UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF NEW HAMPSHIRE

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

State's Factual Summary

I. STATUTORY BACKGROUND

A. The Act

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

The prohibition in the Act is limited to prescription information containing patient and prescriber-identifiable information. Patient and prescriber-identifiable information shall not be licensed, transferred, used or sold for any commercial purpose. A "commercial purpose" is defined to include:

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

The Act contains six specific exemptions to commercial purpose:

1. pharmacy reimbursement;
2. formulary compliance;
3. care management;
4. utilization review by
    a. a health care provider;
    b. the patient's insurance provider; or
    c. the agent of either;
5. health care research; or
6. as otherwise provided by law.

Furthermore, the Act lists activities that are not subject to the Act, including:

1. the dispensing of prescription medications to a patient or to the patient's authorized representative;
2. the transmission of prescription information between an authorized prescriber and a licensed pharmacy;
3. the transfer of prescription information between licensed pharmacies;
4. the transfer of prescription records that may occur in the event a pharmacy ownership is changed or transferred;
5. care management educational communications provided to a patient about:
    a. the patient's health condition,
    b. adherence to a prescribed course of therapy or other information about the drug being dispensed,
    c. treatment options, or
    d. clinical trials.

The Act lists five categories of persons or entities subject to restriction under the Act:

1. pharmacy benefits manager;
2. insurance industry;
3. electronic transmission intermediary;
4. retail, mail order, or Internet pharmacy; or
5. other similar entity.

B. **Legislative History**[1]

The legislative history of House Bill 1346 supports the finding that the Act was passed as a measure to control health care costs in New Hampshire, to protect the health and safety of patients, and to protect the privacy of doctors and patients who use prescription drugs. The legislative solution to these concerns was to restrict the use of prescriber or patient identifiable data.

Representative Rosenwald, the bill's prime sponsor, introduced the bill as follows:

> [N]ot only is patient identity inappropriately used for pharmaceutical marketing, but the identity of the prescribers – doctors, nurse practitioners, optometrists and physician assistants – is routinely bought and sold for marketing. Large data mining corporations produce very sophisticated reports that track the individual behavior of our health care professionals. The use of personal identity is both an unwarranted intrusion into professional privacy and, more to the point, it adds to the financial burden of New Hampshire's health care system by increased pharmaceutical costs for the state, our consumers, and our businesses.

Leg. History at 10.

The Commissioner of Health and Human Services provided testimony in support of the legislation. Gregory Moore, speaking on behalf of the Commissioner, testified that the Department supported the bill to protect the privacy of the doctors and other prescribers in the state of New Hampshire. Leg. History at 15-16. Commissioner Stephen's testimony continued: "The Department also believes that these activities [by data mining companies] ultimately drive up the cost of prescription drugs and the cost of health care in the aggregate. Since no other state has passed legislation like this, it would be hard for us to quantify what that impact might be, but I find it unlikely the drug

[1] The parties have stipulated that the legislative history for HB1346 is contained in records before the Court, attached to the declaration of Jeremy Eggleton, filed as Exhibit 3 to the Plaintiffs' Motion for Preliminary Injunction (bates stamp pages 1-146), and supplemented by exhibits to the Discovery Plan as Exhibits A-C (bates stamp pages 147-187). References to the legislative history in this Memorandum are to the bates stamp pages.

companies are sending details into doctors' offices for the purpose of selling doctors cheaper medication." Leg. History at 16.

Dr. Seddon Savage, spoke in favor of the bill. Leg. History at 23-25. Dr. Savage stated, in part,

> [T]hese corporations [such as IMS] also have the power to undermine doctors' prescribing patterns in a way that serves the interests of the particular companies that they are making data available to, but does not necessarily serve the clinical needs of our patients. Often this is at the expense of equally effective and less costly alternatives. So health care prices or health care costs will go up.
> ...
> Now, most health care providers are highly educated people. We like to think that we are thoughtful people and reflective, but we are not immune to skilled marketing influences. So, we like to think we're objective and we always base our decision making on science and on clinical considerations. Numerous studies have shown that in fact our decision making can be and sometimes is shaped by marketing efforts, skilled marketing efforts.

