



Report of the Vermont State Auditor

January 8, 2008

LITIGATION REPORT

As Required by Act No. 80,
Sec. 22a of the Vermont General
Assembly, 2007-2008 Session

*(Pharmacy Benefit Manager and other
Prescription Drug-related Legislation of
Act No. 80)*

Thomas M. Salmon, CPA
Vermont State Auditor
RPT. No. 08-1

Mission Statement

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**THOMAS M. SALMON, CPA
STATE AUDITOR**



**STATE OF VERMONT
OFFICE OF THE STATE AUDITOR**

January 8, 2008

Mr. Donald G. Milne, Clerk of the House

115 State Street, Drawer 33
Montpelier, VT 05633-5501

Mr. David Gibson, Secretary of the Senate

115 State Street, Drawer 33
Montpelier, VT 05633-5501

Legislative Council

115 State Street, Drawer 33
Montpelier, VT 05633-5301

Dear Colleagues:

As required by Act No. 80, Sec. 22a, of the Public Acts of the 2007 Session, I am submitting the following report.

The statute section above states:

LITIGATION REPORT; AUDITOR

Beginning January 1, 2008 and annually thereafter, the state auditor shall provide a report to the general assembly with a detailed accounting of all amounts paid by the state with state or federal funds in connection with any litigation challenging the validity of this act or a section of this act. The report shall include costs, fees, damages, amounts paid to expert witnesses, salaries and benefits of state employees who work on the litigation, amounts paid to individuals under contract with the state who work on the litigation, attorney's fees awarded to the other party, any other amounts awarded by the court, and the number of hours spent by state employees involved in the litigation.

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Upon inquiry with the Attorney General's Office, we learned that two lawsuits have been filed challenging the Act in the United States District Court for the District of Vermont.

These are:

IMS HEALTH INCORPORATED; VERSIPAN, LLC; and SOURCE HEALTHCARE ANALYTICS, INC., a subsidiary of WOLTERS KLUWER, HEALTH INC., Plaintiffs, v. WILLIAM H. SORRELL, as Attorney General of the State of Vermont, Defendant.

Civil Action No: 2:07 – cv – 00188 Filed August 29, 2007

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA), Plaintiff, v. 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 the Agency of Human Services of the State of Vermont, Defendants.

Civil Action No: 2:07 – cv – 00220 Filed October 22, 2007

The first lawsuit was filed by data-mining firms that publish health care information for use in marketing pharmaceutical drugs. The second lawsuit was filed by a pharmaceutical trade association on behalf of pharmaceutical manufacturers.

According to the Attorney General's Office, both cases primarily challenge Section 17 of the Act, which prohibits the use of prescriber-identifiable information in marketing pharmaceutical drugs unless the prescriber consents to that use and certain disclosures are made to the prescriber.

Further, the lawsuit filed by PhRMA also challenges Section 20 of the Act, which creates a remedy under the Consumer Fraud Act for violations of state and federal laws on false advertising, and Section 21, which imposes a fee on manufacturers of pharmaceutical drugs. Plaintiffs in both cases argue that the Act violates the First Amendment and the Commerce Clause and is preempted by federal law, according to the Attorney General's Office.

The cases were consolidated and are tentatively scheduled for trial beginning in May, 2008.

Since the lawsuits have been filed fairly recently, the Attorney General's Office indicated that expenses related to these actions will be incurred and paid after January 1, 2008. However, a table on the estimated State employee salary expense through December 31, 2007 for work on these cases is included below.

Table 1: Act No. 80 Litigation Report Employee Labor Cost Format

Employee No.	Title/function	Hourly Pay Rate 8/19-9/29	Hourly Pay Rate 9/30-12/31	Hours Worked 8/19-9/29	Hours Worked 9/30-12/31	Total Hours	Estimated Labor Cost 7/1/07 - 12/31/07 w/ Fringe Benefits @ 34.9%
02235	Staff Attorney IV	\$ 32.67	\$ 34.30	26.92	185.67	212.59	9,777
18847	Staff Attorney III	\$ 31.99	\$ 31.99	N/A	N/A	20.50	885
10309	Staff Attorney IV	\$ 39.61	\$ 39.61	N/A	N/A	57.40	3,067
16643	Staff Attorney III	\$ 34.60	\$ 35.64	48.60	180.20	228.80	10,932
16452	Staff Attorney III	\$ 28.02	\$ 28.02	N/A	N/A	49.00	1,852
19806	Staff Attorney I	\$ 21.63	\$ 21.63	N/A	N/A	144.50	4,216
03376	Paralegal	\$ 23.01	\$ 23.01	N/A	N/A	18.90	587
Total						\$	31,317^a

^aNumbers do not add due to rounding.

Our next annual report shall include, for all litigation related to Act No. 80, a detailed accounting of the various costs, fees, damages, and payments, etc. paid by the State of Vermont with State or Federal Funds.

In addition, for your information, as part of this report I have attached (1) Act No. 80 of the Vermont General Assembly, 2007-2008 Session as Appendix I, (2) IMS HEALTH INC; VERISPAN, LLC; AND SOURCE HEALTHCARE ANALYTICS, INC. v. WILLIAM H. SORRELL as Appendix II, and (3) PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA v. WILLIAM H. SORRELL, JIM DOUGLAS, AND CYNTHIA LaWARE as Appendix III.

Please feel free to contact me about this report at anytime.

Sincerely,



Thomas M. Salmon, CPA
Vermont State Auditor

Note: 10 copies of this report are being provided to the State Librarian and a copy has been posted on our website at: www.auditor.vermont.gov.

APPENDIX I

**ACT NO. 80 OF THE VERMONT GENERAL ASSEMBLY
2007-2008 SESSION**

ACT NO. 80 of the 2007-2008 Vermont General Assembly

AN ACT RELATING TO INCREASING TRANSPARENCY OF PRESCRIPTION DRUG PRICING AND INFORMATION.

(S.115)

It is hereby enacted by the General Assembly of the State of Vermont:

Sec. 1. LEGISLATIVE FINDINGS

The general assembly makes the following findings:

(1) The state of Vermont has an interest in maximizing the well-being of its residents and in containing health care costs.

(2) There is a strong link between pharmaceutical marketing activities, health care spending, and the health of Vermonters.

(3) The goals of marketing programs are often in conflict with the goals of the state. Marketing programs are designed to increase sales, income, and profit. Frequently, progress toward these goals comes at the expense of cost-containment activities and possibly the health of individual patients.

(4) The marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that brand-name companies invest in expensive pharmaceutical marketing campaigns to doctors. The one-sided nature of the marketing leads to doctors prescribing drugs based on incomplete and biased information, particularly for prescribers that lack the time to perform substantive research assessing whether the messages they are receiving from pharmaceutical representatives are full and accurate.

(5) The federal Food and Drug Administration (FDA) requires marketing and advertising to be fair and balanced; however, the FDA has limited legal ability to enforce this requirement.

(6) Public health is ill served by the massive imbalance in information presented to doctors and other prescribers.

(7) Newer drugs on the market do not necessarily provide additional benefits over older drugs, but do add costs and as yet unknown side-effects. One example of this is the drug Vioxx, which was removed from the market due to potentially lethal side-effects that were not adequately disclosed initially.

(8) Between 1975 and 2000, 50 percent of all drug withdrawals from the market and “black box warnings” were within the first two years of the release of the drug. One-fifth of all drugs are subject to “black box warnings” or withdrawal from the market because of the serious public health concerns. Marketing which results in prescribers using the newest drugs will also result in prescribing drugs that are more likely to be subject to these warnings and withdrawal.

(9) In 2005, Vermonters spent an estimated \$524 million on prescription and over-the-counter drugs and nondurable medical supplies. In 2000, spending was about \$280 million. The annual increase in spending during this period was 13.3 percent, which was the highest increase in any health care category.

(10) Vermont has been a leader in prescription drug cost-containment and in providing transparency, to the extent allowable, in drug prices. The state has enacted the pharmacy best practices and cost control program, mandatory generic substitution, and mail order purchasing in Medicaid, VPharm, and Vermont Rx and encouraged the department of human resources to have a preferred drug list in the state employees health benefit plans in efforts to control costs, while maintaining best practices in drug prescribing, in our publicly-financed prescription drug programs. The Vermont Medicaid program has been a member of multi-state purchasing pools for several years and aggressively seeks supplemental rebates to lower drug costs in Medicaid program.

(11) In addition, Vermont has sought to control drug prices in private and employer-sponsored insurance by encouraging voluntary participation in Medicaid's preferred drug list, requiring mandatory generic substitution for all prescriptions in Vermont, providing consumers with pricing information about the drugs they are prescribed, and assisting consumers by providing information about purchasing drugs internationally through a safe, regulated program run through the state of Illinois.

(12) Vermont has also sought transparency by requiring marketers of prescription drugs to disclose information about the amount of money spent on marketing activities in Vermont and also to require the disclosure of pricing information to doctors during marketing visits.

(13) Physicians are unable to take the time to research the quickly changing pharmaceutical market and determine which drugs are the best treatments for particular conditions. Because of this, physicians frequently rely on information provided by pharmaceutical representatives.

(14) Nearly one-third of the five-fold increase in U.S. spending on drugs over the last decade can be attributed to marketing induced shifts in doctors' prescribing from existing, effective, and lower cost (often generic) therapies to new and more expensive treatments, which often have little or no increased therapeutic value. According to the same study, the use of more expensive drugs contributed to 36 percent of the rise in retail prescription spending in 2000 and 24 percent in 2001.

(15) According to testimony by Dr. Avorn, M.D., at Brigham and Women's Hospital, detailing affects the cost of medications, because it is generally "confined to high-margin, high-profit drugs, for which the manufacturer has a substantial incentive to increase sales. . . . 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."

(16) According to the June 15, 2006 Marketing Disclosures: Report of Vermont Attorney General William H. Sorrell, as part of their marketing efforts, pharmaceutical companies made direct payments of almost \$2.2 million to prescribers in Vermont, including consulting fees and travel expenses in 2005. Estimates of total costs of marketing to prescribers in Vermont are \$10 million or more, excluding free samples and

direct-to-consumer advertising.

(17) In 2004, the pharmaceutical industry spent \$27 billion marketing pharmaceuticals in the United States, and spent more than any other sector in the United States on its sales force and media advertising. Over 85 percent of these marketing expenditures are directed at the small percentage of the population that practice medicine. Pharmaceutical manufacturers spend twice as much on marketing as on research and development.

(18) Coincident with the rise of physician identity data mining, the pharmaceutical industry increased its spending on direct marketing to doctors by over 275 percent and doubled its sales force to over 90,000 drug representatives. It is estimated that there is a pharmaceutical sales representative for every five office-based physicians.

(19) A significant portion of prescriber time is spent meeting with pharmaceutical representatives. According to a survey recently published in the New England Journal of Medicine, family practitioners reported the highest frequency of meetings with representatives – an average of 16 times per month. To the extent that this meeting time comes at the expense of time spent with patients, quality of care will be negatively affected.

(20) Some doctors in Vermont are experiencing 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.”

(21) Several studies suggest that drug samples clearly affect prescribing behavior in favor of the sample. The presence of drug samples may influence physicians to dispense or prescribe drugs that differ from their preferred drug source according to a study by Chew et al. in the Journal of General Internal Medicine in 2000.

(22) 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.

(23) Prescriber identity data mining allows pharmaceutical companies to track the prescribing habits of nearly every physician in Vermont and link those habits to specific physicians and their identities.

(24) 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.

(25) Prescriber-identified data increase the effect of detailing programs. They support the tailoring of presentations to individual prescriber styles, preferences, and attitudes.

(26) Prescriber identified databases of prescribing habits encourage pharmaceutical companies to increase the quid pro quo nature of relations between pharmaceutical sales representatives and prescribers. Pharmaceutical companies use prescriber identity data-mining to target increased attention and manipulative

practices toward those doctors that they find would lead to increased prescriptions and profitability, including high prescribers, brand loyal prescribers, doctors that show themselves willing to prescribe new medicines, and doctors who are shown to be especially susceptible to sales messages.

(27) Added and unwanted pressure occurs when doctors are informed by sales representatives that they are being monitored – through messages of appreciation for writing prescriptions, or messages of disappointment that they are not prescribing what was implicitly promised.

(28) As with the use of consumer telephone numbers for marketing, the trading of prescriber identities linked to prescription data can result in harassing sales behaviors by pharmaceutical sales representatives toward doctors.

(29) Health care professionals in Vermont who write prescriptions for their patients have a reasonable expectation that the information in that prescription, including their own identity and that of the patient, will not be used for purposes other than the filling and processing of the payment for that prescription. Prescribers and patients do not consent to the trade of that information to third parties, and no such trade should take place without their consent.

(30) The physician data restriction program offered by the American Medical Association (AMA) is not an adequate remedy for Vermont doctors, because many physicians do not know about the program and other health care professionals who prescribe medications may not avail themselves of the AMA program. In addition, approximately 23 percent of Vermont physicians belong to the AMA, which is one of the lowest rates in the nation. Finally, data-mining companies could use other identifiers, including state licensing numbers, to track prescribing patterns.

(31) This act is necessary to protect prescriber privacy by limiting marketing to prescribers who choose to receive that type of information, to save money for the state, consumers, and businesses by promoting the use of less expensive drugs, and to protect public health by requiring evidence-based disclosures and promoting drugs with longer safety records.

Sec. 1a. 33 V.S.A. § 1998 is amended to read:

§ 1998. PHARMACY BEST PRACTICES AND COST CONTROL PROGRAM ESTABLISHED

(a) The director of the office of Vermont health access shall establish and maintain a pharmacy best practices and cost control program designed to reduce the cost of providing prescription drugs, while maintaining high quality in prescription drug therapies. The program shall include:

(1) A Use of an evidence-based preferred list of covered prescription drugs that identifies preferred choices within therapeutic classes for particular diseases and conditions, including generic alternatives and over-the-counter drugs.

~~(A) The director and the commissioner of banking, insurance, securities, and health care administration shall implement the preferred drug list as a uniform, statewide preferred drug list by encouraging all health benefit plans in this state to participate in the program.~~

~~(B) The commissioner of human resources shall use the preferred drug list in the state employees health benefit plan only if participation in the program will provide economic and health benefits to the state employees health benefit plan and to beneficiaries of the plan, and only if agreed to through the bargaining process between the state of Vermont and the authorized representatives of the employees of the state of Vermont. The provisions of this subdivision do not authorize the actuarial pooling of the state employees health benefit plan with any other health benefit plan, unless otherwise agreed to through the bargaining process between the state of Vermont and the authorized representatives of the employees of the state of Vermont. No later than November 1, 2004, the commissioner of human resources shall report to the health access oversight committee and the senate and house committees on health and welfare on whether use of the preferred drug list in the state employees health benefit plan would, in his or her opinion, provide economic and health benefits to the state employees health benefit plan and to beneficiaries of the plan.~~

~~(C) The director shall encourage all health benefit plans to implement the preferred drug list as a uniform, statewide preferred drug list by inviting the representatives of each health benefit plan providing prescription drug coverage to residents of this state to participate as observers or nonvoting members in the director's drug utilization review board, and by inviting such plans to use the preferred drug list in connection with the plans' prescription drug coverage.~~

(2) Utilization review procedures, including a prior authorization review process.

(3) Any strategy designed to negotiate with pharmaceutical manufacturers to lower the cost of prescription drugs for program participants, including a supplemental rebate program.

~~(4) With input from physicians, pharmacists, private insurers, hospitals, pharmacy benefit managers, and the drug utilization review board, an evidence-based research education program designed to provide information and education on the therapeutic and cost-effective utilization of prescription drugs to physicians, pharmacists, and other health care professionals authorized to prescribe and dispense prescription drugs. To the extent possible, the program shall inform prescribers about drug marketing that is intended to circumvent competition from generic alternatives. Details of the program, including the scope of the program and funding~~

~~recommendations, shall be contained in a report submitted to the health access oversight committee and the senate and house committees on health and welfare no later than January 1, 2005.~~

~~(5)~~(4) Alternative pricing mechanisms, including consideration of using maximum allowable cost pricing for generic and other prescription drugs.

~~(6)~~(5) Alternative coverage terms, including consideration of providing coverage of over-the-counter drugs where cost-effective in comparison to prescription drugs, and authorizing coverage of dosages capable of permitting the consumer to split each pill if cost-effective and medically appropriate for the consumer.

~~(7)~~(6) A simple, uniform prescription form, designed to implement the preferred drug list, and to enable prescribers and consumers to request an exception to the preferred drug list choice with a minimum of cost and time to prescribers, pharmacists and consumers.

(7) A joint pharmaceuticals purchasing consortium as provided for in subdivision (c)(1) of this section.

(8) Any other cost containment activity adopted, by rule, by the director that is designed to reduce the cost of providing prescription drugs while maintaining high quality in prescription drug therapies.

* * *

(c)(1) The director may implement the pharmacy best practices and cost control program for any other health benefit plan within or outside this state that agrees to participate in the program. For entities in Vermont, the director shall directly or by contract implement the program through a joint pharmaceuticals purchasing consortium. The joint pharmaceuticals purchasing consortium shall be offered on a voluntary basis no later than January 1, 2008, with mandatory participation by state or publicly funded, administered, or subsidized purchasers to the extent practicable and consistent with the purposes of this chapter, by January 1, 2010. If necessary, the office of Vermont health access shall seek authorization from the Centers for Medicare and Medicaid to include purchases funded by Medicaid. "State or publicly funded purchasers" shall include the department of corrections, the division of mental health, Medicaid, the Vermont Health Access Program (VHAP), Dr. Dynasaur, Vermont Rx, VPharm, Healthy Vermonters, workers' compensation, and any other state or publicly funded purchaser of prescription drugs.

* * *

(f)(1) The drug utilization review board shall make recommendations to the director for the adoption of the preferred drug list. The board's recommendations shall be based upon evidence-based considerations of clinical efficacy, adverse side effects, safety, appropriate clinical trials, and cost-effectiveness. "Evidence-based" shall have the same meaning as in section 4622 of Title 18.

* * *

(6) The director shall encourage participation in the joint purchasing consortium by inviting representatives of the programs and entities specified in subdivision (c)(1) of this section to participate as observers or nonvoting members in the drug utilization review board, and by inviting the representatives to use the preferred drug list in connection with the plans' prescription drug coverage.

Sec. 2. 33 V.S.A. § 1998(g) is added to read:

(g) The office shall seek assistance from entities conducting independent research into the effectiveness of prescription drugs to provide technical and clinical support in the development and the administration of the preferred drug list and the evidence-based education program established in subchapter 2 of Title 18.

* * * Pharmaceutical Marketer Disclosures * * *

Sec. 3. 33 V.S.A. § 2005(a)(3) is amended to read:

(3) The office of the attorney general shall keep confidential all trade secret information, as defined by subdivision 317(b)(9) of Title 1, except that the office may disclose the information to the department of health and the office of Vermont health access for the purpose of informing and prioritizing the activities of the evidence-based education program in subchapter 2 of chapter 91 of Title 18. The department of health and the office of Vermont health access shall keep the information confidential. The disclosure form shall permit the company to identify any information that it claims is a trade secret as defined in subdivision 317(c)(9) of Title 1. In the event that the attorney general receives a request for any information designated as a trade secret, the attorney general shall promptly notify the company of such request. Within 30 days after such notification, the company shall respond to the requester and the attorney general by either consenting to the release of the requested information or by certifying in writing the reasons for its claim that the information is a trade secret. Any requester aggrieved by the company's response may apply to the superior court of Washington County for a declaration that the company's claim of trade secret is invalid. The attorney general shall not be made a party to the superior court proceeding. Prior to and during the pendency of the superior court proceeding, the attorney general shall keep confidential the information that has been claimed as trade secret information, except that the attorney general may provide the requested information to the court under seal.

Sec. 4. 33 V.S.A. § 2005(a)(4) is amended and (d) is added to read:

(4) The following shall be exempt from disclosure:

* * *

- (D) scholarship or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policy-making conference of a national, regional, or specialty medical or other professional association if the recipient of the scholarship or other support is selected by the association; and
- (E) ~~unrestricted grants for continuing medical education programs; and~~
- (F) ~~prescription drug rebates and discounts.~~

* * *

(d) Disclosures of unrestricted grants for continuing medical education programs shall be limited to the value, nature, and purpose of the grant and the name of the grantee. It shall not include disclosure of the individual participants in such a program.

Sec. 5. 33 V.S.A. § 2005a(d) is amended to read:

(d) As used in this section:

* * *

(2) “Pharmaceutical manufacturing company” is defined by subdivision ~~2005(e)(5)~~ 4632(c)(5) of this title.

(3) “Pharmaceutical marketer” is defined by subdivision ~~2005(e)(4)~~ 4632(c)(4) of this title.

* * * Price Disclosure and Certification * * *

Sec. 6. 33 V.S.A. § 2010 is added to read:

§ 2010. ACTUAL PRICE DISCLOSURE AND CERTIFICATION

(a) A manufacturer of prescription drugs dispensed in this state under a health program directed or administered by the state shall, on a quarterly basis, report by National Drug Code the following pharmaceutical pricing criteria to the director of the office of Vermont health access for each of its drugs:

(1) the prices required to be provided to the Medicaid program under federal law, including prices defined in 42 U.S.C. § 1396r-8; and

(2) the price that each wholesaler in this state pays the manufacturer to purchase the drug.

(b) When reporting the prices as provided for in subsection (a) of this section, the manufacturer shall include a summary of its methodology in determining the price. The office may accept the standards of the National Drug Rebate agreement entered into by the U.S. Department of Health and Human Services and Section 1927 of the Social Security Act for reporting pricing methodology.

(c) The pricing information required under this section is for drugs defined under the Medicaid drug rebate program and must be submitted to the director following its submission to the federal government in accordance with 42 U.S.C. § 1396r-8(b)(3).

(d) When a manufacturer of prescription drugs dispensed in this state reports the information required under subsection (a) of this section, the president, chief executive officer, or a designated employee of the manufacturer shall certify to the office, on a form provided by the director of the office of Vermont health access, that the reported prices are the same as those reported to the federal government as required by 42 U.S.C. § 1396r-8(b)(3) for the applicable rebate period. A designated employee shall be an employee who reports directly to the chief executive officer or president and who has been delegated to make the certification under this section.

(e) Notwithstanding any provision of law to the contrary, information submitted to the office under this section is confidential and is not a public record as defined in subsection 317(b) of Title 1. Disclosure may be made by the office to an entity providing services to the office under this section; however, that disclosure does not change the confidential status of the information. The information may be used by the entity only for the purpose specified by the office in its contract with the entity. Data compiled in aggregate form by the office for the purposes of reporting required by this section are public records as defined in subsection 317(b) of Title 1, provided they do not reveal trade information protected by state or federal law.

(f) The attorney general shall enforce the provisions of this section under the Vermont consumer fraud act in chapter 63 of Title 9. The attorney general has the same authority to make rules, conduct civil investigations, and bring civil actions with respect to acts and practices governed by this section as is provided under the Vermont consumer fraud act.

* * * Healthy Vermonters * * *

Sec. 7. 33 V.S.A. § 2003 is amended to read:

§ 2003. PHARMACY DISCOUNT PLANS

(a) The director of the office of Vermont health access shall implement pharmacy discount plans, to be known as the “Healthy Vermonters” program ~~and the “Healthy Vermonters Plus” program~~, for Vermonters without adequate coverage for prescription drugs. The provisions of ~~section 1992 of this title~~ subchapter 8 of this chapter shall apply to the director’s authority to administer the pharmacy discount plans established by this section.

