UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

IMS HEALTH INCORPORATED, a Delaware corporation; VERISPAN, LLC, a Delaware limited liability company, Plaintiffs, vs. KELLY A. AYOTTE, as Attorney General of the State of New Hampshire, Defendant.	)	Case No. 06-CV-280-PB

Plaintiffs' Statement of Facts in Support of Trial Memorandum

Thomas R. Julin & Patricia Acosta
Hunton & Williams LLP
Fla. Bar Nos. 325376 & 614599

1111 Brickell Avenue - Suite 2500
Miami, FL 33131
305.810.2516 Fax 2460
tjulin or pacosta@hunton.com

James P. Bassett & Jeffrey C. Spear
Orr & Reno, P.A.
N.H. Bar Nos. 358 & 14938

One Eagle Square
P.O. Box 3550
Concord, NH 03302-3550
603.223.9100 Fax 9000
jbassett or jspear@orr-reno.com

Attorneys for IMS Health Incorporated & Verispan, LLC

TABLE OF CONTENTS

Statement of Facts Expected to be Proved

Based on the declarations filed in the case and the depositions taken in the case following approval of the parties' discovery plan,[1] the plaintiffs expect to prove the following facts at trial. Citations are to the declarations, depositions, or other evidence that will be offered at trial. The parties have stipulated that declarations are not objectionable as hearsay as long as the witnesses have been made available for deposition and that depositions also are not objectionable on hearsay grounds.

The Health Information Companies

1. IMS Health Incorporated and Verispan LLC (the "health information companies") are the world's leading provider of information, research and analysis to the pharmaceutical and healthcare industries, with data collection and reporting activities in over 100 countries. The health information companies collect health care information from thousands of sources: pharmaceutical wholesalers, pharmacies, physicians, hospitals, and clinics, and process millions of records each week. The information collected is then aggregated with other information, analyzed and made available to customers through dozens of services designed to help them drive decisions and shape strategies. None of the proprietary databases owned by the health information companies contain patient-identifiable data. This means that the health information companies do not collect, process, use or transfer information that contains the identity of

[1] On September 22, 2006, the Court approved the parties' discovery plan and thereafter the State identified five witnesses whom it intends to call at trial. As of the filing of this statement of facts, the State has made available only four of those witnesses for depositions. One of the witnesses, Dr. Gary Sobelson was deposed on November 16, 2006. The other three were not made available for deposition until November 27 and 28, 2006 -- less than two days before the plaintiffs' trial memorandum was due. Therefore, the plaintiffs contemplate supplementing their facts beyond those contained in this statement of facts either with their reply to the trial memorandum or at trial.

patients in any of their subscription services. (Sadek ¶ 2; Fisher ¶ 3).

2. The health information companies provide services to pharmaceutical and biotechnology firms, pharmaceutical distributors, government agencies, consulting organizations, the financial community and others. In addition, the health information companies frequently make information available without charge to academic researchers (researchers at universities throughout the United States), medical researchers (researchers at the Centers for Disease Control, the Institutes of Medicine of the National Academy of Science, the Mayo Clinic and Memorial Sloan-Kettering), humanitarian organizations (American Red Cross), law enforcement authorities (state attorney generals, U.S. Department of Justice, the U.S. Federal Trade Commission, and the U.S. Drug Enforcement Administration). With the aid of the information obtained from the health information companies, these individuals and organizations are able to track patterns of disease and treatment, conduct outcomes research, implement best practices, and apply health economic analyses. The companies' databases are essential to effective implementation of prescription drug recall programs, performance of pharmaceutical market studies, efficient pharmaceutical sales and marketing resource allocation, and assessment of drug utilization patterns (*e.g.*, on-and-off label uses and regional variations in physician prescribing behavior). (Sadek ¶ 4; Fisher ¶ 4).

3. The health information companies' prescriber-level databases are also essential to support research, analysis, development and implementation of practice guidelines and public health policy for the advancement of patient health. (Sadek ¶ 6; Fisher ¶ 4).

The Information at Issue: Prescriber-Identifiable Data

4. In the United States, approximately 1.4 million prescribers are licensed to write prescriptions. Prescriptions are written for approximately 8,000 different pharmaceutical

products and many of these products are dispensed in various forms, strengths, and doses. 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 in the United States are primarily composed of chain pharmacies, independent pharmacies, mass merchandisers and food stores with in-store pharmacies, mail order pharmacies, and long term care pharmacies. (Sadek ¶ 7-9)

5. Retail pharmacies acquire prescription data during the regular course of business. They then license, sell, or transfer the data (without disclosing the patient's identity) to health information companies for two distinct purposes. First, in order to make a profit. Second, they license, sell, or transfer the information to the health information companies because those companies have developed sophisticated methods of aggregating and analyzing the information in order to make the information useful to entities that devote substantial resources to improve the health and welfare of consumers. (Sadek ¶ 14; Fisher ¶ 10).

6. For many years, the health information companies have been purchasing patient-de-identified prescription information from retail pharmacies, pharmacy benefits managers, prescription clearinghouses, payers and software vendors throughout the United States by entering into contracts with these entities directly or through intermediaries. (Sadek ¶ 11; Fisher ¶ 7). The prescription information that the health information companies purchase from New Hampshire pharmacies and these other entities include: the name of the pharmaceutical product, the form, strength and dosage of the product, the quantity dispensed, and the name and address of the prescriber. The health information companies do not purchase or acquire patient-identifiable information from pharmacies or these other entities. (Sadek ¶ 12; Fisher ¶ 7).

