UNITED STATES DISTRICT COURT FOR THE DISTRICT OF VERMONT

IMS HEALTH INCORPORATED;)
VERISPAN, LLC; and SOURCE)
HEALTHCARE ANALYTICS, INC., a)
subsidiary of WOLTERS KLUWER,) Civil Action No. 1:07-cv-188
HEALTH INC.,)
Plaintiffs,)
vs.)
)
WILLIAM H. SORRELL, as Attorney)
General of the State of Vermont,)
Defendant.)
	_)
)
PHARMACEUTICAL RESEARCH AND)
MANUFACTURERS OF AMERICA,) CONSOLIDATED WITH
MANUFACTURERS OF AMERICA, Plaintiff) CONSOLIDATED WITH) Civil Action No. 1:07-cv-220
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	,
Plaintiff	,
Plaintiff	,
Plaintiff vs.	,
Plaintiff vs. WILLIAM H. SORRELL, in his official) Civil Action No. 1:07-cv-220)))))
Plaintiff vs. WILLIAM H. SORRELL, in his official capacity as Attorney General of the State) Civil Action No. 1:07-cv-220)))))
Plaintiff vs. WILLIAM H. SORRELL, in his official capacity as Attorney General of the State of Vermont, JIM DOUGLAS, in his official) Civil Action No. 1:07-cv-220)))))
Plaintiff vs. WILLIAM H. SORRELL, in his official capacity as Attorney General of the State of Vermont, JIM DOUGLAS, in his official capacity as Governor of the State of) Civil Action No. 1:07-cv-220)))))
Plaintiff vs. WILLIAM H. SORRELL, in his official capacity as Attorney General of the State of Vermont, JIM DOUGLAS, in his official capacity as Governor of the State of Vermont, and CYNTHIA D. LAWARE,) Civil Action No. 1:07-cv-220)))))
Plaintiff vs. WILLIAM H. SORRELL, in his official capacity as Attorney General of the State of Vermont, JIM DOUGLAS, in his official capacity as Governor of the State of Vermont, and CYNTHIA D. LAWARE, in her official capacity as the Secretary of) Civil Action No. 1:07-cv-220)))))

DEFENDANTS' PROPOSED FINDINGS

During a July 2, 2008 telephone conference, the Court requested that the parties provide proposed findings of fact in advance of trial. Pursuant to that request, and Rule 52 of the Federal Rules of Civil Procedure, defendants respectfully request that the Court make the following findings. These proposed findings reflect evidence defendants anticipate will be offered at trial. As the Court indicated at the July 2 conference, defendants reserve the right to modify these proposed findings and/or request additional findings after the trial.

The Vermont Legislature Enacted Act 80 After a Thorough and Lengthy Process.

1. The legislative record that will be submitted to the Court reveals that multiple legislative committees spent months amassing and reviewing information and testimony from a broad range of interested parties.

2. There were approximately 41 separate committee hearings on S.115, the bill that eventually became Act 80, with the large majority taking place well before April 30, 2007 (the date the United States District Court for the District of New Hampshire issued its decision in *IMS Health, Inc. v. Ayotte*).

3. The Senate Health & Welfare Committee took up S.115 on nine occasions between January 17 and March 15, 2007. The Senate Finance Committee held fourteen hearings on S.115 from January 19 to March 27, 2007, and the House Health Care Committee addressed S.115 on thirteen separate dates from March 27 through May 3, with all but the final two hearings occurring before April 30. The House Ways & Means Committee held three sessions on S.115 on April 25-27, 2007, and the House Judiciary Committee discussed it on April 27, 2007.