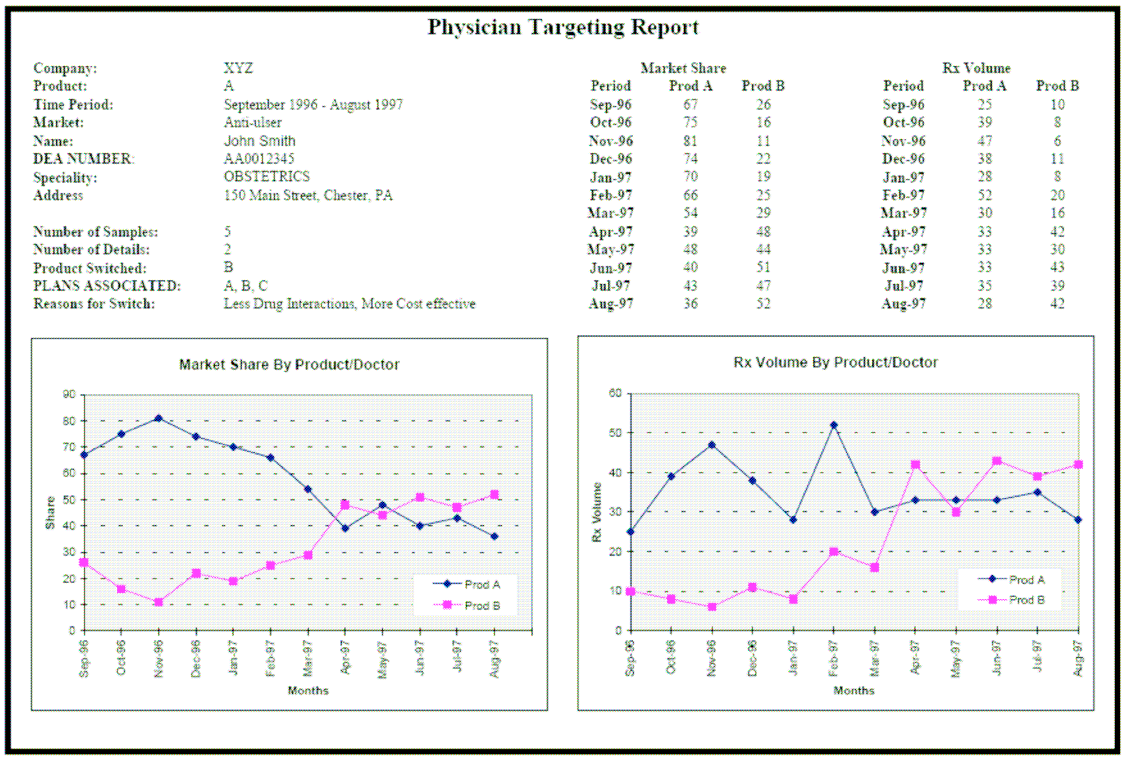
Leg. History at 23-24. Dr. Marc Sadowsky also testified before the legislature as a psychiatrist and President of the New Hampshire Medical Society. His testimony included an example of a patient who had been told to switch from a generic to a name brand medication:

> A patient called me [last week] and said her primary care physician said that a trade name medicine might be better for her than a generic medicine. I said, "Well, you're doing fine on the generic and your co-pay is going to go up to $40 a month, $500 a year. So it is not entirely clear to me why we're doing this." ... I think that was an example of the primary care physician having been marketed to directly and didn't really have a clinical reason for doing it except that that was the last drug rep who came to see him and said this is a better medicine for anxiety, even though the person was asymptomatic at the time.

Leg. History at 27. Janet Monahan also testified on behalf of the New Hampshire Medical Society. She noted that data mining companies tap data from the American Medical Association with biographies on nearly 850,000 physicians. The AMA earns $30 million annually licensing detailed reports on physicians. Leg. History at 34.

In a paper prepared by Paul Kallukaran and Jerry Kagan of co-Plaintiff IMS Health (Leg. History at 47-54), representatives of the Plaintiff IMS explained the advantage of IMS's data mining analysis.[2] The authors provided a generic sample of a "physician targeting report", depicting a physician who had switched from a client's pharmaceutical product to a competitor's product. Leg. History at 49. A copy of IMS's hypothetical prescriber-profile figure from the report is reproduced below.

Figure 2:



Physician Targeting Report

Company:	XYZ
Product:	A
Time Period:	September 1996 - August 1997
Market:	Anti-ulser
Name:	John Smith
DEA NUMBER:	AA0012345
Speciality:	OBSTETRICS
Address	150 Main Street, Chester, PA
Number of Samples:	5
Number of Details:	2
Product Switched:	B
PLANS ASSOCIATED:	A, B, C
Reasons for Switch:	Less Drug Interactions, More Cost effective

Market Share

Period	Prod A	Prod B
Sep-96	67	26
Oct-96	75	16
Nov-96	81	11
Dec-96	74	22
Jan-97	70	19
Feb-97	66	25
Mar-97	54	29
Apr-97	39	48
May-97	48	44
Jun-97	40	51
Jul-97	43	47
Aug-97	36	52

Rx Volume

Period	Prod A	Prod B
Sep-96	25	10
Oct-96	39	8
Nov-96	47	6
Dec-96	38	11
Jan-97	28	8
Feb-97	52	20
Mar-97	30	16
Apr-97	33	42
May-97	33	30
Jun-97	33	43
Jul-97	35	39
Aug-97	28	42

In conclusion, IMS's authors wrote:

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

[2] Plaintiffs object to the use of the term "data mining" in their trial memorandum. Given that the Plaintiffs use this term themselves, the State also refers to them as data miners.

...