(b) The Healthy Vermonters program shall offer beneficiaries an initial discounted cost for covered drugs. Upon approval by the Centers for Medicare and Medicaid Services of a Section 1115 Medicaid waiver program, and upon subsequent legislative approval, the Healthy Vermonters program ~~and the Healthy Vermonters Plus program~~ shall offer beneficiaries a secondary discounted cost, which shall reflect a state payment toward the cost of each dispensed drug as well as any rebate amount negotiated by the commissioner.

* * *

(c) As used in this section:

(1) "Beneficiary" means any individual enrolled in ~~either the Healthy Vermonters program or the Healthy Vermonters Plus program.~~

(2) "Healthy Vermonters beneficiary" means any individual Vermont resident without adequate coverage:

(A) who is at least 65 years of age, or is disabled and is eligible for Medicare or Social Security disability benefits, with household income equal to or less than 400 percent of the federal poverty level, as calculated under the rules of the Vermont health access plan, as amended; or

(B) whose household income is equal to or less than ~~300~~ 350 percent of the federal poverty level, as calculated under the rules of the Vermont Health access plan, as amended.

~~(3) "Healthy Vermonters Plus beneficiary" means any individual Vermont resident without adequate coverage:~~

~~(A) whose household income is greater than 300 percent and equal to or less than 350 percent of the federal poverty level, as calculated under the rules of the Vermont health access plan, as amended; or~~

~~(B) whose family incurs unreimbursed expenses for prescription drugs, including insurance premiums, that equal five percent or more of household income or whose total unreimbursed medical expenses, including insurance premiums, equal 15 percent or more of household income.~~

* * *

* * * PBM Regulation * * *

Sec. 8. 18 V.S.A. chapter 221, subchapter 9 is added to read:

Subchapter 9. Pharmacy Benefit Managers

§ 9471. DEFINITIONS

As used in this subchapter:

(1) "Beneficiary" means an individual enrolled in a health plan in which coverage of prescription drugs is administered by a pharmacy benefit manager and includes his or her dependent or other person provided health coverage through that health plan.

(2) "Health insurer" is defined by subdivision 9402(9) of this title and shall include:

(A) a health insurance company, a nonprofit hospital and medical service corporation, and health maintenance organizations;

(B) an employer, labor union, or other group of persons organized in Vermont that provides a health plan to beneficiaries who are employed or reside in Vermont;

(C) the state of Vermont and any agent or instrumentality of the state that offers, administers, or provides financial support to state government; and

(D) Medicaid, the Vermont health access plan, Vermont Rx, and any other public health care assistance program.

(3) "Health plan" means a health benefit plan offered, administered, or issued by a health insurer doing business in Vermont.

(4) "Pharmacy benefit management" means an arrangement for the procurement of prescription drugs at a negotiated rate for dispensation within this state to beneficiaries, the administration or management of prescription drug benefits provided by a health plan for the benefit of beneficiaries, or any of the following services provided with regard to the administration of pharmacy benefits:

(A) mail service pharmacy;

(B) claims processing, retail network management, and payment of claims to pharmacies for prescription drugs dispensed to beneficiaries;

(C) clinical formulary development and management services;

(D) rebate contracting and administration;

(E) certain patient compliance, therapeutic intervention, and generic substitution programs; and

(F) disease or chronic care management programs.

(5) "Pharmacy benefit manager" means an entity that performs pharmacy benefit management. The term includes a person or entity in a contractual or employment relationship with an entity performing pharmacy benefit management for a health plan.

§ 9472. PHARMACY BENEFIT MANAGERS; REQUIRED PRACTICES

(a) A pharmacy benefit manager that provides pharmacy benefit management for a health plan shall discharge its duties with reasonable care and diligence and be fair and truthful under the circumstances then prevailing that a pharmacy benefit manager acting in like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims. In the case of a health benefit plan offered by a health insurer as defined by subdivision 9471(2)(A) of this title, the health insurer shall remain responsible for administering the health benefit plan in accordance with the health insurance policy or subscriber contract or plan and in compliance with all applicable provisions of Title 8 and this title.

(b) A pharmacy benefit manager shall provide notice to the health insurer that the terms contained in subsection (c) of this section may be included in the contract between the pharmacy benefit manager and the health insurer.

(c) Unless the contract provides otherwise, a pharmacy benefit manager that provides pharmacy benefit management for a health plan shall:

(1) Provide all financial and utilization information requested by a health insurer relating to the provision of benefits to beneficiaries through that health insurer's health plan and all financial and utilization information relating to services to that health insurer. A pharmacy benefit manager providing information under this subsection may designate that material as confidential. Information designated as confidential by a pharmacy benefit manager and provided to a health insurer under this subsection may not be disclosed by the health insurer to any person without the consent of the pharmacy benefit manager, except that disclosure may be made by the health insurer:

(A) in a court filing under the consumer fraud provisions of chapter 63 of Title 9, provided that the information shall be filed under seal and that prior to the information being unsealed, the court shall give notice and an opportunity to be heard to the pharmacy benefit manager on why the information should remain confidential;

(B) when authorized by chapter 63 of Title 9;

(C) when ordered by a court for good cause shown; or

(D) when ordered by the commissioner as to a health insurer as defined in subdivision 9471(2)(A) of this title pursuant to the provisions of Title 8 and this title.

(2) Notify a health insurer in writing of any proposed or ongoing activity, policy, or practice of the pharmacy benefit manager that presents, directly or indirectly, any conflict of interest with the requirements of this section.

(3) With regard to the dispensation of a substitute prescription drug for a prescribed drug to a beneficiary in which the substitute drug costs more than the prescribed drug and the pharmacy benefit manager receives a benefit or payment directly or indirectly, disclose to the health insurer the cost of both drugs and the benefit or payment directly or indirectly accruing to the pharmacy benefit manager as a result of the substitution.

(4) If the pharmacy benefit manager derives any payment or benefit for the dispensation of prescription drugs within the state based on volume of sales for certain prescription drugs or classes or brands of drugs within the state, pass that payment or benefit on in full to the health insurer.

(5) Disclose to the health insurer all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefit manager and any prescription drug manufacturer that relate to benefits provided to beneficiaries under or services to the health insurer's health plan, including formulary management and drug-switch programs, educational support, claims processing, and pharmacy network fees charged from retail pharmacies and data sales fees. A pharmacy benefit manager providing information under this subsection

may designate that material as confidential. Information designated as confidential by a pharmacy benefit manager and provided to a health insurer under this subsection may not be disclosed by the health insurer to any person without the consent of the pharmacy benefit manager, except that disclosure may be made by the health insurer:

(A) in a court filing under the consumer fraud provisions of chapter 63 of Title 9, provided that the information shall be filed under seal and that prior to the information being unsealed, the court shall give notice and an opportunity to be heard to the pharmacy benefit manager on why the information should remain confidential;

(B) when authorized by chapter 63 of Title 9;

(C) when ordered by a court for good cause shown; or

(D) when ordered by the commissioner as to a health insurer as defined in subdivision 9471(2)(A) of this title pursuant to the provisions of Title 8 and this title.

(d) Compliance with the requirements of this section is required for pharmacy benefit managers entering into contracts with a health insurer in this state for pharmacy benefit management in this state.

§ 9473. ENFORCEMENT

(a) Except as provided in subsection (d) of this section, in addition to any remedy available to the commissioner under this title and any other remedy provided by law, a violation of this subchapter shall be considered a violation of the Vermont consumer fraud act in subchapter 1 of chapter 63 of Title 1. Except as provided in subsection (d) of this section, all rights, authority, and remedies available to the attorney general and private parties to enforce the Vermont consumer fraud act shall be available to enforce the provisions of this subchapter.

(b) In connection with any action for violation of the Vermont consumer fraud act, the commissioner's determinations concerning the interpretation and administration of the provisions of this subchapter and any rules adopted hereunder shall carry a presumption of validity. The attorney general and the commissioner shall consult with each other prior to the commencement of any investigation or enforcement action with respect to any pharmacy benefit manager.

(c) The commissioner may investigate, examine, or otherwise enforce a violation of this subchapter by a pharmacy benefit manager under section 9412 of this title as if the pharmacy benefit manager were a health insurer.

(d) The commissioner shall have the exclusive authority to investigate, examine, and otherwise enforce the provisions of this subchapter relating to a pharmacy benefit manager in connection with the pharmacy benefit manager's contractual relationship with, and any other activity with respect to, a health insurer defined by

subdivision 9471(2)(A) of this title.

(e) Notwithstanding the foregoing, the commissioner and the attorney general may bring a joint enforcement action against any person or entity for a violation of this subchapter.

Sec. 9. 18 V.S.A. § 9421 is added to read:

§ 9421. PHARMACY BENEFIT MANAGEMENT; REGISTRATION;

AUDIT

(a) A pharmacy benefit manager shall not do business in this state without first registering with the commissioner on a form and in a manner prescribed by the commissioner.

(b) In accordance with rules adopted by the commissioner, pharmacy benefit managers operating in the state of Vermont and proposing to contract for the provision of pharmacy benefit management shall notify health insurers when the pharmacy benefit manager provides a quotation that a quotation for an administrative-services-only contract with full pass through of negotiated prices, rebates, and other such financial benefits which would identify to the health insurer external sources of revenue and profit is generally available and whether the pharmacy benefits manager offers that type of arrangement. Quotations for an administrative-services-only contract shall include a reasonable fee payable by the health insurer which represents a competitive pharmacy benefit profit. This subsection shall not be interpreted to require a pharmacy benefits manager to offer an administrative-services-only contract.

(c) In order to enable periodic verification of pricing arrangements in administrative-services-only contracts, pharmacy benefit managers shall allow access, in accordance with rules adopted by the commissioner, by the health insurer who is a party to the administrative-services-only contract to financial and contractual information necessary to conduct a complete and independent audit designed to verify the following:

(1) full pass through of negotiated drug prices and fees associated with all drugs dispensed to beneficiaries of the health plan in both retail and mail order settings or resulting from any of the pharmacy benefit management functions defined in the contract;

(2) full pass through of all financial remuneration associated with all drugs dispensed to beneficiaries of the health plan in both retail and mail order settings or resulting from any of the pharmacy benefit management functions defined in the contract; and

(3) any other verifications relating to the pricing arrangements and activities of the pharmacy benefit manager required by the contract if required by the commissioner.

(d) The department's reasonable expenses in administering the provisions of this section may be charged to pharmacy benefit managers in the manner provided for in section 18 of Title 8. These expenses shall be

allocated in proportion to the lives of Vermonters covered by each pharmacy benefit manager as reported annually to the commissioner in a manner and form prescribed by the commissioner. The department shall not charge its expenses to the pharmacy benefit manager contracting with the office of Vermont health access if the office notifies the department of the conditions contained in its contract with a pharmacy benefit manager.

(e) The commissioner may adopt such rules as are necessary or desirable in carrying out the purposes of this section. The rules also shall ensure that proprietary information is kept confidential and not disclosed by a health insurer.

(f) As used in this section:

(1) "Health insurer" is defined in subdivision 9471(2) of this title.

(2) "Health plan" is defined in subdivision 9471(3) of this title.

(3) "Pharmacy benefit management" is defined in subdivision 9471(4) of this title.

(4) "Pharmacy benefit manager" is defined in subdivision 9471(5) of this title.

Sec. 10. APPLICATION

Secs. 8 and 9 of this act apply to contracts executed or renewed on or after September 1, 2007. For purposes of this section, a contract executed pursuant to a memorandum of agreement executed prior to September 1, 2007 is deemed to have been executed prior to September 1, 2007 even if the contract was executed after that date.

Sec. 11. 8 V.S.A. § 4088d is added to read:

§ 4088d. NOTICE OF PREFERRED DRUG LIST CHANGES

On a periodic basis, no less than once per calendar year, a health insurer as defined in subdivisions 9471(2)(A), (C), and (D) of Title 18 shall notify beneficiaries of changes in pharmaceutical coverage and provide access to the preferred drug list maintained by the insurer.

Sec. 12. 18 V.S.A. chapter 91 is amended to read:

CHAPTER 91. ~~GENERIC DRUGS~~ PRESCRIPTION DRUG COST CONTAINMENT

Sec. 13. 18 V.S.A. chapter 91, sections 4601–4608 are designated as subchapter 1 which is added to read:

Subchapter 1. Generic Drugs

Sec. 14. 18 V.S.A. chapter 91, subchapter 2 is added to read:

Subchapter 2. Evidence-Based Education Program

§ 4621. DEFINITIONS

For the purposes of this subchapter:

(1) “Department” means the department of health.

(2) “Evidence-based” means based on criteria and guidelines that reflect high-quality, cost-effective care.

The methodology used to determine such guidelines shall meet recognized standards for systematic evaluation of all available research and shall be free from conflicts of interest. Consideration of the best available scientific evidence does not preclude consideration of experimental or investigational treatment or services under a clinical investigation approved by an institutional review board.

§ 4622. EVIDENCE-BASED EDUCATION PROGRAM

(a)(1) The department, in collaboration with the attorney general, the University of Vermont area health education centers program, and the office of Vermont health access, shall establish an evidence-based prescription drug education program for health care professionals designed to provide information and education on the therapeutic and cost-effective utilization of prescription drugs to physicians, pharmacists, and other health care professionals authorized to prescribe and dispense prescription drugs. To the extent practicable, the program shall use the evidence-based standards developed by the blueprint for health. The department may collaborate with other states in establishing this program.

(2) The program shall notify prescribers about commonly used brand-name drugs for which the patent has expired within the last 12 months or will expire within the next 12 months. The department and the office of Vermont health access shall collaborate in issuing the notices.

(3) To the extent permitted by funding, the program may include the distribution to prescribers of vouchers for samples of generic medicines used for health conditions common in Vermont.

(b) The department shall request information and collaboration from physicians, pharmacists, private insurers, hospitals, pharmacy benefit managers, the drug utilization review board, medical schools, the attorney general, and any other programs providing an evidence-based education to prescribers on prescription drugs in developing and maintaining the program.

(c) The department may contract for technical and clinical support in the development and the administration of the program from entities conducting independent research into the effectiveness of prescription drugs.

(d) The department and the attorney general shall collaborate in reviewing the marketing activities of pharmaceutical manufacturing companies in Vermont and determining appropriate funding sources for the program, including awards from suits brought by the attorney general against pharmaceutical manufacturers.

Sec. 15. GENERIC DRUG VOUCHER PILOT PROJECT

(a) As part of the evidence-based education program established in subchapter 2 of chapter 91 of Title 18,

the department of health, in collaboration with the office of Vermont health access and the University of Vermont area health education centers program, shall establish a pilot project to distribute vouchers for a sample of generic drugs equivalent to frequently prescribed prescription drugs that are used to treat common health conditions.

(b) The office of Vermont health access shall fund the vouchers from the fee established in section 1998b of Title 33 and shall provide payment to the pharmacy dispensing the prescription drugs in exchange for the voucher. The office shall establish a payment rate, including a dispensing fee, using the rules and procedures for the Medicaid program.

Sec. 15a. GENERIC DRUG VOUCHER PILOT; REPORT

(a) By January 15, 2009, the office of Vermont health access, the department of banking, insurance, securities, and health care administration, the area health education centers, and the joint fiscal office shall provide a report to the house committee on health care and the senate committee on health and welfare describing and evaluating the effects of the generic drug voucher pilot program.

(b) The report shall describe how the pilot project is implemented, including which health conditions were targeted, the generic drugs provided with the vouchers, and the geographic regions participating. The report shall compare the distribution of prescribing among generic drugs provided through the vouchers and brand-name drugs before and after the first year of the generic drug sample pilot project and will review a year of prescribing data prior to the implementation of the pilot project to a year of prescribing data during the first year of the pilot project's implementation. The data shall be adjusted to reflect how and where the pilot was implemented.

Sec. 16. PRESCRIPTION DRUG PRICING; FEDERALLY QUALIFIED HEALTH CENTERS

No later than January 1, 2008, the department of health shall create a plan to inform Vermonters of the availability of health services provided by federally qualified health centers (FQHC) and FQHC look-alikes, including information about prescription drug pricing, focusing on state employees, individuals under the supervision of corrections, individuals receiving workers' compensation benefits if applicable, and any other state or publicly funded purchaser of prescription drugs for whom the cost of prescription drugs is likely to be higher than prices under Section 340B of the Public Health Service Act.

* * * Prescription Drug Data Confidentiality * * *

Sec. 17. 18 V.S.A. chapter 91, subchapter 3 is added to read:

Subchapter 3. Information Requirements§ 4631. CONFIDENTIALITY OF PRESCRIPTION INFORMATION

(a) It is the intent of the general assembly to advance the state's interest in protecting the public health of Vermonters, protecting the privacy of prescribers and prescribing information, and to ensure costs are contained in the private health care sector, as well as for state purchasers of prescription drugs, through the promotion of less costly drugs and ensuring prescribers receive unbiased information.

(b) As used in this section:

(1) "Electronic transmission intermediary" means an entity that provides the infrastructure that connects the computer systems or other electronic devices used by health care professionals, prescribers, pharmacies, health care facilities and pharmacy benefit managers, health insurers, third-party administrators, and agents and contractors of those persons in order to facilitate the secure transmission of an individual's prescription drug order, refill, authorization request, claim, payment, or other prescription drug information.

(2) "Health care facility" shall have the same meaning as in section 9402 of this title.

(3) "Health care professional" shall have the same meaning as in section 9402 of this title.

(4) "Health insurer" shall have the same meaning as in section 9410 of this title.

(5) "Marketing" shall include advertising, promotion, or any activity that is intended to be used or is used to influence sales or the market share of a prescription drug, influence or evaluate the prescribing behavior of an individual health care professional to promote a prescription drug, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.

(6) "Pharmacy" means any individual or entity licensed or registered under chapter 36 of Title 26.

(7) "Prescriber" means an individual allowed by law to prescribe and administer prescription drugs in the course of professional practice.

(8) "Promotion" or "promote" means any activity or product the intention of which is to advertise or publicize a prescription drug, including a brochure, media advertisement or announcement, poster, free sample, detailing visit, or personal appearance.

(9) "Regulated records" means information or documentation from a prescription written by a prescriber doing business in Vermont or a prescription dispensed in Vermont.

(c)(1) The department of health and the office of professional regulation, in consultation with the appropriate licensing boards, shall establish a prescriber data-sharing program to allow a prescriber to give consent for his or her identifying information to be used for the purposes described under subsection (d) of this section. The department and office shall solicit the prescriber's consent on licensing applications or renewal forms and shall

provide a prescriber a method for revoking his or her consent. The department and office may establish rules for this program.

(2) The department or office shall make available the list of prescribers who have consented to sharing their information. Entities who wish to use the information as provided for in this section shall review the list at minimum every six months.

(d) A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity may use regulated records which include prescription information containing prescriber-identifiable data for marketing or promoting a prescription drug only if:

(1)(A) a prescriber has provided consent for the use of that data as provided in subsection (c) of this section; and

(B) the entity using the regulated records complies with the disclosure requirements in subsection (f) of this section; or

(2) the entity meets one of the exceptions provided in subsection (e) of this section.

(e) This section shall not apply to:

(1) the license, transfer, use, or sale of regulated records for the limited purposes of pharmacy reimbursement; prescription drug formulary compliance; patient care management; utilization review by a health care professional, the patient's health insurer, or the agent of either; or health care research;

(2) the dispensing of prescription medications to a patient or to the patient's authorized representative;

(3) the transmission of prescription information between an authorized prescriber and a licensed pharmacy, between licensed pharmacies, or that may occur in the event a pharmacy's ownership is changed or transferred;

(4) care management educational communications provided to a patient about the patient's health condition, adherence to a prescribed course of therapy and other information relating to the drug being dispensed, treatment options, recall or patient safety notices, or clinical trials;

(5) the collection, use, or disclosure of prescription information or other regulatory activity as authorized by chapter 84, chapter 84A, or section 9410 of this title, or as otherwise provided by law;

(6) the collection and transmission of prescription information to a Vermont or federal law enforcement officer engaged in his or her official duties as otherwise provided by law; and

(7) the collection, use, transfer, or sale of patient and prescriber data for marketing or promoting if the data do not identify a prescriber, and there is no reasonable basis to believe that the data provided could be used to identify a prescriber.

(f) When a pharmaceutical marketer engages in any form of prescription drug marketing directly to a physician or other person authorized to prescribe prescription drugs as provided for under this section, the marketer shall disclose to the prescriber evidence-based information as provided for by rule describing the specific health benefits or risks of using other pharmaceutical drugs, including drugs available over the counter; which patients would gain from the health benefits or be susceptible to the risks described; the range of prescription drug treatment options; and the cost of the treatment options. As necessary, the office of Vermont health access, in consultation with the department of health, the area centers on health education, the office of professional regulation, and the office of the attorney general, shall develop rules for compliance with this subsection, including the certification of materials which are evidence-based as defined in section 4621 of this title and which conditions have evidence-based treatment guidelines. The rules shall be consistent with the federal Food and Drug Administration's regulations regarding false and misleading advertising. To the extent practicable, the rules shall use the evidence-based standards developed by the blueprint for health.

(g) In addition to any other remedy provided by law, the attorney general may file an action in superior court for a violation of this section or of any rules adopted under this section by the attorney general. The attorney general shall have the same authority to investigate and to obtain remedies as if the action were brought under the Vermont consumer fraud act, chapter 63 of Title 9. Each violation of this section or of any rules adopted under this section by the attorney general constitutes a separate civil violation for which the attorney general may obtain relief.

Sec. 18. 1 V.S.A. § 317(c)(38) and (39) are added to read:

(38) records held by the agency of human services, which include prescription information containing prescriber-identifiable data, that could be used to identify a prescriber, except that the records shall be made available upon request for medical research, consistent with and for purposes expressed in sections 4621, 4631, 4632, 4633, and 9410 of Title 18 and chapter 84 of Title 18, or as provided for in chapter 84A of Title 18 and for other law enforcement activities.

(39) records held by the agency of human services or the department of banking, insurance, securities and health care administration, which include prescription information containing patient-identifiable data, that could be used to identify a patient.

Sec. 19. 18 V.S.A. § 9410(g) is amended to read:

(g) Any person who knowingly fails to comply with the requirements of this section or rules adopted pursuant to this section shall be ~~fin~~ subject to an administrative penalty of not more than \$1,000.00 per

violation. The commissioner may impose an administrative penalty of not more than \$10,000.00 each for those violations the commissioner finds were willful. In addition, any person who knowingly fails to comply with the confidentiality requirements of this section or confidentiality rules adopted pursuant to this section and uses, sells, or transfers the data or information for commercial advantage, pecuniary gain, personal gain, or malicious harm shall be subject to an administrative penalty of not more than \$50,000.00 per violation. The powers vested in the commissioner by this subsection shall be in addition to any other powers to enforce any penalties, fines, or forfeitures authorized by law.

Sec. 20. 33 V.S.A. § 2004 is added to read:

§ 2004. MANUFACTURER FEE

(a) Annually, each pharmaceutical manufacturer or labeler of prescription drugs that are paid for by the office of Vermont health access for individuals participating in Medicaid, the Vermont Health Access Program, Dr. Dynasaur, VPharm, or Vermont Rx shall pay a fee to the agency of human services. The fee shall be 0.5 percent of the previous calendar year's prescription drug spending by the office and shall be assessed based on manufacturer labeler codes as used in the Medicaid rebate program.