7. Currently, health information companies collectively acquire, aggregate and

analyze prescription data relating to billions of prescription transactions per year throughout the United States. They acquire, license, sell, use, or transfer the prescription data for two distinct purposes. First, to make a profit. Second, to improve public health and welfare by licensing, selling, and transferring the data to pharmaceutical companies, and to other persons and entities that devote substantial resources to using the information to improve the health and welfare of consumers. (Sadek ¶ 13-14; Fisher ¶ 9-10).

8. Some of the entities to which the health information companies license, sell, or transfer the information use the information for advertising, marketing, and promotional purposes. These entities and others also use the information for other purposes that are not associated in any way with advertising, marketing, and promotional purposes. (Sadek ¶ 15; Fisher ¶ 11).

How the Prescription Information Is Used

9. Upon receipt of the patient de-identified prescription data, plaintiffs' associates combine the prescription data with prescriber reference files for various purposes, including: (a) to match each prescription to the correct prescriber, (b) to identify and use the correct name of the prescriber, and (c) to add address, specialty and other professional information about the prescriber to the prescription data. These reference files are created using information obtained from various sources. The American Medical Association's Physician Masterfile, for example, is a source of such information for prescribers. The AMA's Masterfile contains demographic, educational, certification, licensure, and specialty information for more than 800,000 active U.S. medical doctors (MDs) and over 90% of the doctors of osteopathy (DOs), including members

and nonmembers alike.[2] (Sadek ¶ 18; Fisher ¶ 14).

10. The health information companies use the patient de-identified prescription data, together with the reference file data, to produce a variety of databases. The health information companies use these databases to create a number of different reports and services regarding prescribed pharmaceutical products, some of which include prescriber-identifiable information and some of which is aggregated and reported at a broader geographic level. They then license the information to third parties for many different uses. (Sadek ¶ 19; Fisher ¶ 15). Prescriber-level data, for example, is used by pharmaceutical and biotech clients to:

a. Prioritize the release of public safety news alerts based on physician prescribing details;

b. Accelerate innovation through insight into the needs and habits of those whose health the new drugs are designed to improve;

c. Determine which products to develop and license and what acquisitions to consider;

d. Disseminate effectively and quickly vital, life-prolonging information to those prescribers for whom the information is relevant and most useful;

e. Allocate effectively valuable, life-prolonging sample medications to those prescribers whose patients need them most and are more likely to use them;

f. Determine whether a particular prescriber is prescribing products the pharmaceutical companies have determined to be inappropriate in light of the development of new products that may be more effective, safer, or less expensive;

g. Implement prescription drug recall programs;

h. Evaluate, segment, target, size, compensate and deploy its sales force;

i. Allocate limited marketing resources to individual prescribers in a manner

[2] As of July 1, 2006, the AMA has made it possible for all physicians, including those located in New Hampshire, to choose whether to prevent the release of prescriber-identifiable information about them to pharmaceutical sales representatives by participating in the Prescribing Data Restriction Program ("PDRP"). *See* www.ama-assn.org/go/prescribingdata .

that reduces cost and saves time; and

j. Understand managed care's effect on the U.S. pharmaceutical marketplace.

(Sadek ¶ 20; Fisher ¶ 16; Ando ¶¶ 16-24).

11. One key component of pharmaceutical company marketing efforts is the distribution of free samples of new drugs to prescribers. Published reports estimate the value of the drugs distributed annually to be more than $11 billion.[3] These programs allow prescribers and their patients to test the efficacy of new drugs for themselves without a financial barrier. The pharmaceutical companies use prescriber-identifiable data to try to ensure that they do not waste sample products on prescribers who are not engaged in practices to which the samples are directly relevant and beneficial. (Frankel ¶ 27). The State's own medial experts who visit with patients on a regular basis in the state of New Hampshire have stated that they interact with pharmaceutical sales representatives and accept the free samples that these sales representatives provide. (Sobelson ¶ 6; Sadowsky 5, 9).

12. Many doctors find it useful that pharmaceutical sales representatives can access data regarding their individual prescribing practices because this (1) helps to ensure that the sales representatives are providing doctors only with information about products that are relevant to their practices, and (2) helps point out to doctors if they may be prescribing products that are not as useful to patient health or as economical or as consistent with the latest Practice Guidelines as other products. (Wharton ¶ 16).

13. Doctors recognize that pharmaceutical sales representatives are attempting to make a profit for their employers, but also find that they often have excellent information about

[3] Natalie Mizik & Robert Jacobson, *Are Physicians 'Easy Marks'? Quantifying the Effects of Detailing and Sampling on New Prescriptions,* 50 Management Science No. 12 at 1704 (Dec. 2004) (hereafter "Mizik & Jacobson").

the products they are selling, including specific testing information they might not otherwise learn about, including recent reports of scientific studies in peer-reviewed medical journals and recent updates of national guidelines. (Wharton ¶ 13). Sales representatives provide FDA-mandated prescribing information for all drugs they discuss (Wharton ¶ 13) and can be a valuable source of information about new drugs that supplements the knowledge of a particular prescriber (Wharton ¶13). Doctors have available to them a myriad of sources of information about new pharmaceutical products, but the information provided by sales representatives can help a prescriber stay on top of the information and answer questions that a prescriber may have after consulting journals, other prescribers, and other sources of information. (Wharton ¶ 13). One prominent New Hampshire cardiologist supporting this lawsuit, Dr. Thomas Wharton, a former Governor of the New Hampshire Chapter of the American College of Cardiology, expressed his view as follows:

> In my opinion, the patient always wins when I make decisions about their health based on multiple sources of the most up-to-date published scientific information and the latest information on drug cost and formulary status rather than based on limited or absent information.

