

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT**

IMS HEALTH INCORPORATED;)
VERISPAN, LLC; and SOURCE)
HEALTH CARE ANALYTICS, INC., a)
Subsidiary of WOLTERS KLUWER,) Civil Action No. 2:07-cv-00188
HEALTH INC.,)
)

Plaintiffs,)
)

vs.)
)

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

Defendant.)
)

PHARMACEUTICAL RESEARCH AND)
MANUFACTURERS OF AMERICA,)
)

Civil Action No. 1:07-cv-220)
)

Plaintiff,)
)

vs.)
)

WILLIAM H. SORRELL, in his official)
capacity as Attorney General of the State)
of Vermont, JIM DOUGLAS, in his official)
capacity as Governor of the State of)
Vermont, and CYNTHIA D. LAWARE,)
in her official capacity as the Secretary of)
the Agency of Human Services of the State)
of Vermont,)
)

Defendants.)
)

**THE PUBLISHER PLAINTIFFS’ AND PhRMA’S JOINT STATEMENT
OF UNDISPUTED FACTS**

Pursuant to the Court’s July 3 and July 22, 2008 Minute Entries, Plaintiffs IMS Health Incorporated, Verispan LLC and Source Health Care Analytics, Inc. (the “Publisher Plaintiffs,” or the “IMS Plaintiffs”) and Plaintiff Pharmaceutical Research and Manufacturers of America

(“PhRMA”) hereby submit their Joint Statement of Undisputed Facts. These facts were derived from Answers to the Plaintiffs’ Amended Complaints as well as from responses to Requests for Admission propounded by the parties. As used herein, the terms “the Act” and “the Vermont Act” refer to Vermont Acts No. 80 (2007), as amended by Vermont Acts No. 89 (2008). Where used, “the State” refers to the State of Vermont.

I. BACKGROUND & LEGISLATIVE HISTORY OF ACT 80

- A.** The Vermont Act was the third law in the nation to restrict the sale, licensing and use of prescriber-identifiable information for marketing purposes. (Defs.’ Responses to Pub. Plaintiffs’ Requests for Admission at ¶ 14, attached hereto as Ex. 1.)
- B.** Vermont Senate Bill 115, Section 17, as originally introduced, was similar to the New Hampshire law. (Defs.’ Answer to Pub. Plaintiffs’ Revised First Amended Complaint at ¶ 5, attached hereto as Ex. 2.)
- C.** Before the Vermont law was enacted, 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. 2007). (Defs.’ Answer to Pub. Plaintiffs’ Revised First Amended Complaint at ¶ 6 (Ex. 2).)
- D.** Vermont Senate Bill 115 was amended prior to its enactment, which was subsequent to the United States District Court of New Hampshire’s ruling on the New Hampshire law. (Defs.’ Answer to Pub. Plaintiffs’ Revised First Amended Complaint at ¶ 7 (Ex. 2).)
- E.** On May 3, 2007, during a hearing on Senate Bill 115, which became Vermont Act 80, Vermont representative Pat O’Donnell stated:

I think it comes as no surprise that I’m not going to be supporting the bill either. But I have huge concerns when our Attorney General’s office sits here and says we could end up in court, and she believes, she thinks, that maybe this bill is okay. So, that’s telling me that we don’t know we’re going to win in court, we don’t know that we’re not passing a law that is unconstitutional. And I think, one of the most important things for me, is that when we’re sworn in for office, we take an oath to uphold the Constitution of this State, and the Constitution of the Country. And, to sit here, last minute, like this and I have to say, I’ve been in this building for 9 years, I’ve never sat, and seen a Committee sit here and pass a bill out of Committee that they’re waiting to deal with out on the floor. And I don’t feel like I even know what’s in this bill now. It’s being pushed past us way too

fast, and there have been way too many changes made, and for us to be voting on a bill that they're going to take up on the floor in 10 minutes, is something I've never seen before. And I don't think it's fair to the people we represent, it doesn't have anything to do with the drug companies -- it has to do with the fact that we have a legal responsibility to follow the law. And one judge, is a very serious judge, when it's a Federal judge, in our case, we'll go in front of a Federal Court. And when you start getting into these lawsuits, you can easily spend millions of dollars. So, what we may save on one end -- if we even save anything -- we're going to spend on the other, and in lawsuits, and that's not fair to the people we represent.

See House Healthcare Hearing Transcript, May 3, 2007, at 229-30, attached hereto as Ex. 3. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 2, attached hereto as Ex. 4.)