(b) Fees collected under this section shall fund collection and analysis of information on pharmaceutical marketing activities under sections 4632 and 4633 of Title 18, analysis of prescription drug data needed by the attorney general's office for enforcement activities, and the evidence-based education program established in subchapter 2 of Title 18. The fees shall be collected in the evidence-based education and advertising fund established in section 2004a of this title.

(c) The secretary of human services or designee shall make rules for the implementation of this section.

Sec. 20a. 33 V.S.A. § 2004a is added to read:

§ 2004a. EVIDENCE-BASED EDUCATION AND ADVERTISING FUND

(a) The evidence-based education and advertising fund is established in the treasury as a special fund to be a source of financing for activities relating to fund collection and analysis of information on pharmaceutical marketing activities under sections 4632 and 4633 of Title 18, analysis of prescription drug data needed by the attorney general's office for enforcement activities, and for the evidence-based education program established in subchapter 2 of Title 18. Monies deposited into the fund shall be used for the purposes described in this section.

(b) Into the fund shall be deposited:

(1) revenue from the manufacturer fee established under section 2004 of this title; and

(2) the proceeds from grants, donations, contributions, taxes, and any other sources of revenue as may be provided by statute, rule, or act of the general assembly.

(c) The fund shall be administered pursuant to subchapter 5 of chapter 7 of Title 32, except that interest earned on the fund and any remaining balance shall be retained in the fund.

* * * Consumer Protection; False Advertising * * *

Sec. 21. 9 V.S.A. § 2466a is added to read:

§ 2466a. CONSUMER PROTECTIONS; PRESCRIPTION DRUGS

(a) A violation of section 4631 of Title 18 shall be considered a violation under this chapter.

(b) As provided in section 9473 of Title 18, a violation of section 9472 shall be considered a violation under this chapter.

(c)(1) It shall be a violation under this chapter for a manufacturer of prescription drugs to present or cause to be presented in the state a regulated advertisement if that advertisement does not comply with the requirements concerning drugs and devices and prescription drug advertising in federal law and regulations under 21 United States Code, Sections 331 and 352(n) and 21 Code of Federal Regulations, Part 202 and state rules. A warning or untitled letter issued by the U.S. Food and Drug Administration shall be prima facie evidence of a violation of federal law and regulations.

(2) For purposes of this section:

(A) “Manufacturer of prescription drugs” means a person authorized by law to manufacture, bottle, or pack drugs or biological products, a licensee or affiliate of that person, or a labeler that receives drugs or biological products from a manufacturer or wholesaler and repackages them for later retail sale and has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 2027.20 (1999).

(B) “Regulated advertisement” means:

(i) the presentation to the general public of a commercial message regarding a prescription drug or biological product by a manufacturer of prescription drugs that is broadcast on television, cable, or radio from a station or cable company that is physically located in the state, broadcast over the internet from a location in the state, or printed in magazines or newspapers that are printed, distributed, or sold in the state; or

(ii) a commercial message regarding a prescription drug or biological product by a manufacturer of prescription drugs or its representative that is conveyed:

(I) to the office of a health care professional doing business in Vermont, including statements by representatives or employees of the manufacturer and materials mailed or delivered to the office; or

(II) at a conference or other professional meeting occurring in Vermont.

(d) No person shall sell, offer for sale, or distribute electronic prescribing software that advertises, uses instant messaging and pop-up advertisements, or uses other means to influence or attempt to influence the prescribing decision of a health care professional through economic incentives or otherwise and which is triggered or in specific response to the input, selection, or act of a health care professional or agent in prescribing a specific prescription drug or directing a patient to a certain pharmacy. This subsection shall not apply to information provided to the health care professional about pharmacy reimbursement, prescription drug formulary compliance, and patient care management.

* * * Insurance Marketing * * *

Sec. 22. 8 V.S.A. § 4804(a) is amended to read:

(a) The commissioner may suspend, revoke, or refuse to continue or renew any license issued under this chapter if, after notice to the licensee and to the insurer represented, and opportunity for hearing, he or she finds as to the licensee any one or more of the following conditions:

* * *

(8) The licensee has committed any unfair trade practice or fraud as defined in this title. It shall be an unfair practice under this section for a licensee to:

(A)(i) sell, solicit, or negotiate the purchase of health insurance in this state through an advertisement which makes use directly or indirectly of any method of marketing which fails to disclose in a conspicuous manner that a purpose of the method of marketing is solicitation of insurance, and that contact will be made by an insurance agent or insurance company.

(ii) Use an appointment that was made to discuss Medicare products or to solicit the sale of Medicare products to solicit sales of any other insurance products unless the consumer requests the solicitation, and the products to be discussed are clearly identified to the consumer in writing at least 48 hours in advance of the appointment.

(iii) Solicit the sale of Medicare products door-to-door prior to receiving an invitation from a consumer.

(B) As used in this subdivision, the term “Medicare products” includes Medicare Part A, Medicare Part B, Medicare Part C, Medicare Part D, and Medicare supplement plans;

* * *

Sec. 22a. LITIGATION REPORT; AUDITOR

Beginning January 1, 2008 and annually thereafter, the state auditor shall provide a report to the general assembly with a detailed accounting of all amounts paid by the state with state or federal funds in connection

with any litigation challenging the validity of this act or a section of this act. The report shall include costs, fees, damages, amounts paid to expert witnesses, salaries and benefits of state employees who work on the litigation, amounts paid to individuals under contract with the state who work on the litigation, attorney's fees awarded to the other party, any other amounts awarded by the court, and the number of hours spent by state employees involved in the litigation.

Sec. 23. RECODIFICATION

The following sections of Title 33 as amended by this act are recodified as follows:

- (1) Section 2005 shall be section 4632 of Title 18.
- (2) Section 2005a shall be section 4633 of Title 18.
- (3) Section 2008 shall be section 4634 of Title 18.
- (4) Section 2006 shall be section 852 of Title 2.

Sec. 24. REPEAL

Section 2009 of Title 33 is repealed.

Sec. 24a. APPROPRIATIONS

(a) The amount of \$200,000.00 is appropriated from the evidence-based education and advertising fund to the department of health for a grant to the area health education centers for the evidence-based education program established under subchapter 2 of Title 18.

(b) The amount of \$300,000.00 is appropriated from the evidence-based education and advertising fund to the office of Vermont health access for the evidence-based education program's generic drug sample pilot project as described in Sec. 15 of this act.

(c) The amount of \$50,000.00 is appropriated from the evidence-based education and advertising fund to the office of attorney general fund for the collection and analysis of information on pharmaceutical marketing activities under sections 4632 and 4633 of Title 18 and analysis of prescription drug data needed by the attorney general's office for enforcement activities.

Sec. 24b. EFFECTIVE DATES

Sec. 17 of this act shall become effective no later than January 1, 2008, except that the department of health and the office of professional regulation may begin any necessary rulemaking, revision of forms, or other administrative actions necessary to implement the program, immediately upon passage. The department and

office may implement Sec. 17 for prescribers with licenses at the time of passage of this act when the prescriber next requests a renewal of the license.

Approved: June 9, 2007

APPENDIX II

**IMS HEALTH INC., VERISPLAN, LLC AND SOURCE
HEALTHCARE ANALYTICS v. WILLIAM H. SORRELL**

U.S. DISTRICT COURT
DISTRICT OF VERMONT
FILED

2007 AUG 29 AM 9:23

CLERK
BY _____
DEPUTY CLERK

IN THE
UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

CASE NO. _____

IMS HEALTH INCORPORATED;)
VERISPAN, LLC; and SOURCE)
HEALTHCARE ANALYTICS, INC., a)
subsidiary of WOLTERS KLUWER,)
HEALTH INC.,)

Plaintiffs,)

vs.)

WILLIAM H. SORRELL, as Attorney)
General of the State of Vermont,)

Defendant.)

PRELIMINARY & PERMANENT
INJUNCTIVE RELIEF SOUGHT
BEFORE JAN. 1, 2008

2:07-cv-188

Complaint for Declaratory & Injunctive
Relief with Respect to Vt. Stat. Ann. tit. 18, § 4631 (2007)

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INTRODUCTION

Plaintiffs, IMS Health Incorporated, Verispan, LLC, and Source Healthcare Analytics, Inc. sue the defendant, William H. Sorrell, as Attorney General of the State of Vermont, and state:

1. This is an action to declare Vt. Acts No. 80, § 17 (2007), codified as Vt. Stat. Ann. tit. 18, § 4631 (2007) (hereinafter “the Prescription Restraint Law”¹ or “the law”), unconstitutional and to preliminarily and permanently enjoin its enforcement. The law violates the First and Fourteenth Amendments of the United States Constitution by prohibiting the communication of lawfully-obtained, truthful, important information without directly advancing important or substantial government interests when alternatives that do not restrict speech are available to achieve the state’s objectives. The law also violates the Commerce Clause of the United States Constitution by regulating transactions that take place wholly outside of Vermont and is preempted by federal law.

2. Plaintiffs, the “health information publishers,” are the world’s leading providers of information, research, and analysis to the pharmaceutical and health care industries. Plaintiffs provide a vital link between physicians and pharmaceutical manufacturers, medical researchers, health economists and regulatory agencies – a link that helps improve public health and ensure patient safety through the collection, analysis, and reporting of vast amounts of information regarding the drugs that doctors prescribe. For more than a decade, this work has helped to ensure that the right doctors receive the right information about the right drugs so that the doctors can make the right choices for their patients. At the same time, this work always has

¹ This is not the official title of the law. The official title is “An Act Relating to Increasing Transparency of Prescription Drug Pricing and Information.” Plaintiffs use the different title for brevity and to emphasize that the effect of the law is to restrain publication of prescription information, not to make drug pricing or information transparent.

safeguarded patient privacy.

3. Last year, the state of New Hampshire enacted an extraordinary law – the first of its kind in the United States – that attempted to put an end to this work by prohibiting pharmacies and similar entities from communicating lawfully-obtained, truthful information about doctors’ prescribing practices in prescription records. The State of New Hampshire enacted the law on the basis of speculation that restricting targeted marketing by pharmaceutical companies by cutting off the flow of information about doctors’ prescribing practices would lower healthcare costs in that state. The State also passed the law in order to keep physician prescription decisions from public scrutiny.

4. Two of the plaintiffs in this suit challenged the constitutionality of the New Hampshire law because the prohibition against communications concerning the prescription decisions of New Hampshire doctors violated the health information publishers’ First Amendment Rights without directly advancing a substantial governmental interest and because the state had other alternative means to achieve its goals without infringing on plaintiffs’ First Amendment rights.

5. At the same time that the New Hampshire district court was considering the New Hampshire law, the Vermont Legislature took steps to enact similar legislation. Section 17 of Vermont Senate Bill No. 115 (2007), as originally proposed, was modeled after and was almost identical to the New Hampshire Prescription Information Law.

6. Before the Vermont law was enacted, however, the New Hampshire district court declared the New Hampshire law unconstitutional and permanently enjoined its enforcement. *See IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163 (D.N.H. April 30, 2007), *appeal docketed*, No. 07-1945 (1st Cir. June 20, 2007).

7. The Vermont Legislature then hastily amended its bill to try to avoid constitutional defects found in the New Hampshire legislation. In doing so, it made the legislation even more constitutionally suspect by vesting in prescribers themselves the decision as to whether the speech of third parties will be restrained. This increases the danger that the law will be used to shield poor prescribing practices and that this will increase, rather than decrease, the rising costs of healthcare. In addition, legislative findings were hastily added to the Vermont bill only after the New Hampshire court ruled that a legislative body is not entitled to deference when it does not make findings. The so-called “findings” are little more than conclusory statements based on no actual evidence of any connection between the supposed ill the law is intended to cure – rising drug costs – and the publication of truthful prescribing information conveyed by entities such as the plaintiffs.

8. Nevertheless, on June 9, 2007, the Vermont governor signed the bill into law, and it became 2007 Vt. Acts No. 80, which becomes effective on January 1, 2008.² Section 17 of Vermont Act No. 80, codified as Vt. Stat. Ann. tit. 18, § 4631 (2007), contains the provisions attacked in this complaint as unconstitutional. Section 1 of Vermont Act No. 80 contains findings that purportedly justify the law. By restraining publication of vital prescribing information, Vermont’s new law, much like the New Hampshire law, will violate plaintiffs’ First Amendment rights without directly advancing any substantial governmental interest.

9. The American Medical Association, which opposes restrictions on the collection and disclosure of physician prescribing data, has observed that prescriber level data “is critical to improving the quality, safety and efficacy of pharmaceutical prescribing through evidence-based medical research.” Just as critical, the Vermont law is contrary to the national movement toward

² A copy of 2007 Vt. Acts No. 80, as enacted into law, is attached hereto as Exhibit A.

more transparency in healthcare practices. The success of initiatives designed to improve healthcare quality, ensure patient safety and manage costs depends on publication of more information – not less. Without prescriber-identifiable data, the healthcare community will lose a powerful tool to help monitor the safety of new medications and ensure that patients taking them are not harmed. Without such information, medical researchers will be unable to conduct studies that can improve public health. Without it, pharmaceutical and biotechnology companies will be deprived of information necessary to effectively comply with federal safety regulations, implement drug recall programs and communicate to prescribers information about innovative, life-saving treatments. In sum, by restraining publication of prescriber-identifiable data, the Vermont law takes healthcare in the wrong direction while doing nothing to improve the well-being of Vermont’s citizens.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337 and 1343(a)(3) and (4), because the action arises under the Commerce Clause, the Supremacy Clause and the First and Fourteenth Amendments to the United States Constitution and under 21 U.S.C. §§ 301 et seq. and 42 U.S.C. §§ 1983 & 1988.

11. Venue is proper in this district under 28 U.S.C. § 1391(b) and (c), because plaintiffs’ claims arise in this district and the defendant is a public official located within this district.

THE PARTIES

12. Plaintiff, IMS Health Incorporated (“IMS Health”), is a Delaware corporation with its principal place of business for U.S. operations in Plymouth Meeting, Pennsylvania.

13. Plaintiff, Verispan, LLC, (“Verispan”), is a Delaware limited liability company with its principal place of business in Yardley, Pennsylvania.

14. Plaintiff, Source Healthcare Analytics, Inc. (“Source Healthcare”), is a Delaware corporation and a wholly owned subsidiary of Wolters Kluwer Health, Inc., with its principal place of business in Phoenix, Arizona.

15. Defendant, William H. Sorrell, is the Attorney General of the State of Vermont and the chief legal officer charged with the responsibility of enforcing Vt. Stat. Ann. tit. 18, § 4631 (2007).

OTHER COMMON FACTUAL ALLEGATIONS

The following allegations are common to all of the counts of the complaint:

Publishing Activities of IMS Health Incorporated

16. IMS Health is a publicly traded company that was founded as Intercontinental Marketing Services in 1954. IMS Health is the world’s leading provider of information, research and analysis to the pharmaceutical and healthcare industries, with data collection and reporting activities in over 100 countries. The company receives and processes vast quantities of health care data each year. In the United States alone, IMS Health collects information from thousands of sources: pharmaceutical wholesalers, pharmacies, physicians, hospitals, and clinics, and processes millions of records each week. The information collected is then aggregated with other information, analyzed and made available to IMS Health’s subscribers through dozens of services designed to help them drive decisions and shape strategies. All of IMS Health’s proprietary databases are composed of patient de-identified data. This means that IMS Health neither uses nor transfers information that contains the identity of patients in any of its subscription services.

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

18. IMS Health's prescriber-level databases are also essential to support research, analysis, development and implementation of practice guidelines and public health policy for the advancement of patient health. Examples of these activities include:

a. Asthma in low income areas. A study in New York used IMS Health's prescriber-level information to examine physician-prescribing patterns in under-served urban areas to determine patterns of under-treatment of patients with asthma. There was substantial evidence that asthma controller medications were underutilized, which reflected issues in both physician education and public perceptions. Feedback on the study findings was provided to

physicians to engage them in implementing appropriate public health solutions.

b. Community intervention to reduce overuse of antibiotics. A research study relied on IMS Health's prescriber-level data to complete a pediatric study on the judicious use of antibiotics. The objective of the study was to assess the impact of parent and clinician education on antibiotic prescribing and carriage of penicillin-nonsusceptible streptococcus pneumonia in children. The study resulted in a multifaceted education program that led to community-wide reductions in antibiotic prescribing.

c. Regional impact of bioterrorist threats on prescribing. Wisconsin researchers at the Marshfield Clinic Research Foundation used IMS Health's prescriber-level information to determine if the public demand for fluoroquinolones, such as Cipro, post-9/11 bioterrorist threats would spread to communities not directly affected by anthrax scares in New York, New Jersey, Connecticut, Pennsylvania, Virginia, Maryland and Florida.

Publishing Activities of Verispan LLC

19. Verispan is a healthcare information publisher founded by Quintiles Transnational Corp. and McKesson Corp. Verispan is one of the major providers of healthcare information in the United States. Since its founding as Scott-Levin Associates, Inc. in 1982 and along with its constituent companies formerly known as Kelly-Waldron, SMG, Synergy, and Amaxis, Verispan has served the pharmaceutical and healthcare industries in the United States with an important source of healthcare information. Verispan contracts to receive nearly half of all U.S. prescriptions and nearly one-quarter of all U.S. electronic medical transactions annually. Verispan captures a sample of data from a near-census of U.S. retail pharmacies. By focusing on breadth of data coverage, Verispan is able to improve insight into prescription and medical activity at the national, regional and individual prescriber level.

20. All of Verispan's proprietary databases are composed of patient de-identified data. This means that Verispan neither uses nor transfers information that contains the identity of patients in any of its subscription services. With the aid of Verispan's vast amount of data, the medical, scientific, pharmaceutical and healthcare management communities are able to track patterns of disease and treatment, conduct outcomes research, implement best practices, and apply health economic analyses. The company's databases, including physician-identifiable data, are essential to effective implementation of prescription drug recall programs, performance of pharmaceutical market studies, efficient pharmaceutical sales and marketing resource allocation, and assessment of drug utilization patterns (*e.g.*, on-and-off label uses and regional variations in physician prescribing behavior).

21. Verispan's databases are also essential to the effective implementation of healthcare studies. For example, Verispan's data is currently used by the Department of Health and Human Services through the Food and Drug Administration. The FDA uses Verispan de-identified prescription data to monitor the incidence by which any two dispensed drugs are used with one another. This is used by FDA as the backing to many interaction studies they perform in assessing the safety of ethical prescription medications. Verispan's data has also been used by many of its subscribers to effectively identify eligible prescribers for clinical trials. In these cases accurate prescriber level data is crucial to perform accurate and expeditious clinical trials, which may provide critical healthcare options to patients in need of alternative treatment.

Publishing Activities of Source Healthcare Analytics, Inc.

22. Wolters Kluwer is a leading multinational publisher and information services company active in many markets. One division, Wolters Kluwer Health, Inc. ("Wolters Kluwer Health"), a wholly owned subsidiary of Wolters Kluwer U.S. Corporation, is a primary supplier

of information to professionals and students in the fields of medicine, nursing, allied health, and pharmacy, as well as entities in the pharmaceutical industry. It produces textbooks, reference products, journals, and other informational materials that professionals employ in the knowledge-intensive, rapidly changing practice of medicine. Source Healthcare Analytics, Inc. (“Source Healthcare”), a wholly owned subsidiary of Wolters Kluwer Health, sells a variety of information products that use “prescriber-identified prescription data,” i.e., records that match prescriptions to prescribers. To create these information products, Source Healthcare purchases prescriber-identified data from pharmacies or other originating entities, then aggregates, analyzes, and packages it for use by subscribers and other customers.

23. Source Healthcare’s subscribers and other customers use the data in a broad range of activities. For example, pharmaceutical manufacturers use it to identify doctors who may be interested in their products and who may have patients who would be suitable participants in clinical trials of promising new drugs. Source Healthcare’s subscribers and customers use the data to report to governmental agencies, including the FDA, discharging their regulatory and law enforcement responsibilities. Products like Source Healthcare’s can help governmental agencies direct drug safety alert letters toward doctors whose prescribing practices make them relevant, and enforce civil and criminal laws against abusive prescribing practices. In addition, a variety of individuals and organizations use the data in research concerning drug usage, interactions, effectiveness, and costs.

The Information at Issue: Prescriber-Identifiable Data

24. In the United States, approximately 1.4 million prescribers are licensed to write prescriptions. Prescriptions are written for approximately 8,000 different pharmaceutical products, and many of these products are dispensed in various forms, strengths, and doses.

25. Prescriptions are dispensed by approximately 54,000 retail pharmacies throughout the United States, as well as other medical facilities licensed to fill prescriptions.

26. Retail pharmacies in the United States are primarily composed of chain pharmacies, independent pharmacies, mass merchandisers and food stores with in-store pharmacies, mail order pharmacies, and long-term care pharmacies.

27. Retail pharmacies acquire prescription data during the regular course of business. For each prescription filled, a record is kept that includes the name of the patient, information identifying the prescriber, the name, dosage and quantity of the prescribed drug, and the date the prescription is filled. If the pharmacy is part of a larger organization with multiple retail outlets, each outlet's prescription data is ultimately aggregated with data from other outlets and stored in a central location.

28. After retail pharmacies acquire prescription data, they then license, sell, or transfer the data (without disclosing the patient's identity) to health information publishers for two distinct purposes. First, in order to make a profit. Second, they license, sell, or transfer the information to the health information publishers because those companies have developed sophisticated methods of aggregating and analyzing the information in order to make the information useful to entities that devote substantial resources to improving the health and welfare of consumers.

29. The patient de-identified information that the health information publishers purchase from pharmacies and similar entities include: the name of the pharmaceutical product, information identifying the prescriber, the name, dosage and quantity of the prescribed drug, and the date the prescription is filled.

30. Currently, health information publishers collectively acquire, aggregate and analyze information relating to billions of prescription transactions per year throughout the United States.

31. Plaintiffs acquire, license, sell, use, or transfer the information for two distinct purposes. First, to make a profit. Second, to improve public health and welfare by licensing, selling, and transferring it to pharmaceutical companies and to other entities that devote substantial resources to using the information to improve the health and welfare of consumers.

32. Some of the entities to which the plaintiffs license, sell, or transfer the information use the information for advertising, marketing, and promotional purposes. These entities and others also use the information for other purposes that are not associated in any way with advertising, marketing, and promotional purposes.

33. Plaintiffs strongly believe that the widespread dissemination and use of the prescription information that they gather and analyze improves the health and welfare of consumers.

How the Prescription Information Is Gathered & Published

34. Plaintiffs purchase prescriber-identifiable data from participating pharmacies and other sources. To comply with state and federal laws regarding patient privacy, participating pharmacies allow plaintiffs to install software on their computers that encrypts any information identifying the patients before it is transferred to plaintiffs' computers. After patient information is de-identified in this way, a number is assigned to each de-identified patient that permits prescription information to be correlated for each patient but does not allow the patient's identity to be determined. The prescription information is then transferred to the plaintiffs' computers.

35. Plaintiffs obtain all of their prescription information, including information on prescriptions filled in Vermont, from computers that are located outside of Vermont.