> In the future, IMS plans on expanding the product to include the prescribing behavior of managed care plans, enabling pharmaceutical companies to identify trends in HMOs and PPOs across the United States. IMS is also planning to provide statistical tools that would allow companies to do more in-depth analysis, finding out not only who is switching brands, but more importantly, why they are switching.

Leg. History at 53.

The New Hampshire General Court also considered various news articles documenting the tactics used by pharmaceutical companies to convince prescribers to sell their product. This included a Novo District Manager's e-mail to sales representatives:

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

Leg. History at 101 (emphasis added)(excerpted from a January 28, 2006 New York Times, introduced by Janet Monahan of the New Hampshire Medical Society, Leg. History at 35).

The legislature considered the health implications of pharmaceutical detailing, and ultimately the adverse consequences on patient health and safety. Dr. Savage testified that "these corporations also have the power to undermine doctors' prescribing patterns in a way that serves the interests of the particular companies that they are making data available to, but does not necessarily serve the clinical needs of our patients. Often this is at the expense of equally effective and less costly alternatives." Leg. History at 23. Dr. Savage went on to testify that the law "will deter marketing intended to manipulate the practice of individual physicians that is intended to increase market share for the individual companies, possibly at the expense of appropriate decision making for the patients." Leg. History at 24-25.

Lee Carver, RPh, MBA, provided written testimony in support of the Act. Leg. History at 62-63. He wrote

> Data mining is the anabolic steroid of the pharmaceutical industry ... If you aren't doing it, then the competition is likely hitting more home runs than you are! Writing a prescription for a patient is unlike any other form of purchase. A physician makes a decision that not only influences, but 'prescribes' what his patient needs to purchase....I wish to reiterate that rejecting this bill will not only increase our healthcare costs but it interferes with doctor-patient relationships by pressuring prescribing physicians to order products that they may not have chosen.

Id.

The legislature also had before it a white paper on the practice and problems of pharmaceutical detailing prepared by the California Public Research Interest Group. Leg. History at 104-114. Much of what is written in that report reveals that pharmaceutical detailing results in increased healthcare costs and compromises patient health and safety.

> [According to an article in JAMA], surveys show that as many as 70% of patients believe these gifts significantly impact prescribing, and as many as two thirds believe they increase the overall cost of medications for the public. Leg. History at 109.

> As indicated by a wide range of studies and the ever-increasing prevalence of the practice, this type of promotion is highly effective at changing the prescriptions that physicians write. *According to the Center for Policy Alternatives, studies consistently prove that the practice of detailing causes doctors to prescribe the newest drugs, even when overwhelming medical evidence shows that less expensive, tried and true remedies would be much cheaper, just as effective, and often safer. Id* (emphasis added).

> Because companies focus their promotions on the newest, most expensive medicines, virtually any time a physician switches to a promoted drug, the price increases....A recent study in Pennsylvania found that 40% of patients in a state assistance program were given hypertension medicines different than those recommended by medical guidelines. If doctors had prescribed according to those guidelines, the state could have saved $11.6 million, or nearly 24% of the total money it spent on hypertension medication. The study suggested that pharmaceutical promotion was partly at fault for the variance between the medicines that were recommended versus those that were prescribed. Leg. History at 109-10.

Carolyn Finocchhiaro, Associate Clinical Director of the Cholesterol Management Center at Catholic Medical Center testified in support of HB1346. She gave two examples of how she feels pressured to prescribe the detailers product. In her second example, Dr. Finocchhiaro wrote:

> Recently, another drug rep ... said to me, "your patients would have better outcomes if you used more Niaspan."... Even though the rep obviously knows exactly how many prescriptions I write for Niaspan, what does she know about my patients' outcomes?...Further, there is no clinical data to show that prescribing expensive Niaspan versus generic niacin would have any beneficial effect on outcomes. It would only cost more for my patients and their insurance companies. The benefit is to the drug rep and her company, not the patients.

Leg. History at 117.

During the course of the deliberations in the Senate, Senator Kenney spoke on behalf of the Committee on Executive Departments and Administration, which heard the testimony on HB1346. Senator Kenney stated "current marketing practices which rely on patient and prescriber data can unfairly interfere with Doctors' prescribing practices and are not in the best interests of the patient." Leg. History at 140. Senator Kenney continued, specifically noting the weakness of the AMA's opt-out program: "[E]ven if this opt-out plan goes through and physicians buy into it, there are still going to be ways of accessing the information. But this bill, if it were to pass into law, would basically strengthen the privacy of the doctor-patient relationship when it comes to drug prescription information." Leg. History at 140-41.

Senator Larson spoke during deliberations in support of the bill:

> [T]he committee's amendment protects the right of a prescriber, a doctor, to make prescriptions based [on] their best information and what's best for the patient. ... House Bill 1346 will protect the privacy rights of the patient, and the prescriber. It will prohibit the use of data for pharmaceutical sales or marketing, and will reduce prescription drug costs for patients, employers and the NH Medicaid program.