(Wharton ¶ 13). Dr. Wharton also observed "that many of the physicians that refuse to interact with sales representatives may be generally less-informed about current advances in pharmacology and slower to adopt the newest best practices." (Wharton ¶ 15).

14. The State's own experts in this case have recognized that marketing efforts by pharmaceutical companies can be useful to the medical profession. (Avorn Dep. at 47-48).

15. Pharmaceutical sales representatives' access to information about an individual doctors' prescribing practices does not result in undue influence to doctors. because doctors are professionally, ethically and legally obligated to make decisions that are in the best interest of the patient based on the most up-to-date scientific and economic information. Doctors are likewise

obligated to do everything they can to stay abreast of this most current information. (Wharton ¶ 16).

16. It is worth noting that when a generic drug first becomes available on the market, pharmaceutical companies very quickly lose most of the market share to the generic drug due to the lower price at which the generic drug may be marketed. As a consequence, pharmaceutical companies do not devote any substantial marketing resources to promoting branded drugs for which generics are available. Such promotion would be a waste of valuable resources that could be used to promote the sales of branded drugs for which generics are not available. (Frankel ¶ 25).

17. Prescriber-level data compiled and analyzed by the plaintiffs for profit is not, of course, used solely in connection with pharmaceutical company marketing efforts. The plaintiffs also license the information free of charge to academic researchers, medical researchers, government agencies, industry observers and others who use the data for a variety of purposes that are unrelated to the sale of a particular product (*e.g.* to support research, analysis, development and implementation of practice guidelines and public health policy for the purpose of advancing patient health. (Hunkler ¶ 9).

18. Because of the extensive uses of prescriber-identifiable data, doctors do not expect that information in their prescriptions about their prescribing practices will be kept private from the public. Rather, they expect that their patients will share the information with the patients' other physicians, insurers and with friends, family, and others; that pharmacies and other similar entities will make the information available to health information companies that aggregate, analyze, and sell the data for research purposes, and that the data will be made widely available to academic researchers, government agencies, pharmaceutical companies and other

entities interested in understanding and improving public health. Doctors who do not share these expectations, in the opinion of Dr. Wharton, are not fulfilling their professional obligation to put their patients' and the public's interest in better healthcare above their own putative interests in maintaining the privacy of their prescription decisions. (Wharton ¶ 16).

19. Still, some doctors believe that the ideal way for doctors to make prescribing decisions is based on peer-reviewed data rather than from information received from pharmaceutical sales representatives. (Avorn Dep. at 45). In order to accommodate these prescribers without entirely destroying the public health value that is gained through the ready availability of prescriber-identifiable data, the American Medical Association recently adopted a program which uses health information companies' dependence on the AMA Masterfile to allow any physician to "opt out" of having his or her prescribing information released to pharmaceutical company sales representatives. The program is called Prescribing Data Restriction Program ("PDRP") (Hunkler ¶ 1). Under the PDRP, if a physician advises the AMA that she does not want prescribing information regarding her prescribing practices made available to pharmaceutical company sales representatives, the AMA license of its Masterfile requires that such prescribing information be shielded from pharmaceutical company sales representatives. (Hunkler ¶ 12).

The Legislative History
of the Prescription Restraint Law

20. On April 19, 2006, New Hampshire Representative Cindy Rosenwald introduced House Bill 1346 in the New Hampshire Senate as a law that was meant to protect *patient* privacy, by preventing pharmacies from using information about *patients* to send them

advertising.[4] She explained that the law would close loopholes in the federal law that protects *patient* privacy.[5] She also claimed that the proposed law should be enacted to protect New Hampshire doctors from "an unwarranted intrusion into professional privacy and, more to the point, adds to the financial burden of New Hampshire's health care system by increased pharmaceutical costs for the state, our consumers, and our business."[6] She explained that in her view, the ability of pharmaceutical companies to identify the drugs being prescribed by individual prescribers allowed them to focus their marketing efforts and that this led to prescribers writing more prescriptions for the marketed drugs.[7]

21. House Rep. Pamela Price, a co-sponsor, speculated that preventing pharmaceutical companies from accessing prescriber-identifiable data might reduce the state's payment for prescription drugs through the Medicaid program. She noted that the Medicaid program had developed a list of drugs by category that "would be acceptable within their range based upon the prescribing physician's interest or . . . belief that one product better suits the needs for an individual patient or another."[8] She briefly noted that some of the drugs within a category were more expensive than others and expressed support for the proposed legislation on

---

[4] Requiring Certain Persons to Keep the Contents of Prescription Confidential: Hearing on H.B. 1346 Before the S. Comm. on Exec. Dep'ts & Admin. (N.H. Apr. 19, 2006) (statement of Rep. Cindy Rosenwald, Member, House Comm. Health, Human Servs. & Elderly Affairs) at 10. A transcript of the hearing has been filed as exhibit 3 to the Plaintiffs' Request for Judicial Notice (hereinafter "Senate Hearing"). See also Declaration of Jeremy Eggleton regarding the method by which the plaintiffs compiled the legislative history. Page citations in the legislative history are to the consecutive page numbers at the lower right-hand corner of the pages, rather than to the page numbers of individual documents within the history.