36. Plaintiffs add value to prescriber-identifiable data by combining the data with prescriber reference information contained in their databases. This allows the plaintiffs to, among other things (a) match each prescription to the correct prescriber, (b) identify and use the correct name of the prescriber, and (c) add address, specialty and other professional information about the prescriber to the prescription data. Prescriber reference files are created using information obtained from various sources, including the American Medical Association's Physician Masterfile. The AMA's Masterfile contains demographic, educational, certification, licensure, and specialty information for more than 800,000 active U.S. medical doctors (MDs) and over 90% of the doctors of osteopathy (DOs), including members and nonmembers alike.³ The health information publishers use the patient de-identified prescription data, together with the reference file information, to produce a variety of databases.

37. Plaintiffs use these databases to create a number of different reports and services regarding prescribed pharmaceutical products, some of which include prescriber-identifiable information and some of which is aggregated and reported at a broader geographic level. Plaintiffs then license the information from these reports and services to third parties for many different uses.

38. The patient de-identified prescription data that the plaintiffs supply to their pharmaceutical and biotechnology subscribers are used for many purposes. The prescription data, for example, are used by these subscribers to:

³ As of July 1, 2006, the AMA has made it possible for all physicians, including those in Vermont, to choose whether to prevent the release of prescriber-identifiable information about them to pharmaceutical sales representatives by participating in the Prescribing Data Restriction Program ("PDRP"). See www.ama-assn.org/go/prescribingdata.

- a. Prioritize the release of public safety news alerts based on physician prescribing details;
- b. Accelerate innovation through insight into the needs and habits of those whose health the new drugs are designed to improve;
- c. Determine which products to develop and license and which acquisitions to consider;
- d. Disseminate effectively and quickly vital, life-prolonging information to those prescribers for whom the information is relevant and most useful;
- e. Allocate effectively valuable, life-prolonging sample medications to those prescribers whose patients need them most and are more likely to use them;
- f. Determine whether a particular prescriber is prescribing products that the pharmaceutical companies have determined to be inappropriate in light of the development of new products that may be more effective, safer, or less expensive;
- g. Implement prescription drug recall programs;
- h. Evaluate, segment, target, size, compensate and deploy its sales force;
- i. Allocate limited marketing resources to individual prescribers in a manner that reduces cost and saves time; and
- j. Understand managed care's effect on the U.S. pharmaceutical marketplace.

39. Plaintiffs also provide patient de-identified prescription data without charge to academic researchers, medical researchers, government agencies, industry observers and others for a variety of purposes that are unrelated to the sale of a particular product.

40. Plaintiffs do not sell, market or promote pharmaceutical products or drugs to prescribers.

41. Patient de-identified prescription information without prescriber-identifiable information is not an adequate substitute for accurate information regarding the actual prescriptions written by individual physicians for many reasons, including: (a) pharmacies fill prescriptions that come from distant prescribers, (b) information from pharmacies frequently

does not include accurate zip code information for the prescriber, (c) information from pharmacies does not include the specialty of the prescribers who wrote the prescription, (d) the information is not useful for all of the uses described in paragraphs 38-39 above, and (e) significant errors in the information cannot be ascertained.

History of the Prescription Restraint Law

42. The sponsors of the Prescription Restraint Law have asserted that restrictions on the use or disclosure of prescriber-identifiable prescribing information are necessary for two reasons: to protect the privacy of prescribers and prescribing information, and to ensure costs are contained in the private health care sector, as well as for state purchasers of prescription drugs. They have argued that the disclosure of prescriber-identifiable information to pharmaceutical companies gives pharmaceutical sales representatives (also known as “detailers”) too much insight into prescriber behavior that often leads to inappropriate confrontation or coercion of prescribers about the products they prescribe.

43. The sponsors and supporters of the Prescription Restraint Law have also argued that (a) pharmaceutical sales representatives usually sell new branded drugs, (b) branded drugs are more expensive than generic drugs, and (c) by knowing the behavior of prescribers, the sales representatives will be better equipped to target their advertising and persuade the doctors to prescribe the branded drugs over the less costly generic drugs.

44. These assertions ignore that pharmaceutical sales have occurred for decades and the Prescription Restraint Law does nothing to stop or regulate inappropriate detailing practices. More importantly, the assertions made to justify the enactment of the Prescription Restraint Law make the following unstated assumptions: (a) prescribers, all of whom are highly-educated and licensed healthcare professionals, are incapable of evaluating for themselves truthful and

accurate information regarding their own prescribing practices, rejecting or simply ignoring such information if they do not find it significant; (b) prescribers are unable to consider information from various sources (including information from pharmaceutical companies) to make a professional judgment regarding the most appropriate medication for each patient; (c) higher cost branded pharmaceuticals will always result in higher overall costs of patient care; and (d) if government regulators decide what information should be communicated by pharmaceutical companies, then the cost of prescription drugs to consumers will decline. These assumptions are unsupported by experience, evidence, or logic.

45. No studies have been performed that would support the conclusion that the price of prescription drugs would decrease if pharmaceutical companies were unable to use prescriber information in connection with their targeted marketing activities. In fact, the price of prescription drugs may increase because the costs associated with marketing pharmaceutical drugs are likely to increase as pharmaceutical companies are unable to focus their resources to the relevant market. In addition, overall healthcare costs are likely to increase because prescribers will have less information regarding the drugs they should be prescribing.

46. The legislative history of the Prescription Restraint Law reflects that the Vermont Legislature had intended to enact a law that would have been similar to the New Hampshire law, but that when the Legislature learned that the New Hampshire law had been declared unconstitutional, it created findings to attempt to support the bill within a matter of several days and amended the bill to allow the use of prescriber-identifiable data in prescription records for marketing or promoting a prescription drug if (a) the prescriber who is the subject of the information expressly consents to such use, and (b) the entity using the information for such purpose makes certain disclosures to be provided for by rule.

The Prescription Restraint Law

47. The Prescription Restraint Law, as enacted, Vt. Acts No. 80 § 17 (2007), amended title 18 of the Vermont Statutes to provide:

§ 4631. CONFIDENTIALITY OF PRESCRIPTION INFORMATION

(a) It is the intent of the general assembly to advance the state's interest in protecting the public health of Vermonters, protecting the privacy of prescribers and prescribing information, and to ensure costs are contained in the private health care sector, as well as for state purchasers of prescription drugs, through the promotion of less costly drugs and ensuring prescribers receive unbiased information.

(b) As used in this section:

(1) "Electronic transmission intermediary" means an entity that provides the infrastructure that connects the computer systems or other electronic devices used by health care professionals, prescribers, pharmacies, health care facilities and pharmacy benefit managers, health insurers, third-party administrators, and agents and contractors of those persons in order to facilitate the secure transmission of an individual's prescription drug order, refill, authorization request, claim, payment, or other prescription drug information.

(2) "Health care facility" shall have the same meaning as in section 9402 of this title.

(3) "Health care professional" shall have the same meaning as in section 9402 of this title.

(4) "Health insurer" shall have the same meaning as in section 9410 of this title.

(5) "Marketing" shall include advertising, promotion, or any activity that is intended to be used or is used to influence sales or the market share of a prescription drug, influence or evaluate the prescribing behavior of an individual health care professional to promote a prescription drug, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.

(6) "Pharmacy" means any individual or entity licensed or registered under chapter 36 of Title 26.

(7) "Prescriber" means an individual allowed by law to prescribe and administer prescription drugs in the course of professional practice.

(8) “Promotion” or “promote” means any activity or product the intention of which is to advertise or publicize a prescription drug, including a brochure, media advertisement or announcement, poster, free sample, detailing visit, or personal appearance.

(9) “Regulated records” means information or documentation from a prescription written by a prescriber doing business in Vermont or a prescription dispensed in Vermont.

(c)(1) The department of health and the office of professional regulation, in consultation with the appropriate licensing boards, shall establish a prescriber data-sharing program to allow a prescriber to give consent for his or her identifying information to be used for the purposes described under subsection (d) of this section. The department and office shall solicit the prescriber’s consent on licensing applications or renewal forms and shall provide a prescriber a method for revoking his or her consent. The department and office may establish rules for this program.

(2) The department or office shall make available the list of prescribers who have consented to sharing their information. Entities who wish to use the information as provided for in this section shall review the list at minimum every six months.

(d) A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity may use regulated records which include prescription information containing prescriber-identifiable data for marketing or promoting a prescription drug only if:

(1)(A) a prescriber has provided consent for the use of that data as provided in subsection (c) of this section; and

(B) the entity using the regulated records complies with the disclosure requirements in subsection (f) of this section; or

(2) the entity meets one of the exceptions provided in subsection (e) of this section.

(e) This section shall not apply to:

(1) the license, transfer, use, or sale of regulated records for the limited purposes of pharmacy reimbursement; prescription drug formulary compliance; patient care management; utilization review by a health care professional, the patient’s health insurer, or the agent of either; or health care research;

(2) the dispensing of prescription medications to a patient or to the patient's authorized representative;

(3) the transmission of prescription information between an authorized prescriber and a licensed pharmacy, between licensed pharmacies, or that may occur in the event a pharmacy's ownership is changed or transferred;

(4) care management educational communications provided to a patient about the patient's health condition, adherence to a prescribed course of therapy and other information relating to the drug being dispensed, treatment options, recall or patient safety notices, or clinical trials;

(5) the collection, use, or disclosure of prescription information or other regulatory activity as authorized by chapter 84, chapter 84A, or section 9410 of this title, or as otherwise provided by law;

(6) the collection and transmission of prescription information to a Vermont or federal law enforcement officer engaged in his or her official duties as otherwise provided by law; and

(7) the collection, use, transfer, or sale of patient and prescriber data for marketing or promoting if the data do not identify a prescriber, and there is no reasonable basis to believe that the data provided could be used to identify a prescriber.

(f) When a pharmaceutical marketer engages in any form of prescription drug marketing directly to a physician or other person authorized to prescribe prescription drugs as provided for under this section, the marketer shall disclose to the prescriber evidence-based information as provided for by rule describing the specific health benefits or risks of using other pharmaceutical drugs, including drugs available over the counter; which patients would gain from the health benefits or be susceptible to the risks described; the range of prescription drug treatment options; and the cost of the treatment options. As necessary, the office of Vermont health access, in consultation with the department of health, the area centers on health education, the office of professional regulation, and the office of the attorney general, shall develop rules for compliance with this subsection, including the certification of materials which are evidence-based as defined in section 4621 of this title and which conditions have evidence-based treatment guidelines. The rules shall be consistent with the federal Food and Drug Administration's regulations regarding false and misleading advertising. To the extent practicable, the rules shall use the evidence-based standards developed by the blueprint for health.

(g) In addition to any other remedy provided by law, the attorney general may file an action in superior court for a violation of this section or of any rules adopted under this section by the attorney general. The attorney general shall

have the same authority to investigate and to obtain remedies as if the action were brought under the Vermont consumer fraud act, chapter 63 of Title 9. Each violation of this section or of any rules adopted under this section by the attorney general constitutes a separate civil violation for which the attorney general may obtain relief.

Violations of the Law are Punishable by Severe Penalties

48. Section 21 of Vt. Acts No. 80 (2007) amends 9 V.S.A., chapter 63, to make a violation of section 17 a violation of the consumer protection and false advertising laws. Chapter 63 authorizes injunctive relief and the imposition of a civil penalty of not more than \$10,000.00 for each violation of its general provisions); imprisonment of up to 18 months or fines not more than \$10,000, or both, for making prohibited telephone solicitations; and imprisonment of up to 1 year or fines not more than \$1,000, or both, for violations of children's product safety provisions. The new law leaves unclear whether all of these civil and criminal remedies are available to punish a violation of the Prescription Restraint Law. Because the plaintiffs acquire and publish millions of discrete pieces of information from regulated records, the Attorney General could seek to impose vast penalties on the plaintiffs and their sources, subscribers, or customers if they continued to engage in their ordinary business practices after the effective date of the law.

Damage Inflicted by the Law on the Plaintiffs & Others

49. The Prescription Restraint Law imposes serious and irreparable injury on (a) the plaintiffs' use of regulated records which include prescription information containing prescriber-identifiable data for marketing or promoting a prescription drug, (b) pharmacies' and other entities' use of regulated records which include prescription information containing prescriber-identifiable data for marketing or promoting a prescription drug, and (c) pharmaceutical companies, health care researchers, prescribers, and patients, all of whom benefit from the plaintiffs' and other entities' use of regulated records which include prescription

information containing prescriber-identifiable data for marketing or promoting a prescription drug.

50. If the health information publishers cannot use the information other than for purposes identified as permissible in the Prescription Restraint Law, neither the health information publishers nor any other persons or entities will be able to continue acquiring the information, aggregating the information, analyzing the information, and distributing the information to third parties, either for purposes allowed or for purposes prohibited by the Prescription Restraint Law.

51. It is highly improbable that a significant number of prescribers will avail themselves of the procedures to consent to the use of the regulated records for marketing and promotion of prescription drugs or that manufacturers that use the information from the regulated records would or could agree to make disclosures required by the law in connection with their marketing and promotion activities. The law therefore will operate to freeze all or virtually all communication of prescriber identifiable information from the regulated records.

52. Section 24b of Vt. Acts No. 80 (2007) provides that the act shall become effective no later than January 1, 2008, except that the Department of Health and the Office of Professional Regulation may begin any necessary rulemaking, revision of forms, or other administrative actions necessary to implement the program, immediately upon passage. It also provides that the Department and Office may implement the Prescription Restraint Law for prescribers with licenses at the time of passage of the law when the prescriber next requests a renewal of the license.

The Imminent Threat & Reasonable Fear of Enforcement

53. After the law was enacted, plaintiffs' counsel wrote to the Attorney General's

office to determine whether the plaintiffs, their sources, and their subscribers would be subject to an enforcement action if they continued their existing business practices.

54. To date, the attorney general has provided no assurances that the law would not be enforced as soon as it becomes effective.

55. Plaintiffs have concrete plans to engage, after January 1, 2008, in activity proscribed by the law: purchasing and selling prescription information showing the prescribing practices of prescribers doing business in Vermont or whose prescriptions are filled in Vermont.

56. Plaintiffs have a reasonable fear that an action for injunctive relief and damages would be brought by the Attorney General if they execute those concrete plans on or after January 1, 2008.

Count I

The Prescription Restraint Law Violates the First Amendment by Prohibiting the Plaintiffs' Commercial Speech

57. Plaintiffs re-allege paragraphs 1 through 56 and incorporate them herein by reference.

58. The Prescription Restraint Law prohibits commercial speech through its restriction on the use of records relative to prescription information containing prescriber-identifiable data for specified "marketing" and "promotional" purposes.

59. The Prescription Restraint Law does not directly advance the interests that it purports to serve. Indeed, the statute appears to be taking the most indirect route that it possibly could take to achieve its objectives. Instead of imposing direct regulations on the manner in which pharmaceutical companies market their products or the pricing of the products, the statute attempts to prevent the information that pharmaceutical companies would like to consider in deciding how to market their products from being licensed, sold, used or transferred for any of a

broad range of commercial purposes, many of which may be unrelated to advertising. The State of Vermont may regulate the marketing or promotional practices or the pricing decisions of pharmaceutical companies, but it may not, without violating the First Amendment, do so indirectly by imposing restrictions on the dissemination of truthful information used by such companies to make advertising and other decisions in the hope that such indirect regulation will have the intended regulatory effect. There is no evidence, of course, that the Prescription Restraint Law would directly advance any of the justifications that the State may assert justify the legislation. Imposition of direct regulation on the advertising and pricing of pharmaceutical companies itself raises a host of constitutional concerns, but the State should not be permitted to achieve indirectly by suppression of constitutionally protected speech what it is prohibited from regulating directly.

60. The Prescription Restraint Law also is broader than necessary to accomplish the interests that it purports to serve. The State of Vermont has either failed to implement and test or has rejected less restrictive alternatives to the Prescription Restraint Law. If it is the State's contention that prescribers are mis-prescribing pharmaceutical products for personal gain, the State can, among other things, prosecute physicians for engaging in such practices. If it is the State's contention that prescribers are being misled by pharmaceutical companies with false and misleading information, the State can, among other things, impose severe penalties on pharmaceutical companies for doing so. If it is the State's contention that prescribers do not have sufficient information concerning competing generic drugs that are not marketed by pharmaceutical companies, then the State can, among other things, provide additional information to prescribers or require education of prescribers in this regard as a condition of

continued licensing. None of these alternatives would require the suppression of constitutionally protected speech in order to achieve the State's objectives.

61. The Prescription Restraint Law therefore violates the First and Fourteenth Amendments of the United States Constitution as it is applied to the commercial speech in which the plaintiffs engage in the regular course of their business.

Count II

The Prescription Restraint Law Violates the First Amendment by Restricting the Plaintiffs' Non-Commercial Speech

62. Plaintiffs reallege paragraphs 1 through 56 and incorporate them herein by reference.

63. The Prescription Restraint Law prohibits the use of records relative to prescription information containing prescriber-identifiable data for specified "marketing" and "promotion" of prescription drugs.

64. "Marketing" is broadly defined in the statute as "advertising, promotion or any activity that is intended to be used or is used to influence sales or the market share of a prescription drug, influence or evaluate the prescribing behavior or an individual health care professional to promote a prescription drug, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing force."

65. "Promotion" or "promote" is broadly defined in the statute as "any activity or product the intention of which is to advertise or publicize a prescription drug, including a brochure, media advertisement or announcement, poster, free sample, detailing visit, or personal appearance."

66. These definitions sweep within their ambit substantial non-commercial speech in which the plaintiffs engage that would not be regarded as "commercial speech."

67. The fact that information may be sold for a profit does not transform the speech into “marketing” or “promotion.” Newspapers, magazines, and other publishers of information all sell information for a profit; yet their speech is recognized as “non-commercial” because it serves important public purposes unrelated to advertisement. Commercial speech is speech that does no more than propose a commercial transaction.

68. When pharmacies and other entities with prescription information sell patient de-identified information to the health information publishers, they are not proposing a commercial transaction, and certainly they are not engaged in marketing or promotion of a prescription drug. They are conveying truthful information that lawfully is in their possession to a third party that is interested in learning the information and using the information for a myriad of purposes, including both commercial purposes and non-commercial purposes. A substantial amount of the commercial purposes for which the information is obtained are for profit, but are not for the purpose of proposing a commercial transaction.

69. Many of the purposes for which the information is obtained are not for advertising, promotional, or marketing activities, but for purposes that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual healthcare professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.

70. When the plaintiffs license, sell or transfer patient de-identified prescription information to third parties, the third parties use the information for a myriad of purposes. While some of the uses to which they put the information are for the purpose of proposing a commercial transaction, many of the purposes to which they put the information are not for proposing a commercial transaction.

71. The Prescription Restraint Law restricts non-commercial speech on the basis of its content.

72. The State of Vermont lacks a compelling justification for prohibiting non-commercial speech through its prohibition against the use of prescription records containing prescriber-identifiable data by health insurers, self-insured employers, electronic transmission intermediaries, pharmacies or similar entities for “marketing” or “promotion” of prescription drugs, as those terms are broadly defined in the statute.

73. The Prescription Restraint Law is not the least restrictive means of achieving the purpose of the Prescription Restraint Law.

74. In addition, the Prescription Restraint Law is not limited in its operation to the imposition of fines upon violators; it also sets up a system of prior restraint against future speech that communicates truthful, important and lawfully-obtained information about a prescriber. Any system of prior restraint comes to this Court bearing a heavy presumption against its constitutional validity. In order to be constitutional, the statute must fit within one of the narrowly defined exceptions to the prohibition against prior restraints and must include procedural safeguards that reduce the danger of suppressing constitutionally protected speech. The statute does not fit within any recognized category of valid prior restraints, and it does not contain procedural safeguards that are required for a valid system of prior restraints.

75. The Prescription Restraint Law also lacks the procedural safeguards that are required to uphold a law that creates a system of prior restraint. The law prohibits private parties in *advance* of publication of publishing lawfully-obtained, truthful, and important information about the prescribing practices of individual prescribers. By allowing prescribers to lift the ban, the state has designated each prescriber as the licensor of the pharmacy’s right to distribute

prescriber-identifiable data, but has defined no criteria to prevent exercise of this unfettered power for improper censorial purposes and no time restraints on when a prescriber would be required to act on a request to publish data pertaining to him or her. Accordingly, the law is an invalid restraint on speech.

76. The Prescription Restraint Law therefore violates the First and Fourteenth Amendments of the United States Constitution facially and as it is applied to the non-commercial speech in which the plaintiff health information publishers engage in the regular course of their businesses.

Count III

The Prescription Restraint Law is Void for Vagueness & Overbreadth

77. Plaintiffs reallege paragraphs 1 through 56 and incorporate them herein by reference.

78. The Prescription Restraint Law is vague and overbroad.

79. Section 4631(d), 18 Vt. Stat. Ann., provides that the covered entities may use regulated records which include prescription information containing prescriber identifiable data for marketing or promoting a prescription drug only if a prescriber has provided consent for the use of that data and the entity using the regulated records complies with certain disclosure requirements or the entity meets one of several specified exceptions.

80. Section 4631(b) defines “marketing” as “advertising, promotion or any activity that *is intended* to be used or is used to influence sales or the market share of a prescription drug, influence or evaluate the prescribing behavior or an individual health care professional to promote a prescription drug, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing force.” (emphasis added). This section makes it

unclear whether the use of covered data by a covered entity that merely is “intended to be used” for marketing or promotion, but is not actually used by the covered entity for such purposes, would violate the statute in the absence of consent and compliance with required disclosure requirements or the application of exceptions. Moreover, the definition does not specify whether the intended use refers to the intention of the pharmacy or similar entity, the intention of the health information publishers, or the intention of the pharmaceutical or biotechnology company that must be taken into account before prescriber-identifiable data can be used in a manner consistent with the statute. Further, the definition does not specify whether the controlling purpose or intent is the purpose at the time of the affected transaction or the purpose or intent at some subsequent time such as the time of the actual use of the information in marketing and promotion of prescription drugs.

81. Section 4631(d) does not state whether the marketing or promotion must be conducted by the acquirer of the information, the provider of the information, the ultimate consumer of the information, or some combination of all of these. The statute does not inform a reader which entity or person must conduct the marketing or promotion before running afoul of section 4631(d).

82. The disclosure requirements referenced in section 4631(d) are set forth in section 4631(f). It states:

When a pharmaceutical marketer engages in any form of prescription drug marketing directly to a physician or other person authorized to prescribe prescription drugs as provided for under this section, the marketer shall disclose to the prescriber evidence-based information as provided for by rule describing the specific health benefits or risks of using other pharmaceutical drugs, including drugs available over the counter; which patients would gain from the health benefits or be susceptible to the risks described; the range of prescription drug treatment options; and the cost of the treatment options. As necessary, the office of Vermont health access, in consultation with the department of health, the area centers on health education, the office of professional regulation, and the office of

the attorney general, shall develop rules for compliance with this subsection, including the certification of materials which are evidence-based as defined in section 4621 of this title and which conditions have evidence-based treatment guidelines. The rules shall be consistent with the federal Food and Drug Administration's regulations regarding false and misleading advertising. To the extent practicable, the rules shall use the evidence-based standards developed by the blueprint for health.

83. Section 4631(f) does not indicate what is meant by the language "as provided for under this section." It may mean that the disclosures must be made if the pharmaceutical marketer uses prescriber-identifiable data, or it may mean that disclosures must be made whether the pharmaceutical marketer uses prescriber-identifiable data or not.