Leg. History at 141. Senator Foster also spoke in favor of the legislation.

> What this data allows people to do is to target physicians who are prescribing perfectly good generic drugs which may cost twenty five per prescription, and convince them, you know the latest and greatest, it's a little bit better, you ought to look at it, and they're prescribing eighty five. And guess who pays for that? All of us do.

Leg. History at 143.

The bill passed the Senate 18-4. The bill passed the House Committee on Health, Human Services and Elderly Affairs by a 13-0 vote, and by the full House on a voice vote.

C. **Role of Pharmaceutical Marketing**

Pharmaceutical companies expend significant resources on direct marketing to prescribers. These marketing efforts directed at physicians include personal selling through sales representatives (called "detailing"); providing samples at no cost; presenting and sponsoring physician meetings and events; and advertisements in medical journals. Phil, Honka, *Symposium Pharmaceutical Innovation and Cost: An American Dilemma*, 5 Yale J. Health Pol'y, L. & Ethics 785, 785-786 (Summer 2005). The Phil and Honka study contradicts the Plaintiffs' claims regarding the educational and altruistic role of the pharmaceutical industry's marketing to prescribers. With regard to the impact detailing has on physician prescribing habits, the authors 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. at 809 (emphasis added).

In another report, the authors pose, and answer, the following question:

> So why does the pharmaceutical industry devote such large sums of money to advertising? Drug companies are not foolish, and they would not spend billions of dollars on marketing if the medications sold themselves. The medical literature bears out [the] contention that meetings with drug representatives and the provision of free samples do influence the prescribing practices of physicians and the likelihood that they will request that a new drug be added to their hospital formulary. She also points out that even young idealistic doctors in training are susceptible to the pharmaceutical industry's direct marketing practices, which include giving physicians gifts of expensive meals, books, medical equipment, and even luggage and resort vacations. The Pharmaceutical Research and Manufacturers of America (PhRMA) recently adopted a new Code on Interactions with Healthcare Professionals, which significantly limits gift-giving and entertainment to physicians, but the code is purely voluntary.

Lawrence, *The High Cost of Prescription Drugs: The Price of Success?*, 4 Yale J. Health Pol'y, L. & Ethics 165, 167 (Winter 2004).

Even the data mining industry itself acknowledges the beneficial use of prescriber profiling when targeting physicians for sales visits by the pharmaceutical industry. The purpose of such visits is not purely educational, but is specifically tailored to ensure the prescriber either continues to prescribe the desired drug, or switches, and begins to prescribe that drug. Dendrite International, another data marketing company, touts the benefits of ScripMaxMD, "the pharmaceutical industry's 'first comprehensive marketing tool capable of providing physician-level insight to assist in the return on all channels of promotion.'" Appendix at 185.[3] Dendrite's marketing material states "[s]pecific prescribing behavioral patters, such as how often brand-switching occurs or when a brand is typically added to an existing therapy, can be identified at the deepest possible level – the prescriber. **This enables a company to take the most appropriate, targeted, and**

[3] References to the "Appendix" are to the State's Appendix filed in Support of it Memorandum of Law in Support of its Objection to Preliminary Injunction.

timely action to achieve sales and marketing objectives." Appendix at 185 (emphasis added). Dendrite's company marketing brochure states:

> **Now, pharmaceutical manufacturers who partner with Dendrite can gain a level of insight that allows them to predict and influence physician-prescribing behavior like never before.** After 20 years devoted entirely to the life sciences industry, Dendrite is still on familiar ground – leading the charge in the latest pharma sales revolution."

Appendix at 68 (emphasis added).

Pharmaceutical manufacturers invest considerable resources in these marketing efforts; for example, in 2000, the industry spent around $15.7 billion on marketing, $4 billion of which was dedicated to these direct-to-physician strategies. More recent estimates are that the industry currently spends between $25 billion and $30 billion per year on marketing. Exhibit 1, Avorn Declaration 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 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 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. Avorn Declaration 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. Avorn Declaration at 7.

For example, extensive marketing campaigns were initiated in the 1990s to promote new antihypertensive medications called calcium-channel blockers (CCBs)[4], despite the fact that professional guidelines did not consider them first-choice therapies for the treatment of hypertension. As a result of detailing and other marketing efforts, revenues for CCBs grew consistently throughout the decade. 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 at 7. An analysis for one large state-funded program found that the use of such heavily marketed products for the treatment of hypertension in the elderly alone added over $1 billion to the national expenditure for this condition. *Id.*

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,

[4] Representative Pamela Price testified before the Senate regarding the actual cost of CCBs in New Hampshire. Leg. History at 13-14.

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 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 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.*

As to how much of pharmaceutical marketing is negative, Dr. Avorn testified

> I would say that for all drug categories, taken as a whole, based on my having studied this issue for about 25 years, well over half of the effect of marketing is negative in the sense that it pushes utilization toward more expensive products that are not better for patients. How much more than half, I don't think I could put a number to you right now.

