



Report of the Vermont State Auditor

January 16, 2009

LITIGATION REPORT FOR CALENDAR YEAR 2008

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. 09-01

Mission Statement

The mission of the Auditor's Office is to be a catalyst for good government by promoting reliable and accurate financial reporting as well as promoting economy, efficiency, and effectiveness in state government.

This report is a work of the Office of the State Auditor, State of Vermont, and is not subject to copyright protection in the United States. It may be reproduced and distributed in its entirety without further permission from the State of Vermont or the Office of the State Auditor. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately. Please contact the Office of the State Auditor if you have questions about reproducing this report.

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



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

January 16, 2009

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, we are submitting our second annual report to the General Assembly on the State's litigation costs related to challenges to Act No. 80.

Litigation overview

The statute cited 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.

132 State Street • Montpelier, Vermont 05633-5101
Auditor: (802) 828-2281 • Toll-Free (in VT only): 1-877-290-1400 • Fax: (802) 828-2198
email: auditor@state.vt.us • website: www.auditor.vermont.gov

As noted in last year's report, upon inquiry with the Attorney General's Office, we learned that two lawsuits had been filed challenging the Act in the United States District Court for the District of Vermont.

These were:

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 acquire information from prescription records, including prescriber-identifiable information, and sell and/or license the 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 challenged Section 17 of the Act, which prohibits the use of prescriber-identifiable information in marketing pharmaceutical drugs unless the prescriber consents to that use.

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 federal law, and Section 21, which imposes a fee on manufacturers of pharmaceutical drugs. Plaintiffs in both cases argued that the Act violates the First Amendment and the Commerce Clause and is preempted by federal law, according to information from the Attorney General's Office.

Pretrial preparations included depositions of approximately 40 witnesses over a period of several months in 2008, according to the Attorney General's Office. A trial was conducted in the federal district court in Brattleboro in July and August 2008.

The trial schedule, included in this report as Appendix I, identifies some of the proposed witnesses in the case.

The parties filed written arguments and rebuttals over a period of several months after the trial, most recently in late December, and are awaiting a decision by the Court.

Cost Summary

We have received and reviewed a cost report from the business manager of the Attorney General’s Office which summarizes litigation costs related to the legislation passed in Act No. 80 of the 2007 Session.

The total reported costs are \$368,687. The salary costs do not include those of the Attorney General or other high-level supervisors involved in the litigation. According to the business manager, the supervisory hours are important but not extensive and therefore do not constitute a large additional cost. We will ask the Attorney General’s Office to provide a summary of supervisory or review hours by the Attorney General or high-level staff regarding this litigation for next year’s report.

Act No. 80 Litigation Report Employee Labor Costs & Operating Expenses

Calendar Year 2008 (unaudited)

Pos. No.	Hourly Pay Rate 1/01/08- 7/05/08	Hourly Pay Rate 7/06/08- 12/31/08	Hours Paid	Hours Worked	Avg Hours Paid 1/01/08- 7/05/08	Avg Hours Paid 7/06/08- 12/31/08	Gross Hourly Cost 1/01/08- 12/31/08	Estimated Labor Cost 7/1/07 - 12/31/07 w/ Fringe Benefits @34.9%
<u>Attorney</u>								
1970xx	35.64	35.64	1140	1606	88	1052	40,629.60	54,809.33
1970xx	33.59	33.59	870	870	67	803	29,223.30	39,422.23
1970xx	34.30	34.30	798	927	61	737	27,371.40	36,924.02
1970xx	21.63	22.91	494	639	38	456	11,268.90	15,201.75
1970xx	39.61	39.61	44	44	3	41	1,742.84	2,351.09
1970xx	29.42	29.42	515	591	40	475	15,151.30	20,439.10
<u>Staff</u>								
1900xx	19.42	19.64	170	170	13	157	3,335.92	4,500.16
1900xx	23.01	23.42	830	830	64	766	19,412.42	26,187.36
1900xx	19.49	19.84	68	68	5	63	1,347.29	1,817.49
1900xx	23.01	24.72	145	145	11	134	3,565.33	4,809.63
1900xx	20.63	21.63	70	70	5	65	1,508.72	2,035.26
1900xx	14.73	15.54	25	25	2	23	386.94	521.99
1900xx	19.50	19.85	30	30	2	28	594.69	802.24
			5199	6015			Total Labor Costs	209,821.64
							Direct Operating Expenses	
							OOS Travel	23,480
							Subpoena	7,651
							Transcripts	45,994
							Software Support	5,794
							Experts	74,530
							Misc	1,417
							Total Operating	158,866
							Grand Total	158,865.89
								\$368,687.53

Last year's report, available on the Auditor's website, contains copies of:

- a. Act No. 80 of the Vermont General Assembly, 2007-2008 Session, as Appendix I;
- b. The initial filing of IMS HEALTH INC; VERISPAN, LLC; AND SOURCE HEALTHCARE ANALYTICS, INC. v. WILLIAM H. SORRELL, as Appendix II; and
- c. The initial filing of 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,