[5] *Id*. at 9.

[6] *Id.* at 10.

[7] *Id.* at 11.

[8] *Id.* at 14 (statement of Rep. Pamela Price, Member, House Comm. Health, Human Servs. & Elderly Affairs).

the strength of her conjecture that if pharmaceutical companies could not obtain prescriber-identifiable data, prescribers would prescribe the cheaper drugs.[9] Rep. Price did not explain how the proposed restriction on the disclosure of prescriber identifiable information would persuade doctors to prescribe the cheaper drugs, she presented no studies that prescription of the cheaper drugs would lower overall healthcare costs, and she offered no evidence that the cheaper drugs were in fact as effective as the more expensive drugs.

22. Stuart Trachy of the New Hampshire Association of Chain Drug Stores testified against the law explaining that it is not needed to protect patient privacy in light of existing federal legislation.[10] He also urged the legislators to consider the fact that the AMA's PDRP opt out program "should take care of any concerns that we have heard in terms of specific doctors being concerned that their prescribing data is out there."[11] He also submitted into the record the AMA's written statement in which the AMA emphasized that prescribing data is "critical to improving quality, safety and efficacy of pharmaceutical prescribing through evidence-based research."[12]

23. Dr. Seddon Savage, president elect of the New Hampshire Medical Society testified in support of the bill,[13] but acknowledged that physician interaction with pharmaceutical representatives is "often very helpful."[14] She explained that she nevertheless supported the law; that while "most health care providers are highly educated people," that "studies have shown that

---

[9] *Id*. at 14.

[10] *Id*. at 18-19 (statement of Stuart Trachy, N.H. Assoc. of Chain Drug Stores).

[11] *Id*. at 20.

[12] *Id*. at 20 & 76.

[13] *Id*. (statement of Seddon Savage, Pres. Elect N.H. Medical Society) at 23.

[14] *Id*. at 24.

in fact our decision making can be and sometimes is shaped by marketing efforts."[15] She expressed her view that it is "generally better to start from the position of more restrictive access to information and to really specify what can be released rather than to work backwards as we are doing now."[16]

24. Dr. Marc Sadowsky, president of the New Hampshire Medical Society also testified in support of the proposed law.[17] Like the others at the hearing, he introduced no evidence or studies supporting the view that the use of prescriber-identifiable data causes doctors to prescribe one drug versus another. Yet, speculated that "doctors switch people from generic medicine to a trade name medicine for no apparent reason except presumably that they have been marketed to effectively."[18] He cited to the Legislature as supposed evidence of this one hearsay example of a patient who claimed that another physician had recommended to him that he switch from a generic drug to a trade name medicine.[19] Sadowsky said he told the patient that it "'was not entirely clear'" to him why the other physician had recommended the change and he then speculated from this incident that the other physician had recommended the change in response to marketing efforts.[20]

25. Sadowsky acknowledged that the sample drugs he receives from pharmaceutical sales representatives are "an important thing because these medicines cost people thousands of dollars a year and I have a good number of citizens in New Hampshire that I am giving free samples to and I know this is due to the largess for the drug companies, but it is through the

---

[15] *Id*.

[16] *Id*. at 26.

[17] *Id*. (statement of Marc Sadowsky, Pres. N.H. Medical Society) at 26.

[18] *Id*. at 27.

[19] *Id*.

[20] *Id*.

instrument of me who is doing it."[21]

26. In sum, the legislative record reveals a general displeasure by the proponents of the legislation and their supporters with the effectiveness with which pharmaceutical companies market their products using lawfully obtained information about prescribers' historical prescribing practices. The displeasure is borne out of the belief that "virtually any time that a physician switches to a promoted drug the price increases" because "pharmaceutical companies focus their promotions on their newest, most expensive medicines."[22] Yet, there is no evidence in the legislative record that the legislature found or even considered any study suggesting that restricting the flow of prescriber-identifiable information to pharmaceutical companies, without more, will help reduce the cost of prescriptions in New Hampshire. There is also no evidence in the legislative record showing that the legislature considered other alternative means for achieving its goal of reducing the cost of prescription costs in the state that do not infringe on the speech rights of the health information companies.

The Prescription Restraint Law is Enacted

27. On May 11, 2006, the New Hampshire Legislature passed House Bill 1346 and the Governor signed the bill into law on June 30, 2006. The bill is now 2006 N.H. Laws 328, codified at N.H. Rev. Stat. Ann. §§ 318:47-f & 318:47-g & 318-B:12, IV (2006).[23]

The Prescription Restraint Law Imposes Serious Criminal & Civil Penalties

28. Any person violating the provisions of N.H. Rev. Stat. Ann. § 318, except as otherwise provided, shall be guilty of a misdemeanor if a natural person, or guilty of a felony if

---

[21] *Id*. at 27.

[22] *Id.* at 35 & 105.

[23] The text of the statute appears on the parties' Joint Stipulation of Facts filed on November 30, 2006.

any other person. N.H. Rev. Stat. Ann. § 318:55.[24] A civil penalty not to exceed $5,000 also may be imposed upon any person who willfully or repeatedly violates any provision of chapter 318. N.H. Rev. Stat. Ann. § 318:55.