Avorn Deposition at 49.

The information presented to physicians by detailers has also occasionally been found to be inaccurate. Avorn Declaration 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. Avorn Declaration 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 4-32. 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 9.

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 10. 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 16-17.

As an example of how far a pharmaceutical company will go to increase its market share, on March 17, 2005 the State of New Hampshire and Warner-Lambert LLC entered into a settlement that addressed claims brought in criminal and civil actions brought in the U.S. District Court, District of Massachusetts. Appendix at 33-43. The State alleged that Warner-Lambert marketed the drug Neurontin for purposes other than those purposes

approved by the FDA ("off-label uses"). Among other things, Warner-Lambert was alleged to have: offered and paid illegal remuneration to doctors, either directly or through third parties, to induce them to promote and prescribe Neurontin for off-label uses; made false statements in presentations and marketing literature sales personnel provided to doctors concerning the uses for which the FDA had approved Neurontin; made false statements regarding the conditions for which the use of Neurontin was otherwise medically accepted and/or the existence of adequate evidence of the safety and efficacy for such use. As a result, Medicaid programs paid for the use of Neurontin for conditions not medically accepted for its use. Such overuse resulted in additional costs to the State of New Hampshire. Warner-Lambert agreed to plead guilty to the criminal action, pay nationally $152 million to settle federal Medicaid claims, and pay $68.4 million to settle state Medicaid claims.

The Neurontin case is not an isolated case. On August 29, 2006, an agreement with Schering-Plough Corporation ("Schering") became public. Appendix at 44-62. In that action, Schering settled civil and criminal actions arising out of the sale of Claritin Redi-Tabs, K-Dur 20, Temodar, PEG-Intron, Rebetron and PEG-Intron Combination Therapy. The settlement included claims that Schering: offered and paid illegal remuneration to induce physicians to start patients on various treatment regements through improper sales and marketing programs; promoted the sale and use of Temodar for brain metastases and certain brain tumors for which FDA had not approved Temodar and such uses were not medically-accepted; and offered and paid illegal remuneration to physicians and physicians' practices for the utilization of Intron A for superficial bladder cancer, including improper preceptorships, advisory boards, entertainment and placement of

clinical studies. In addition to the guilty plea by Schering's Sale Corporation, including criminal penalties of $180million, Schering agreed to pay $255 million to settle civil liabilities to reimburse federal and state Medicaid programs. The settlement of conduct in the State of New Hampshire was $476,073.34, to be split by the State and federal government for Medicaid payments made under the State program.

D. Adverse Effect of Prescriber Specific Data

A report in *Psychiatric Times* described detail-related spending on psychiatrists. Ellen, *Visits From Pharmaceutical Reps*, Pharmacy Times, January 2001, Vol. XVIII, Issue 1 (Appendix at 63-66). Jody Fisher, a product manager with the independent pharmaceutical marketing firm Scott-Levin, told *Psychiatric Times*

> she believes the increase [in detail related spending to psychiatrists] is largely due to sales opportunities associated with new indications for existing drugs such as Paxil (paroxetine), Prozac (fluoxetine) and Zoloft (sertraline) and said selective serotonin reuptake inhibitors remain the most heavily marketed drugs. Explosive growth in the number of sales representatives has also driven up the number of visits paid to psychiatrists and other physicians. **The practice of buying prescription records from pharmacy chains has allowed sales reps to pinpoint the prescription practices of individual physicians, enabling pharmaceutical companies to better target marketing efforts.**

Id., Appendix at 63-64 (emphasis added).

Dr. Jerry Avorn is 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 Declaration at 1. An internist, geriatrician, and drug epidemiologist, he studies the intended and adverse effects of drugs, physician prescribing practices, and health policy, including its effects on medication use, clinical care and patient outcomes. His major areas of research include: the scientific, policy, and social factors that influence physicians' drug choices;

medication compliance by patients; the identification and prevention of adverse drug effects; programs to improve the appropriateness of prescribing and drug taking; and pharmaceutical cost-effectiveness analysis. Avorn Declaration at 1-2. His 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 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 at 2.

Dr. Avorn concluded that the 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.

> Prescriber-identifiable prescription data shows details of physicians' drug use patterns, both in terms of their gross number of prescriptions and their inclinations to prescribe particular drugs. Pharmaceutical manufacturers seek out such data to design their sales presentations to physicians, attacking the attributes of competitive drugs they know a target doctor is using, and reinforcing (or otherwise more tangibly rewarding) use of their company's products. With this data, manufacturers can identify the ratio of brand-name to generic drugs, uptake of or resistance to specific new products, and response to detailer visits and other larger marketing campaigns. In this way, manufacturers can adjust the marketing message that detailers bring to individual physicians.