4. Those proceedings encompassed oral testimony and written submissions from a multi-faceted cross-section of public and private interests. Witnesses testifying and submitting information on behalf of State agencies and departments included: Legislative Council and Joint Fiscal Office staff tasked with drafting and researching S.115 (Robin Lunge, Maria Royle, and Steve Kappel); the Department of Health (Commissioner Sharon Moffatt, OVHA Director Joshua Slen, and OVHA Deputy Director Ann Rugg); the Attorney General's Office (AAG Julie Brill); the Department of Banking, Insurance, Securities, and Health Care Administration (Commissioner Paulette Thabault and General Counsel Herb Olson); the Office of Professional Responsibility (Director Chris Winters); Agency of Human Services (Secretary Cynthia LaWare); Department of Human Resources (Commissioner Linda McIntire and Director of Benefits Cathy Callahan); and Trinka Kerr (State Health Care Ombudsperson).

5. Each committee also heard from the full range of private-sector stakeholders including plaintiffs—during these deliberations, including oral and written testimony from the following entities and individuals: Vermont Medical Society; AARP; Drs. Jerry Avorn and Aaron Kesselheim; Sean Flynn (professor at American University School of Law and counsel to the National Legislative Association on Prescription Drugs); IMS's in-house counsel, IMS's Vice-President, External Affairs, and IMS lobbyists; employees of and lobbyists for PhRMA, as well as for PhRMA members Eisai, Inc. and Glaxo SmithKline; a lobbyist for the Vermont Pharmacists Association, Vermont Retail Druggist Association, and Vermont Association of Chain Drugstores; Medco, Express Scripts, and other Prescription Benefit Managers ("PBMs"); CVS/Caremark; Mylan Pharmaceuticals; Burlington Drug Company; MVP Healthcare; Vermont doctors Deborah Richter, Carol Boerner, Carol Vassar, and Frank Landry; Maine Representative Sharon Treat; Hunt Blair (Director of Bi-State Primary Care); Peter Riggs (Director of Forum on Democracy and Trade); Peter Martin, WCAX-TV; Ed Miller (lobbyist for VT Police Association); and David Balto (former Director of Policy for the Federal Trade Commission).

Act 80's Legislative Findings Are Supported by the Legislative Record.

6. In crafting Act 80's 31 findings, the Vermont Legislature drew reasonable inferences based on substantial evidence in the legislative record. In particular, the following findings, which are especially pertinent to the claims before the Court, are supported by substantial evidence in the legislative record:

- a. The state of Vermont has an interest in maximizing the well-being of its residents and in containing health care costs. Act 80, § 1(1).
- b. Newer drugs on the market do not necessarily provide additional benefits over older drugs, but do add costs and as yet unknown side effects. *Id.* § 1(7).
- c. Pharmaceutical marketing, including detailing, is generally confined to highmargin, high-profit drugs, for which the manufacturer has a substantial incentive to increase sales. *Id.* § 1(15).
- d. Some doctors in Vermont have experienced an undesired increase in the aggressiveness of pharmaceutical sales representatives and a few have reported that they felt coerced and harassed. The Vermont Medical Society, an organization representing two-thirds of Vermont doctors, unanimously passed a resolution stating "the use of physician prescription information by sales representatives is an intrusion into the way physicians practice medicine." *Id.* § 1(20).
- e. Prescriber-identifiable prescription data show details of physicians' drug use patterns, both in terms of their gross number of prescriptions and their inclinations to prescribe particular drugs. *Id.* § 1(22).
- f. Prescriber identity data mining allows pharmaceutical companies to track the prescribing habits of Vermont prescribers and link those habits to specific prescribers and their identities. *Id.* § 1(23).
- g. Monitoring of prescribing practices also allows the sales representatives to assess the impact of various gifts and messages on a particular physician to help them select the most effective set of rewards. *Id.* § 1(24).
- h. Prescriber-identifiable data increase the effect of detailing programs. They support the tailoring of presentations to individual prescriber styles, preferences, and attitudes. *Id.* § 1(25).

The Prescription Drug Market

7. In a March 2007 news release, IMS reported that U.S. sales of prescription drugs in 2006 totaled \$274.9 billion. The cost of prescription drugs in the United States has steadily increased over the last two decades.