- F.** On May 3, 2007, during a hearing on Senate Bill 115, which became Vermont Act 80, Vermont representative Keogh stated:

I'll be voting no on this amendment. I want to appreciate all the work that Steve and Robin did on the findings and supporting those findings, but I think we need more time to address some of the issues that we're trying to address here, and we just haven't had the time, devoted the time to do that. We have -- I think we have to allow time for educating doctors, and what their responsibilities are, and to see if some of the counter-detailing to be done by Medical Society is effective. And, kind of support this type of legislation which could very well be faulty, and could be the subject of a litigation down the road, and I certainly would not like to be part of any legislation which would cause us to go to court, and be costly to the tax payers. We have not addressed the Commerce Clause which, while that has been discounted by New Hampshire, I think that is an element that another judge might look at. And I don't think we've addressed that, as well.

See House Healthcare Hearing Transcript, May 3, 2007, at 222-23, attached hereto as Ex. 5. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 2 (Ex. 4).)

- G.** On May 2, 2007, Representative Peg Flory stated:

We took time to debate, on this floor, the Iraq resolution. We took time, on this floor, to debate the Impeachment resolution. It was said we did this so that people could be informed and have their say. Yet this evening, we refused to send this bill to the committee that has jurisdiction over Constitutional matters and refused to allow time for review of a 17 page amendment to an even larger bill, that we received less than four hours ago, that will potentially place us in a court costing us millions of dollars. This is a travesty [sic] and we dishonor the oath we all took to protect our Constitution.

See The Journal of the House, May 3, 2007, attached hereto as Ex. 6. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 3 (Ex. 4).)

- H.** The Vermont Act was signed into law on June 9, 2007. (Defs.' Answer to Pub. Plaintiffs' Revised First Amended Complaint at ¶ 8 (Ex. 2).)
- I.** On February 22, 2008, the Vermont Legislature amended 18 V.S.A. § 4631 by passage of H.750. The Governor signed that bill into law on March 5, 2008, and it became Vermont Act 89. (Defs.' Answer to Pub. Plaintiffs' Revised First Amended Complaint at ¶ 9 (Ex. 2).)
- J.** Section 7(a) of Act 89 provides that Act 89 shall take effect on passage, and Section 7(b) of Act 89 provides "Notwithstanding the effective dates of this section and of No. 80 of the Acts of 2007, the provisions of Sec. 17 of No. 80 of the Acts of 2007 (adding 18 V.S.A. chapter 91, subchapter 3; prescription drug data confidentiality) and Sec. 21 of No. 80 of the Acts of 2007 (adding 9 V.S.A. § 2466a; consumer protection; prescription drugs) shall not be effective until July 1, 2009; except that the department of health and the office of professional regulation may, immediately upon passage, begin any necessary rulemaking, revision of forms, or other administrative actions necessary to implement the program established in 18 V.S.A. chapter 91, subchapter 3 on July 1, 2009." (Defs.' Answer to Pub. Plaintiffs' Revised First Amended Complaint at ¶ 10 (Ex. 2).)

II. PARTIES

- A.** Members of Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA") purchase data regarding drug prescriptions written or filled in Vermont ("prescriber-identifiable data"), from companies, including Co-Plaintiffs IMS Health, Inc., Verispan, LLC, and Source Healthcare Analytics, Inc., that collect and process such data. (Defs.' Answer to PhRMA's Amended Complaint at ¶ 25, attached hereto as Ex. 7.)
- B.** IMS Health, Incorporated ("IMS Health") is a publicly traded company. (PhRMA's First Amended Responses to Defs.' Requests for Admission at ¶ 91, attached hereto as Ex. 8; Pub. Plaintiffs' Responses to Defs.' Requests for Admission at ¶ 91, attached hereto as Ex. 9.)
- C.** Source Healthcare Analytics, Inc. ("Source Healthcare") is a wholly-owned subsidiary of Wolters Kluwer Health Inc., which is a publicly traded company. (PhRMA's First Amended Responses to Defs.' Requests for Admission at ¶ 93 (Ex. 8).)
- D.** In 2006, IMS Health's revenue grew 12% to \$1.96 billion. (Pub. Plaintiffs' Responses to Defs.' Requests for Admission at ¶ 98 (Ex. 9).)