Avorn Declaration at 9.[5]

Dr. Avorn has used "academic detailing", which uses information such as prescriber information, to choose physicians to offer personal educational visits by clinical

[5] Interestingly, the Plaintiffs note that Dr. Avorn acknowledged 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. Plaintiffs' Statement of Fact at ¶52. As Dr. Avorn testified, he simply had not previously thought of the idea. Once presented to him, he considered it to be a good idea. Avorn Depo. at 9, 14, 23, 91, 290, 310.

pharmacists along with a series of mailed "unadvertisements"; these interventions reduced the inappropriate prescribing of target drugs by 14%. The prescriber information is used to improve the appropriateness of prescribing, rather than to increase the market share of particular products. Avorn Declaration at 10.

In another study, Dr. Avorn identified potential overuse of psychoactive drugs in nursing homes and implemented an educational program aimed at teaching appropriate prescription practices related to geriatric psychopharmacology. The nursing homes offered the educational program showed significant reductions in over-used sedating drugs, which translated into less deterioration in the cognitive function of their residents. *Id.*

Through these studies, both published in *The New England Journal of Medicine,* Dr. Avorn has experienced first-hand the power of such prescriber-specific prescribing data in targeting behavior-change strategies. *Id.*

But when these techniques are used by pharmaceutical companies to increase product sales, the impact on patients and on the health care system are quite different. The studies cited by Dr. Avorn 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 at 10-11. More patients will be exposed to the risks of heavily marketed pharmaceutical agents whose side effect profile is not fully evaluated, as well as to the risk that detailers may mislead physicians about the risk/benefit profile of particular agents by providing distorted or even incorrect information.

It has been suggested that states could simply counter this tsunami of pharmaceutical marketing by mounting their own extensive state-funded programs of academic detailing, to provide an "antidote" to all the sales messages provided to doctors by drug companies. *See* Plaintiffs' Trial Memorandum at 40. Based on Dr. Avorn's unique perspective as the pioneer of the concept of academic detailing, and based on his group's involvement in academic detailing with the Commonwealth of Pennsylvania and elsewhere, he is uniquely qualified to evaluate this contention. States simply cannot marshal the enormous expense required to un-do the distorted sales information that is lavished upon doctors so broadly by drug manufacturers. All programs of this kind in the United States are far too small to counter the tens of billions of dollars spent by the industry for this purpose. The capacity of the drug industry to target sales messages to doctors that are based (usually without the physician's knowledge) on their own personal drug prescribing patterns makes this a particularly difficult problem to overcome. Avorn Declaration at 11.

Although preventing commercial sale of prescriber-identifiable prescription data will not end the ability of pharmaceutical manufacturers to market their products, making 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 at 11-12.

Plaintiffs note that Dr. Avorn also testified in his deposition that he could not know with absolute certainty what impact the statute would have on prescription decisions because no studies had been conducted of the impact of a statute prohibiting the sale of

prescriber-identifiable data. Plaintiff's trial memo, 31-32. Dr. Avorn noted that New Hampshire's law was the first of its kind, and therefore has not been the subject of study. He compared it to a regulation prohibiting pollution:

> But I guess for me it's kind of analogous to if a company is dumping a lot of pollutants into a river, and a law is passed saying the company can't dump pollutants into the river, a priori, one can't prove that the river will become cleaner as a result -- and I assume people would want to track that. But one wouldn't oppose the statute or say that it's not helpful to prevent the company from putting the pollutants into the river, because no one had yet done the study showing that it would clean up the river. It's -- some things that are done in legislation simply are done because they make sense, and then later on people can come along and evaluate the outcome.

Avorn Deposition at 38-39.

Dr. Avorn believes the Act will serve an important contribution to the goal of reducing the overall cost of prescriptions in the State of New Hampshire, and improve patient health and safety. Avorn Depo. at 190-91. The most important advantage of the Act, according to Dr. Avorn, is that it is actionable and practical and can be implemented in a way that does not interfere with the practice of medicine or with doctors' prerogatives or with patients' rights or with the flow of information from science to the bedside. Avorn Depo at 192-93.

E. <u>Experience of Dr. Sobelson</u>

Dr. Sobelson is a family doctor with Concord Family Medicine. Sobelson Declaration at 1. The majority of patient contacts at Concord Family Medicine are by telephone, receiving approximately 200 – 300 calls per day from patients regarding clinical needs and questions. Sobelson Declaration at ¶4. Dr. Sobelson has first hand experience with pharmaceutical detailing by interacting with pharmaceutical reps in his office, at Concord Hospital, at lunches, at conferences and via email. Sobelson Declaration at ¶5.

Pharmaceutical reps are consistently friendly, attractive and well dressed. They are extremely skilled at developing a positive, friendly relationship with physicians and nurses. Sobelson Declaration at ¶8. Pharmaceutical reps will provide lunch to his group approximately once a week. *Id.* Dr. Sobelson's primary contact with pharmaceutical reps occurs when he enters the hospital. At the Concord Hospital, pharmaceutical reps are allowed to work at a table near the physician's entrance to the Hospital. He will typically interact with the reps at the tables for a couple of minutes on those occasions when he stops. Sobelson Declaration at ¶9. Use of prescriber-specific information is especially important given the brevity of the doctor-detailer interaction.