84. Section 4631(f) fails to provide sufficiently specific criteria for the Office of Vermont Health Access (OVHA) to develop rules necessary to implement the disclosure requirements.

85. Section 4631(f) fails to impose any time limits on OVHA for developing rules necessary to implement the disclosure requirements.

86. OVHA cannot promulgate the rules required by section 4631(f) because thousands of drugs are being marketed and it is impossible to determine for each such drug the specific health benefits or risks of using *other* pharmaceutical drugs, including drugs available over the counter; which patients would gain from the health benefits or be susceptible to the risks described; the range of prescription drug treatment options; and the cost of the treatment options.

87. Section 4631(f) fails to define what is meant by the term "other pharmaceutical drugs," and this term cannot reasonably be ascertained by either an ordinary reader or a highly sophisticated reader. The term not only is extraordinarily vague, but also constitutes an unlawful delegation of legislative authority.

88. Section 4631(f) requires the referenced rules to be "consistent with the federal Food and Drug Administration's regulations regarding false and misleading advertising."

OVHA cannot determine whether rules describing disclosure requirements for the thousands of drugs being marketed are “consistent” with such regulations.

89. The exceptions to the prohibition imposed by section 4631(d) include “patient care management,” “utilization review,” “health care research” or “as otherwise provided by law.” The statute does not define these terms, and they are subject to broadly varying interpretations.

90. Section 4631(f) does not specify whether marketing that uses prescriber-identifiable data may continue without making the statutory disclosures until such time as OVHA promulgates rules that describe the disclosures that the statute requires; may continue until such time as OVHA promulgates rules that describe the disclosures that the statute requires, but must make the disclosures required by the statute itself; or must halt such marketing until such rules are promulgated. Thus, plaintiffs cannot determine from the vague language of the statute whether they may continue to sell prescriber-identifiable data for marketing purposes to pharmaceutical marketers even where they have the consent of prescribers to do so.

91. Even if OVHA were to adopt rules consistent with the requirements of section 4631(f) and pharmaceutical marketers were to assert that they would comply with the required disclosure requirements, the plaintiffs would have no means of reliably determining whether the pharmaceutical marketers were making the disclosures or whether such disclosures were in fact made in compliance with the statute and rules because the disclosures required by the statute are so vague. Nevertheless, the statute imposes severe penalties for communicating prescriber-identifiable data to pharmaceutical marketers for marketing purposes if the pharmaceutical marketers themselves fail to make the required disclosure. Under these circumstances, plaintiffs will not take the risk of communicating prescriber-identifiable data to pharmaceutical marketers

for marketing purposes even if rules are enacted describing the required disclosures and even if pharmaceutical marketers contend that they will comply with the rules and the statute and the plaintiffs have the consent of prescribers to use prescriber-identifiable data for marketing purposes.

92. Given the vague contours of the coverage and requirements of the statute, it will silence a substantial amount of speech that the state has no justification for silencing. Health information publishers, including the plaintiffs, no longer will communicate for *any* purpose information from prescription records that shows the prescribing practices of individual prescribers doing business in Vermont or whose prescriptions are dispensed in Vermont because of the real risk that they, their sources, and their subscribers and customers will be charged with violating the statute.

93. This law fails to give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he or she may act accordingly. It may trap the innocent by not providing fair warning.

94. The vagueness of the law also creates a risk of arbitrary and discriminatory enforcement by impermissibly delegating basic policy matters to administrative agencies, law enforcement officers, judges, and juries for resolution on an ad hoc and subjective basis, with the attendant dangers of arbitrary and discriminatory application.

95. The vagueness of the Prescription Restraint Law also is a matter of special concern for two additional reasons:

a. First, the Prescription Restraint Law is a content based regulation of speech. The vagueness of such a regulation raises special First Amendment concerns because of its obvious chilling effect on free speech.

b. Second, the Prescription Restraint Law imposes severe monetary penalties and potential imprisonment for violations. The severity of the sanctions may well cause speakers to remain silent rather than communicate even arguably lawful words, ideas, and images. As a practical matter, this increased deterrent effect, coupled with the “risk of discriminatory enforcement” of vague regulations, poses grave First Amendment concerns.

96. The uncertain meaning of the law will force plaintiffs to “steer far wider of the unlawful zone than if the boundaries of the forbidden areas were clearly marked.”

97. The Prescription Restraint Law accordingly violates the First and Fourteenth Amendments for vagueness and overbreadth.

Count IV

The Prescription Restraint Law Violates the Commerce Clause

98. Plaintiffs reallege paragraphs 1 through 56 and incorporate them herein by reference.

99. The Prescription Restraint Law impermissibly regulates conduct occurring wholly outside of Vermont.

100. The plaintiff health information publishers are located outside of Vermont. They collect outside of Vermont prescriber identifiable data relating to prescribers who do business in Vermont and whose prescriptions are dispensed in Vermont and store this data in databases located outside of Vermont. All of the prescriber identifiable data received by the health information publishers is supplied by companies located outside of Vermont. The Prescription

Restraint Law makes it illegal for pharmacies and other similar entities to continue providing prescriber identifiable data to the health information publishers for purposes restricted by the Prescription Restraint Law in the absence of prescriber consent and the making of certain disclosures or the applicability of various exceptions. As a result, all such data received by the health information publishers cannot be licensed, transferred, used, or sold anywhere, even outside of Vermont.

101. Accordingly, the Prescription Restraint Law violates the Commerce Clause of the United States Constitution.

Count V

The Prescription Restraint Law Is Preempted

102. Plaintiffs reallege paragraphs 1 through 56 and incorporate them herein by reference.

103. Congress has occupied the field of regulation of marketing of prescription drugs through enactment of the Federal Food, Drug and Cosmetic Act. 21 U.S.C. §§ 301 et seq.

104. Congress also has given the Food and Drug Administration (FDA) extensive authority to regulate communications between drug marketers and prescribers, and a pervasive scheme of federal regulation exists. The FDA has broad authority to regulate drug advertisements and promotional labeling.

105. The FDA itself has asserted that its authority preempts state law that imposes greater disclosure requirements on pharmaceutical manufacturers than those required by the FDA itself. See *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006).

106. The Prescription Restraint Law also requires pharmaceutical marketers who engage in marketing directly to a physician to make disclosures that are in conflict with federal law and the regulatory authority of the FDA.

107. Accordingly, the Prescription Restraint Law is preempted by the Food & Drug Act, the Food Drug & Cosmetic Act, regulations promulgated thereunder, and the FDA.

DEMAND FOR RELIEF

Wherefore the plaintiffs demand:

A. A declaration that the Prescription Restraint Law is unconstitutional, as applied to commercial speech.

B. A declaration that the Prescription Restraint Law is unconstitutional both facially and as applied to non-commercial speech.

C. A declaration that the Prescription Restraint Law is unconstitutional, both facially and as applied because it regulates speech using such vague and overly broad terms which will result in the silencing of an amount of protected speech that is proportionally vast when compared to the amount of unprotected speech, if any, that the law constitutionally may restrain.

D. A declaration that the Prescription Restraint Law violates the Commerce Clause of the United States Constitution by regulating transactions in commerce that take place wholly outside of the State of Vermont.

E. A declaration that the Prescription Restraint Law is preempted by the Federal Food Drug & Cosmetic Act, preambles, rules, and regulations thereunder, and by the FDA.

F. A permanent and preliminary injunction against the enforcement of the Prescription Restraint Law.

G. The costs and attorneys' fees that the plaintiffs have incurred in bringing this

action, as is provided for by 42 U.S.C. § 1988.

H. Such other relief that the Court may deem to be necessary or appropriate to afford the plaintiffs the full relief to which they are entitled.

Respectfully submitted,

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**U.S. District Court
District of Vermont (Brattleboro)
CIVIL DOCKET FOR CASE #: 1:07-cv-00188-jgm**

IMS Health Incorporated et al v. Sorrell
Assigned to: Judge J. Garvan Murtha
Member case: ([View Member Case](#))
Cause: 42:1981 Civil Rights

Date Filed: 08/29/2007
Jury Demand: None
Nature of Suit: 440 Civil Rights: Other
Jurisdiction: Federal Question

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Date Filed	#	Docket Text
08/29/2007	<u>1</u>	COMPLAINT (Preliminary and Permanent Injunctive Relief Sought Before Jan. 1, 2008) against William H. Sorrell filed by IMS Health Incorporated; Verispan, LLC; Source Healthcare Analytics, Inc. (Filing fee \$350) Summons issued. (Attachments: # <u>1</u> Exhibit A (1 of 2)# <u>2</u> Exhibit A (2 of 2)# <u>3</u> Civil Cover Sheet)(law) (Entered: 08/29/2007)

08/29/2007	<u>2</u>	MOTION for Admission Pro Hac Vice by IMS Health Incorporated; Verispan, LLC; Source Healthcare Analytics, Inc. (Attachments: # <u>1</u> Declaration of Thomas R. Julin# <u>2</u> Declaration of Patricia Acosta# <u>3</u> Declaration of Michelle Milberg# <u>4</u> Declaration of Mark Ash)(law) (Attachment: # <u>5</u> Main document (replaced) 10/10/2007)(jmm) (Entered: 08/29/2007)
08/30/2007	<u>3</u>	CORPORATE DISCLOSURE STATEMENT pursuant to Local Rule 5.2(b) by IMS Health Incorporated; Verispan, LLC; Source Healthcare Analytics, Inc. (law) (Entered: 08/30/2007)
08/30/2007	<u>4</u>	MOTION for Early Rule 16 Conference by IMS Health Incorporated; Verispan, LLC; Source Healthcare Analytics, Inc.(law) (Entered: 08/30/2007)
08/30/2007	<u>5</u>	MOTION to Exceed Page Limitation for Memorandum in Support of Motion for Preliminary Injunction by IMS Health Incorporated; Verispan, LLC; Source Healthcare Analytics, Inc.(law) (Entered: 08/30/2007)
08/30/2007	<u>6</u>	MOTION for Preliminary Injunction by IMS Health Incorporated; Verispan, LLC; Source Healthcare Analytics, Inc. (Attachments: # <u>1</u> Memorandum in Support (1 of 3)# <u>2</u> Memorandum in Support (2 of 3)# <u>3</u> Memorandum in Support (3 of 3)# <u>4</u> Declaration of Randolph B. Frankel# <u>5</u> Declaration of Hossam Sadek# <u>6</u> Declaration of Jody Fisher# <u>7</u> Declaration of Carol Livingston# <u>8</u> Declaration of Thomas P. Wharton Jr., M.D., F.A.C.C.# <u>9</u> Declaration of Andrew J. Cole, M.D., F.R.C.P. (C.) (1 of 2)# <u>10</u> Declaration of Andrew J. Cole, M.D., F.R.C.P. (C.) (2 of 2)# <u>11</u> Declaration of Goran Ando# <u>12</u> Declaration of John Glaser# <u>13</u> Declaration of CVS Caremark Corporation# <u>14</u> Declaration of Rite Aid# <u>15</u> Declaration of Michael A. Turner, Ph.D. (1 of 4)# <u>16</u> Declaration of Michael A. Turner, Ph.D. (2 of 4)# <u>17</u> Declaration of Michael A. Turner, Ph.D. (3 of 4)# <u>18</u> Declaration of Michael A. Turner, Ph.D. (4 of 4)# <u>19</u> Declaration of Joseph W. Duncan)(law) (Entered: 08/30/2007)
08/30/2007	<u>7</u>	REQUEST for Judicial Notice by IMS Health Incorporated; Verispan, LLC; Source Healthcare Analytics, Inc. (Attachments: # <u>1</u> Affidavit 1 (Part 1 of 8)# <u>2</u> Exhibit 1 (Part 2 of 8)# <u>3</u> Exhibit 1 (Part 3 of 8)# <u>4</u> Exhibit 1 (Part 4 of 8)# <u>5</u> Exhibit 1 (Part 5 of 8)# <u>6</u> Exhibit 1 (Part 6 of 8)# <u>7</u> Exhibit 1 (Part 7 of 8)# <u>8</u> Exhibit 1 (Part 8 of 8)# <u>9</u> Exhibit 2# <u>10</u> Exhibit 3 (Part 1 of 9)# <u>11</u> Exhibit 3 (Part 2 of 9)# <u>12</u> Exhibit 3 (Part 3 of 9)# <u>13</u> Exhibit 3 (Part 4 of 9)# <u>14</u> Exhibit 3 (Part 5 of 9)# <u>15</u> Exhibit 3 (Part 6 of 9)# <u>16</u> Exhibit 3 (Part 7 of 9)# <u>17</u> Exhibit 3 (Part 8 of 9)# <u>18</u> Exhibit 3 (Part 9 of 9)# <u>19</u> Exhibit 4) (NOTE: exhibits too voluminous for one entry, please see <u>8</u> and <u>9</u> for Exhibits 5 &6)(law) (Entered: 08/30/2007)
08/30/2007	<u>8</u>	EXHIBIT 5 & EXHIBIT 6 (Part 1 of 2) re: Request for Judicial Notice by IMS Health Incorporated; Verispan, LLC; Source Healthcare Analytics, Inc. (Attachments: # <u>1</u> Exhibit 5 (Part 1 of 5)# <u>2</u> Exhibit 5 (Part 2 of 5)# <u>3</u> Exhibit 5 (Part 3 of 5)# <u>4</u> Exhibit 5 (Part 4 of 5)# <u>5</u> Exhibit 5 (Part 5 of 5)# <u>6</u> Exhibit 6 (CD 07)# <u>7</u> Exhibit 6 (CD 47 and CD 48) (Part 1 of 2)# <u>8</u> Exhibit 6 (CD 47 and CD 48) (Part 2 of 2)# <u>9</u> Exhibit 6 (CD 51) (Part 1 of 2)# <u>10</u> Exhibit 6 (CD 51) (Part 2 of 2)# <u>11</u> Exhibit 6 (CD 52) (Part 1 of 2)# <u>12</u> Exhibit 6 (CD 52) (Part 2 of 2)# <u>13</u> Exhibit 6 (CD 54 and CD 55) (Part 1 of 2)# <u>14</u> Exhibit 6 (CD 54 and CD 55) (Part 2 of 2)# <u>15</u> Exhibit 6 (CD 56) (Part 1 of 2)# <u>16</u> Exhibit 6 (CD 56) (Part 2 of 2)# <u>17</u> Exhibit 6 (CD 57) (Part 1 of 2)# <u>18</u> Exhibit 6 (CD 57) (Part 2 of 2)) (NOTE: see <u>9</u> for continuation of Exhibit 6)(law) (Entered: 08/30/2007)
08/30/2007	<u>9</u>	EXHIBIT 6 (Part 2 of 2) re: <u>7</u> Request for Judicial Notice by IMS Health Incorporated; Verispan, LLC; Source Healthcare Analytics, Inc. (Attachments: # <u>1</u> Exhibit 6 (CD 43)# <u>2</u> Exhibit 6 (CD 46) (Part 1 of 2)# <u>3</u> Exhibit 6 (CD 46) (Part 2 of 2)# <u>4</u> Exhibit 6 (CD 49)# <u>5</u> Exhibit 6 (CD 50)# <u>6</u> Exhibit 6 (CD 51)# <u>7</u> Exhibit 6 (CD 52) (Part 1 of 2)# <u>8</u> Exhibit 6 (CD 52) (Part 2 of 2)# <u>9</u> Exhibit 6 (CD 53)# <u>10</u> Exhibit 6 (CD 54)# <u>11</u> Exhibit 6 (CD 56)# <u>12</u> Exhibit 6 (CD 57)# <u>13</u> Exhibit 6 (CD 58)# <u>14</u> Exhibit 6 (CD 87, CD 88 and CD 89) (Part 1 of 2)# <u>15</u> Exhibit 6 (CD 87, CD 88 and CD 89) (Part 2 of 2)# <u>16</u> Exhibit 6 (CD 90)# <u>17</u> Exhibit 6 (CD 117) (Part 1 of 2)# <u>18</u> Exhibit 6 (CD 117) (Part 2 of 2)# <u>19</u> Exhibit 6 (CD 118 and 119) (Part 1 of 2)# <u>20</u> Exhibit 6 (CD 118 and 119) (Part 2 of 2)# <u>21</u> Exhibit 6 (CD 122) (Part 1 of 2)# <u>22</u> Exhibit 6 (CD 122) (Part 2 of 2)) (law) (Entered: 08/30/2007)

08/30/2007	<u>10</u>	MOTION for Hearing on <u>6</u> MOTION for Preliminary Injunction by IMS Health Incorporated; Verispan, LLC; Source Healthcare Analytics, Inc.(law) (Entered: 08/30/2007)
09/05/2007	<u>11</u>	SUMMONS RETURNED Executed. William H. Sorrell served on 8/31/2007, answer due 9/20/2007. (Hemley, Robert) (Entered: 09/05/2007)
09/05/2007	<u>12</u>	NOTICE OF APPEARANCE by Bridget C. Asay, Caroline S. Earle, Kate G. Duffy on behalf of William H. Sorrell. (Asay, Bridget) (Entered: 09/05/2007)
09/11/2007	<u>13</u>	NOTICE of Filing of Declaration of Peter Barton Hutt by IMS Health Incorporated re <u>6</u> MOTION for Preliminary Injunction (Attachments: # <u>1</u> Declaration of Peter Barton Hutt)(Hemley, Robert) (Entered: 09/11/2007)
09/12/2007	<u>14</u>	NOTICE of Filing Senate Bill 115 Testimony Transcripts by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc. (Hemley, Robert) (Entered: 09/12/2007)
09/14/2007	<u>15</u>	(UNSIGN)ED MOTION for Extension of Time to File Responses to <u>6</u> MOTION for Preliminary Injunction and <u>7</u> REQUEST for Judicial Notice by William H. Sorrell.(Duffy, Kate) (Please refer to <u>17</u> for signed document)(jmm) (Entered: 09/14/2007)
09/14/2007	<u>16</u>	(UNSIGN)ED AFFIDAVIT in Support of <u>15</u> MOTION for Extension of Time to File Responses to <u>6</u> Motion for a Preliminary Injunction and <u>7</u> Request for Judicial Notice filed by William H. Sorrell. (Duffy, Kate) (Please refer to <u>18</u> for signed document)(jmm) (Entered: 09/14/2007)
09/17/2007	<u>17</u>	MOTION for Extension of Time to File Responses to <u>6</u> MOTION for Preliminary Injunction and <u>7</u> REQUEST for Judicial Notice by William H. Sorrell.(Duffy, Kate) (Entered: 09/17/2007)
09/17/2007	<u>18</u>	AFFIDAVIT of Kate G. Duffy in Support of <u>17</u> MOTION for Extension of Time to File Responses to <u>6</u> Motion for Preliminary Injunction and <u>7</u> Request for Judicial Notice by William H. Sorrell. (Duffy, Kate) (Entered: 09/17/2007)
09/19/2007	<u>19</u>	RESPONSE to <u>17</u> MOTION for Extension of Time to File Responses to <u>6</u> MOTION for Preliminary Injunction and <u>7</u> REQUEST for Judicial Notice filed by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc. (Attachments: # <u>1</u> Declaration of Robert B. Hemley)(Hemley, Robert) (Entered: 09/19/2007)
09/20/2007	<u>20</u>	ANSWER to Complaint by William H. Sorrell.(Duffy, Kate) (Entered: 09/20/2007)
09/20/2007	<u>21</u>	ENE LETTER re: Potential Evaluators sent; responses due by 10/9/2007. (law) (Entered: 09/20/2007)
09/21/2007	<u>22</u>	MEMORANDUM in Support of <u>17</u> Motion for Extension of Time to File Response re: <u>6</u> to Motion for a Preliminary Injunction by William H. Sorrell. (Attachments: # <u>1</u> Certificate of Service)(Duffy, Kate) Text Modified on 10/1/2007 (jse). (Entered: 09/21/2007)
09/24/2007	<u>23</u>	ORDER OF REASSIGNMENT. Case reassigned to Judge J. Garvan Murtha for all further proceedings. Judge William K. Sessions, III no longer assigned to case. Signed by Judge William K. Sessions III on 09/20/2007. (law) (Entered: 09/24/2007)
09/26/2007	<u>24</u>	DISCOVERY CERTIFICATE – Initial Disclosures by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc..(Byrne, Matthew) (Entered: 09/26/2007)
09/27/2007	<u>25</u>	ORDER re: Telephone Status Conference. TAKE NOTICE that this case has been scheduled for a Telephone Status Conference on Monday, October 1, 2007 at 11:00 a.m. before the Honorable J. Garvan Murtha. Plaintiff's counsel shall be responsible for initiating the call with chambers and opposing counsel. (This is a text-only order). Signed by Judge J. Garvan Murtha on 09/27/07. (jse) (Entered: 09/27/2007)