Damage Inflicted by the Prescription
Restraint Law on the Plaintiffs & Others

29. Following passage of the act and as a consequence of the severe criminal and civil penalties that it authorizes, sources of prescription data required restrictions placed on the prescription data in order to ensure compliance with the act. (Sadek ¶ 27). In order to continue acquiring prescription data while it challenges the constitutionality of the Prescription Restraint Law, 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 until such time as the act is declared unconstitutional or otherwise invalidated or enjoined. (Sadek ¶28). Verispan also has modified 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. Specifically, Verispan has decided to modify its databases so that it can identify and suppress the prescriber-identifiable data from New Hampshire prescriptions from its subscription services before the prescription information can be released to pharmaceutical companies or other third parties. (Fischer ¶ 22).

[24] N.H. Rev. Stat. Ann. § 318 does not specify a classification of the misdemeanor and therefore the misdemeanor is classified as class A. N.H. Rev. Stat. Ann. § 625:9, IV(a)(2). A natural person convicted of a class A misdemeanor may be imprisoned for up to one year and fined up to $2,000, and a corporation convicted of a felony may be fined up to $100,000, plus double the amount of any amount made by the commission of the felony. N.H. Rev. Stat. Ann. § 651:2, II.(d), IV.(a) & IV.(b). Any person who violates any provision of N.H. Rev. Stat. Ann. § 318-B for which a penalty is not provided by other paragraphs shall be guilty of a class B felony if a natural person, or guilty of a felony if any other person. N.H. Rev. Stat. Ann. § 318-B:26, XI. A natural person convicted of a class B felony may be imprisoned for up to seven years and fined $4,000. *See* N.H. Rev. Stat. Ann. § 651:2, II.(b) & IV. (a).

30. Thus, both IMS Health and Verispan have had to cease some of their regular business practices in buying and selling records containing prescriber-identifiable data because pharmacies and other similar entities cannot continue providing prescriber-identifiable data to IMS Health for purposes restricted by the act. (Sadek ¶ 28; Fisher ¶ 23).

31. The Prescription Restraint Law is inflicting damage on the New Hampshire pharmacies who are s a willing speakers in the possession of information that is of great public importance and wish to provide that information to others who would use the information for important purposes. (Dobish ¶ 12).

32. Moreover, because IMS Health is unable to provide customers with prescriber-identifiable data originating from New Hampshire, IMS is unable to continue licensing this information to customers for a fee. (Sadek ¶ 31; Fisher ¶ 24). As important, the plaintiffs are being injured each day that the Prescription Restraint Law remains in force because they are unable to communicate to pharmaceutical companies lawfully obtained, truthful information about matters of public importance and concern -- the prescribing practices of New Hampshire prescribers. While the information remains locked in the plaintiffs files, it cannot be used by pharmaceutical companies and others for all of the socially useful purposes described above. The statute also inflicts irreparable injury on the pharmaceutical companies that wish to communicate with prescribers, and most importantly, it prevents important information from getting to prescribers to help them make the best decisions they can make about the drugs that they will prescribe for their patients. (Sadek ¶ 32).

33. Ultimately, the plaintiffs succeed as companies only as long as they can continue to deliver valuable information that helps pharmaceutical companies and others efficiently deliver effective, innovative and safe healthcare products to the public. The Prescription

Restraint Law directly impairs the ability of the plaintiffs to fulfill that mission in New Hampshire. (Sadek ¶ 33; Fischer ¶ 25).

34. Dr. Göran Ando, who has served as the director of research and development for two of the world's largest pharmaceutical companies -- Glaxo and Pharmacia -- explains in his declaration that the decision of health information companies not to continue providing prescriber-level health information due to the risks created by the Prescription Restraint Law seriously impairs the ability of pharmaceutical companies to do basic medical research as well as to carry out marketing functions that are necessary to obtain market adoption of drugs that improve public health. (Ando Dec. ¶¶ 13-24).

35. Dr. Ando explained that the prescriber-level data is especially needed in phase 3 human clinical trials of new drugs which now require a substantial number of patients. (Ando Dec. ¶ 13). Identifying suitable patients for phase 3 trial can be very difficult because each phase 3 clinical trial establishes a rigorous protocol for exclusion or inclusion of a patient in a trial to find a homogeneous population. (Ando Dec. ¶ 13). Prescriber-identifiable data from prescription records shows which prescribers are writing large numbers of prescriptions for drugs for patients who would be logical participants in phase 3 human clinical trials of the new drugs and allows companies to contact those prescribers to ask that they ask their patients to consider participation in the trials. (Ando Dec. ¶ 13). Use of the prescriber-level data reduces the time that is needed to locate patients for clinical trials from three to six months for many clinical trials. (Ando Dec. ¶ 13).

36. Dr. Ando also explained that prescriber-identifiable data is essential to carrying out Risk Minimization Action Plans or Risk MAPs required by the United States Food & Drug Administration. (Ando ¶ 14). Risk MAPs explain how a manufacturer intends to study the

health effects of a new drug on patients after the drug has been approved and is being prescribed. In order to execute Risk MAPs, pharmaceutical companies must be able to identify prescribers who are prescribing a certain drug so that they can obtain information about health effects of a new drug on patients. (Ando ¶ 15). Without prescriber-identifiable prescription data, pharmaceutical companies have a much more difficult time executing Risk MAPs and cannot execute them as quickly and efficiently as they now do. (Ando ¶ 15).