George Thabault
Deputy State Auditor

cc: Thomas M. Salmon, CPA, Vermont State Auditor
William H. Sorrell, Attorney General

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

Proposed Court Schedule IMS Health Inc. & Pharmaceutical Researchers and Manufacturers Association of America v. State of Vermont (generally)

Case 1:07-cv-00188-jgm Document 346 Filed 07/09/2008

Case No. 1:07-cv-188-jgm
Consolidated with Case No. 1:07-cv-220

Neither the Pharmaceutical Researchers and Manufacturers Association of America nor the defendants have agreed to the proposed order of proof below or to the suggested times, but publisher plaintiffs will endeavor to obtain their agreement and to address any disagreements with the Court at the status conference scheduled for Monday, July 21, 2008, at 10 a.m.

1. Plaintiff's Case

Monday - July 28, 2008

- 9:00 - 9:30 a.m.
a. Remaining Pretrial Issues
- 9:30 - 10:30 a.m.
b. Opening Statements
- 10:30 - 11:30 a.m.
c. Hossam Sadek,
General Manger, Business Line Development
IMS Health Incorporated

Mr. Sadek will testify regarding IMS's business practices of gathering, analyzing and publishing prescriber-identifiable information and how the Prescription Restraint Law restricts IMS Health's publishing activities.

- 11:30 a.m. - 12 noon
d. Carol Livingston
Vice President of Customer Operations
Source Healthcare Analytics

Ms. Livingston will testify regarding Source Healthcare Analytic's business practices of gathering, analyzing and publishing prescriber-identifiable information and how the Prescription Restraint Law restricts Source's publishing activities.

- 12 noon - 1 p.m.
e. Lunch

Appendix I

Proposed Court Schedule IMS Health Inc. & Pharmaceutical Researchers and Manufacturers Association of America v. State of Vermont (generally)

Case 1:07-cv-00188-jgm Document 346 Filed 07/09/2008

Case No. 1:07-cv-188-jgm
Consolidated with Case No. 1:07-cv-220

- 1:00 - 1:30 p.m.
f. Jody Fisher
Vice President of Product Management
Verispan LLC

Mr. Fisher will testify regarding Verispan's business practices of gathering, analyzing and publishing prescriber-identifiable information and how the Prescription Restraint Law restricts Verispan's publishing activities.

- 1:30 - 2:30 p.m.
g. Lori Reilly, PhRMA

Ms. Reilly will testify regarding PhRMA members' practices of obtaining and using prescriber identifiable information for marketing purposes and how the members business practices are affected by the Prescription Restraint Law.

- 2:30 - 3:30 p.m.
h. Dr. Tom Wharton
Cardiologist, Exeter Hospital

Dr. Wharton will testify regarding his extensive experience with pharmaceutical sales representatives and how diversity and transparency of information enable doctors make the right prescription choices for their patients.

- 3:30 - 3:45 p.m.
i. Afternoon Break

- 3:45 - 4:15 p.m.
j. Dr. Andrew Cole
Massachusetts General Hospital
Director, Epilepsy Service

Dr. Cole will explain distinctions between generic and branded drugs and why doctors sometimes prescribe branded drugs even though a generic version of the same molecule is available.

- 4:15 - 5:00 p.m.
k. Dr. Ken Ciongoli (Depo. Video)
Vermont Neurologist

Dr. Cingoli will testify regarding his extensive experience and interactions with sales representatives and the different ways in

Appendix I

Proposed Court Schedule IMS Health Inc. & Pharmaceutical Researchers and Manufacturers Association of America v. State of Vermont (generally)

Case 1:07-cv-00188-jgm Document 346 Filed 07/09/2008

Case No. 1:07-cv-188-jgm
Consolidated with Case No. 1:07-cv-220

which he and his patients benefits from the information they provide to him.

Tuesday - July 29, 2008

9:00 - 10 a.m.

- l. Peter B. Hutt
Covington & Burling, LLP

Mr. Hutt will provide expert testimony on a variety of issues relating to the approval process for new pharmaceutical and generic drugs and the balance intended to be achieved by the Drug Price Competition and Patent Term Restoration Act of 1984 ("the Hatch-Waxman Act").

10:00 - 10:30 a.m.

- m. Scott Tierney & Williams Wolfe
CVS Caremark Corporation Rite-Aid Corp.

Mr. Tierney and/or Mr. Wolfe will testify regarding pharmacies' license of patient de-identified prescriber-identifiable information to the plaintiffs and the locations from which the information is transmitted to the plaintiffs.

10:30 - 10:45 a.m.

- n. Mid-Morning Break

10:45 - 12 noon

- o. Eugene Kolassa

Professor Kolassa will provide expert testimony regarding pharmaceutical marketing, training of sales representatives and the likely consequences that the Prescription Restraint Law will have on interactions between sales representatives and Vermont physicians.