09/27/2007	<u>26</u>	NOTICE of Hearing: Telephone Status Conference set for 10/1/2007 at 11:00 AM in Brattleboro Chambers before Hon. J. Garvan Murtha. Pltfs' counsel shall be responsible for initiating the call with chambers and opposing counsel.(wjf) (Entered: 09/27/2007)
09/28/2007	<u>27</u>	SUPPLEMENTAL AFFIDAVIT of Kate G. Duffy <i>in Support of <u>17</u> Motion for Extension of Time to Respond to <u>6</u> Motion for Preliminary Injunction</i> by William H. Sorrell. (Duffy, Kate) (Entered: 09/28/2007)
09/28/2007	<u>28</u>	CERTIFICATE OF SERVICE re: <u>27</u> Supplemental Affidavit of Kate Duffy in Support of <u>17</u> Motion for Extension of Time to Respond to <u>6</u> Motion for Preliminary Injunction by William H. Sorrell. (Duffy, Kate) (Entered: 09/28/2007)
10/01/2007	29	MINUTE ENTRY for proceedings held before Judge J. Garvan Murtha: Telephone Status Conference held in chambers on 10/1/2007. Participating were Matthew Byrne, Esq., Robert Hemley, Esq., Mark Ash, Esq., and Thomas Julin, Esq. for the pltfs and Bridget Asay, Esq. and Kate Duffy, Esq. for the dft. Statements by counsel. ORDERED: Pltfs' <u>2</u> Motion for Pro Hac Vice will be granted by written order, Pltfs' <u>4</u> Motion for Early Rule 16 Conference DENIED, Pltfs' <u>10</u> Motion for Hearing DENIED, Dft's <u>17</u> Motion for Extension of time GRANTED. Parties to agree upon and submit to Court a proposed discovery schedule. Parties to agree upon date of combined hearing re: <u>6</u> Motion for Preliminary Injunction with at least one Rule 16 conference to be held prior to hearing. (Court Reporter: Coughlin) (kak) (Entered: 10/01/2007)
10/01/2007	30	ORDER granting <u>5</u> Motion to Exceed Page Limit re: Memorandum in Support of Motion for Preliminary Injunction. Signed by Judge J. Garvan Murtha on 10/01/07. (This is a text only Order.) (jse) (Entered: 10/01/2007)
10/01/2007		Reset response deadlines to 10/31/2007 as to <u>6</u> MOTION for Preliminary Injunction and <u>7</u> Request for Judicial Notice pursuant to ruling of J. Garvan Murtha at status conference held 10/1/2007. (kak) (Entered: 10/09/2007)
10/09/2007	<u>31</u>	STIPULATED MOTION for Leave to Exceed Page Limit <i>for Defendant's Opposition to <u>6</u> Motion for Preliminary Injunction</i> by William H. Sorrell.(Asay, Bridget) (Entered: 10/09/2007)
10/10/2007	32	ORDER granting <u>31</u> Stipulated Motion for Leave to Exceed Page Limit for Defendant's Opposition to <u>6</u> Motion for Preliminary Injunction. Signed by Judge J. Garvan Murtha on 10/10/2007. (This is a text only Order.) (kbl) (Entered: 10/10/2007)
10/10/2007	<u>33</u>	ORDER granting <u>2</u> MOTION for Appearance Pro Hac Vice of Thomas R. Julin, Patricia Acosta, Michelle Milberg and Mark Ash filed by Source Healthcare Analytics, Inc., Verispan, LLC, IMS Health Incorporated. Signed by Judge J. Garvan Murtha on 10/10/2007. (wjf) (Entered: 10/10/2007)
10/11/2007	<u>34</u>	STIPULATED JOINT MOTION to Excuse Case from ENE by William H. Sorrell, IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc. (Attachments: # <u>1</u> Certificate of Service)(Byrne, Matthew) (Entered: 10/11/2007)
10/12/2007	35	ORDER granting <u>34</u> Stipulated Motion to Be Excused from Early Neutral Evaluation Process. Signed by Judge J. Garvan Murtha on 10/12/2007. (This is a text only Order.) (kbl) (Entered: 10/12/2007)
10/19/2007	<u>36</u>	PROPOSED STIPULATED DISCOVERY SCHEDULE/ORDER by IMS Health Incorporated; Verispan, LLC; William H. Sorrell; Source Healthcare Analytics, Inc. (Julin, Thomas) (Text clarified, filers added 10/23/2007)(jmm) (Entered: 10/19/2007)
10/19/2007	<u>37</u>	CERTIFICATE OF SERVICE re: <u>36</u> Proposed Stipulated Discovery Schedule/Order by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc. (Julin, Thomas) (Entered: 10/19/2007)
10/22/2007	<u>38</u>	STIPULATED DISCOVERY SCHEDULE/ORDER: Discovery due by 2/28/2008. Motions due by 2/28/2008. Trial to commence on 3/24/2008. Signed

		by Judge J. Garvan Murtha on 10/22/2007. (kak) (Entered: 10/22/2007)
10/23/2007	<u>61</u>	MOTION for Preliminary Injunction by Pharmaceutical Research and Manufacturers of America. Transfer of pending motion from member case.(kak) (Entered: 12/03/2007)
10/26/2007	<u>39</u>	UNOPPOSED MOTION for Extension of Time to File Response to <u>6</u> Motion for Preliminary Injunction/Request for Judicial Notice by William H. Sorrell.(Duffy, Kate) (Entered: 10/26/2007)
10/26/2007	<u>40</u>	CERTIFICATE OF SERVICE re: <u>39</u> Motion for Extension of Time to File Response by William H. Sorrell. (Duffy, Kate) (Entered: 10/26/2007)
10/26/2007	<u>41</u>	ORDER granting <u>39</u> Unopposed Motion to Extend Time to File Response re <u>6</u> MOTION for Preliminary Injunction. Dft's response shall be filed on or before 11/7/2007. Signed by Judge J. Garvan Murtha on 10/26/2007. (This is a text only Order.) (kbl) (Entered: 10/26/2007)
10/31/2007	<u>42</u>	NOTICE of Attorney Substitution by David R. Cassetty for Caroline S. Earle as to William H. Sorrell.(Cassetty, David) (Entered: 10/31/2007)
10/31/2007	<u>43</u>	DISCOVERY CERTIFICATE – Initial Disclosures by William H. Sorrell.(Duffy, Kate) (Entered: 10/31/2007)
11/01/2007	<u>44</u>	DISCOVERY CERTIFICATE – Plaintiffs' Amended Initial Disclosures by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc.(kak) (Entered: 11/01/2007)
11/06/2007	<u>45</u>	RESPONSE in Opposition to <u>7</u> REQUEST for Judicial Notice by William H. Sorrell. (Attachments: # <u>1</u> Exhibit A)(Asay, Bridget) (Text clarified 11/6/2007)(jmm) (Entered: 11/06/2007)
11/07/2007	<u>46</u>	DISCOVERY CERTIFICATE – First Set of Interrogatories and Requests to Produce by William H. Sorrell.(Duffy, Kate) (Entered: 11/07/2007)
11/07/2007	<u>47</u>	MOTION for Partial Summary Judgment by William H. Sorrell. (Attachments: # <u>1</u> Memorandum in Support # <u>2</u> Statement of Undisputed Facts in Support of Motion for Partial Summary Judgment# <u>3</u> Affidavit of Joshua Slen)(Asay, Bridget) (Entered: 11/07/2007)
11/07/2007	<u>48</u>	RESPONSE in Opposition re <u>6</u> MOTION for Preliminary Injunction filed by William H. Sorrell. (Attachments: # <u>1</u> Memorandum in Support of Opposition to Motion for Preliminary Injunction# <u>2</u> Appendix)(Asay, Bridget) (Entered: 11/07/2007)
11/08/2007	<u>49</u>	DISCOVERY CERTIFICATE – First Set of Interrogatories and Request for Production of Documents by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc.(wjf) (Entered: 11/08/2007)
11/16/2007	<u>50</u>	MOTION to Consolidate Case (with 1:07–CV–220) by William H. Sorrell.(Duffy, Kate) (same image as <u>51</u>)(jmm) (Entered: 11/16/2007)
11/16/2007	<u>51</u>	MOTION for Status Conference re: <u>50</u> Motion to Consolidate Case (with 1:07–CV–220) by William H. Sorrell. (same image as <u>50</u>)(kak) (Entered: 11/19/2007)
11/16/2007	<u>62</u>	STIPULATED MOTION to be Excused from ENE by William H. Sorrell, Jim Douglas and Cynthia D. LaWare. Transfer of pending motion from member case.(kak) (Entered: 12/03/2007)
11/20/2007	<u>52</u>	MOTION for Extension of Time to File Reply to <u>6</u> MOTION for Preliminary Injunction and to File Response to <u>47</u> MOTION for Partial Summary Judgment and MOTION to Permit Reply Brief to Exceed Page Limit by IMS Health Incorporated.(Byrne, Matthew) (Text re: Motion to Exceed Page Limit added 11/26/2007)(jmm) (Entered: 11/20/2007)
11/21/2007	<u>53</u>	SUPPLEMENT Indicating Consent to <u>52</u> MOTION for Extension of Time to File Reply to <u>6</u> MOTION for Preliminary Injunction and to File Response to <u>49</u> Motion for Partial Summary Judgment by IMS Health Incorporated.(Byrne,

		Matthew) (Entered: 11/21/2007)
11/26/2007	<u>54</u>	REPLY to Response to <u>7</u> Request for Judicial Notice filed by IMS Health Incorporated. (Attachments: # <u>1</u> Affidavit of Matthew B. Byrne) (jmm) (Entered: 11/26/2007)
11/28/2007	<u>55</u>	ORDER granting <u>52</u> Motion for Extension of Time to File Response re <u>47</u> MOTION for Partial Summary Judgment, and Reply re: <u>48</u> Opposition to <u>6</u> Motion for Preliminary Injunction. Plaintiffs' Response/Reply shall be filed on or before 12/14/2007. Signed by Judge J. Garvan Murtha on 11/28/2007. (This is a text only Order.) (kbl) (Entered: 11/28/2007)
11/28/2007	<u>56</u>	ORDER granting <u>51</u> Request for Status Conference re: <u>50</u> Motion to Consolidate Case (with 1:07-CV-220). A status conference will be held on 11/30/2007 at 11:00 a.m. in Brattleboro, Vt. Signed by Judge J. Garvan Murtha on 11/28/2007. (This is a text only Order.) (kbl) (Entered: 11/28/2007)
11/28/2007	<u>57</u>	NOTICE of Hearing: Status Conference re: <u>50</u> Motion to Consolidate Case (with 1:07-CV-220) set for 11/30/2007 at 11:00 AM in Brattleboro Courtroom before J. Garvan Murtha. (kak) (Entered: 11/28/2007)
11/28/2007		Set/Reset Deadlines. Response to <u>47</u> MOTION for Partial Summary Judgment due 12/14/2007. Reply to <u>48</u> Opposition to <u>6</u> MOTION for Preliminary Injunction due 12/14/2007 pursuant to 55 text only order. (kak) (Entered: 11/29/2007)
11/29/2007	<u>58</u>	RESPONSE to <u>50</u> MOTION to Consolidate Case (with 1:07-CV-220), <u>51</u> MOTION for Status Conference re: <u>50</u> Motion to Consolidate Case (with 1:07-CV-220) filed by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc. (Acosta, Patricia) (Entered: 11/29/2007)
11/29/2007	<u>59</u>	REPLY to Response to <u>50</u> MOTION to Consolidate Case (with 1:07-CV-220) filed by William H. Sorrell. (Duffy, Kate) (Entered: 11/29/2007)
11/30/2007	<u>60</u>	MINUTE ENTRY for proceedings held before Judge J. Garvan Murtha: Status conference and motion hearing held 11/30/2007. Present were Robert Hemley, Esq. and Thomas Julin, Esq. for pltfs, and Kate Duffy, Esq. and Bridget Asay, Esq. for dft. Statements by counsel re: Dfts <u>50</u> Motion to Consolidate Case with 1:07-CV-220. ORDERED: <u>50</u> Motion to Consolidate is GRANTED. Parties shall submit to the Court a revised stipulated discovery schedule/order which shall include a date for at least one pretrial conference. Hearing on <u>6</u> Motion for Preliminary Injunction and trial on the merits shall be continued from 3/24/2008 until 5/5/2008. (Court Reporter: Coughlin) (kak) (Entered: 11/30/2007)
12/03/2007	<u>63</u>	DISCOVERY CERTIFICATE – Notice of Deposition of <i>Joshua Slen</i> by IMS Health Incorporated.(Byrne, Matthew) (Entered: 12/03/2007)
12/04/2007	<u>64</u>	ORDER granting <u>62</u> Stipulated Motion to be Excused from ENE. Signed by Judge J. Garvan Murtha on 12/4/2007. (This is a text only Order.) (kbl) (Entered: 12/04/2007)
12/07/2007	<u>65</u>	STIPULATED MOTION for Extension of Time to Respond to Defendants' Discovery by IMS Health Incorporated, Jim Douglas, Cynthia D. LaWare, Pharmaceutical Research and Manufacturers of America, William H. Sorrell, Source Healthcare Analytics, Inc., Verispan, LLC.(Byrne, Matthew) (Filers added 12/7/2007)(jmm) (Entered: 12/07/2007)
12/10/2007	<u>66</u>	ORDER granting <u>65</u> Motion for Extension of Time to Complete Discovery. Response due on or before 12/21/2007. Signed by Judge J. Garvan Murtha on 12/10/07. (This is a text only Order.) (jse) (Entered: 12/10/2007)
12/11/2007	<u>67</u>	PROPOSED STIPULATED DISCOVERY SCHEDULE/ORDER by Pharmaceutical Research and Manufacturers of America, Jim Douglas, IMS Health Incorporated, Cynthia D. LaWare, William H. Sorrell, Source Healthcare Analytics, Inc., Verispan, LLC.(Cohen, Linda) (Filers added 12/12/2007)(jmm) (Entered: 12/11/2007)

12/12/2007	<u>68</u>	DISCOVERY CERTIFICATE – Initial Disclosures by William H. Sorrell, Jim Douglas, Cynthia D. LaWare.(Duffy, Kate) (Entered: 12/12/2007)
12/12/2007	<u>69</u>	LETTER to counsel re: <u>67</u> proposed Stipulated Discovery and Trial Schedule. (law) (Entered: 12/12/2007)
12/12/2007		Set Deadliness: compliant Proposed Discovery Schedule due by 12/27/2007 pursuant to <u>69</u> . (law) (Entered: 12/12/2007)
12/12/2007	<u>70</u>	DISCOVERY CERTIFICATE – Initial Disclosures by Pharmaceutical Research and Manufacturers of America.(Cohen, Linda) (Entered: 12/12/2007)
12/14/2007	<u>71</u>	PROPOSED STIPULATED DISCOVERY SCHEDULE/ORDER by Pharmaceutical Research and Manufacturers of America.(Cohen, Linda) (Entered: 12/14/2007)
12/14/2007	<u>72</u>	STIPULATED DISCOVERY SCHEDULE/ORDER: Discovery shall be completed by 3/31/2008. Motions in limine shall be filed on or before 4/10/2008. Consolidated Preliminary Injunction Hearing and Trial on the Merits shall commence 5/5/2008. Signed by Judge J. Garvan Murtha on 12/14/2007. (wjf) (Entered: 12/14/2007)
12/14/2007	<u>73</u>	RESPONSE to <u>47</u> MOTION for Partial Summary Judgment filed by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc. (Attachments: # <u>1</u> Statement of Additional Undisputed Facts)(Julin, Thomas) (Entered: 12/14/2007)
12/14/2007	<u>74</u>	REPLY to Response to <u>6</u> MOTION for Preliminary Injunction filed by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc. (Attachments: # <u>1</u> Vermont Medical Society Resolution – Document 3055)(Acosta, Patricia) (Entered: 12/14/2007)
12/17/2007	<u>75</u>	DISCOVERY CERTIFICATE – Interrogatories and Requests to Produce by William H. Sorrell, Jim Douglas, Cynthia D. LaWare.(Duffy, Kate) (Entered: 12/17/2007)
12/17/2007	<u>76</u>	DISCOVERY CERTIFICATE – First Set of Interrogatories and Requests to Produce by Pharmaceutical Research and Manufacturers of America.(Cohen, Linda) (Entered: 12/17/2007)
12/17/2007	<u>77</u>	DISCOVERY CERTIFICATE – Notice of Deposition Duces Tecum of <i>Frank Landry, M.D. and Sharon Moffat</i> by IMS Health Incorporated, Verispan LLC, Source Healthcare Analytics, Inc.(Hemley, Robert) (Entered: 12/17/2007)
12/17/2007	<u>78</u>	DISCOVERY CERTIFICATE – Notice of Deposition Duces Tecum of <i>Paul Harrington and Madeleine Mongan</i> by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc.(Hemley, Robert) (Entered: 12/17/2007)
12/19/2007	<u>79</u>	NOTICE OF APPEARANCE by Michael N. Donofrio on behalf of William H. Sorrell, Jim Douglas, Cynthia LaWare. (Asay, Bridget) (Entered: 12/19/2007)
12/19/2007	<u>80</u>	RESPONSE to <u>7</u> Request for Judicial Notice filed by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Duffy, Kate) (Entered: 12/19/2007)
12/19/2007	<u>81</u>	UNOPPOSED MOTION for Leave to Exceed Page Limit re: Response to <u>61</u> Motion for Preliminary Injunction by William H. Sorrell, Jim Douglas, Cynthia D. LaWare.(Duffy, Kate) (Link corrected 12/21/2007)(jmm) (Entered: 12/19/2007)
12/19/2007	<u>82</u>	MOTION for Partial Summary Judgment by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Attachments: # <u>1</u> Memorandum in Support, # <u>2</u> Statement of Undisputed Facts)(Asay, Bridget) (Entered: 12/19/2007)
12/19/2007	<u>83</u>	NOTICE OF FILING: CORRECTED AND INADVERTENTLY OMITTED EXHIBITS re: <u>7</u> REQUEST for Judicial Notice by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc. (Attachments: # <u>1</u> Exhibit 5 (1 of 7), # <u>2</u> Exhibit 5 (2 of 7), # <u>3</u> Exhibit 5 (3 of 7), # <u>4</u> Exhibit 5 (4 of 7), # <u>5</u> Exhibit 5 (5 of 7), # <u>6</u> Exhibit 5 (6 of 7), # <u>7</u> Exhibit 5 (7 of 7), # <u>8</u> Exhibit 6 (CD 47 and CD 48) (1 of 2), # <u>9</u> Exhibit 6 (CD 47 and CD 48) (2 of 2), # <u>10</u> Exhibit 6

		(CD 125), # <u>11</u> Exhibit 6 (CD 140), # <u>12</u> Exhibit 6 (CD 143 and CD 144) (1 of 2), # <u>13</u> Exhibit 6 (CD 143 and CD 144) (2 of 2), # <u>14</u> Exhibit 6 (CD 148), # <u>15</u> Exhibit 6 (CD 159), # <u>16</u> Exhibit 6 (CD 151), # <u>17</u> Exhibit 6 (CD 163), # <u>18</u> Exhibit 6 (CD 165 and CD 167) (1 of 3), # <u>19</u> Exhibit 6 (CD 165 and CD 167) (2 of 3), # <u>20</u> Exhibit 6 (CD 165 and CD 167) (3 of 3)(Julin, Thomas) (Text clarified 12/20/2007)(jmm) (Entered: 12/19/2007)
12/20/2007	<u>84</u>	RESPONSE to <u>61</u> MOTION for Preliminary Injunction filed by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Attachments: # <u>1</u> Memorandum of Law)(Asay, Bridget) (Entered: 12/20/2007)
12/20/2007	<u>85</u>	CERTIFICATE OF SERVICE re: <u>79</u> Notice of Appearance of Michael N. Donofrio for William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Asay, Bridget) (Entered: 12/20/2007)
12/21/2007	<u>86</u>	DISCOVERY CERTIFICATE – Responses to Interrogatories and Requests to Produce by William H. Sorrell, Jim Douglas, Cynthia D. LaWare.(Duffy, Kate) (Entered: 12/21/2007)
12/21/2007	<u>87</u>	ORDER granting <u>81</u> Unopposed Motion to Exceed Page Limitation re: dfts' memorandum in response to <u>61</u> Motion for Preliminary Injunction. Signed by Judge J. Garvan Murtha on 12/21/2008. (This is a text only Order.) (kbl) (Entered: 12/21/2007)
12/21/2007	<u>88</u>	DISCOVERY CERTIFICATE – Notice of Deposition of <i>Joshua Slen</i> by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc.(Byrne, Matthew) (Entered: 12/21/2007)
12/21/2007	<u>89</u>	DISCOVERY CERTIFICATE re: Responses to Defendant's First Interrogatories and Responses to Defendant's First Request for Production by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc.(Julin, Thomas) (Entered: 12/21/2007)
12/27/2007	<u>90</u>	NOTICE of Hearing: Initial Pretrial/Status Conference set for 2/20/2008 at 10:30 AM in Brattleboro Courtroom before Hon. J. Garvan Murtha.(kak) (Entered: 12/27/2007)
12/27/2007	<u>91</u>	NOTICE of Hearing: Final Pretrial Conference and hearing on any pending motions set for 4/29/2008 10:30 AM in Brattleboro Courtroom before Hon. J. Garvan Murtha. (kak) (Entered: 12/27/2007)
12/28/2007	<u>92</u>	NOTICE of Supplemental Authority by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc. (Attachments: # <u>1</u> IMS Health Incorporated v. Rowe, No. 07-127-B-W WL 4480639)(Acosta, Patricia) (Entered: 12/28/2007)

APPENDIX III

**PHARMACEUTICAL RESEARCH AND MANUFACTURERS
OF AMERICA v. WILLIAM H. SORRELL, JIM DOUGLAS,
AND CYNTHIA D. LaWARE**

BY
 CLERK
 DEPUTY CLERK

PHARMACEUTICAL RESEARCH AND)
MANUFACTURERS OF AMERICA,)
)
Plaintiff,)
)
v.)
)
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 the Agency of)
Human Services of the State of Vermont,)
)
Defendants.)

DOCKET NO.

1:07-cv-220

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA") alleges as follows:

INTRODUCTION

1. In this action, PhRMA challenges certain provisions of Vt. Acts No. 80 (2007) (hereinafter "the Vermont Act" or "the Act"), attached as Exhibit A, because they violate the United States Constitution. Although the Vermont Act purportedly seeks to promote less-expensive drugs, protect the privacy of prescribers, and improve public health, in practice it will achieve none of those goals. It restricts pharmaceutical company speech in violation of the

First and Fourteenth Amendments to the United States Constitution. It conflicts with comprehensive federal regulation of promotional activities involving prescription drugs and thus violates the Supremacy Clause. And it discriminates against out-of-state interests in favor of in-state interests in violation of the Commerce Clause. For these reasons, the Court should declare that each provision of the Act described below is invalid, and the Court should enjoin enforcement of those provisions.

2. In summary, the Vermont Drug Act would:

- require pharmaceutical company representatives, when marketing a prescription drug directly to a physician using prescriber-identifiable data (data illustrating the prescribing practices of a particular physician), to provide “evidence-based” information regarding the benefits, risks, and costs of *other* drugs (the “mandatory counter-detailing provision”);
- restrict use of records containing prescriber-identifiable data without the prior consent of the prescriber and in the absence of the counter-detailing information described above (the “prescription restraint provision”);
- create a cause of action under the Vermont Consumer Fraud Act against a manufacturer of prescription drugs for promotional materials “printed, distributed, or sold” in Vermont that violate federal and State rules, deeming United States Food and Drug Administration (“FDA”) warning or untitled letters *prima facie* evidence of a violation of State law (the “advertising restraint provision”); and
- commandeer a fee from pharmaceutical manufacturers to fund an “evidence-based education” program developed and implemented by a consortium of state and private interests (the “manufacturer fee” provision).

3. Predicated on legislative “findings” inserted just prior to its passage, the Vermont Act overtly favors manufacturers of generic drugs over manufacturers of brand-name pharmaceuticals and demonstrates a lack of confidence in Vermont prescribers. Even more troubling, the legislative findings demonstrate a specific intent to restrict and regulate the speech of pharmaceutical companies to remedy a perceived imbalance in the “marketplace for ideas.” For example, the Legislature concludes, without meaningful support, that:

- marketing by “brand-name [pharmaceutical] companies” results in a one-sided “marketplace for ideas on medicine safety and effectiveness” which “leads to doctors prescribing drugs based on incomplete and biased information”;
- “pressure” on doctors by brand-name pharmaceutical company representatives causes the “[p]ublic health” to be “ill served by the massive imbalance in information presented to doctors and other prescribers”;
- new drugs are no better than older ones, and that, if anything, new drugs are more dangerous;
- data on the number of prescriptions written by particular doctors enable pharmaceutical companies to “target increased attention and manipulative practices toward those doctors that they find would lead to increased prescriptions and profitability”;
- free drug samples influence doctors to prescribe drugs for reasons unrelated to the best interests of the patient; and
- trained physicians are incapable of determining which “drugs are the best treatments for particular conditions.”

4. With these findings as context, the mandatory counter-detailing provision compels pharmaceutical company representatives to speak about competitors’ products in certain circumstances when marketing a drug to a Vermont physician. This compelled disclosure requirement imposes State controls on the free “marketplace for ideas,” in violation of the First and Fourteenth Amendments. It also conflicts on its face with FDA regulations, which prohibit pharmaceutical companies from making comparative claims about other products in the absence of appropriate studies. Moreover, to the extent it can be read to reach out-of-state conduct and to exclude in-state interests, such as the wholesaler that resides in Vermont, the mandatory counter-detailing provision also violates the Commerce Clause.

5. The advertising restraint provision empowers the Attorney General and private plaintiffs to sue under state law whenever a manufacturer of prescription drugs “presents or causes to be presented” a “regulated advertisement” that allegedly does not comply with federal

law or state rules that are yet to be identified. The Act defines “regulated advertisement” broadly to include any “commercial message . . . broadcast on television, cable, or radio from a station or cable company that is physically located in the state, broadcast over the internet from a location in the state, or printed in magazines or newspapers that are printed, distributed, or sold in the state.” The out-of-state reach of this provision violates the Commerce Clause.