37. Prescriber-identifiable data also is useful in the development of new drugs because it provides researchers a means of identifying the prescribers who are most frequently prescribers of certain drugs or a class of drugs. (Ando ¶ 16). This allows researchers who are attempting to develop new drugs to contact prescribers who prescribe certain drugs directly to learn about the uses to which the prescribed drugs are being put. (Ando ¶ 16). This, in turn, can help researchers ascertain whether new drugs can and should be developed for the same use. In some instances, new drugs can be far less costly for treating a particular health problem than existing drugs. (Ando ¶ 16). Moreover, knowledge about individual prescriber practices greatly facilitates research regarding the health outcomes of using drugs in combination. This is one of the most rapidly developing areas of drug research. (Ando ¶ 16).

38. If pharmaceutical companies and their sales representatives are unable to obtain information about prescribing practices, they will not, of course, discontinue their sales efforts because the Prescription Restraint Law does not prohibit them from marketing directly to prescribers. Instead, sales representatives will continue to market their products, but they will be unable to focus those marketing efforts on the prescribers who are most likely to prescribe the drugs they are marketing. (Frankel ¶ 27). Marketing campaigns that are not focused by prescriber information typically are much more expensive than marketing campaigns that are not

focused by such information. Unfocused campaigns allocate inadequate samples to the doctors who need them and who will use them the most. Instead, samples are evenly distributed among all doctors according to specialty. As a result, waste of the samples occurs. This type of unfocused marketing drives up the cost of marketing products and may ultimately drive up the cost of the products themselves. This also slows adoption of drugs by the market. (Frankel ¶ 27).

39. Without information about prescribing practices, pharmaceutical companies are unable to identify those prescribers who are willing to adopt innovative drugs when the drugs first become available in the market. The benefits of rapid market adoption of new drugs is demonstrated by the innovations that the pharmaceutical industry has produced and the fact that at each stage of life -- from early infancy through old age -- innovative drug discoveries now help millions of patients lead longer, healthier, happier, and more productive lives. But modern drugs do even more than save lives and improve the well-being of patients. As they improve health, they also save money by keeping people out of hospitals, emergency rooms, and nursing homes. A goal of pharmaceutical sales representatives is to identify opportunities to accelerate the adoption of highly valuable innovations that will benefit patients and help contain overall health costs. (Frankel ¶ 29).

40. If so-called "early adopters" cannot be identified, then marketing must be directed to all prescribers, including those who are least likely to adopt an innovative drug. This can drastically slow acceptance of a new drug in the market because some prescribers rely on early adopters to prescribe a new drug so that additional information regarding the safety and effectiveness of the drug will be reported before the prescriber prescribes the drug. This not only denies the late adopting prescriber's patients the benefits of the new drug, but also deprives those

patients of information crucial to their decision on whether or not to use the new drug (*i.e,* that wide-scale early adopter market use of a drug will reveal side-effects not discovered in the drug testing and approval process). Neither early adoption nor later adoption of new drugs is necessarily the "best practice" -- both approaches can be defended -- but it is a reality of the drug marketplace that is important for pharmaceutical companies to be aware of so that they can market the new drugs to prescribers who will prescribe them. When new drugs that have been tested and approved are not adopted or adopted very slowly this generally harms public health and increases the overall cost of public healthcare. (Frankel ¶ 28).

41. The New Hampshire Legislature's assumption that the marketing of new, branded drugs by pharmaceutical companies discourages physicians from writing prescriptions for equivalent generic drugs ignores the fact that manufacturers stop marketing branded drugs as soon a they lose patent protection or exclusivity rights for a particular drug. (Cole ¶¶ 9-10). Thus, prohibiting pharmacies and similar entities from communicating prescriber-identifiable data from prescription records will not, in Dr. Cole's opinion, significantly reduce the number of prescriptions being written for branded drugs that are not protected by patents or other exclusivity rights. (Cole ¶ 21).

42. In addition, the New Hampshire Legislature did not consider the fact that prescribers have good reasons unrelated to the messages they receive from pharmaceutical companies to continue to prescribe branded drugs for a significant number of patients. In prescribing medication for some illnesses, like epilepsy, physician prescribers pay close attention to the precise amount of medication that is absorbed by the patient and avoid switching patients from a branded drug to a generic drug to avoid the risk that the patient will absorb significantly more or less of the medication than the patient was absorbing while taking the branded drug and

that the new level of absorption will place the patient outside of the range necessary to control the patient's seizures. (Cole ¶ 13-15) . This is one reason that certain doctors, particularly those who treat epileptic patients, such as Dr. Cole, have been reluctant in their practice to switch a patient from a branded drug to a generic drug. *Id.* Thus, regardless of the marketing associated with a epilepsy drugs, some doctors realize that branded drugs are produced by a single manufacturer while a generic drugs may be produced by many different manufacturers and each manufacturer may produce the generic drug in a manner that alters the bioavailability of the active ingredient in the drug. (Cole ¶ 16). This alteration in the absorption rate may result in the patient experiencing seizures that otherwise would have been avoided if the absorption rate had remained steady. (Cole ¶ 16). Moreover, Dr. Cole believes that the subtle differences in formulation of the filler, dye, and shape allowed for generic drugs as well as complaints from patients who do not believe that a generic drug will be as effective as a branded drug also may account for different reactions that patients have to a generic drug and to a doctor's decision to prescribe a branded drug versus a generic drug. (Cole ¶ 15-18).