12 noon - 1 p.m.

- p. Lunch

1:00 - 3:00 p.m.

- q. Manufacturer Representative

This witness will testify regarding training of sales representatives, use of prescriber-identifiable information and the limitations imposed by the Prescription Restraint Law on their ability to communicate with prescribers.

Appendix I

Proposed Court Schedule IMS Health Inc. & Pharmaceutical Researchers and Manufacturers Association of America v. State of Vermont (generally)

Case 1:07-cv-00188-jgm Document 346 Filed 07/09/2008

Case No. 1:07-cv-188-jgm
Consolidated with Case No. 1:07-cv-220

r. 3:00 - 3:15 p.m.
Break

s. 3:15 - 3:45 p.m.
Dr. Michael Turner
Policy & Economic Research Council

Mr. Turner will provide expert opinions regarding the generally accepted methodology in the field of political economy to make predictive judgments about the impact of laws that restrict the flow of personally-identifiable information on the market in which such information is used to market goods and services.

t. 3:45 - 4:45 p.m.
Randy Frankel
Vice President for External Affairs
IMS Health Incorporated

Mr. Frankel will provide expert testimony regarding the many alternatives available to the State of Vermont to achieve objectives of the Prescription Restraint Law.

u. 4:45 - 5:00 p.m.
Timeline Summary

v. 5:00 - 5:15 p.m.
Summary of the Legislative Record Tom Julin

- (1) Witnesses
- (2) Documents
- (3) Bill Drafts

Wednesday - July 30, 2008

2. Defendants' Case

Wednesday - July 30, 2008

a. 9:00 - 9:45 a.m.
Dr. Ashley Wazana

Dr. Wazana is a child psychiatrist who will provide opinion regarding the effect of gifts and sales representatives' interactions with the pharmaceutical industry.

Appendix I

Proposed Court Schedule IMS Health Inc. & Pharmaceutical Researchers and Manufacturers Association of America v. State of Vermont (generally)

Case 1:07-cv-00188-jgm Document 346 Filed 07/09/2008

Case No. 1:07-cv-188-jgm
Consolidated with Case No. 1:07-cv-220

b. 9:45 - 10:15 a.m.
Shahram Ahari

Mr. Ahari is a former Eli Lilly sales representative who will testify concerning his experiences at Eli Lilly.

c. 10:15 - 10:30 a.m.
Break

d. 10:30 - 11:15 a.m.
Dr. Meredith Rosenthal

Dr. Rosenthal is a professor who will provide expert opinion regarding the extent to which the amount spent by payers on prescription drugs will decrease if doctors prescribe more generic drugs instead of patent-protected drugs.

e. 11:15 - 12:15 p.m.
Dr. David Grande

Dr. Grande is a medical doctor and university professor who will provide expert opinion that by reducing the use of prescriber-identifiable data for marketing purposes, pharmaceutical sales representatives will be less able to target prescribers and develop messages designed to place the economic interests of the pharmaceutical company over the interests of the of patients.

f. 12:15 - 1:15 p.m.
Lunch

g. 1:15 - 3:15 p.m.
Dr. Aaron Kesselheim

Dr. Kesselheim is a medical doctor and patent lawyer who will provide opinion regarding the federal law approval of new drugs and the interactions that prescribers have with sales representatives as has been reported in literature.

h. 3:15 - 3:30 p.m.
Break

Appendix I

Proposed Court Schedule IMS Health Inc. & Pharmaceutical Researchers and Manufacturers Association of America v. State of Vermont (generally)

Case 1:07-cv-00188-jgm Document 346 Filed 07/09/2008

Case No. 1:07-cv-188-jgm
Consolidated with Case No. 1:07-cv-220

- 3:30 - 4:15 p.m.
i. Amanda Kennedy
U. of Vt. Academic Detailing

Ms. Kennedy is a research assistant who will testify regarding the Vermont Academic Detailing Program

- 4:15 - 5:00 p.m.
j. Madeleine Mongan
Vermont Medical Society

Ms. Mongan is vice president for policy of the Vermont Medical Society and will testify regarding the Society's support for the Prescription Restraint Law.

Thursday, Aug. 1, 2008

- 9:00 - 10:00 a.m.
k. Craig Jones
Vt. Blue Print of Health

Mr. Jones will testify regarding the implementation of regulations governing the manufacturing fee provision.

- 11:00 - 11:45 a.m.
l. PhRMA's Closing

- 11:45 - 1:00 p.m.
m. Lunch

- 1:00 - 1:45 p.m.
n. Publisher Plaintiffs' Closing

- 1:45 - 3:45 p.m.
o. Defendants' Closing

- 3:45 - 4:00 p.m.
p. PhRMA's Reply

- 4:00 - 4:15 p.m.
q. Publisher Plaintiffs' Reply

The parties have identified additional witnesses who may be called as needed.