- E.** In 2006, IMS Health returned \$880 million to its shareholders in the form of stock repurchases. (Pub. Plaintiffs' Responses to Defs.' Requests for Admission at ¶ 99 (Ex. 9).)
- F.** IMS Health's revenue grew by 13% compound annual growth from 2002 to 2006. (Pub. Plaintiffs' Responses to Defs.' Requests for Admission at ¶ 100 (Ex. 9).)
- G.** IMS Health's operating income was \$444 million in 2006. (Pub. Plaintiffs' Responses to Defs.' Requests for Admission at ¶ 101 (Ex. 9).)
- H.** IMS Health's operating income grew at a 2% compound annual pace from 2002 to 2006. (Pub. Plaintiffs' Responses to Defs.' Requests for Admission at ¶ 102 (Ex. 9).)
- I.** Defendant William H. Sorrell is the Attorney General of Vermont and the chief legal officer charged with enforcing 18 V.S.A. § 4631 and 9 V.S.A. § 2466a. (Defs.' Answer to PhRMA's Amended Complaint at ¶ 13 (Ex. 7).)
- J.** 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 33 V.S.A. § 2004, and proposing the rules required by this provision, is an executive branch agency. (Defs.' Answer to PhRMA's Amended Complaint at ¶ 14 (Ex. 7).)
- K.** 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 33 V.S.A. § 2004. Secretary LaWare is responsible for proposing the rules required by this provision. (Defs.' Answer to PhRMA's Amended Complaint at ¶ 15 (Ex. 7).)

III. DATA PURCHASE & ANALYSIS BY IMS PLAINTIFFS

- A.** CVS Caremark Corporation ("CVS") is a corporation with its retail headquarters and principal place of business in Woonsocket, Rhode Island. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 47 (Ex. 1).)
- B.** CVS owns retail pharmacies throughout the United States, including retail pharmacies in Vermont. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 49 (Ex. 1).)
- C.** Rite Aid Corporation ("Rite Aid") is a corporation with its headquarters and principal place of business in Camp Hill, Pennsylvania. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 48 (Ex. 1).)
- D.** Rite Aid operates approximately 5,100 retail pharmacies in thirty (30) states and the District of Columbia, including thirty-nine (39) retail pharmacies in Vermont. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 50 (Ex. 1).)

- E.** CVS and Rite Aid are in the business of selling pharmaceutical medicines and other products to members of the general public. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 51 (Ex. 1).)
- F.** Some of the medicines and products sold by CVS and Rite-Aid are sold over the counter; others require a prescription before they can be sold to anyone. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 52 (Ex. 1).)
- G.** CVS's and Rite Aid's customers originate from many states. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 53 (Ex. 1).)
- H.** Some of CVS's and Rite Aid's customers are given prescriptions that are dispensed in Vermont or written by prescribers doing business in Vermont. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 54 (Ex. 1).)
- I.** When a customer brings a prescription to a CVS or Rite Aid pharmacy, the pharmacist inputs prescription information into a CVS or Rite Aid computer that stores the patient's name, the prescribed drug, the dosage of the drug, and the name of the prescriber who prescribed the medication. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 55 (Ex. 1).)
- J.** CVS and Rite Aid use software designed to comply with federal and state laws and regulations requiring protection of confidential patient information. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 56 (Ex. 1).)
- K.** Each of the IMS Plaintiffs is located outside of Vermont, and CVS and Rite Aid transfer prescriber-identifiable prescription records from prescriptions written or dispensed in Vermont to the IMS Plaintiffs *via* computers located outside of Vermont. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 58 (Ex. 1).)
- L.** The IMS plaintiffs analyze prescriber-identifiable data to identify: (1) prescribers who are switching from one prescription drug to another; (2) prescribers who are high prescribers of patent-protected drugs; and (3) prescribers who are early adopters of patent-protected drugs. (Pub. Plaintiffs' Responses to Defs.' Requests for Admission at ¶¶ 79-81, 83-85, 87-89 (Ex. 9).)
- M.** The Act prohibits a pharmacy that stores prescriber identifiable information in regulated records (meaning "a prescription dispensed in Vermont and written by a prescriber doing business in Vermont") outside of Vermont from selling to a company located outside of Vermont that information for marketing or promoting a prescription drug, unless the prescriber consents. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 62 (Ex. 1).)

IV. SALE OF PRESCRIBER-IDENTIFIABLE DATA BY PHARMACIES

- A.** Pharmacies generally do not advise prescribers or patients that the pharmacy sells prescriber-identifiable data to one or more of the IMS Plaintiffs. (Pub. Plaintiffs' Responses to Defs.' Requests for Admission at ¶ 16 (Ex. 9).)
- B.** Pharmacies generally do not seek the consent of prescribers or patients before selling prescriber-identifiable data to the IMS Plaintiffs. (Pub. Plaintiffs' Responses to Defs.' Requests for Admission at ¶ 17 (Ex. 9).)