6. The advertising restraint provision also deems warning or untitled letters issued by FDA *prima facie* evidence of an actionable violation of *state* law. In so doing, Vermont law superimposes on federal regulatory tools penalties that FDA never intended. It thus conflicts with, and stands as an obstacle to, FDA regulation of pharmaceutical marketing in violation of the Supremacy Clause.

7. Moreover, the Vermont Act imposes a fee on PhRMA members to subsidize a so-called “evidence based education” program that would promote competitor products and that would issue statements about those products that PhRMA members would finance, but not shape. These promotional campaigns serve the interests of some private parties while undermining the interests of the PhRMA members who finance it, and thus violate the First and Fourteenth Amendments.

8. Finally, the prescription restraint provision prohibits use of regulated records containing prescriber-identifiable data unless the prescriber has consented and the user has provided the counter-detailing information described above regarding the costs and benefits of competitors’ treatment options. This provision again injects the State into the “marketplace for ideas” and restricts speech in violation of the First and Fourteenth Amendments.

9. The mandatory counter-detailing, advertising restraint, manufacturer fee, and prescription restraint provisions of the Vermont Act will irreparably harm PhRMA members by

impeding effective communication with health care providers and by compelling PhRMA members to subsidize speech that they do not shape or control. The Act as a whole will also harm the broader public interest. Health care providers in Vermont will receive less information regarding scientific developments and health-related issues, speech between pharmaceutical companies and prescribers will be chilled, and the Act will not serve the best interests of Vermont residents.

10. For these reasons, as detailed below, PhRMA respectfully urges the Court to declare the mandatory counter-detailing, advertising restraint, manufacturer fee, and prescription restraint provisions of the Vermont Act invalid and to issue an order preliminarily and permanently enjoining their enforcement.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 because PhRMA's causes of action arise under the United States Constitution.

12. Venue is proper in this district under 28 U.S.C. § 1391(b) because PhRMA's claims arise in this district and Defendants Attorney General William H. Sorrell, Governor Jim Douglas, and Secretary Cynthia D. LaWare are public officials who are residents of this District.

PARTIES

13. PhRMA is a non-profit corporation organized and existing under the laws of the State of Delaware, with its headquarters located in Washington, D.C. PhRMA members are the leading research-based pharmaceutical and biotechnology companies, devoted to discovering and developing new medications that allow people to live longer, healthier, and more productive lives. PhRMA serves as the pharmaceutical industry's principal policy advocate,

representing the interests of its members in matters before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. Among other objectives, PhRMA is committed to advancing public policies that foster continued medical innovation and to educating the public about the process for discovering and developing new drugs. A list of PhRMA members is available at <http://www.phrma.org>.

14. Defendant William H. Sorrell is the Attorney General of Vermont and the chief legal officer charged with enforcing Section 17 of the Act, codified at 18 V.S.A. § 4631, and Section 21 of the Act, codified at 9 V.S.A. § 2466a. Attorney General Sorrell is sued in his official capacity.

15. Defendant Jim Douglas is the Governor of the State of Vermont. The Agency of Human Services, which is charged with collecting the fees required by Section 20 of the Act, codified at 33 V.S.A. § 2004, and proposing the rules required by this provision, is an executive branch agency. Governor Douglas is sued in his official capacity.

16. Defendant Cynthia D. LaWare is the Secretary of the Agency of Human Services of Vermont and the executive officer charged with collecting the fees required by Section 20 of the Act, codified at 33 V.S.A. § 2004. Secretary LaWare is responsible for proposing the rules required by this provision. Secretary LaWare is sued in her official capacity.

COMMON FACTUAL ALLEGATIONS

The following allegations are common to all counts of the Complaint:

17. PhRMA members develop life-saving and life-enhancing new medicines, which are promoted, prescribed, and sold in Vermont. No PhRMA member is either incorporated in Vermont or has its principal place of business in Vermont.

18. PhRMA members promote their prescription drug products, in accordance with federal law and FDA regulations, to health care providers with prescription privileges in Vermont (“prescribers”). PhRMA members promote their prescription drug products in Vermont through detailing, national advertising, mail, electronic mail, telephone, and through meetings of medical societies and symposia.

19. “Detailing” describes communications by individual pharmaceutical company representatives with prescribers to promote specific prescription drug products. Detailing is an important but limited means by which PhRMA members communicate with Vermont prescribers. Prescribers generally allot a short period of time to meet with pharmaceutical company representatives in the detailing process.

20. In detailing any prescription drug product in Vermont, and in accordance with federal law and FDA regulations, pharmaceutical company representatives provide prescribers with important information regarding the drug being promoted, including its risk profile, approved dosing, and use in special populations. In addition, they often provide reprints of studies published in the peer-reviewed medical literature, as well as other scientific and safety-related information.

21. Detail visits are an occasion for health care providers to report possible unanticipated side effects they may have observed in their patients who have used a particular prescription drug. Pharmaceutical company representatives relay this information to their employers, who in turn take appropriate actions based on the information, including those actions required under federal statutes and regulations.

22. A “Dear Health Care Professional” letter is one way that PhRMA members communicate with Vermont prescribers about scientific or safety-related developments. When

a PhRMA member identifies a new side effect or risk associated with a prescription drug product or when it changes the labeling of a prescription drug, the company and FDA often work together to prepare a “Dear Health Care Professional” letter to alert prescribers, including prescribers in Vermont.

23. PhRMA members provide other health-related information to Vermont prescribers, including materials promoting compliance with a treatment regimen, encouraging effective management of a chronic disease, or facilitating management of the risks inherent in a particular prescription drug therapy.

24. Congress has charged FDA with “protect[ing] the public health by ensuring that ... human ... drugs are safe and effective.” 21 U.S.C. § 393(b). In the recently enacted Federal Food and Drug Administration Amendments Act of 2007 (“FDAAA”), Congress reaffirmed the primacy of FDA’s role in regulating the pharmaceutical drug industry. *See* Pub. L. No. 110-85, 121 Stat. 823 (2007).

25. The Office of Vermont Health Access currently pays for certain prescription drug products manufactured by PhRMA members.

26. PhRMA members purchase data regarding drug prescriptions written or filled in Vermont (“prescriber-identifiable data”), from companies, including IMS Health Inc., Verispan, LLC, and Source Healthcare Analytics, Inc., that collect and process such data.

Mandatory Counter-Detailing

27. Section 17(f) of the Vermont Act, codified at 18 V.S.A. § 4631(f) (the mandatory counter-detailing provision), requires “pharmaceutical marketer[s]” who are “marketing directly to a physician or other person” with prescription privileges to disclose “evidence-based information as provided for by rule describing the specific health benefits or risks of using other

pharmaceutical drugs, including drugs available over the counter; which patients would gain from the health benefits or be susceptible to the risks described; the range of prescription drug treatment options; and the cost of treatment options.” This disclosure regarding competitors’ products is referred to herein as “counter-detailing.”

28. The mandatory counter-detailing provision takes effect when rules are promulgated, and in no event later than January 1, 2008. *See* Act § 24(b).

29. A failure to conduct the mandatory counter-detailing program when required is a violation of the State Consumer Fraud Act. *See* Act § 21(a), codified at 9 V.S.A. § 2466a(a). The Consumer Fraud Act, Chapter 63 of Title 9 of the Vermont Statutes, authorizes the State Attorney General to sue for injunctive relief and civil penalties of up to \$10,000 per violation. The Consumer Fraud Act also authorizes consumers, acting as private attorneys general, to seek injunctive relief, attorneys fees, and treble damages for each alleged violation.

30. PhRMA members employ pharmaceutical marketers, as defined by 33 V.S.A. § 2005(c)(4), recodified as 18 V.S.A. § 4632(c)(4). This statutory provision defines a “pharmaceutical marketer” as “a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs in this state to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe, dispense, or purchase prescription drugs.” *Id.* Under the plain terms of the statute, the term “pharmaceutical marketer” *excludes* “a wholesale drug distributor or the distributor’s representative who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug.” *Id.*

31. The Vermont Act defines “marketing” as “advertising, promotion, or any activity that is intended to be used or is used to influence sales or the market share of a prescription drug, *influence or evaluate the prescribing behavior of an individual health care professional to promote a prescription drug, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.*” Act §17(b)(5), codified at 18 V.S.A. § 4631(b)(5) (emphasis added).

32. By its terms, the definition of “marketing” in the Vermont Act includes “promotion.” Act §17(b)(5), codified at 18 V.S.A. § 4631(b)(5). The Act defines “promotion” as including “any activity or product the intention of which is to advertise or *publicize a prescription drug, including a brochure, media advertisement or announcement, poster, free sample, detailing visit, or personal appearance.*” *Id.* at § 17(b)(8), codified at 18 V.S.A. § 4631(b)(8) (emphasis added).

33. While the mandatory counter-detailing requirements are triggered only when a pharmaceutical marketer markets “*directly to a physician or other person authorized to prescribe prescription drugs,*” Act § 17(f), codified at 18 V.S.A. § 4631(f) (emphasis added), the Act does not define the term “directly.”

34. It appears that the Legislature intended the mandatory counter-detailing requirement to apply only where pharmaceutical marketers use what the Act calls “prescriber-identifiable” data in promoting a prescription drug product to prescribers in Vermont. *See* Act § 17(f), codified at 18 V.S.A. § 4631(f) (emphasis added).

35. In this regard, the mandatory counter-detailing provision applies “when a pharmaceutical marketer engages in any form of prescription drug marketing directly to a physician or other person authorized to prescribe prescription drugs as provided for *under this*

section.” (emphasis added). The phrase “under this section” appears to refer to the prescriber-restraint provision, which is an earlier subpart of Section 17 of the Act.

36. This interpretation is supported by the legislative history of the mandatory counter-detailing provision. *See* Conf. Cmt. (May 7, 2007) at 17; *accord* Letter from Julie Brill, Assistant Attorney General, to Cynthia LaWare, *et al.* (Sept. 27, 2007). However, because the counter-detailing requirements of the Act are vague and ambiguous, they could be subject to a broader construction. Under any possible construction, the provisions are unconstitutional.

37. The mandatory counter-detailing provision provides that, “to the extent practicable,” the rules promulgated to implement the provision “shall use the evidence-based standards developed by the blueprint for health.” Act § 17(f), codified at 18 V.S.A. § 4631(f). By law, the executive committee of the Blueprint for Health must include, *inter alia*, two representatives of the insurance industry, a representative of the Vermont Association of Hospitals and Health Systems, a representative of the complementary and alternative medicine profession, and a primary care professional. *See* 18 V.S.A. § 702(c)(1). It does not include a representative of the pharmaceutical manufacturing industry. *See id.* Even if pharmaceutical manufacturers were permitted to participate in this process, however, the mandatory counter-detailing provision would be unconstitutional.

38. As of the date of this filing, Vermont has proposed no rules regarding the information that must be provided to a Vermont prescriber whenever the Vermont Act’s mandatory counter-detailing requirements are triggered. In the absence of rulemaking, but with the possibility of substantial penalties and private lawsuits under the Act, PhRMA members must consider the possibility of broad counter-detailing obligations.

39. The Vermont Act requires that counter-detailing information be provided regarding a “range of prescription drug treatment options” for a condition. What constitutes a valid treatment option depends on many factors, including the definition of the condition being treated, the characteristics of the patient population, and the characteristics of an individual patient. Even where the condition being treated is well-defined, identifying *comparable* treatments is often a matter of medical debate and potential disagreement.

40. The mandatory counter-detailing provision thus requires someone -- whether it be the Blueprint for Health, the State, or a pharmaceutical manufacturer -- to make subjective judgments regarding the “range of prescription drug treatment options” for a particular treatment before a pharmaceutical marketer may engage in “any form of promotion” directly to a prescriber in Vermont. It then forces pharmaceutical manufacturers to incorporate those subjective judgments into its communications with prescribers.

41. When triggered, the mandatory counter-detailing requirements would apply to all activities directly to a prescriber “intended ... to influence ... the prescribing behavior of an individual health care professional” or to publicize a prescription drug. Act §§ 17(b)(5), 17(b)(8), codified at 18 V.S.A. §§ 4631(b)(5), 4631(b)(8).

42. While apparently not the intention of the Vermont Legislature, the fact is that any pharmaceutical marketer’s interactions with a prescriber -- including detailing, advertising, distributing reprints, supporting audioconferences, and providing safety information -- could conceivably be intended to *influence* the prescriber’s prescribing behavior. For example, the very purpose of issuing a safety alert is that prescribers consider that information in balancing the risks and benefits of the drug in making prescribing decisions.

43. To limit the risk of liability under the Act, PhRMA members must change their detailing, marketing, advertising, and scientific communications in Vermont, which will impose substantial additional costs, restrict their speech, and impede effective interactions with prescribers.

44. Two entities that manufacture or sell pharmaceuticals are residents of Vermont. Burlington Drug Company, a Vermont corporation, is a wholesale drug distributor that provides wholesale drug distribution services in Vermont. The Vermont Legislature was concerned about the effect of the Act on Burlington Drug Company's business, with one Senator asking specifically whether a different provision of an earlier version of the Act would "put Burlington Drug at a competitive disadvantage." Senate Finance, 3/27/07, at 9. In excusing Burlington Drug Company from the mandatory counter-detailing provision, the Vermont Act discriminates against out-of-state residents in favor of in-state residents.

45. Mylan Technologies, a Vermont corporation, is a manufacturer of generic transdermal drug products. In enacting the Vermont Act, the Legislature sought to promote the use of generic drugs, like those manufactured by Mylan. During a Ways and Means Committee hearing, one Member of the House explained to a representative of Mylan that, "[A] major component of this bill is to encourage the use of generic drugs like the ones that you manufacture in Vermont." House Ways and Means, 4/27/07, at 8. Generic drug manufacturers, like Mylan Technologies, generally do not market their generic drug products directly to prescribers.

The Advertising Restraint Provision

46. The advertising restraint provision of the Vermont Act, Section 21(c), codified at 9 V.S.A. § 2466a(c), makes it a violation of the State Consumer Fraud Act for "a manufacturer

of prescription drugs to present or cause to be presented in the State a regulated advertisement” if that advertisement does not comply with federal law and undefined “state rules.” Act § 21(c)(1), codified at 9 V.S.A. § 2466a(c)(1). The advertising restraint provision further declares that warning letters and untitled letters from FDA constitute *prima facie* evidence of a violation. *See id.* Individual consumers may bring actions for violation of advertising restraint provision under the Consumer Fraud Act. *See id.*

47. The Vermont Act defines “regulated advertisements” to include a “presentation to the general public of a commercial message regarding a prescription drug or biological product by a manufacturer of prescription drugs that is broadcast on television, cable, or radio from a station or cable company that is physically located in the state, broadcast over the internet from a location in the state, or printed in magazines or newspapers that are printed, distributed, or sold in the state.” Act § 21(c)(2)(B)(i), codified at 9 V.S.A. § 2466a(c)(2)(B)(i). Regulated advertisements also include “commercial message[s] regarding a prescription drug or biological product by a manufacturer of prescription drugs or its representative that is conveyed: (I) to the office of a health care professional doing business in Vermont ...; or (II) at a conference or other professional meeting occurring in Vermont.” *Id.* § 21(c)(2)(B)(ii), codified at 9 V.S.A. § 2466a(c)(2)(B)(ii).

48. The FDA comprehensively regulates the advertising practices of PhRMA members. As described in the recent decision of the Third Circuit, *Penn. Employee Benefit Trust Fund v. Zeneca, Inc.*, “the extent of [FDA’s] involvement in regulating prescription drug advertising is extensive and specific.” -- F.3d --, 2007 WL 2376312, at *8 (3d Cir. Aug. 17, 2007) (citing 21 C.F.R. § 202.1(e)(6)(i)-(xx) and (e)(7)(i)-(xiii)) (identifying more than thirty circumstances under which FDA asserts that prescription drug advertising is or may be false,

lacking in fair balance, or otherwise misleading); Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions; Withdrawal; Availability, 69 Fed. Reg. 6308-01 (Feb. 10, 2004) (announcing draft guidances to “improve information provided to consumers and health care practitioners by medical product firms about medical products and health conditions”).

49. Under the federal Food, Drug, and Cosmetic Act, a prescription drug product may be misbranded if its advertising is “false or misleading,” or if the advertising fails to contain a “true statement” in “brief summary” of the product’s risks, side effects, and contraindications, along with any effectiveness claims. *See* 21 U.S.C. § 352(n); 21 C.F.R. § 202.1(e)(3), (e)(5)-(7). If prescription drug advertising is inconsistent with the FDA-approved labeling, the FDA may consider it false or misleading, rendering the product misbranded and therefore illegal. *E.g.*, 21 C.F.R. §§ 202.1(e)(6)(xi), (xvii), 202.1(k); [FDAAA, H.R. 3580, 110th Cong. (2007)].

50. FDA regulates the content of advertising and labeling materials for prescription drugs through its Division of Drug Marketing, Advertising and Communications (“DDMAC”). *See, e.g.*, FDA Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising and Communications, DDMAC Frequently Asked Questions, *available at* <http://www.fda.gov/cder/ddmac/faqs.htm> (last accessed September 19, 2007); FDA Center for Drug Evaluation and Research, The CDER Handbook 49 (1998), *available at* <http://www.fda.gov/cder/handbook/index.htm> (last accessed September 19, 2007).

51. Manufacturers are required to submit copies of advertising and labeling materials to DDMAC at the time of first publication or dissemination, and are expected voluntarily to submit any advertising or labeling materials related to an initial drug approval or an approval of

a new indication or condition of use prior to dissemination. *See, e.g.*, 21 C.F.R. § 314.81(b)(3)(i); 21 C.F.R. § 202.1(j)(4); CDER Handbook, *supra*, at 51.

52. If DDMAC determines that labeling or advertising materials are false or misleading in any respect, DDMAC will not allow distribution of those materials. *See, e.g.*, 21 U.S.C. § 352(a); 21 C.F.R. § 202.1(e).

53. PhRMA members are “manufacturer[s] of prescription drugs,” as the term is defined by State law, Vermont Act § 21(c)(2)(A), codified at 9 V.S.A. § 2466a(c)(2)(A). No other entity involved with pharmaceutical advertising, other than a “manufacturer of prescription drugs” is potentially subject to liability under the advertising restraint provision.

54. As of the date of this filing, Vermont has proposed no rules implementing this provision of the Act.

55. Warning letters are FDA’s “principal means of achieving prompt voluntary compliance with the federal Food, Drug, and Cosmetic Act.” FDA, *Regulatory Procedures Manual* at 4-2 (Mar. 2007), available at http://www.fda.gov/ora/compliance_ref/rpm/pdf/ch4.pdf. Contrary to the premise of the advertising restraint provision, issuance of a warning letter does not mean that a promotional statement is false or misleading under federal law. Instead, warning letters are just what their name suggests -- a warning. They are intended to spur dialogue between the FDA and the pharmaceutical company, and often are resolved without any enforcement action being taken. Warning letters do not impose penalties, and they are not final agency action.

56. Untitled letters merely “request” rather than “require” a response to the FDA. Thus, as with a warning letter, the issuance of an untitled letter does not warrant any conclusion about the accuracy of a pharmaceutical promotion that is the subject of such a letter.

57. The advertising restraint provision of the Vermont Act thus superimposes legal consequences on untitled and warning letters which they do not have under federal law. It also disregards important distinctions drawn by FDA, the agency responsible for preparing and issuing such letters, between untitled and warning letters. *See, e.g., FDA, Regulatory Procedures Manual, supra*, at 4-24-25. (instructing that untitled letters should be issued for “violations that do not meet the threshold of regulatory significance for a Warning Letter”).

58. By its terms, the advertising restraint provision makes it a violation of the Vermont Consumer Fraud Act to “present or cause to be presented in the state a regulated advertisement if that advertisement does not comply with” federal law and regulations and State rules. Act § 21(c), codified at 9 V.S.A. § 2466a(c). This language is vague and ambiguous, as it could be construed to apply to an entirely out-of-state transaction that “causes” an advertisement to be presented in Vermont, as well as the other 49 states. Given the risk of liability, PhRMA members must consider the possibility of a broad reading of the Act.

59. To limit the risk of liability, PhRMA members may change their advertising practices, which would impose substantial additional costs and impede their effective communication with prescribers.

Manufacturer Fee

60. Section 20 of the Vermont Act, codified at 33 V.S.A. § 2004 (the “manufacturer fee” provision), requires that “each pharmaceutical manufacturer or labeler of prescription drugs that are paid for by the office of Vermont Health Access for individuals participating in Medicaid, the Vermont Health Access Program, Dr. Dynasaur, VPharm, or Vermont Rx shall pay a fee to the agency of human services” equal to “0.5% of the previous year’s prescription drug spending by the office.” Act § 20, codified at 33 V.S.A. § 2004(a).

61. The Vermont Act earmarks the manufacturer fee to “fund collection and analysis of information on pharmaceutical marketing activities under section 4632 [gift reporting] and 4633 [pharmaceutical marketer price disclosure] of Title 18, analysis of prescription drug data needed by the attorney general’s office for enforcement activities, and the evidence-based education program established in subchapter 2 of Title 18.” Act § 20(b), codified at 33 V.S.A. § 2004(b).

62. The “Evidence-Based Education Program” would, among other objectives, “provide information and education on the therapeutic and cost-effective utilization of prescription drugs” to various health care professionals. Act § 14, codified at 18 V.S.A. § 4622(a)(1).

63. PhRMA members whose prescription drug products are paid for by the office of Vermont Health Access through Medicaid, the Vermont Health Access Program, Dr. Dynasaur, VPharm, or Vermont Rx, are subject to the manufacturer fee provision of the Vermont Act.

64. The provisions of the Vermont Act concerning the “Evidence-Based Education Program,” funded by the manufacturer fee, indicate that the Program will reflect the views of various private interests, but not pharmaceutical manufacturers. The Program must, “[t]o the extent practicable,” use “evidence-based standards developed by the blueprint for health.” Act § 14, codified at 18 V.S.A. § 4622(a)(1).

65. Vermont law requires the Blueprint for Health to have an executive committee with representation by several private groups, including, *inter alia*, two representatives of the insurance industry, a representative of the Vermont Association of Hospitals and Health Systems, a representative of the complementary and alternative medicine profession, and a primary care professional. *See* 18 V.S.A. § 702(c)(1). It does not include a representative of

the pharmaceutical manufacturing industry. *See id.* Even if pharmaceutical manufacturers were permitted to participate in this process, however, the manufacturer fee provision would be unconstitutional.

66. In connection with the Evidence-Based Education Program, the Department of Health “shall request information and collaboration from physicians, pharmacists, private insurers, hospitals, pharmacy benefit managers, the drug utilization review board, medical schools, [and] the attorney general,” as well as any other programs providing evidence-based education to prescribers regarding prescription drugs. Act § 14, codified at 18 V.S.A. § 4622(b). No pharmaceutical company or representative of the pharmaceutical industry is included in this process.

67. Requiring PhRMA members to support the Evidence-Based Education Program through payment of the manufacturer fee constitutes compelled subsidization of speech, which is intended to benefit certain manufacturers (particularly, manufacturers of generic drugs) at the expense of other manufacturers (particularly, PhRMA members). The Legislature quite explicitly is seeking to intervene in the “marketplace for ideas,” to give certain favored private parties (generic manufacturers) an advantage over others (innovator drug manufacturers), under the guise of “evidence-based education.”

