

---

---

**In The  
Supreme Court of the United States**

---

---

WILLIAM H. SORRELL, as Attorney General of the  
State of Vermont; PETER SHUMLIN, in his Capacity  
as Governor of the State of Vermont; and DOUGLAS A.  
RACINE, in his Capacity as Secretary of the  
Agency of Human Services of the State of Vermont,

*Petitioners,*

v.

IMS HEALTH INC.; VERISPAN, LLC; SOURCE  
HEALTHCARE ANALYTICS, INC., A Subsidiary of  
Wolters Kluwer Health, Inc.; and PHARMACEUTICAL  
RESEARCH AND MANUFACTURERS OF AMERICA,

*Respondents.*

---

---

**On Writ Of Certiorari To The United States  
Court Of Appeals For The Second Circuit**

---

---

**JOINT APPENDIX, VOLUME I**

---

---

THOMAS C. GOLDSTEIN  
*Counsel of Record*  
GOLDSTEIN, HOWE & RUSSELL, PC  
7272 Wisconsin Avenue  
Bethesda, Maryland 20814  
(301) 941-1913  
tgoldstein@ghrfirm.com  
*Counsel for Respondents IMS  
Health Inc., Verispan, LLC, and  
Source Healthcare Analytics, Inc.*

LISA S. BLATT  
*Counsel of Record*  
ARNOLD & PORTER LLP  
555 12th Street, N.W.  
Washington, DC 20004  
(202) 942-5000  
Lisa.Blatt@aporter.com  
*Counsel for Respondent Pharmaceutical  
Research and Manufacturers of America*

WILLIAM H. SORRELL  
Attorney General  
BRIDGET C. ASAY  
Assistant Attorney  
General  
*Counsel of Record*  
OFFICE OF THE  
ATTORNEY GENERAL  
109 State Street  
Montpelier, Vermont  
05609-1001  
(802) 828-3181  
basay@atg.state.vt.us  
*Counsel for Petitioners*

---

---

**Petition For Certiorari Filed December 13, 2010  
Certiorari Granted January 7, 2011**

---

---

## TABLE OF CONTENTS

	Page
Relevant Docket Entries from the United States District Court for the District of Vermont, No. 1:07-cv-00188-jgm .....	1
Relevant Docket Entries from the United States Court of Appeals for the Second Circuit, No. 09-1913-cv.....	44
Relevant Docket Entries from the United States District Court for the District of Vermont, No. 1:07-cv-00220-jgm .....	47
Relevant Docket Entries from the United States Court of Appeals for the Second Circuit, No. 09-2056-cv.....	48
Amended Complaint, Dist. Ct. Doc. No. 221 (filed Apr. 29, 2008).....	49
Revised First Amended Complaint, Dist. Ct. Doc. No. 220 (filed May 14, 2008).....	76
Excerpt from Plaintiffs' Supplemental Responses to Defendants' First Request for Production, (Feb. 8, 2008).....	129
Excerpts from Trial Transcript, No. 1:07-cv-00188-jgm (D. Vt.):	
July 28, 2008:	
Testimony of Hossam Sadek .....	132
Testimony of Jody Fisher .....	155
Testimony of Carol Livingston.....	167
Testimony of James Cole .....	171

## TABLE OF CONTENTS – Continued

	Page
July 29, 2008:	
Testimony of Peter Hutt .....	187
Testimony of Lori Reilly .....	198
Testimony of Thomas Kolassa .....	202
Testimony of Thomas Wharton.....	212
July 30, 2008:	
Testimony of Thomas Wharton.....	234
Testimony of Jeffrey Robertson .....	240
Testimony of Scott Tierney.....	245
Testimony of Michael Turner .....	255
Deposition Testimony of Kenneth Ciongoli (Publisher Plaintiffs' Trial Exhibit 9A).....	271
Testimony of Ashley Wazana.....	288
Testimony of Randolph Frankel .....	296
July 31, 2008:	
Testimony of Randolph Frankel.....	302
Testimony of David Grande.....	322
Testimony of Meredith Rosenthal.....	337
Testimony of Shahram Ahari .....	340
August 1, 2008:	
Testimony of Aaron Kesselheim.....	347