V. 18 V.S.A. § 4631(d)

A. STATUTORY LANGUAGE & EFFECT

1. 18 V.S.A. § 4631(d) prohibits pharmaceutical manufacturers and pharmaceutical marketers from using prescriber-identifiable information "for marketing or promoting a prescription drug unless the prescriber consents as provided in subsection (c) of this section." Act 89 § 3, codified at 18 V.S.A. § 4631(d). (Defs.' Answer to PhRMA's Amended Complaint at ¶ 7 (Ex. 7).)
2. 18 V.S.A. § 4631(d) provides that covered entities "shall not sell, license or exchange for value regulated records containing prescriber-identifiable information, nor permit the use of regulated records containing prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents as provided in subsection (c) of this section." (Defs.' Answer to Pub. Plaintiffs' Revised First Amended Complaint at ¶ 86 (Ex. 2).)
3. The Act defines "marketing" to "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." 18 V.S.A. § 4631(b)(5). (Defs.' Answer to PhRMA's Amended Complaint at ¶ 51 (Ex. 7).)
4. The Act defines "marketing" to include "promotion," Act 80, § 17, codified at 18 V.S.A. § 4631(b)(5), and defines "promotion" 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." 18 V.S.A. § 4631(b)(8). (Defs.' Answer to PhRMA's Amended Complaint at ¶ 52 (Ex. 7).)
5. The Act provides that "[a] violation of section 4631 of Title 18 shall be considered a prohibited practice under [the Vermont Consumer Fraud Act]." 9 V.S.A. § 2466a(a). (Defs.' Answer to PhRMA's Amended Complaint at ¶ 54 (Ex. 7).)

B. STATED GOALS OF ACT 80

1. The Vermont Act states that it seeks to protect prescriber privacy and improve public health. (Defs.' Answer to PhRMA's Amended Complaint at ¶ 1 (Ex. 7).) Another purpose of the Act is to contain the costs of prescription drugs. (Defs.' Answer to Pub. Plaintiffs' Revised First Amended Complaint at ¶ 44 (Ex. 2).)
2. One of the goals of Act 80 as a whole is to increase use of generic drugs. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 4 (Ex. 4).)

C. PRESCRIBER PRIVACY

1. Under the Vermont Act, prescribers may refuse to consent to the disclosure of information about their prescribing practices for any or no reason. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 11 (Ex. 1).)
2. The Vermont Act does not prohibit prescribers from selling their own identifiable information for marketing purposes directly to the pharmaceutical companies for a profit. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 13 (Ex. 1).)
3. The Vermont Act does not prevent patients from transferring prescriber-identifiable information to others for marketing purposes. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 19 (Ex. 1).)
4. Retail pharmacies acquire certain prescription data during the regular course of business. (Defs.' Answer to Pub. Plaintiffs' Revised First Amended Complaint at ¶ 29 (Ex. 2); *see also* Defs.' Responses to PhRMA's Requests for Admission at ¶ 13 (Ex. 4).)
5. Prescriber-identifiable data are used: (a) for research purposes; (b) by insurance companies; and (c) by pharmacy benefit managers. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 11 (Ex. 4).)
6. Prescriber-identifiable data are used by the State of Vermont: (a) to implement Vermont's preferred drug list; (b) for law enforcement purposes; (c) for the Vermont Department of Health's prescription monitoring program; (d) in conjunction with Vermont's multi-payer database; (e) in conjunction with Vermont's Medicaid program; (f) in conjunction with Vermont's Care Management Program; and (g) in conjunction with Vermont's Care Coordination Program. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 12 (Ex. 4).)
7. Prescriber-identifiable data are used by the federal government. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 14 (Ex. 4).)

8. Physicians in Vermont have the right to refuse to see pharmaceutical sales representatives. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 39 (Ex. 4).)

9. Act 80 does not bar pharmaceutical sales representatives from visiting Vermont prescribers. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 40 (Ex. 4).)

10. Act 80 does not impose limits on the amount of detailing engaged in by pharmaceutical sales representatives. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 41 (Ex. 4).)

11. Only a person who is licensed to do so may write prescriptions for prescription drugs that are marketed by pharmaceutical sales representatives. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 42 (Ex. 1).)

D. PATIENT PRIVACY

1. Through the use of prescriber-identifiable data, pharmaceutical manufacturers can learn the drugs a prescriber has prescribed, but they do not learn the identities of patients to whom the drugs were prescribed. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 45 (Ex. 1).)

