not abridge freedom of speech under the First Amendment.

II. THE ACT SURVIVES FIRST AMENDMENT INTERMEDIATE SCRUTINY BECAUSE IT DIRECTLY ADVANCES SUBSTANTIAL STATE INTERESTS AND IS NO MORE EXTENSIVE THAN NECESSARY TO SERVE THOSE INTERESTS.

Even if New Hampshire's Prescription Confidentiality Act is regarded as regulating constitutionally protected speech, it 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 easily survives the lower level of judicial scrutiny applicable to commercial speech regulations.

If commercial speech[1] is neither misleading nor related to unlawful activity, State regulation of that communication survives First Amendment scrutiny if (1) 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.

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[1] As discussed in section I, *supra*, the State disputes that the Act places any restrictions on constitutionally protected speech.

First, the State has a substantial interest in controlling health care costs in New Hampshire, protecting the health and safety of New Hampshire citizens, and protecting 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. *See Assn. for Amer. Physicians and Surgeons v. Weinberger,* 395 F. Supp. 125, 140 (N.D. Ill. 1975), *aff'd*, *Assn. For Amer. Physicians and Surgeons v. Mathews*, 423 U.S. 975 (1975) ("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 statutory scheme designed to achieve better cost control in the field of health care is outside the competency of the federal government."). 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 Supreme Court has recognized that States have a substantial interest in regulating commercial speech that threatens professional standards. *See Edenfield v. Fane*, 507 U.S. 761, 770 (1993); *Ohralik*, 436 U.S. at 460 ("[T]he State bears a special responsibility for maintaining standards among members of the licensed professions."). Detailing, as a form of in-person solicitation, "exert[s] pressure" on physicians through "one-sided presentation[s]" that "may disserve the individual and societal interests . . . in facilitating informed and reliable decisionmaking." *Ohralik*, 436 U.S. at 457 (quotation marks and citation omide). The Prescription Confidentiality Act addresses this State interest by limiting the potential for undue influence on the medical profession and 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 (emphasis added).

IMS Health and Verispan 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.

The harms 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'"); *see also Tennessee Secondary School Athletic Assoc. v. Brentwood Academy*, 127 S.Ct. 2489, 2495-96 (2007) (noting that "empirical data" was unnecessary to reach the "common-sense conclusion" that direct recruitment of middle school students for high school athletic programs could lead to exploitation, distort competition between high school teams, and foster an environment in which athletics are prized more highly than academics - harms that the antirecruiting rule sought to prevent).

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. Common sense dictates that pharmaceutical companies would not spend significant amounts of money purchasing prescriber-identifiable prescription data if that data did not greatly assist them in selling the high cost branded drugs they market. 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 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 persuade physicians into changing their prescriptions from less costly medications to name brand drugs for reasons unrelated to the clinical needs of patients.

The State's expert witness, Jerry Avorn, M.D., cited studies which "indicate that more physician-specific detailing will lead to more prescriptions of brand-name agents, often with no additional patient benefit but at much higher cost to patients and to state-based insurance programs, which will continue to drive up the cost of health care in New Hampshire." Avorn Declaration, Appendix at 10-11. Avorn further declared that "[m]aking it more difficult for manufacturers to tailor their marketing strategies to the prescribing histories of individual physicians would actually encourage detailers to present physicians with a more neutral description of the product that would emphasize presentation of information over promotion." Avorn Declaration, Appendix at 12. Like the disclosure requirements at issue in *Pharmaceutical Care Mgt Assoc. v. Rowe*, 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.

429 F.3d 294, 310 (1st Cir. 2005), *cert. denied*, 126 S. Ct. 2360 (2006). New Hampshire's Act directly affects the marketing practices of pharmaceutical

companies by preventing pharmaceutical detailers from using prescriber-identifiable prescription data to modify physician prescribing behavior toward a more expensive drug regardless of whether the more expensive drug will achieve 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[2] 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. Under the Act, IMS Health and Verispan can continue to collect prescriber-identifiable prescription

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[2] As discussed in section I, *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 if it will be 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).

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 IMS Health and Verispan as uses for which the data is put remain permissible under the Act. IMS Health and Verispan 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, Addendum at 57-58.

In ruling that the Act is overly restrictive, the District Court suggests that the State could engage in "counter-detailing" to balance the message detailers deliver. 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 evidence presented at trial does not support this proposition. Rather, the evidence demonstrates that access to prescriber-identifiable prescription data encourages use of that information by pharmaceutical companies to subtly manipulate physicians, in ways physicians are often unaware, to change their prescriptions for reasons other than the clinical needs of patients. *See* Avorn Declaration, Appendix at 9-11. Simply providing physicians with more information about generic drugs, without addressing the problems created by

the subtle 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 District Court's suggestion of "counter-detailing" 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. *See* Avorn Declaration, Appendix at 11 (refuting the contention that states could adequately counter pharmaceutical company detailing). With the pharmaceutical industry's outlay of 20-30 billion dollars toward marketing, New Hampshire would be unable to compete. Avorn testimony [76-79] 28-30. Indeed, even if feasible, such a solution would simply treat the symptom; New Hampshire's Prescription Confidentiality Act is an effort to treat the disease itself.