The Prescription Restraint Provision

68. Section 17(d) of the Vermont Act, codified at 18 V.S.A. § 4631(d) (the “prescription restraint” provision), prohibits use of “regulated records” containing prescriber-identifiable data by certain identified entities unless the prescriber has consented to use of his or her identifying information and the entity using such data complies with the mandatory counter-detailing requirements, described in Paragraphs 1 through 67 above.

69. The “regulated records” to which the prescription restraint provision applies include “information or documentation from a prescription written by a prescriber doing business in Vermont or a prescription dispensed in Vermont.” Act § 17(b)(9), codified at 18 V.S.A. § 4631(b)(9).

70. The legislative findings describe prescriber-identifiable data as data that “show details of physicians’ drug use patterns, both in terms of their gross number of prescriptions and their inclinations to prescribe particular drugs.” Act § 1(22).

71. In prohibiting certain “uses” of regulated records containing prescriber-identifiable data, the prescription restraint provision prevents covered entities from engaging in “*any activity* that is intended to be used or is used to ... market prescription drugs to patients.” *See* Act § 17(b) (5), codified at 18 V.S.A. § 4631(b)(5) (prohibiting use of prescriber-identifiable data to market or promote a prescription drug, defining marketing to include “any activity that is intended to be used or is used to influence the sales or the market share of a prescription drug”). As described in Paragraph 29, *supra*, the Vermont Act deems a violation of Section 17 of the Act (both the prescription restraint and mandatory counter-detailing provisions) a violation of the State Consumer Fraud Act. *See* Act § 21, codified at 9 V.S.A. § 2466a.

72. By its terms, the prescription restraint provision applies to a “health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity.” Act § 17(d), codified at 18 V.S.A. § 4631(d). PhRMA members are neither among the listed entities nor similar to them, but PhRMA members are among the principal “users” of prescriber-identifiable data. Given the potential liability, PhRMA members must consider the

possibility of a broad reading, potentially requiring them to change and restrict their marketing practices to comply with the provision.

PLAINTIFF'S CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Declaratory/Injunctive Relief - Mandatory Counter-Detailing Requirements
Violate the First Amendment by Excessively Burdening Speech)

73. PhRMA realleges and incorporates herein by reference paragraphs 1 through 72.

74. The mandatory counter-detailing requirements burden the speech of PhRMA members by compelling them to provide both information regarding competitors' products and non-commercial information regarding treatment options, by restricting their ability to communicate with health care providers, and by imposing burdens and limitations that are not content-neutral.

75. The Legislature's claimed interest in rectifying a perceived imbalance in the "marketplace for ideas," which, under the First Amendment of the United States Constitution, is supposed to be a free market, is neither compelling nor substantial.

76. The Legislature's other asserted objectives of maximizing the well-being of Vermonters and containing health care costs are not directly advanced by the mandatory counter-detailing requirements of the Vermont Act. On the contrary, the mandatory counter-detailing requirements will adversely affect public health and increase health care costs by, among other things, depriving Vermont prescribers of important health-related information that otherwise would be provided by pharmaceutical marketers.

77. The mandatory counter-detailing requirements are not narrowly tailored, and are broader than necessary to accomplish the interests that they purport to serve.

78. The mandatory counter-detailing program violates the First and Fourteenth Amendments of the United States Constitution.

SECOND CLAIM FOR RELIEF

(Declaratory/Injunctive Relief - Mandatory Counter-Detailing and Prescription Restraint Provisions Are Preempted and Violate the Supremacy Clause)

79. PhRMA realleges and incorporates herein by reference paragraphs 1 through 78.

80. Congress has delegated authority to FDA to regulate communications between PhRMA members and prescribers. Pursuant to its authority, FDA has promulgated specific and comprehensive regulations.

81. Under FDA regulations, statements made in prescription drug promotional labeling must not be “false or misleading.” In addition, such statements must be consistent with the drug’s FDA-approved label, which FDA is required to approve as neither “false” nor “misleading.” 21 U.S.C. § 352(a), (n); 21 C.F.R. §§ 201.100, 202.1; *see also Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3,922, 3,960 (Jan. 24, 2006) (“[S]tatements made in promotional labeling and advertisements must be consistent with all information included in labeling under proposed § 201.57(c) to comply with current §§ 201.100(d)(1) and 202.1(e).”).

82. Moreover, the mandatory counter-detailing provision imposes obligations on PhRMA members that may conflict with their obligations under federal law and that interfere with FDA’s regulatory objectives. For example, it requires PhRMA members to supply information on the risks and benefits of using other drugs, including over the counter drugs. It is virtually inevitable that this across-the-board requirement -- entailing in FDA’s view implicit or explicit comparisons between drugs -- would directly conflict with FDA regulations precluding unsubstantiated comparative claims regarding another drug in promotional labeling

or advertising. *See, e.g.*, 21 U.S.C. § 352; 21 C.F.R. §§ 201.56(a), (b), 201.57(c)(2)(iii), 201.80(c)(3)(v), 201.100(d)(1), 202.1(e)(6)(ii).

83. Contrary to FDA regulations, the mandatory counter-detailing provision of the Vermont Act makes it a violation of the Vermont Consumer Fraud Act for PhRMA members to provide truthful, non-misleading information to prescribers that is consistent with the FDA-approved label, unless such information is accompanied by materials on other drugs as provided in the Act or regulations to be promulgated pursuant to the Act. The Vermont Act thus conflicts with federal requirements.

84. The mandatory counter-detailing program will interfere with safety and risk-related provisions of the recently-enacted Federal Food and Drug Administration Amendments Act of 2007 (“FDAAA”), Pub. L. No. 110-85, 121 Stat. 823 (2007).

85. The mandatory counter-detailing program conflicts with and is an obstacle to the accomplishment and execution of the full purposes and objectives of the federal prescription drug regulatory scheme, and thus is preempted by federal law and under the Supremacy Clause of the United States Constitution, Article VI, cl.2.

THIRD CLAIM FOR RELIEF

(Declaratory/Injunctive Relief - Mandatory Counter-Detailing Requirements Violate the Commerce Clause by Discriminating Against Out-of-State Companies)

86. PhRMA realleges and incorporates herein by reference paragraphs 1 through 85.

87. No PhRMA member has a principal place of business or is incorporated in Vermont.

88. The mandatory counter-detailing provision discriminates against out-of-state entities by excluding from its onerous requirements wholesale drug distributors, which includes a Vermont corporation.

89. Because it discriminates on its face against out-of-state entities, the counter-detailing provision violates the Commerce Clause, Article I, Section 8 of the United States Constitution.

FOURTH CLAIM FOR RELIEF

(Declaratory/Injunctive Relief - *Prima Facie* Significance Afforded to FDA Regulatory Letters Is Preempted and Violates the Supremacy Clause)

90. PhRMA realleges and incorporates herein by reference paragraphs 1 through 89.

91. The advertising restraint provision makes it a violation of the State Consumer Fraud Act “to present or cause to be presented in the state” an advertisement that does not comply with federal and state law, and it provides that a warning or untitled letter from FDA is a *prima facie* violation of federal law and regulations and Vermont consumer fraud law.

92. By imputing *prima facie* significance to warning letters and untitled letters, the advertising restraint provision conflicts with federal law because the issuance of such letters does not necessarily mean that an advertisement is false or misleading.

93. FDA has issued detailed and specific regulatory requirements regarding pharmaceutical companies’ advertising and promotional labeling. *See, e.g.*, 21 C.F.R. §§ 201.56, 201.57, 201.80, 201.100, 202.1. To enforce these requirements, federal law provides FDA with the tools to investigate, deter, and punish violations of FDA’s regulations. *See, e.g.*, 21 U.S.C. §§ 332, 333, 337. Warning and untitled letters are an integral part of this regulatory scheme.

94. Rendering warning and untitled letters *prima facie* evidence of a violation of state law would frustrate FDA’s stated goal of promoting voluntary compliance with federal law. By according undue weight to these letters under state law, the advertising restraint provision skews the regulatory balance FDA seeks to strike. It stands as an obstacle to the

accomplishment and execution of the full purposes and objectives of the federal prescription drug regulatory scheme, and is preempted by federal law under the Supremacy Clause of the United States Constitution, Article VI, cl. 2.

FIFTH CLAIM FOR RELIEF

(Declaratory/Injunctive Relief - Regulation of Prescription Drug Advertising
Violates the Commerce Clause)

95. PhRMA realleges and incorporates herein by reference paragraphs 1 through 94.

96. The advertising restraint provision purports to regulate certain advertisements that PhRMA members “cause to be presented in the state.” Moreover, the “regulated advertisements” to which the provision applies include advertisements that are created outside of the State and disseminated predominantly outside of the State, so long as those advertisements are also “printed, distributed, or sold” within the State.

97. Because national print, television, radio, and internet advertisements are generated outside Vermont and are freely disseminated to all 50 states, and because advertisers have limited, and in many instances, no practical ability to differentiate among jurisdictions, the advertising restraint provision excessively burdens interstate commerce by requiring PhRMA members to change their detailing, marketing, advertising, and scientific communication practices outside the State of Vermont.

98. Because FDA comprehensively regulates prescription drug advertising and other promotional conduct, the putative incremental benefit of the advertising restraint provision in Vermont is minimal, if any.

99. The advertising restraint provision violates the Commerce Clause, Article I, Section 8 of the United States Constitution.

SIXTH CLAIM FOR RELIEF

(Declaratory/Injunctive Relief - Manufacturer Fee
Violates the First Amendment by Compelling Speech)

100. PhRMA realleges and incorporates herein by reference paragraphs 1 through 99.

101. The manufacturer fee and the Evidence-Based Education Program it funds burden the speech of PhRMA members by compelling PhRMA members to subsidize speech about competitor products.

102. By earmarking the manufacturer fee to support the Evidence-Based Education Program, the Legislature is attempting to give certain private parties an advantage in the “marketplace for ideas” under the guise of “evidence-based education.”

103. The standards to be used in the Evidence-Based Education Program are not government speech because they will be established by the Blueprint for Health, which is comprised in part of private interests.

104. The manufacturer fee thus violates the First and Fourteenth Amendments of the United States Constitution.

SEVENTH CLAIM FOR RELIEF

(Declaratory/Injunctive Relief - Prescription Restraint Provision
Violates the First Amendment by Excessively Burdening Speech)

105. PhRMA realleges and incorporates herein by reference paragraphs 1 through 104.

106. The prescription restraint provision burdens the lawful and non-misleading speech of PhRMA members by requiring mandatory counter-detailing about alternative treatment options each time regulated records containing prescriber-identifiable data are used in a promotional context.

107. The Legislature's claimed interests are neither compelling nor substantial. Prescriber privacy is not a compelling or substantial interest because prescribers are sophisticated professionals who do not need the State's protection from lawful, non-harassing and truthful speech by PhRMA members and because the information at issue is not the type to which privacy protections extend.

108. The prescription restraint provision does not directly advance the Legislature's asserted interests of containing health care costs or maximizing the well-being of Vermonters.

109. The prescription restraint provision will adversely affect public health and possibly increase health care costs by depriving Vermont prescribers of important health-related information provided by pharmaceutical marketers.

110. The prescription restraint provision is broader than necessary to accomplish the interests that it purports to serve, and less restrictive alternatives are available. The Legislature failed to calculate any of the costs and benefits associated with the prescription restraint provision. The Legislature also failed to consider the impact of available, less restrictive alternatives.

111. The prescription restraint provision violates the First and Fourteenth Amendments of the U.S. Constitution.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff PhRMA prays:

- A. For a declaration that the mandatory counter-detailing requirements of the Vermont Act, which are found in Section 17(f) and enforced pursuant to Section 21(a), are invalid;
- B. For a declaration that the Vermont Act's restraint of advertising, imposed by Section 21(c), is invalid;
- C. For a declaration that the manufacturer fee, created by Section 20, is invalid;
- D. For a declaration that the prescription restraint provision, set forth in Section 17(d), is invalid;
- E. For a permanent and preliminary injunction enjoining Defendant Sorrell from enforcing the mandatory counter-detailing requirements of the Act;
- F. For a permanent and preliminary injunction enjoining Defendant Sorrell from enforcing the advertising restraint provision of the Act;
- G. For a preliminary and permanent injunction enjoining Defendants Douglas and LaWare from enforcing the manufacturer fee provision of the Act;
- H. For a permanent and preliminary injunction enjoining Defendant Sorrell from enforcing the prescription restraint provision of the Act;
- I. For such costs and reasonable attorneys' fees to which it might be entitled by law;
and
- J. For such other relief as this Court may deem just and appropriate.

DATED at Burlington, Vermont this 22nd day of October, 2007.

Respectfully Submitted,



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**U.S. District Court
District of Vermont (Brattleboro)
CIVIL DOCKET FOR CASE #: 1:07-cv-00220-jgm**

Pharmaceutical Research and Manufacturers of America v.
Sorrell et al
Assigned to: Judge J. Garvan Murtha
Lead case: [1:07-cv-00188-jgm](#)
Member case: [\(View Member Case\)](#)
Cause: 28:1331 Fed. Question

Date Filed: 10/22/2007
Date Terminated: 11/30/2007
Jury Demand: None
Nature of Suit: 950 Constitutional – State
Statute
Jurisdiction: Federal Question

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V.

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Defendant

Cynthia D. LaWare
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of the Agency of Human Resources of the
State of Vermont*

represented by **Kate G. Duffy**
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ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
10/22/2007	<u>1</u>	COMPLAINT for Declaratory and Injunctive Relief against William H. Sorrell, Jim Douglas, Cynthia D. LaWare filed by Pharmaceutical Research and Manufacturers of America. (Filing fee \$350) Summonses issued. (Attachments: # <u>1</u> Exhibit A# <u>2</u> Civil Cover Sheet)(law) (Entered: 10/22/2007)
10/22/2007	<u>2</u>	MOTION for Admission Pro Hac Vice of Robert N. Weiner, Jeffrey L. Handwerker, Laura Riposo VanDruff, and Sarah M. Brackney by Pharmaceutical Research and Manufacturers of America. (Attachments: # <u>1</u> Exhibit A# <u>2</u> Exhibit B# <u>3</u> Exhibit C# <u>4</u> Exhibit D)(law) (Entered: 10/23/2007)
10/23/2007	<u>3</u>	NOTICE OF APPEARANCE by Linda J. Cohen on behalf of Pharmaceutical Research and Manufacturers of America (Cohen, Linda) (Entered: 10/23/2007)
10/23/2007	<u>4</u>	CORPORATE DISCLOSURE STATEMENT pursuant to Local Rule 5.2(b) by Pharmaceutical Research and Manufacturers of America. (Cohen, Linda) (Entered: 10/23/2007)
10/23/2007	<u>5</u>	MOTION for Leave to Exceed Page Limit re: <u>7</u> Memorandum in Support of <u>6</u> Motion for Preliminary Injunction by Pharmaceutical Research and Manufacturers of America.(Cohen, Linda) (Entered: 10/23/2007)
10/23/2007	<u>6</u>	MOTION for Preliminary Injunction by Pharmaceutical Research and Manufacturers of America.(Cohen, Linda) (Entered: 10/23/2007)
10/23/2007	<u>7</u>	MEMORANDUM by Pharmaceutical Research and Manufacturers of America in support of <u>6</u> MOTION for Preliminary Injunction. (Attachments: # <u>2</u> Appendix A, Exhibit 15 # <u>3</u> Appendix A, Exhibit 16 # <u>4</u> Appendix A, Exhibit 17 # <u>5</u> Appendix A, Exhibit 18 # <u>6</u> Appendix A, Exhibit 19 # <u>7</u> Appendix A, Exhibit 20 # <u>8</u> Appendix 1, Exhibit 21 # <u>9</u> Appendix 1, Exhibit 22 # <u>10</u> Appendix 1, Exhibit 23 # <u>11</u> Appendix A, Exhibit 24 # <u>12</u> Appendix B, Exhibits 25-30)(Cohen, Linda) (# <u>14</u> Appendix A, Exhibits 1-14 (corrected)) (jmm) (# <u>15</u> Appendix B, Exhibit 31 added per 13 Order)(10/29/2007)(jmm) (Entered: 10/23/2007)

10/24/2007	8	ORDER granting <u>2</u> Motion for Admission Pro Hac Vice re: Robert N. Weiner, Esq., Jeffrey L. Handwerker, Esq., Laura Riposo VanDruff, Esq. and Sarah M. Brackney, Esq. on behalf of plaintiff. Signed by Judge J. Garvan Murtha on 10/24/2007. (This is a text only Order.) (kbl) (Entered: 10/24/2007)
10/24/2007	9	ORDER granting <u>5</u> Motion to Exceed Page Limit re: <u>7</u> Memorandum in Support of <u>6</u> Motion for Preliminary Injunction. Signed by Judge J. Garvan Murtha on 10/24/2007. (This is a text only Order.) (kbl) (Entered: 10/24/2007)
10/24/2007	<u>10</u>	REQUEST for Judicial Notice by Pharmaceutical Research and Manufacturers of America. (Attachments: # <u>1</u> Exhibit 1# <u>2</u> Exhibit 2# <u>3</u> Exhibit 3# <u>4</u> Exhibit 4# <u>5</u> Exhibit 5# <u>6</u> Exhibit 6# <u>7</u> Exhibit 7# <u>8</u> Exhibit 8# <u>9</u> Exhibit 9# <u>10</u> Exhibit 10# <u>11</u> Exhibit 11# (14) Exhibit 13# <u>15</u> Exhibit 14# <u>16</u> Exhibit 15# <u>19</u> Exhibit 17# <u>20</u> Exhibit 18# <u>21</u> Exhibit 19# <u>22</u> Exhibit 20# <u>23</u> Exhibit 21)(law) (Corrected attachments added: # <u>24</u> Exhibit 12 (1 of 2) # <u>25</u> Exhibit 12 (2 of 2) # <u>26</u> Exhibit 16 (1 of 2) # <u>27</u> Exhibit 16 (2 of 2) on 10/25/2007) (jmm) (Entered: 10/25/2007)
10/25/2007	<u>11</u>	NOTICE of DOCKET ENTRY CORRECTION re: <u>10</u> Request for Judicial Notice. The original images associated with Exhibits 12 and 16 were mis-scanned and have been removed from <u>10</u> . The corrected images for Exhibits 12 and 16 are attached to <u>10</u> and to this entry. (Attachments: # <u>1</u> Exhibit 12 (2 of 2)# <u>2</u> Exhibit 16 (1 of 2)# <u>3</u> Exhibit 16 (2 of 2)) (jmm) (Entered: 10/25/2007)
10/26/2007	<u>12</u>	MOTION for Leave to File <i>Declaration in Support of <u>6</u> Motion for Preliminary Injunction</i> by Pharmaceutical Research and Manufacturers of America. (Attachments: # <u>1</u> Appendix B, Exhibit 31)(Cohen, Linda) (Entered: 10/26/2007)
10/26/2007	13	ORDER granting <u>12</u> Motion for Leave to File Declaration in Support of <u>6</u> Motion for Preliminary Injunction. Signed by Judge J. Garvan Murtha on 10/26/2007. (This is a text only Order.) (kbl) (Entered: 10/26/2007)
10/30/2007	<u>14</u>	NOTICE of DOCKET ENTRY CORRECTION re: <u>7</u> Memorandum in Support. Appendix B, Exhibit 31 has been added to <u>7</u> pursuant to 13 Order. The image is also attached to this entry. (jmm) (Entered: 10/30/2007)
10/30/2007	<u>15</u>	SUMMONS RETURNED Executed. William H. Sorrell served on 10/23/2007, answer due 11/13/2007. (kak) (Entered: 10/30/2007)
10/30/2007	<u>16</u>	SUMMONS RETURNED Executed. Jim Douglas served on 10/23/2007, answer due 11/13/2007. (kak) (Entered: 10/30/2007)
10/30/2007	<u>17</u>	SUMMONS RETURNED Executed. Cynthia D. LaWare served on 10/23/2007, answer due 11/13/2007. (kak) (Entered: 10/31/2007)
11/01/2007	<u>18</u>	UNOPPOSED MOTION for Extension of Time to File Response to <u>6</u> Motion for a Preliminary Injunction and Request to Take Judicial Notice by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Attachments: # <u>1</u> Certificate of Service # <u>2</u> Declaration of Kate G. Duffy)(Duffy, Kate) (Entered: 11/01/2007)
11/02/2007	19	ORDER granting <u>18</u> Unopposed Motion to Enlarge Time to Respond re <u>6</u> Motion for Preliminary Injunction. Dfts' response shall be filed on or before 11/16/2007. Signed by Judge J. Garvan Murtha on 11/2/2007. (This is a text only Order.) (kbl) (Entered: 11/02/2007)
11/15/2007	<u>20</u>	ANSWER to Complaint by William H. Sorrell, Jim Douglas, Cynthia D. LaWare.(Duffy, Kate) (Entered: 11/15/2007)
11/16/2007	<u>21</u>	STIPULATED MOTION to Consolidate Case (with 1:07-CV-188) by William H. Sorrell, Jim Douglas, Cynthia D. LaWare.(Duffy, Kate) (same image as <u>22</u>) (Entered: 11/16/2007)
11/16/2007	<u>22</u>	STIPULATED MOTION for Status Conference re: <u>21</u> Stipulated Motion to Consolidate Case (with 1:07-CV-188) and STIPULATED MOTION to be Excused from ENE by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (same image as <u>21</u>) (kak) (Entered: 11/19/2007)
11/28/2007	23	ORDER granting <u>22</u> Request for Status Conference re: <u>21</u> Stipulated Motion to Consolidate Case (with 1:07-CV-188). A status conference will be held on

		11/30/2007 at 11:00 a.m. in Brattleboro, Vt. Signed by Judge J. Garvan Murtha on 11/28/2007. (This is a text only Order.) (kbl) (Entered: 11/28/2007)
11/28/2007	<u>24</u>	NOTICE of Hearing: Status Conference re: <u>21</u> Stipulated Motion to Consolidate Case (with 1:07-CV-188) set for 11/30/2007 at 11:00 AM in Brattleboro Courtroom before J. Garvan Murtha. (wjf) (Entered: 11/28/2007)
11/30/2007	25	MINUTE ENTRY for proceedings held before Judge J. Garvan Murtha: Status conference and motion hearing held 11/30/2007. Present for pltf were Robert Weiner, Esq., Jeffrey Handwerker, Esq., Karen McAndrew, Esq. and Linda Cohen, Esq.; Kate Duffy, Esq. and Bridget Asay, Esq. present for dfts. Statements by counsel re: <u>21</u> Stipulated Motion to Consolidate Case with 1:07-cv-188. ORDERED: <u>21</u> Stipulated Motion to Consolidate is GRANTED. Parties shall submit to the Court a revised stipulated discovery schedule/order which shall include a date for at least one pretrial conference. Hearing on <u>6</u> Motion for Preliminary Injunction and trial on the merits to commence on 5/5/2008. (Court Reporter: Coughlin) (kak) (Entered: 11/30/2007)
12/19/2007	<u>26</u>	RESPONSE in Opposition re <u>6</u> MOTION for Preliminary Injunction filed by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Attachments: # <u>1</u> Memorandum in Support)(Asay, Bridget) (Entered: 12/19/2007)