## TABLE OF CONTENTS – Continued

	Page
Excerpts from Joint Trial Exhibit 1, admitted July 30, 2008:	
Vermont Medical Society Resolution adopted Oct. 14, 2006 .....	376
New York Times, “High-Tech Stealth Being Used To Sway Doctor Prescriptions,” Nov. 16, 2000 .....	379
Written Testimony of Dr. Richard Entel.....	380
Excerpt from Written Testimony of Dr. Benjamin Schaefer.....	381
Excerpt from Joint Trial Exhibit 2, admitted July 30, 2008:	
PLOS Medicine, “Following the Script: How Drug Reps Make Friends and Influ- ence Doctors,” Vol. 4, Issue 4, Apr. 24, 2007.....	384
Excerpt from Joint Trial Exhibit 3, admitted July 30, 2008:	
Journal of the House, Thursday, May 3, 2007.....	397
Excerpts from Publisher Plaintiffs’ Trial Exhib- it 11 (Legislative Hearing Transcripts), ad- mitted July 31, 2008:	
February 16, 2007:	
Testimony of Madeleine Mongan .....	399
February 21, 2007:	
Testimony of Madeleine Mongan .....	401

## TABLE OF CONTENTS – Continued

	Page
April 10, 2007:	
Testimony of Representative Dr. Harry Chen.....	404
April 13, 2007:	
Testimony of Dr. Carol Boerner.....	406
April 20, 2007:	
Testimony of Dr. Frank Landry.....	409
May 2, 2007:	
Testimony of Joshua Slen & Attendees.....	415
Testimony of Robin Lunge & Attendees.....	417
May 3, 2007:	
Testimony of Paul Harrington .....	419
Testimony of Julie Brill.....	421
Testimony of Representative Patricia O'Donnell .....	422

Table of Contents continued in Volume II

**RELEVANT DOCKET ENTRIES FOR  
THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF VERMONT**

**CIVIL DOCKET FOR CASE #: 1:07-cv-00188-jgm**

<b>Date Filed</b>	<b>#</b>	<b>Docket Text</b>
08/29/2007	1	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: # 1 Exhibit A (1 of 2)# 2 Exhibit A (2 of 2)# 3 Civil Cover Sheet) (law) (Entered: 08/29/2007)
08/30/2007	6	MOTION for Preliminary Injunction by IMS Health Incorporated; Verispan, LLC; Source Healthcare Analytics, Inc. (Attachments: # 1 Memorandum in Support (1 of 3)# 2 Memorandum in Support (2 of 3)# 3 Memorandum in Support (3 of 3)# 4 Declaration of Randolph B. Frankel# 5 Declaration of Hossam Sadek# 6 Declaration of Jody Fisher# 7 Declaration of Carol Livingston# 8 Declaration of Thomas P. Wharton Jr., M.D., F.A.C.C.# 9 Declaration of Andrew J. Cole, M.D., F.R.C.P. (C.) (1 of 2)# 10 Declaration of Andrew J. Cole, M.D., F.R.C.P. (C.) (2 of 2)# 11 Declaration of Goran Ando# 12 Declaration of John

Glaser# 13 Declaration of CVS  
Caremark Corporation# 14 Declara-  
tion of Rite Aid# 15 Declaration of  
Michael A. Turner, Ph.D. (1 of 4)# 16  
Declaration of Michael A. Turner,  
Ph.D. (2 of 4)# 17 Declaration of  
Michael A. Turner, Ph.D. (3 of 4)# 18  
Declaration of Michael A. Turner,  
Ph.D. (4 of 4)# 19 Declaration  
of Joseph W. Duncan) (law)  
(Entered: 08/30/2007)

- 08/30/2007 10 MOTION for Hearing on 6 MOTION  
for Preliminary Injunction by IMS  
Health Incorporated; Verispan, LLC;  
Source Healthcare Analytics, Inc.  
(law) (Entered: 08/30/2007)
- 09/20/2007 20 ANSWER to Complaint by  
William H. Sorrell.(Duffy, Kate)  
(Entered: 09/20/2007)
- 09/27/2007 25 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. Plaintiffs 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)

- 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' 2 Motion for Pro Hac Vice will be granted by written order, Pltfs' 4 Motion for Early Rule 16 Conference DENIED, Pltfs' 10 Motion for Hearings DENIED, Dft's 17 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: 6 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)
- 10/23/2007 61 MOTION for Preliminary Injunction by Pharmaceutical Research and Manufacturers of America. Transfer of pending motion from member case. (kak) (Entered: 12/03/2007)
- 11/07/2007 48 RESPONSE in Opposition re 6 MOTION for Preliminary Injunction filed by William H. Sorrell.  
(Attachments: # 1 Memorandum in Support of Opposition to

Motion for Preliminary Injunction#  
2 Appendix) (Asay, Bridget)  
(Entered: 11/07/2007)

- 11/16/2007 50 MOTION to Consolidate Case (with  
1:07-CV-220) by William H. Sorrell.  
(Duffy, Kate) (same image as 51)  
(jmm) (Entered: 11/16/2007)
- 11/30/2007 60 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 50 Motion to  
Consolidate Case with 1:07-CV-220.  
ORDERED: 50 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 6 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)
- 12/14/2007 74 REPLY to Response to 6 MOTION  
for Preliminary Injunction filed by  
IMS Health Incorporated,  
Verispan, LLC, Source Healthcare  
Analytics, Inc. (Attachments: # 1