8. Generic drugs generally cost between 30% and 80% less than corresponding brand-name drugs. In 2004, Vermont's Medicaid generic utilization rate was 51%. Single-source drugs for which no bioequivalent generic drug was available comprised 43% of the drugs dispensed in Vermont in 2004. For the quarter ended June 30, 3006, Vermont's Medicaid generic dispensing rate was 61.47%.

9. From 1975 to 2000, approximately 50% of all withdrawals from the market of drugs identified by the FDA as new molecular entities occurred within the first two years of the introduction of the drug into the marketplace.

10. Approximately 35% of all drug withdrawals occur within the first two years of a drug's introduction into the marketplace.

11. One-fifth of the drugs approved by the FDA are later withdrawn from the market because of public health concerns or are required to include "black box warnings" on their labeling.

The IMS Plaintiffs

12. IMS Health, Inc. ("IMS"), Verispan LLC ("Verispan"), and Source Healthcare Analytics, Inc. ("Source") (collectively, the "IMS plaintiffs") provide information, research, and analysis to the pharmaceutical and health care industries.

13. To carry out this function, the IMS plaintiffs acquire prescription data, which shows the prescribing practices of individual prescribers, from pharmacies.

14. The IMS plaintiffs' primary purpose in acquiring such data is to make a profit.

15. The IMS plaintiffs use sophisticated computer programs to acquire, analyze, and assemble prescriber-identifiable data into numerous forms that can be used by pharmaceutical manufacturers. Among other things, the IMS plaintiffs analyze prescriber-identifiable data to identify: (1) prescribers who switch from prescribing one prescription drug to another prescription drug; (2) prescribers who prescribe high volumes of particular drugs or categories of drugs; and (3) prescribers who are early adopters of a drug or drugs.

16. Pharmacies are licensed by the state of Vermont and required to comply with state and federal confidentiality requirements.

17. Retail pharmacies acquire prescription data during the regular course of business. Pharmacies keep a record for each prescription filled which includes the patient's name; the prescriber's name and address; the name, dosage, and quantity of the drug; and the date the prescription was filled. The pharmacies cause the patient information to be removed or encrypted and sell the records to the IMS plaintiffs.

18. Pharmacies' primary purpose in selling prescriber-identifiable data is to make a profit.

19. Neither patients nor prescribers have any choice about providing identifying information to pharmacies. They must provide the information so that patients can obtain necessary health care.

20. Pharmacies generally do not advise prescribers or patients that they sell prescriber-identifiable data to one or more of the IMS plaintiffs. Similarly, pharmacies generally do not seek the consent of prescribers or patients before selling prescriber-identifiable data to one or more of the IMS plaintiffs.

21. The IMS plaintiffs purchase prescription data originating in Vermont. Specifically, each IMS plaintiff purchases data from corporations that own pharmacies and operate retail stores in Vermont. The data is recorded by Vermont pharmacies as they dispense prescriptions in Vermont.

22. Pharmaceutical manufacturers purchase prescriber-identifiable data from the IMS plaintiffs and use the data for advertising, marketing, and promotional purposes. The data are particularly useful to pharmaceutical companies in identifying those prescribers, so-called early adopters, who are willing to adopt innovative drugs when the drugs first become available.

23. The IMS plaintiffs require their subscribers and customers to keep the data they purchase, including prescriber-identifiable data, completely confidential. Specifically, the IMS plaintiffs require their subscribers and customers to agree not to disclose the data to any third parties, including prescribers.

24. As a result, pharmaceutical sales representatives are not permitted to, and do not, allow prescribers access to any prescriber-identifiable data in marketing and promoting prescription drugs. Sales representative are trained to deflect prescriber inquiries about the use of prescriber-identifiable data.

25. The IMS plaintiffs do not publish prescriber-identifiable data in a publicly accessible form.

26. The IMS plaintiffs do not disseminate prescriber-identifiable data to prescribers, health care consumers, or the general public.

27. Substantially all of IMS's revenue from its United States operations comes from sales to the pharmaceutical industry.