2. Patient-identified data are not provided to or sold to pharmaceutical companies. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 6 (Ex. 4).)

3. Defendants are not aware of any instance in which a specific patient's identity was discovered through review of prescriber-identifiable, patient-de-identified data. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 70 (Ex. 4).)

4. No prescriber testified before the Vermont Legislature prior to the passage of Act 80 that use of prescriber-identifiable data by pharmaceutical companies in the State of Vermont jeopardized his or her patients' privacy rights. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 68 (Ex. 4).)

5. No patient testified before the Vermont Legislature prior to the passage of Act 80 that use of prescriber-identifiable data by pharmaceutical companies in the State of Vermont jeopardized his or her privacy rights. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 69 (Ex. 4).)

E. HEALTH CARE COSTS

1. Physicians in the State of Vermont are required to be licensed by the State of Vermont in order to practice medicine in the State of Vermont. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 15 (Ex. 4).)

2. Physicians practicing in the State of Vermont are required by Vermont law to renew their medical licenses every two years. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 16 (Ex. 4).)
3. Only a prescriber who is permitted by law to do so may write prescriptions for pharmaceuticals in the State of Vermont. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 18 (Ex. 4).)
4. Prescribers in Vermont are expected to exercise their best medical judgment when making treatment decisions. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 19 (Ex. 4).)
5. The Vermont Legislature did not conduct a controlled study to determine whether there is a causal relationship between the use of prescriber-identifiable data by pharmaceutical companies and increases in health care costs. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 65 (Ex. 4).)
6. The Vermont Act does not prohibit prescribers from prescribing patent-protected drugs that are more expensive than other similar drugs covered by the patient's insurance or formulary. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 17 (Ex. 1).)
7. The Vermont Act does not require prescribers to prescribe only the prescription drugs listed in the formulary of the payer of the drug. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 18 (Ex. 1).)
8. The restrictions in 18 V.S.A. § 4631(d) apply whether or not the pharmaceutical being marketed or promoted has a generic equivalent. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 43 (Ex. 4).)
9. The restrictions in 18 V.S.A. § 4631(d) apply whether or not the pharmaceutical being marketed or promoted is not the most expensive pharmaceutical available. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 44 (Ex. 4).)
10. The restrictions in 18 V.S.A. § 4631(d) apply whether or not the pharmaceutical being marketed or promoted is a single source pharmaceutical. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 45 (Ex. 4).)
11. The restrictions in 18 V.S.A. § 4631(d) apply whether or not the pharmaceutical being marketed or promoted is priced lower than other drugs. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 46 (Ex. 4).)
12. The restrictions in 18 V.S.A. § 4631(d) apply whether or not the pharmaceutical being marketed or promoted would result in lower health care costs for a patient if prescribed. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 47 (Ex. 4).)

F. PUBLIC HEALTH

1. The restrictions in 18 V.S.A. § 4631(d) apply whether or not the pharmaceutical being marketed or promoted could result in better patient outcomes if prescribed. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 48 (Ex. 4).)
2. The Vermont Act does not directly prohibit the prescribing of unnecessary drugs. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 15 (Ex. 1).)
3. Health care providers may occasionally report side effects during a detailing visit. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 42 (Ex. 4).)
4. Some of the pharmaceutical drugs promoted, prescribed and sold in Vermont are beneficial. (Defs.' Answer to PhRMA's Amended Complaint at ¶ 16 (Ex. 7).)
5. Defendant Sorrell has stated that "the availability of new drugs has contributed to the health and longevity of Americans." *See* National Association of Attorneys General, Presidential Report Addressing the Costs and Benefits of Prescription Drugs, at 5 (2005), *available at* <http://heartland.temp.siteexecutive.com/pdf/17452.pdf> (last accessed May 14, 2008). (Defs.' Responses to PhRMA's Requests for Admission at ¶ 7 (Ex. 4).)
6. In some situations, it is appropriate for a prescriber to prescribe a brand-name pharmaceutical rather than a generic equivalent. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 49 (Ex. 4).)
7. Patent-protected drugs may be an appropriate treatment option for certain patients. (Defs.' Responses to PhRMA's Second Set of Requests for Admission at ¶ 36, attached hereto as Ex. 10.)
8. In some instances, new drugs can provide clinically effective treatment. (Defs.' Responses to PhRMA's Second Set of Requests for Admission at ¶ 47 (Ex. 10).)
9. In some situations, a patient may respond clinically to some pharmaceuticals in a therapeutic class but not respond clinically to others in the same class. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 50 (Ex. 4).)
10. Vermont's preferred drug list includes both generic and brand-name pharmaceuticals. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 57 (Ex. 4).)