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.

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. Sobelson Declaration at ¶12.

By way of another example, Zithromax is a product marketed for conditions frequently effectively treated with generic amoxicillin. The major reported advantage to this new product was reduced dosing frequency. When Dr. Sobelson was first detailed for the drug Zithromax, it was his understanding that it was comparable in cost to amoxicillin. As a result, he began prescribing Zithromax where amoxicillin would have been an appropriate generic prescription. In 2006, he was approached by Anthem with data showing he had been prescribing Zithromax for approximately two and one-half years at a cost of approximately four times that of generic amoxicillin. In virtually all of those cases, he would have prescribed generic amoxicillin if he had known of the significant price difference. Because he was targeted by the pharmaceutical reps to increase his prescriptions for Zithromax, combined with his misunderstanding about the cost difference between Zithromax and generic amoxicillin, he prescribed Zithromax when he should have been prescribing generic amoxicillin. Because pharmaceutical representatives were pushing Dr. Sobelson toward sales of a particular drug, and because he did not have complete information, he prescribed the higher cost drug. Sobelson Declaration at ¶13.

Dr. Sobelson has also observed that pharmaceutical detailers will use irrelevant data to sell their drug. For example, a drug may be marketed as achieving results 25% faster than another drug. This presents a positive message about the drug, and may in fact be true. In reality, however, a drug that achieves clinical results in sixty days instead of eighty days may be irrelevant for a drug that may be taken by the patient for the next twenty years. Sobelson Declaration at ¶14.

Dr. Sobelson believes that the use of prescriber-specific information has an adverse effect on patient health and safety, health care costs, and prescriber privacy. Prescriber detail information available from data mining companies such as IMS 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 reps in their goal of increasing sales of a name brand drug. Sobelson Declaration at ¶15.

While most patients would have an improved result if the only purpose of pharmaceutical detailing were to provide objective information about drug efficacy, the reality is that pharmaceutical detailing is designed to sell more of a specific drug, to the detriment of a competitor's drug, or to the detriment of a generic substitute. Sobelson Declaration at ¶16. "Early prescribers" provide the human test population for each new drug. Early prescribers are identified via prescriber specific information currently being sold to data mining companies. Thus, early prescribers are being delivered a message about new drugs by the industry that has every incentive to maximize sales of the drug as quickly as possible before it goes off patent. Furthermore, many patients would benefit clinically if they were prescribed less expensive generic drugs that would achieve similar treatment objectives. For patients who are paying for a percentage of their drugs, or are paying the entire cost of their drugs, cost can be a determinative factor in whether or not the patient complies with the treatment instructions. Sobelson Declaration at ¶17-18.

F. Dr. Sadowsky's Testimony

Dr. Marc Sadowsky is a board certified psychiatrist, with a subspecialty certification in geriatric psychiatry and is the current President of the New Hampshire Medical Society ("NHMS").[6] The NHMS membership is comprised of approximately 2200 practicing and retired New Hampshire physicians. Sadowsky Declaration at ¶2-3.

In a review recently published in the American Journal of Psychiatry (163:185- 194, February 2006), the authors performed an exploratory analysis to head-to-head comparison studies of second generation antipsychotics. The authors reviewed results of head-to-head studies of second-generation antipsychotics funded by pharmaceutical companies to determine if a relationship existed between the sponsor of the trial and the drug favored in the study's overall outcome. Of the 42 reports identified by the authors, 33 were sponsored by a pharmaceutical company. In 90.0% of the studies, the reported overall outcome was in favor of the sponsor's drug. This pattern resulted in contradictory conclusions across studies when the findings of studies of the same drugs but with different sponsors were compared. Potential sources of bias occurred in the areas of doses and dose escalation, study entry criteria and study populations, statistics and methods, and reporting of results and wording of findings. Sadowsky Declaration at ¶6.

This conclusion is supported by a 2003 study published in JAMA. In that study, the authors wrote "In randomized drug trials from a randomly selected sample of reviews published in the Cochrane Library, we found that conclusions of trials were significantly more likely to recommend the experimental drug as the drug of choice if trials were funded by for-profit organizations. This result is in accordance with previous studies." JAMA August 20, 2003, Vol. 290, No. 7. Sadowsky Declaration at ¶7.

[6] Dr. Sadowsky also testified before the legislature in support of the legislation. Leg. History at 130.