28. In 2006, IMS's revenue grew 12% to \$1.96 billion.

29. In 2006, IMS returned \$880 million to its shareholders in the form of stock repurchases.

30. IMS's revenue grew at a 13% compound annual growth rate from 2002 to 2006.

31. IMS's operating income was \$444 million in 2006.

32. IMS's operating income grew at a 2% compound annual growth rate from 2002 to 2006.

PhRMA

33. Plaintiff PhRMA serves as the pharmaceutical industry's principal policy advocate in matters before all branches of state and federal government.

34. PhRMA does not produce any products, nor does it market prescription drugs to prescribers. It does not implement drug recall programs, track patterns of disease and treatment, conduct clinical trials, implement best practices (including those related to the use of prescription drugs), or issue drug safety alerts.

35. PhRMA itself purchases and obtains data, other than prescriber-identifiable data, from the IMS plaintiffs. It does not obtain prescriber-identifiable data, and does not use the data it obtains to promote products.

Pharmaceutical Manufacturers Use Prescriber-Identifiable Data to Enhance the Effectiveness of Their Sales and Marketing Efforts.

36. The pharmaceutical manufacturers who purchase prescriber-identifiable data from the IMS plaintiffs are for-profit companies. They primarily use the prescriber-identifiable data they purchase to market patent-protected drugs, to allocate sales and marketing resources, and to focus and improve the efficiency of their sales and marketing efforts.

37. Pharmaceutical manufacturers spend millions of dollars annually to purchase prescriber-identifiable data from the IMS plaintiffs.

38. Pharmaceutical manufacturers do not seek consent from prescribers before using prescriber-identifiable data for marketing and promoting prescription drugs.

39. Pharmaceutical manufacturers employ sales representatives who promote their prescription drugs. Pharmaceutical sales representatives are trained to increase the number of prescriptions written by the prescribers they visit for the drugs they promote. The sale representatives are also trained to access and use prescriber-identifiable data in prioritizing their sales calls and tailoring their sales messages.

40. Pharmaceutical sales representatives are not trained to: provide prescribers with information about treatment guidelines issued by national medical societies or associations; promote compliance with treatment guidelines issued by national medical societies or associations; or promote principles of evidence-based medicine.

41. Prescriber-identifiable data is not essential to pharmaceutical manufacturers to track patterns of disease and treatment, conduct outcomes research, implement best practices, implement drug recall programs, or issue drug safety alerts. Pharmacies and the FDA conduct drug recall programs and issue safety alerts.

42. Through the use of prescriber-identifiable data, pharmaceutical manufacturers learn what drugs a prescriber prescribes to specific, though anonymous, patients. The manufacturers can then use prescriber-identifiable data to identify, and to enable their sales force to identify, prescribers who may be more likely to prescribe a particular product. They also use prescriber-identifiable data to identify early adopters of drugs which are new to the market.

43. Pharmaceutical manufacturers design marketing programs aimed at increasing sales of their products. To that end, pharmaceutical manufacturers spend billions of dollars annually marketing drugs directly to physicians.

44. For example, in 2005, the pharmaceutical industry spent approximately \$7.2 billion on drug marketing.

45. In 2003, the pharmaceutical industry spent approximately \$7.4 billion on drug marketing.

46. In 1998, the pharmaceutical industry spent approximately \$4.6 billion on drug marketing.

47. In 1996, the pharmaceutical industry spent approximately \$9.26 billion on total promotion expense. In 2000, that figure increased to \$15.7 billion.

48. Prescriber-identifiable data enables pharmaceutical manufacturers to enhance the effectiveness of their marketing programs by engaging in targeted marketing of their products. Targeted marketing is a mode of marketing that includes establishing different marketing practices for different customers.

49. "Detailing" describes communications by individual pharmaceutical company representatives to a prescriber for the purpose of promoting a specific prescription drug. Detailing is an important but limited means by which pharmaceutical manufacturers communicate with Vermont prescribers.