Vermont Medical Society Resolution  
– Document 3055) (Acosta, Patricia) (Entered: 12/14/2007)

- 12/19/2007 104 OPPOSITION to 61 MOTION for Preliminary Injunction filed by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Attachments: # 1 Memorandum in Opposition) (law) (Entered: 01/22/2008)
- 01/23/2008 111 REPLY MEMORANDUM by Pharmaceutical Research and Manufacturers of America in support of 6 MOTION for Preliminary Injunction. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D) (Cohen, Linda) (Entered: 01/23/2008)
- 01/31/2008 117 MINUTE ENTRY for proceedings held before Judge J. Garvan Murtha: Discovery Conference held 1/31/2008. Present were Robert Hemley, Esq., Thomas Julin, Esq., Mark Ash, Esq., and Matthew Byrne, Esq. for pltfs IMS Health, Inc., Verispan, LLC and Source Healthcare Analytics, Inc.; Jeffrey Handwerker, Esq., Karen McAndrew, Esq., Laura VanDruff, Esq., and Linda Cohen, Esq., for pltf Pharmaceutical Research and Manufacturers of America; Kate Duffy, Esq. and David Cassetty, Esq. for dfts. Statements by counsel. ORDERED: Parties to

reach agreement, if possible, on depositions of members of Legislative Council. They shall inform the Court at next hearing on 2/20/2008 if the matter is unresolved. The parties' request to file amicus briefs is GRANTED. Plaintiffs shall be limited to 5 and defendants shall be limited to 3. Amicus briefs to be filed by 4/1/2008. Trial memoranda to be filed by 4/1/2008. Written explanation (joint or by each party) of difference between VT legislation and that of NH and ME to be filed by 2/20/2008. (Court Reporter: Coughlin) (kak) (Entered: 01/31/2008)

- 02/15/2008 128 CONFIDENTIALITY STIPULATION AND ORDER. Signed by Judge J. Garvan Murtha on 2/14/2008. (kak) (Entered: 02/15/2008)
- 02/20/2008 133 MINUTE ENTRY for proceedings held before Judge J. Garvan Murtha: Initial Pretrial Conference held 2/20/2008. Present were Robert Hemley, Esq., Thomas Julin, Esq. and Mark Ash, Esq. for pltfs IMS Health, Inc., Verispan, LLC and Source Healthcare Analytics, Inc.; Jeffrey Handwerker, Esq., Karen McAndrew, Esq. and Robert Weiner, Esq. for pltf Pharmaceutical Research and Manufacturers of

America; and Kate Duffy, Esq. for dfts. Statements by counsel. Dfts move to continue trial date until March 2009. Motion granted in part. Trial continued until 8/18/2008. Counsel shall submit a proposed amended discovery schedule that includes two pretrial conferences, the final one to be scheduled 2-3 weeks prior to trial. Court defers ruling on 7 and 116 Requests for Judicial Notice until the parties decide whether there are any differences regarding what the legislative record contains. Dfts will withdraw those portions of 47 and 82 Motions for Partial Summary Judgment that are affected by the passage of the anticipated legislative amendment. Court defers ruling on the oral motion for protective order re: depositions of individuals involved in legislative process; parties shall attempt to resolve the issue and inform the Court if they are unable to do so. (Court Reporter: Coughlin) (kak) (Entered: 02/20/2008)

02/20/2008 134 STIPULATED PROTECTIVE ORDER. Signed by Judge J. Garvan Murtha on 2/20/2008. (Attachments: # 1 Exhibit A) (kak) (Entered: 02/20/2008)

- 03/12/2008 151 PARTIAL MOTION to Dismiss  
*for Mootness* by William H. Sorrell,  
Jim Douglas, Cynthia D. LaWare.  
(Attachments: # 1 Memorandum  
in Support, # 2 Exhibit A –  
Act 89) (Asay, Bridget) (Text  
clarified 3/13/2008) (jmm)  
(Entered: 03/12/2008)
- 03/27/2008 168 CROSS-MOTION for Partial  
Summary Judgment by  
Pharmaceutical Research and  
Manufacturers of America.(Cohen,  
Linda) Modified on 3/27/2008  
(jmm). (Entered: 03/27/2008)
- 03/27/2008 169 MEMORANDUM by Pharmaceutical  
Research and Manufacturers of  
America. in support of 168 CROSS  
MOTION for Summary Judgment.  
(Attachments: # 1 Exhibit 1 –  
House Healthcare, 5/2/07, # 2  
Exhibit 2 – House Healthcare,  
4/4/07, # 3 Exhibit 3 – Excerpts  
Moffatt Depo, # 4 Exhibit 4 –  
House Ways & Means, 4/27/07, Pt.  
2, # 5 Exhibit 5 – House Ways &  
Means, 4/27/07, Pt. 1, # 6 Exhibit 6  
– Excerpts Slen Depo) (Cohen,  
Linda) **(WITHDRAWN and  
substituted with 177)** (4/3/2008)  
(jmm) (Entered: 03/27/2008)
- 03/27/2008 170 STATEMENT OF UNDISPUTED  
FACTS by Pharmaceutical  
Research and Manufacturers of  
America re: 168 CROSS MOTION