43. By preventing companies from acquiring prescriber-identifiable data for the "commercial purpose" of influencing sales or market share of a pharmaceutical product and to influence and evaluate the prescribing behavior of an individual health care professional, the Prescription Restraint Law potentially affects organizations that are not in the business of manufacturing or selling pharmaceutical drugs but are nonetheless devoted to improve the quality, safety and efficiency of medical care.

44. For example Dr. John Glaser, vice president and chief information officer of Partners HealthCare in Massachusetts, has expressed concern about the Prescription Restraint Law's potential to affect activities of New Hampshire prescriber organizations that seek to use

prescriber data to improve their practices. Partners HealthCare has implemented a variety of systems to monitor the prescribing practices of doctors to ensure that members of Partners are prescribing according to current practices. These systems attempt to improve collectively the prescribing practices of all doctors participating as members of Partners HealthCare. In order to determine whether patients are getting appropriate care, Partners HealthCare needs to know not just what is prescribed by the doctor, but also what prescriptions actually are filled by the pharmacist. (Glaser ¶ 10). Partners HealthCare's systems therefore collects information about the drugs that member doctors are prescribing and about the prescriptions that are being filled. Partners HealthCare uses that information to help educate doctors about breakthrough drugs that have become available and that may offer their patients better alternatives to the drugs that are currently being prescribed, drugs that are more cost effective than the drugs that are being prescribed and drugs that are safer than the drugs that are being prescribed. (Glaser ¶ 11). This information about the prescribing practices of its physicians is collected through managed care organizations and depicts the drugs prescribed and drugs that the patient takes. Partners HealthCare regularly analyzes that information and then communicates directly with its members about alternative prescribing practices that might improve the health of patients in order to attempt to improve the quality, safety and cost effectiveness of the care delivered by its doctors. (Glaser ¶12-13). The potential for increased doctor income is also a critical consideration in the acceptability of this oversight. *Id.* Partners HealthCare's systems for analyzing the prescribing practices of individual members often are used to influence sales or market share of a pharmaceutical product and to influence and evaluate the prescribing behavior of an individual health care professional. (Glaser ¶15). Thus, the activities of Partners HealthCare and its use of prescriber identifiable data closely resemble the activities of pharmaceutical manufacturers, who

like physicians, are interested in improving the practice of medical care and increasing their profitability and do so with the use of prescriber identifiable data. Therefore, the Prescription Restraint Law's restrictions on the flow of prescribe-identifiable data has the potential of affecting a whole range of activities conducted by organizations other than pharmaceutical manufacturers.

Plaintiffs Seek Guidance as to Their Rights Under the Law

45. After passage of Prescription Restraint Law, IMS Health sought guidance from the Attorney General both in writing and in person on how the State would seek to interpret and enforce the law. Assistant Attorney General Richard Head tried to be helpful, but ultimately was unable to provide any assurance that the health information companies or their sources could not or would not be prosecuted if they continued their existing business practices. Asst. Atty. Gen. Head confirmed that the Attorney General would enforce all provisions of the law and defend its constitutionality if it were challenged. (Mahon Dec. ¶ 7-15).

46. The plaintiffs have concrete plans to engage immediately in activity which appears to be proscribed by the Prescription Restraint Law. Those concrete plans are to continue the purchasing and selling of patient-de-identified prescription information for commercial purposes that are ostensibly prohibited by the Prescription Restraint Law. The plaintiffs therefore have a reasonable fear that they will be prosecuted criminally for executing their plans and that an action for injunctive relief and damages will be brought against them by the Attorney General, a County Attorney or by private citizens if they execute those concrete plans. (Mahon ¶¶ 8-9).

The Health Information Companies Challenge the Prescriptions Restraint Law

47. On July 28, 2006, the health information companies filed a complaint for declaratory and injunctive relief and motion for preliminary injunction asking the Court to

invalidate the portions of the Prescription Restraint Law that criminalize the licensing, sale, transfer and use of prescriber-identifiable data for commercial purposes. The health information companies emphasized that they were not challenging the portions of the Prescription Restraint Law that addressed *patient*-identifiable data.

48. On August 7, 2006, the plaintiffs moved for an expedited status conference. At a status conference that took place on September 5, 2006, the plaintiffs asked the Court to schedule a an expedited hearing on the motion for preliminary injunction because the plaintiffs First Amendment rights were being affected with each day that the Prescription Law remained in effect. The Court decided to allow the State an opportunity to engage expert witnesses to defend the constitutionality of the statute and engage in discovery of the plaintiffs' witnesses.

49. On September 21, 2006, the Court approved the parties' discovery plan and schedule the case for trial to commence on January 25, 2006. On October 13, 2006, the Court amended the trial period to commence on January 29, 2006.

The State's Experts

50. Pursuant to the parties' discovery plan, the State identified five witnesses whom it intends to call at trial. The depositions that have been completed of the State's witnesses reveal the State's intention to engage in post-hoc attempts to justify the Prescription Restraint Law through their experts. The State's expert witnesses Drs. Jerry Avorn and Gary A. Sobelson testified that they were not consulted by the state of New Hampshire prior to the passage of the law and had no input in the drafting of the legislation. (Avorn Dep. at 7; Sobelson Dep. 12-13).