50. Prescriber-identifiable data assists pharmaceutical manufacturers to engage in targeted marketing and detailing by enabling them to prioritize the prescribers to be visited by their sales representatives. Manufacturers use prescriber-identifiable data to generate rankings of prescribers which are then given to the sales force. The sales representatives then use those rankings to decide which prescribers to meet with. Prescriber-identifiable data is also used to determine how frequently a sales representative will meet with a given prescriber.

51. Because prescriber-identifiable data enables pharmaceutical manufacturers to track any given prescriber's prescription behavior over time, manufacturers can use it to track how profitable a given prescriber's practice is.

52. 18 V.S.A. § 4631 restricts the use of prescriber-identifiable data for marketing purposes; it does not restrict the content of marketing and it will not stop marketing by pharmaceutical manufacturers.

Pharmaceutical Manufacturers Use Prescriber-Identifiable Data to Evaluate Their Marketing Efforts and Compensate Their Sales Forces.

53. Pharmaceutical manufacturers use prescriber-identifiable data to evaluate their sales forces' performance and determine the compensation of members of their sales forces. Sales representatives are given quotas or sales targets with respect to the drugs they are responsible for promoting. The manufacturers use prescriber-identifiable data to develop those sales goals.

54. Sales representatives' compensation is based, in part, on the extent to which they achieve their sales goals and the number of prescriptions written for the drugs they promote.

55. In some instances, the managers to whom sales representatives report also are compensated based in part on the extent to which their reports meet their sales goals.

56. Pharmaceutical manufacturers also use prescriber-identifiable data to conduct marketing research to evaluate the success of their marketing efforts.

Defendants' Expert Witnesses

Defendants expect to call the following expert witnesses at trial. The proposed findings that follow reflect the evidence defendants anticipate they will elicit from each expert.

Dr. Aaron Kesselheim

57. Dr. Kesselheim is a practicing medical doctor, board certified in internal medicine, and also a faculty member at Harvard Medical School. He has over thirty publications to his credit, including articles in the New England Journal of Medicine and the Journal of the American Medical Association. He is qualified to provide expert testimony about prescription drugs, pharmaceutical marketing, and physicians' prescribing practices.

58. Many newly approved patent-protected drugs offer little or no therapeutic improvements over existing drugs, although they are more expensive than older drugs. Yet because these drugs are heavily marketed by the pharmaceutical companies that make them, they are often widely prescribed.

59. Newly approved drugs pose enhanced safety risks, because those risks may not become apparent, or fully elucidated, until after the drug is approved and used in substantial numbers of patients. Serious warnings and safety-related recalls are much more likely to occur in the first few years a drug is on the market.

60. The use of prescriber-identifiable data in pharmaceutical marketing efforts contributes to inappropriate prescribing, including prescribing practices that increase risks to patient safety and health care costs.

61. Physicians are influenced by the marketing efforts of pharmaceutical companies. Those marketing efforts, in turn, unnecessarily increase costs and increase risks to patient health.

62. Detailers are trained to increase market share for their products, not to promote optimal prescribing practices.

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63. Prescriber-identifiable data plays a key role in detailing. Detailing is conducted to increase sales of the drugs that are being promoted, with resulting negative consequences for both patient safety and health care costs, and it is the use of prescriber-identifiable data that permits effective targeted marketing leading to these consequences.

64. Detailing is generally confined to high-margin, high-profit drugs for which the manufacturer has a substantial incentive to increase sales. These drugs are invariably the newest drugs, which have market exclusivity because no generic alternatives are available. Most pharmaceutical manufacturers spend months to years training their sales forces in anticipation of a new drug's approval, and the detailers can begin promoting the drug soon after its approval.

65. Even if a generic drug is available which is equally effective to the newly approved drug (as with generic omeprazole and Nexium), there is unlikely to be any promotional activity encouraging the generic's use. Because generic drugs have a small profit margin and are made by multiple sources, there is virtually no economic incentive for the manufacturers of generic drugs to send sales representatives to visit physicians about their products, even where there is clear evidence that generic medications can provide therapeutically equivalent and much more affordable and cost-effective treatment.