Dr. Sadowsky has decided to limit his interactions with detailers. During one meeting with a detailer, the detailer asked Dr. Sadowsky if he knew he was the second highest prescriber in the region. This made him a target for detailers. In another incident, he was asked why he prescribed more of a competitor's drug during the prior month than the detailer's drug. This fact was tied to a sales message about the detailer's drug. In addition, the detailer left the implied message that the detailer had spent a great deal of time and effort developing a relationship with Dr. Sadowsky, and that relationship should be rewarded with more prescriptions of his drug. Those two incidents, as well as reports on the manipulative effect detailers have on the prescribing behavior of physicians have led him to limit how Dr. Sadowsky interacts with detailers. Sadowsky Declaration at ¶8-9.

Dr. Sadowsky opined that drug representatives change prescribing behavior of physicians, resulting in diminished health care for patients, and unnecessary increased expenditures on drugs. Sadowsky Declaration at ¶9.

House Bill 1346 was strongly supported by the NHMS. The primary reasons for supporting the legislation were clinical care and access to unbiased information. Some members also expressed their support for the legislation based on privacy concerns. The NHMS actively supported this legislation before the New Hampshire General Court. Sadowsky Declaration at ¶10.

The American Medical Association's opt-out Physician Data Restriction Program ("PDRP") is an inadequate substitute for the New Hampshire law. Only the pharmaceutical detailer is denied access to prescriber profiling data. It does not limit the availability of information to the data mining company, nor does it limit the data given to

the pharmaceutical company. Thus, while the sales representative who contacts a physician who has chosen to opt-out cannot have the data, the pharmaceutical sales representative's employer can. Sadowsky Declaration at ¶12.

G. <u>Pharmaceutical Detailer's Perspective</u>

Shahram Ahari has provided testimony in support of the Act. Mr. Ahari was a pharmaceutical detailer for Eli Lilly from 1999 -2000. While offering a façade of friendship, reps observe doctors to influence physician prescribing practices. Representatives, on a daily basis, relay all personal and professional information gleaned during a visit back to their companies. Ahari Declaration at ¶4. The primary goal of a pharmaceutical rep is to maximize the sales of the rep's drug. To achieve this goal it is important to ensure that the physician/client is unaware of the fact he or she is being manipulated. Ahari Declaration at ¶6.

Prescribing profile data pinpoints a physician's prescribing history, and his or her current prescribing habits. Prescriber specific information was useful to Mr. Ahari to maximize the efficiency of his resources and to maximize sales in his 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 rep's drugs. Ahari Declaration at ¶8-9.

Prescriber profiles help identify prescribers who are big movers, i.e. who have changed their prescribing habits the most or who prescribe large quantities of drugs the rep is pushing. The profiles also can provide a comparison of prescribing patterns of the rep's drug vs. a competitor's drug and trends in prescribing habits. Ahari Declaration at ¶16.

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 reps 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 my territory. The number of visits physicians received was 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. Ahari Declaration at ¶17-18.

Jody Fisher, Vice President of Product Management for Verispan described how Verispan does the ranking referenced by Mr. Ahari. He described it as "segmentation", which is

> basically a profiling of what type of doctor the physician is evaluated to be based on their prescribing performance. And it's not just the product choices they make, it's the number of medications, the number of prescriptions that they actually write. Most segmentation is done based on really two axies, which is the volume of product that is written by the prescriber within a category and the -- and the product choices that they make within that category. ...
> ...
> So just to keep it simple, once again let's just talk about cholesterol reducing medications, there are doctors who may write a lot of cholesterol reducing medications, a thousand a month, there's some doctors that might write ten prescriptions per month, and those can be rank ordered on that axis from the ones that write the most to the ones that write the least. And when you rank order them, you can then segment them in logical buckets, typically what are called deciles which is just breaking up the prescriptions into equal categories so you have your deciles of physicians. The other thing that you can do is evaluate them based on their product choices that they make. So you have may have a doctor that writes

> Lipitor in the main and Crestor sometimes or you may have a doctor that writes generics in the main and every now and again they write a branded medication or really any combination therein. And that is typically the type of information that will then be used to segment the physicians into whether or not they're high or low writers or whether or not their product preferences lead towards a particular -- one drug or another. ... [A]t the end of the day they're given some sort of label which may be a score.

Fisher Deposition at 70-72.

Even physicians who refuse to see reps, or only provide access, are heavily detailed. Sometimes an effective detail does not require direct contact with the physician – the physician's staff can be targeted to deliver the reps' message to the physician.[7] A successfully communicated message from staff to the physician can be more effective than one communicated by a rep. Ahari Declaration at ¶19.

Although perhaps obvious, pharmaceutical reps do not use prescriber profiles to direct physicians to prescribe drugs manufactured by a competitor. A drug's strengths are highlighted and contrasted to the perceived weaknesses of a competitor's drug. Ahari Declaration at ¶20

Prescriber profiles are used by detailers for the sole purpose of marketing drugs to physicians, and increasing sales. Mr. Ahari testified that, based on his experience, detailing is extremely effective at changing prescribing behavior. Ahari Declaration at ¶21-22.

[7] This is consistent with the lunches provided for Dr. Sobelson's staff. Sobelson Declaration at ¶8.

Respectfully submitted,

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

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