11. The Office of Vermont Health Access currently pays for certain prescription drug products manufactured by PhRMA members. (Defs.' Answer to PhRMA's Amended Complaint at ¶ 24 (Ex. 7).)
12. The State of Vermont imposes no continuing medical education requirements on medical doctors. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 21 (Ex. 1).)
13. The State of Vermont imposes no continuing medical education requirements on medical doctors about appropriate drug selection. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 20 (Ex. 1).)
14. The State of Vermont imposes no continuing medical education requirements on medical doctors about marketing information provided by pharmaceutical sales representatives. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 23 (Ex. 1).)
15. Physicians in Vermont are not required by the State to undergo training regarding marketing of pharmaceuticals. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 17 (Ex. 4).)
16. The State does not require licensing, training, or continuing education of sales representatives. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 24 (Ex. 1).)
17. The State of Vermont has not enacted a mandatory ethical code or statute regarding pharmaceutical marketing practices. (Defs.' Responses to Pub. Plaintiffs' Requests for Admissions at ¶ 25-26 (Ex. 1).)
18. The State of Vermont does not prohibit pharmaceutical manufacturers from giving gifts to prescribers. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 27 (Ex. 1).)
19. The State of Vermont does not prohibit pharmaceutical manufacturers from buying meals for prescribers. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 28 (Ex. 1).)
20. The State of Vermont does not prohibit pharmaceutical manufacturers from providing scholarships or other support for medical students, residents, and fellows to attend educational, scientific, or policy-making conferences or other professional association meetings. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 31 (Ex. 1).)
21. The State of Vermont does not require prescribers to disclose gifts, fees, and other items of economic benefit received from pharmaceutical manufacturers. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 32 (Ex. 1).)

22. Since 2002, the State of Vermont has required disclosure of gifts of value exceeding \$25.00 from pharmaceutical companies pursuant to its Pharmaceutical Marketing Disclosure Law. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 54 (Ex. 4).)

23. The State of Vermont does not require pharmaceutical manufacturers to disclose 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. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 36 (Ex. 1).)

24. The University of Vermont, which receives financial support from the State of Vermont, has an academic detailing program. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 55 (Ex. 4).)

25. Some physicians hold the opinion that an academic detailing program might result in cost savings. (Defs.' Responses to PhRMA's Second Set of Requests for Admission at ¶ 29 (Ex. 10).)

26. It has been reported that an academic detailing module implemented in Pennsylvania regarding gastrointestinal drugs resulted in cost savings. (Defs.' Responses to PhRMA's Second Set of Requests for Admission at ¶ 30 (Ex. 10).)¹

27. The State of Vermont enacted a generic voucher program as part of Act 80. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 52 (Ex. 4).)

28. Act 80 provides that prescribers will be notified of patent expirations. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 53 (Ex. 4).)

29. Vermont has a price disclosure law applicable to pharmaceutical prices. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 59 (Ex. 4).)

30. The State of Vermont has a preferred drug list for its Medicaid program. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 56 (Ex. 4).)

31. Some formularies can decrease the total amount spent on prescription drugs. (Defs.' Responses to PhRMA's Second Set of Requests for Admission at ¶ 52 (Ex. 10).)

32. As part of its Medicaid program, Vermont participates in a multi-state purchasing pool for the purchase of pharmaceutical products. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 58 (Ex. 4).)

¹ Defendants' Response to PhRMA's Second Set of Requests for Admission is mis-numbered, and thus this cited response by Defendants in fact responds to PhRMA's Request No. 31.

33. Vermont has a generic substitution law that requires pharmacies to substitute a bioequivalent generic for brand-name pharmaceuticals whenever available, unless the prescriber has specifically instructed otherwise in writing on the prescription. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 60 (Ex. 4).)

34. No prescriber testified before the Vermont Legislature prior to the passage of Act 80 that: (a) he or she prescribed pharmaceuticals based solely on biased information received from a pharmaceutical sales representative; (b) he or she prescribed pharmaceuticals based solely on incomplete information received from a pharmaceutical sales representative; or (c) he or she prescribed pharmaceuticals based solely on inaccurate information received from a pharmaceutical sales representative. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 68 (Ex. 4).)

VI. 9 V.S.A. § 2466a(c)(1)

A. STATUTORY LANGUAGE & EFFECT

1. As amended by Act 89, 9 V.S.A. § 2466a(c)(1) provides that “[i]t shall be a prohibited practice under section 2453 of this title 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.” (Defs.' Answer to PhRMA's Amended Complaint at ¶ 27 (Ex. 7).)