66. Because detailing involves the newest drugs on the market, the drugs most commonly the subject of the detailers' messages tend to be agents developed on the heels of a well-known successful agent – like Nexium or Clarinex – that offer no substantial additional clinical benefits, or agents for which the side-effect profile has not been fully investigated, like Vioxx.

67. Because drug detailing is intended to accelerate the uptake of newly approved drugs, it can have a substantial effect on patients' clinical outcomes. When new drugs are approved for marketing, their side-effect profiles are often not fully understood. In addition, when detailers meet with physicians, they frequently highlight the potential benefits of drugs and downplay any known risks in order to encourage drug sales.

68. Drug detailing encourages the rapid expansion of use of newly approved products, beyond their recommended limits. For example, as discussed above, the widespread adoption of Vioxx led to significant health problems for patients, even though Vioxx was never shown to be a more powerful analgesic than the older drugs like aspirin or ibuprofen that it was supposed to replace. Another example is nesiritide (Natrecor), a medication approved for the treatment of acute exacerbations of congestive heart failure in 2001, despite the fact that pre-marketing studies suggested increased rates of kidney failure and mortality among patients who received the drug. The product was immediately marketed by detailers to cardiologists, and sales of the drug reached \$400 million in 2004. Its manufacturer helped persuade some cardiologists to prescribe it for a much wider population of heart failure patients than it was approved for, including outpatients, who were given costly infusions in an ambulatory setting. The adverse

events were not featured prominently in its marketing campaigns. Ultimately, in 2005, that use decreased dramatically when the early findings were re-analyzed and Natrecor was found to be associated with increased rates of kidney disease and death.

69. Contributing to the risk posed by newly patented drugs is the fact that information presented to physicians by detailers can be inaccurate. One study of detailers showed that 11% of statements made by detailers 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 Merck to divert attention away from concerns about the cardiac risk posed by Vioxx. In fact, the printed sales materials used by detailers and given to prescribers continued to understate the data on the cardiac risk of Vioxx even after the company was in possession of more accurate data.

70. Since detailing points physicians towards expensive patent-protected products (as it is designed to do), it also contributes to the strain on health care budgets for individuals as well as health care programs, especially Medicaid. For example, in the 1990s a class of drugs called calcium-channel blockers were approved for the management of hypertension. Studies did not show that these drugs were more effective than hydrochlorothiazide, a diuretic and the standard, off-patent treatment for hypertension. Yet extensive marketing campaigns led to a surge in their prescription as an initial treatment for hypertension, despite the fact that professional guidelines did not consider them first-choice therapies. 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. Brand-name pharmaceutical detailers drive drug use towards the most expensive products, even though they may not necessarily have better outcomes for patients.

71. Increased prescription drug costs contributed to increased health care costs and adverse patient outcomes. Substantial cost savings can arise if physicians prescribe generic products, according to established treatment guidelines, that are currently available.

72. Prescriber-identifiable data serves several purposes in pharmaceutical marketing – all of which contribute to the effectiveness of marketing campaigns without regard for cost or patient health: (1) the data allows marketers to identify the doctors most susceptible to marketing, and plan their detailing visits accordingly; (2) the data allows detailers to tailor their advertising messages in an effort to increase the number of prescriptions written, such as by giving gifts to low prescribers; (3) the data allows marketers to measure the effectiveness of detailing visits by tracking prescriptions, and to reinforce or adjust their marketing techniques as a result; and (4) pharmaceutical companies use the data to determine the overall effectiveness of particular detailers, promoting those who are most successful at gaining prescriptions and replacing those who are less effective.

73. The limitations imposed by 18 V.S.A. § 4631 on the use of prescriber-identifiable data will lead to more optimal prescribing practices. These more optimal prescribing practices will, in turn, reduce health risks to Vermonters, including the risks caused by the overexpansion of use of newly approved patent-protected drugs that have limited safety records, and decrease the amount spent in Vermont on prescription drugs.