The District Court also suggested that the State of New Hampshire implement a Medicaid Pharmacy Program to address cost issues. Indeed, New Hampshire already has established a preferred drug list and a prior authorization process. *See* N.H. Admin. Rules, He-W 570. The Court's suggestion fails to take into account that the formulary program affects

prescriptions issued to Medicaid patients, not all patients. Nor does the Court take into account the fact that formularies are also susceptible to marketing by pharmaceutical companies. Studies show that meetings with detailers had a direct relationship to physician requests to add drugs to a formulary that had "little or no therapeutic advantage over existing formulary drugs." Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 J. Am. Med. Assn. 373, 375. (2000). Trial Exhibit A6.

Furthermore, Dr. Avorn testified that Medicaid formularies are also subject to an entirely different type of marketing by the pharmaceutical industry, direct to consumer advertising ("DTC Advertising"). Avorn testimony, Trial Transcript (Trial Court Doc. No. 114) at 125-127. Dr. Avorn testified that DTC Advertising was introduced "right at the time that HMOs and Medicaid programs, exactly as you [the Court] suggest, were starting to have restricted formularies; and to combat that the companies very intelligently realized they could make their patients be their advocates." *Id*.

Indeed, despite the District Court's efforts to identify alternatives to the New Hampshire legislature's bill, Dr. Avorn testified that New

Hampshire's law was not a flippant effort. Avorn testimony, Trial Transcript (Trial Court Doc. No. 114) at 98. Dr. Avorn noted that the bill

> was more of a sense of people have tried everything they can try and we still have this massive distortion of what doctors are prescribing and what the State, and its citizens, are paying for drugs because of the very heavily and very effective promotional strategies that are going on out there; and this seemed like – given that those other avenues are probably not going to be viable, that this seemed to be a way of preserving the company's ability to give me their best shot in their sales argument, but not to do so with a kind of knowledge that really shouldn't have anything to do with teaching me something, to know that I like Simvastatin more than I like Lipitor. If [the detailers are] really trying to teach me, that should not be necessarily be part of what they need to know to teach me something.

Avorn testimony, Trial Transcript (Trial Court Doc. No. 114) at 98-99. Dr. Avorn noted that other remedies have been tried, in terms of restricting "freebies," providing physicians with other means of learning, and requiring physicians take continuing education courses. Avorn testimony, Trial Transcript (Trial Court Doc. No. 114) at 150.

Finally, the District Court should have given greater deference to the New Hampshire legislature. The District Court declined to afford the New Hampshire legislature's decision deference, reasoning that the New Hampshire legislature did not produce an extensive record and acted quickly after the bill was introduced. Memorandum and Order, dated April 30, 2007, at 35-3, FN 12, Addendum at 94-95.

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]."

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[3] The State inserts this standard on the basis that the District Court ruled that the Act restricts speech protected by the First Amendment. As noted in Section I, *supra*, the State argues that the First Amendment is not implicated by the Act. When the First Amendment is not implicated, the Supreme Court has used even broader 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).

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, independent government interest"); *Assn of Am. Physicians and Surgeons* 395 F. Supp. at 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).

Furthermore, 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. "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. As testified to by Dr. Avorn, he was able to obtain a 14% shift in prescribing behavior in physicians away from inappropriate prescribing practices using prescriber identifiable data. A 14% shift is, by itself, a sufficient basis for the legislature to express a concern and to seek a remedy. Avorn testimony [76] 28.

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, 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 trial testimony.

As stated by Dr. Avorn, the benefits of prescriber specific data accrue to the drug manufacturers in terms of being able to manipulate doctor prescribing, with no clear overwhelming benefit toward teaching and providing data to doctors. Avorn testimony, Trial Transcript (Trial Court Doc. No. 114) at 151-52. "If [detailers] can't make their argument on the basis of the data justifying the use of their drug and it requires knowing the doctor's prescribing habits to make that case, then I would say that's not a

case that ought to get made. It ought to be about the data and the merits of the product, not about my professional history." *Id*. at 152-53.

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.

CONCLUSION

The trial court erred when it ruled that the Act violates IMS Health and Verispan's First Amendment right to engage in free speech. This Court should reverse the ruling below and state conclusively that the Act does not violate the First Amendment.

Respectfully submitted,

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I hereby certify that two copies of the foregoing Brief of Appellant, Kelly A. Ayotte, Attorney General of New Hampshire, and all addenda and appendices have been mailed this day, First Class Mail, postage prepaid, to:

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ADDENDUM

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