2. A private party may bring an action under the Vermont Consumer Fraud Act consistent with the requirements of 9 V.S.A. § 2461(b). (Defs.' Answer to PhRMA's Amended Complaint at ¶ 27 (Ex. 7).)

3. 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.” 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.” 9 V.S.A. § 2466a(c)(2)(B)(ii). (Defs.' Answer to PhRMA's Amended Complaint at ¶ 29 (Ex. 7).)

4. 9 V.S.A. § 2466a(c)(1) only applies to a “manufacturer of prescription drugs” as defined in the Act, which 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).” (Defs.’ Answer to PhRMA’s Amended Complaint at ¶ 28 (Ex. 7).)

B. PREEMPTION

1. FDA regulates the advertising practices of pharmaceutical manufacturers. (Defs.’ Answer to PhRMA’s Amended Complaint at ¶ 30 (Ex. 7).)

2. FDA regulates advertising and labeling materials for prescription drugs. (Defs.’ Answer to PhRMA’s Amended Complaint at ¶ 32 (Ex. 7).)

3. FDA has authority to issue warning letters and untitled letters concerning advertising by pharmaceutical manufacturers. (Defs.’ Answer to PhRMA’s Amended Complaint at ¶ 36 (Ex. 7).)

4. Pharmaceutical sales representatives are required to comply with the Federal Food, Drug, and Cosmetic Act as well as FDA regulations. (Defs.’ Responses to PhRMA’s Requests for Admission at ¶ 21 (Ex. 4).)

5. The Federal Food, Drug, and Cosmetic Act and FDA regulations govern the communications pharmaceutical sales representatives are permitted to engage in with prescribers. (Defs.’ Responses to PhRMA’s Requests for Admission at ¶ 22 (Ex. 4).)

6. Under the Federal Food, Drug, and Cosmetic Act, a prescription pharmaceutical product may be misbranded if its advertising or promotional labeling is false or misleading. (Defs.’ Responses to PhRMA’s Requests for Admission at ¶ 23 (Ex. 4).)

7. Under FDA regulations, pharmaceutical advertising or promotional labeling, including communications by pharmaceutical sales representatives, is false or misleading if inconsistent with the FDA approved labeling. (Defs.’ Responses to PhRMA’s Requests for Admission at ¶ 24 (Ex. 4).)

8. FDA regulates the content of written advertising and promotional labeling materials through its Division of Drug Marketing, Advertising and Communications (“DDMAC”). (Defs.’ Responses to PhRMA’s Requests for Admission at ¶ 25 (Ex. 4).)

9. Pharmaceutical companies are required to submit copies of written advertising and promotional labeling materials to DDMAC at the time of first

publication or dissemination. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 26 (Ex. 4).)

10. Pharmaceutical companies submit proposed written advertising materials to DDMAC in connection with approval of a new drug or approval of a new indication or condition of use for a previously approved drug. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 27 (Ex. 4).)

11. DDMAC has authority to determine whether written promotional labeling or advertising materials are false and/or misleading. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 28 (Ex. 4).)

C. COMMERCE CLAUSE

1. No PhRMA member is (a) incorporated in Vermont, or (b) has its principal place of business in Vermont. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 1 (Ex. 4).)

2. Some pharmaceutical advertisements appear in magazines and medical journals that are circulated nationwide. (Defs.' Responses to PhRMA's Requests for Admission at ¶¶ 29-30 (Ex. 4).)

VII. MARKETING BY PHRMA MEMBERS

- A.** PhRMA has a "Code on Interactions with Healthcare Professionals," adopted in 2002, and amended in July 2008. The amendments take effect in January 2009. (Defs.' Responses to PhRMA's Requests for Admission at ¶ 86 (Ex. 4); http://www.phrma.org/news_room/press_releases/phrma_code_reinforces_commitment_to_responsible_interactions_with_healthcare_professionals/ (last visited July 27, 2008).)
- B.** Pharmaceutical sales representatives are trained to comply with laws and regulations enacted by the FDA. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 40 (Ex. 1).)
- C.** Pharmaceutical sales representatives are trained to comply with their respective company policies when communicating with prescribers. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 41 (Ex. 1).)
- D.** Pharmaceutical sales representatives receive training to discuss with prescribers the benefits and risks of the drugs the representatives promote. (Defs.' Responses to Pub. Plaintiffs' Requests for Admission at ¶ 43 (Ex. 1).)
- E.** Some PhRMA members require that a prospective sales representative have a college degree, but no other degrees, as a condition of employment. (PhRMA's First Amended Responses to Defs.' Requests for Admission at ¶ 29 (Ex. 8).)