74. Educational outreach efforts (such as academic detailing) are not sufficient and cannot be developed quickly enough to counter the billions of dollars spent on marketing each year by the pharmaceutical industry.

75. Mandatory generic substitution only applies where a bioequivalent generic is available and thus does not does not address those instances where it may be appropriate to substitute lower-cost therapeutically equivalent drugs such as generic omeprazole for Nexium, or where it may be more effective to recommend a different type of treatment, such as a change in diet or lifestyle.

76. The relatively low generic drug utilization rate in Vermont suggests that significant progress can still be made in expanding the appropriate use of generic drugs.

Dr. Meredith Rosenthal

77. Dr. Rosenthal has a Ph.D. in health policy from Harvard University, where she teaches health economics and policy. Her expertise is in the economics of the health care industry, including pharmaceuticals. She is qualified to provide expert testimony on these subjects.

78. Generic drugs are significantly less expensive than brand-name drugs – on average, about 71% cheaper.

79. Additional cost savings are potentially available to Vermont through increased prescribing of generic drugs.

80. While Vermont has a high rate of mandatory substitution of bioequivalent generic drugs, the State's overall utilization of generic drugs is substantially lower. In some cases, there are therapeutic (as opposed to bioequivalent) generic substitutes that could be prescribed for patients instead of more expensive branded drugs.

81. Marketing can reduce the generic utilization rate for prescription drugs. Marketing efforts promote the use of branded drugs for which no bioequivalent generic drug is available. Where those branded drugs have generic competitors (drugs that are therapeutic equivalents but not bioequivalents), marketing efforts can reduce the prescribing of generic drugs. Consequently, the amount spent on prescription drugs overall increases. 82. The State would see substantial annual savings from even a 1% decrease in the prescribing of single-source drugs.

83. The use of prescriber-identifiable data does not reduce drug prices.

84. Restricting the use of prescriber-identifiable data will not cause prescribers to spend more time with detailers.

85. There is no good evidence to support the claim that rapid, widespread adoption of new drugs improves life expectancy and health or decreases the costs of health care. A reasonable assessment of the performance of new drugs would acknowledge that some new drugs make important contributions to health and may reduce other health care spending, while others simply add to cost.

Dr. Ashley Wazana

86. Dr. Wazana is a practicing psychiatrist and faculty member at McGill University. He is qualified to provide expert testimony about the influence of marketing on physicians.

87. Most physicians do not perceive themselves to be unduly influenced by marketing messages delivered by pharmaceutical representatives, but, contrary to this perception, physicians are negatively influenced by their interactions with the pharmaceutical industry.

88. A comprehensive review of relevant studies indicates negative outcomes associated with physician-pharmaceutical industry interactions. These negative influences include an impact on knowledge, such as an inability to identify wrong claims about medications. There is also a negative impact on attitude, including awareness, preference, and rapid prescription of new drugs. Most importantly, a negative impact was seen on behavior, including non-rational prescribing behavior, the prescribing of fewer generic drugs without rationale, and formulary requests for medications with little or no advantages over existing drugs.

89. Despite physicians' perceptions of themselves as immune from undue marketing influence, there are significant negative outcomes associated with the interaction between physicians and the pharmaceutical industry.

Dr. David Grande

90. Dr. Grande is a licensed physician who teaches at the University of Pennsylvania School of Medicine. From 2005 to 2007, he was a Robert Wood Johnson Health and Society Scholar at the University of Pennsylvania. Dr. Grande has researched the influence that marketing of prescription drugs has on the medical profession, and, in particular, clinical decision-making, and has analyzed the role that prescriber-identifiable data plays in the marketing of prescription drugs and the influence it exerts on clinical practice.

91. The use of prescriber-identifiable data and profiling of prescribers is deeply embedded in the practice of pharmaceutical detailing. Health information organizations, including the IMS plaintiffs, provide pharmaceutical marketers with near real-time, physicianspecific data on prescribing habits. These data are a powerful tool for pharmaceutical sales representatives. A representative can assess the drugs prescribed by a physician on a hand-held computer, enabling that representative to deliver a tailored marketing pitch to physicians who are pre-selected for their current prescribing practices. The sales representative can also monitor each physician's response to the tailored message as well as the prescriber's response to any inducements offered by the sales representative such as gifts, meals, and samples.