51. Notably, the testimony of the State's experts showed that the Prescription Restraint Law will do little, if anything, to stop doctors from prescribing branded drugs when generic drugs become available because there are a number of factors, other than pharmaceutical

detailing, that affect a physician's decision to prescribe a branded drug when a generic drug is available. Dr. Gary A. Sobelson, for example, acknowledged that he prescribes branded drugs when generic drugs are available not necessarily because of pharmaceutical detailing but because branded names are easier to remember, he is not always aware of the existence of generic equivalents or simply because he relies on pharmacies to dispense available generic drugs even he prescribes branded drugs. (Sobelson Dep. 141-43).

52. Moreover, none of the State's experts were able to point to the existence of any studies showing that restricting the free flow of prescriber-identifiable data will result in an increase of prescriptions of generic drugs in the state of New Hampshire. Dr. Jerry Avorn acknowledged that although he has 25 years of experience in the filed of pharmacoepidemiology and pharmacoeconomics, he had never previously advocated imposition of a restriction on the dissemination of prescriber-identifiable data as a means of increasing the likelihood that a prescriber would prescribe a generic drug in lieu of a branded drug. (Avorn Dep. at 21, 103).

53. He testified that although he has advocated for many years the curb of excessive influence of pharmaceutical promotion, he never advocated the enactment of legislation of the type at issue in this case. (Avorn Dep. at 13-14).

54. Dr. Avorn's testimony brought to light the many different alternatives that the New Hampshire could have pursued to achieve its objectives that do not involve the restriction of speech. For example, Dr. Avorn acknowledged that any suboptimal prescribing practices that are caused by the effectiveness of the marketing conducted by detailers can be counteracted through the implementation of "academic detailing" whereby doctors are exposed to science-based information about drug performances. (Avorn Dep. 54-57). This approach, which has been implemented in the state of Pennsylvania, advocates more, not less, information to be made

available to doctors to help them drive decisions. (Avorn Dep. 58). Yet the state of New Hampshire does not appear to have attempted to implement an academic detailing program at any time prior to the passage of the Prescription Restraint Law. (Avorn Dep. 64).

55. Other alternatives that Dr. Avorn advocates to counteract suboptimal prescription practices include: (a) a the requirement of prior authorization from the payor the drugs before a doctor could prescribe a branded drug for which a less costly generic is available, modification (Avorn Dep. 64-69); a differential co-payment system whereby patients are required to pay for the difference between a branded and a generic drug when they choose to purchase the branded drug; (Avorn Dep. 73-4); modification of existing patents law to make more difficult for pharmaceutical companies to manufacture new drugs that have result in minimal or no improvement over existing drugs (75-6); and drug importation whereby patients could feely purchase cheaper drugs from other nations outside the United States. (Avorn Dep. 77-79).

56. Dr. Avorn and Dr. Sobelson both acknowledged that not all pharmaceutical detailing results in costlier or suboptimal prescribing and that there are instances in which such detailing could be useful to the medical community. (Avorn Dep. 44, 48-49; Sobelson Dep. 82-83). Yet they believe that the Prescription Restraint law is a step in the right direction because it would make it more difficult for manufacturers to present their messages to prescribers. (Avorn Dep. 228; Sobelson Dep. 150-51).

57. In late October, the Attorney General hired for the flat fee of $5,000, Shahram Ahari (Ahari Dep. 16), an Eli Lilly sales representative for a year and a half (Ahari Dep. 148), to testify concerning how he and others employed by manufacturers used prescriber identifiable data more than six years ago. He testified that the information allowed sales representatives to identify the prescribers to whom they would direct their messages and that the messages that

they delivered were always truthful. (Ahari Dep. 78). He testified he resigned as a sales representative in June 2000 because he came to believe that even truthful messages led some prescribers to make less than optimal decisions. (Ahari Dep. 148-52). He testified he could not, consistent with his own morality, continue to work for Eli Lilly, although he did not tell Eli Lilly this when he resigned. (Ahari Dep. 151). He also testified, however, that when he could not find other employment, that he applied to become a sales representative with Novartis, another manufacturer, but that company rejected his employment application. (Ahari 191). He explained that his current knowledge of detailing practices is based largely on his recent contact with "Jenna," an "acquaintance" and current employee of Eli Lilly whose last name, telephone number, and e-mail address he could not recall during his deposition. (Ahari Dep. 163-64). Today Mr. Ahari is a temporary employee of the University of California at San Francisco. He tries to identify cases of poisonings that may have adverse public health consequences. He expects that employment to terminate in April 2007. (Dep. Ahari 203-04).

Respectfully submitted,

Hunton & Williams LLP

By /s/ Thomas R. Julin

Thomas R. Julin & Patricia Acosta
Fla. Bar Nos. 325376 & 614599
Admitted *Pro Hac Vice*
1111 Brickell Avenue - Suite 2500
Miami, FL 33131
305.810.2516 Fax 2460
tjulin or pacosta@hunton.com

Orr & Reno, P.A.
James P. Bassett & Jeffrey C. Spear
New Hampshire Bar Nos. 358 & 14938
One Eagle Square - P.O. Box 3550
Concord, NH 03302-3550
603.223.9100 Fax 9000
jbassett or jspear@orr-reno.com

Attorneys for IMS Health Incorporated and Verispan LLC

CERTIFICATE OF SERVICE

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

Richard Head
Assistant Attorney General of the State of New Hampshire
33 Capitol Street
Concord, NH 03301
603.271.3658 Fax 2110

s/ Thomas R. Julin