- F.** PhRMA members' sales representatives do not promote drugs that are not manufactured, distributed, or marketed by their respective companies. (PhRMA's First Amended Responses to Defs.' Requests for Admission at ¶ 51 (Ex. 8).)
- G.** Some PhRMA members compensate their sales representatives, in part, based upon sales representatives' success in achieving certain goals, some of which relate to the number of prescriptions written for a promoted drug. (PhRMA's First Amended Responses to Defs.' Requests for Admission at ¶ 36 (Ex. 8).)
- H.** Some PhRMA members use prescriber-identifiable data to market patent-protected prescription drugs. (PhRMA's First Amended Responses to Defs.' Requests for Admission at ¶ 4 (Ex. 8).)
- I.** Some PhRMA members use prescriber-identifiable data to focus and improve the efficiency of their sales and marketing efforts, and to make these efforts less disruptive to doctors. (PhRMA's First Amended Responses to Defs.' Requests for Admission at ¶ 41 (Ex. 8).)
- J.** Some PhRMA members use prescriber-identifiable data to identify prescribers who may be more likely to prescribe particular types of products being promoted. (PhRMA's First Amended Responses to Defs.' Requests for Admission at ¶ 39 (Ex. 8).)
- K.** Targeted marketing is a marketing strategy sometimes used by some PhRMA members. Subject to FDA regulations and company policies, targeted marketing may include establishing different marketing practices for different customers. (PhRMA's First Amended Responses to Defs.' Requests for Admission at ¶¶ 44-45 (Ex. 8).)
- L.** If the retail value of samples is excluded, detailing accounted for the largest promotional expenditure by PhRMA members in 2006. (PhRMA's First Amended Responses to Defs.' Requests for Admission at ¶ 108 (Ex. 8).)
- M.** The retail value of a sample does not reflect the true cost of the sample to the pharmaceutical manufacturer. (Def.'s Responses to PhRMA's Requests for Admission at ¶ 64 (Ex. 4).)
- N.** Pharmaceutical sales representatives generally do not inform prescribers that they use prescriber-identifiable data in marketing and promoting prescription drugs. (PhRMA's First Amended Responses to Defs.' Requests for Admission at ¶ 25 (Ex. 8); Pub. Plaintiffs' Responses to Defs.' Requests for Admission at ¶ 25 (Ex. 9).)
- O.** Some PhRMA members design marketing programs consistent with FDA regulations and company policies, with the goal, among others, of increasing sales of their products. (PhRMA's First Amended Responses to Defs.' Requests for Admission at ¶ 55 (Ex. 8).)

- P.** Data from IMS Health show that the pharmaceutical industry, including PhRMA members and non-members, spent approximately \$7.2 billion dollars on office promotion, hospital promotion, and journal advertising in 2006 (including all direct costs of marketing such as sales representatives' salaries and training). (PhRMA's First Amended Responses to Defs.' Requests for Admission at ¶ 54 (Ex. 8).)
- Q.** Data from IMS Health show that the pharmaceutical industry, including PhRMA members and non-members, spent \$12 billion on all combined drug promotional activities (as defined by IMS) for 2006. (PhRMA's First Amended Responses to Defs.' Requests for Admission at ¶ 56 (Ex. 8).)

VIII. PHARMACEUTICAL SALES

- A.** In a March 8, 2007 news release, IMS Health reported that U.S. sales of prescription drugs in 2006 totaled \$274.9 billion dollars. (PhRMA's First Amended Responses to Defs.' Requests for Admission at ¶ 114 (Ex. 8).)
- B.** In a March 2007 news release, IMS Health reported that sales of lipid regulators in 2006 totaled \$21.6 billion dollars. (PhRMA's First Amended Responses to Defs.' Requests for Admission at ¶ 116 (Ex. 8).)
- C.** In a March 2007 press release, IMS Health reported that 2006 sales of Lipitor totaled \$8.6 billion, and that 2006 sales of Zocor totaled \$3.1 billion. (PhRMA's First Amended Responses to Defs.' Requests for Admission at ¶ 117 (Ex. 8).)
- D.** Some PhRMA members use subsidiaries or third parties to sell authorized generic versions of their drugs. (PhRMA's First Amended Responses to Defs.' Requests for Admission at ¶ 50 (Ex. 8).)

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