92. The targeted and strategic marketing permitted by prescriber-identifiable data improves profit margins for pharmaceutical companies by a significant amount and leads to a substantial increase in the initial uptake of new drugs.

93. Prescriber-identifiable data allows marketers to influence prescribing practices of physicians and other prescribers in ways that threaten medical professionalism. The motive of marketers is to sell their products. Patient welfare, however, is a fundamental principle of medical professionalism and requires physicians to make medical decisions free from the undue influence of marketers.

94. An extensive body of literature demonstrates, however, that marketing tactics exert a subtle and unconscious influence on people, even when they do not think they are being influenced. While trained in the sciences, prescribers, like most people, can be influenced by carefully crafted marketing efforts by pharmaceutical marketers. Prescriber-identifiable data increases the likelihood that prescribers will be vulnerable to influence.

95. Reducing the use of prescriber-identifiable data for marketing purposes will make pharmaceutical sales representatives less able to target prescribers and develop messages designed to place the economic interests of the pharmaceutical company over the interests of patients.

96. 18 V.S.A. § 4631 will result in prescribing decisions that are less vulnerable to influence from profit-centered marketers and prescribing practices that reflect a higher degree of professionalism and insulate the physician-patient relationship from unwarranted intrusion.

<u>Shahram Ahari</u>

97. Mr. Ahari is a former sales representative for Eli Lilly. He has a master's degree in public health from the University of California and works as a consultant for Georgetown

Medical School's PharmedOut Project. Based on his training, experience, and education, he is qualified to provide expert testimony about the work of pharmaceutical sales representatives and the marketing uses of prescriber-identifiable data.

98. Mr. Ahari's experience confirms the testimony of defendants' other experts and other evidence about pharmaceutical marketing and prescriber-identifiable data. Sales representatives do not share prescriber-identifiable data with doctors and are trained to deflect any questions about its use.

99. Sales representatives are not trained to educate doctors but to persuade doctors to prescribe the company's products. They have little or no training in the sciences. Sales representatives are compensated in part based on the number of prescriptions written for the products they promote.

100. Prescriber-identifiable data is used in this effort to maximize the company's market share, in part by identifying doctors that already prescribe large amounts of drugs and are susceptible to marketing tactics. Prescriber-identifiable data helps identify prescribers who are "big movers," meaning the prescribers who change their prescribing practices the most or who prescribe large quantities of the drug(s) the sales representative is selling. Prescribers are ranked for their "prescribing power" and many prescribers receive no visits from detailers.

101. Prescriber-identifiable data is also used to develop sales strategies to change a doctor's prescriptions from competing products to the company's products. The purpose of doing so is not to educate the prescriber but to get the prescriber to prescribe the company's products in every instance.

102. Prescriber-identifiable data allows marketers to influence prescribing practices of prescribers, without prescribers being aware of that influence. Restricting the use of prescriber-identifiable data for marketing purposes will make pharmaceutical sales representatives less able to target prescribers and develop messages designed to place the economic interests of the pharmaceutical manufacturer and the sales representative over the interests of patients.

DATED: July 21, 2008, at Montpelier, Vermont.

WILLIAM H. SORRELL ATTORNEY GENERAL STATE OF VERMONT

By: /s/ Kate G. Duffy

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CERTIFICATE OF SERVICE

I hereby certify that on July 21, 2008, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

Patricia Acosta, Esq. Mark A. Ash, Esq. Sarah M. Brackney, Esq. Matthew B. Byrne, Esq. Linda J. Cohen, Esq. Jeffrey L. Handwerker, Esq. Robert B. Hemley, Esq. Thomas R. Julin, Esq. Karen McAndrew, Esq. Michelle R. Milberg, Esq. Robert N. Weiner, Esq.

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