for Summary Judgment. (Attachments: # 1 Exhibit A – CMS Annual Report, Pt. 1, # 2 Exhibit A – CMS Annual Report, Pt. 2, # 3 Exhibit B – Excerpts Slen Depo) (Cohen, Linda) (Entered: 03/27/2008)

- 03/27/2008 171 CONSENTED-TO MOTION to Amend Complaint and OPPOSITION to Defendant's 151 Partial Motion to Dismiss for Mootness filed by Pharmaceutical Research and Manufacturers of America.(Cohen, Linda) (Attachments added 3/28/2008: # 1 Exhibit 1 – proposed Amended Complaint, # 2 Exhibit A (to Exhibit 1), # 3 Exhibit B (to Exhibit 1), # 4 Exhibit 2 – Red-lined Original Complaint) (jmm) (Entered: 03/27/2008)
- 03/27/2008 172 MEMORANDUM in Support of 171 CONSENTED-TO MOTION to Amend Complaint and Opposition to Defendant's 151 Partial Motion to Dismiss for Mootness filed by Pharmaceutical Research and Manufacturers of America. (Attachments removed 3/28/2007. E-filed erroneously/should have been attached to 171) (jmm) (Entered: 03/27/2008)
- 03/28/2008 175 MINUTE ENTRY for proceedings held before Judge J. Garvan Murtha: Motion Hearing held by telephone in chambers on

3/28/2008. Participating were Patricia Acosta, Esq., Matthew Byrne, Esq., Robert Hemley, Esq., Mark Ash, Esq., and Thomas Julin, Esq. for the pltfs IMS, Verispan LLC and Source Healthcare Analytics, Inc.; Robert Weiner, Esq., Jeffrey Handwerker, Esq. and Karen McAndrew, Esq. for pltf Pharmaceutical Research; and Kate Duffy, Esq. and David Cassetty, Esq. for the dfts. Statements by counsel. ORDERED: The discussion at the 1/31/2008 conference re: depositions of members of Legislative Counsel (Robin Lunge, Steve Kappel and Maria Royle) will be treated as an oral motion by dfts for a protective order. The motion is GRANTED in part. The three witnesses shall attend their deposition but they may assert a qualified privilege which shall be limited to communications between an elected legislative member and the three staff members, involving opinions, recommendations or advice about legislative decisions. The witnesses may testify regarding non-confidential factual matter aggregated, analyzed and collected for the edification and use of legislators. 156 Motion for Protective Order as to Dfts' Eight Deposition Notices and 19 Document Subpoenas

to Non-Party PhRMA Members is DENIED. The parties shall continue to negotiate to see if they can reach partial agreement on a stipulation. The dfts shall be permitted to depose 7 designated manufacturer representatives, one PhRMA representative, and one IMS, Verispan and Source Healthcare representative. The dfts may proceed with the subpoenas of the manufacturers. (Court Reporter: Coughlin) (kak) (Entered: 03/31/2008)

- 03/31/2008 176 MOTION to Amend 169 Memorandum in Support of 168 Cross-Motion for Summary Judgment by Pharmaceutical Research and Manufacturers of America.(Cohen, Linda) Modified on 4/1/2008 (jmm). (Entered: 03/31/2008)
- 03/31/2008 177 AMENDMENT to 169 Memorandum in Support of 168 Cross Motion for Summary Judgment by Pharmaceutical Research and Manufacturers of America. (Cohen, Linda) Modified on 4/1/2008 (jmm) (Entered: 03/31/2008)
- 04/02/2008 178 ORDER granting 176 PhRMA's Motion to Amend 169 Memorandum in Support of 168 Cross-Motion for Summary Judgment. Signed by Judge J. Garvan Murtha on 4/2/2008. (This is a

text only Order.) (kbl)  
(Entered: 04/02/2008)

- 04/11/2008 192 RESPONSE in Opposition re 151 PARTIAL MOTION to Dismiss *for Mootness* filed by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc.. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Exhibit F, # 7 Exhibit G, # 8 Exhibit H, # 9 Exhibit I, # 10 Exhibit J, # 11 Exhibit K, # 12 Exhibit L, # 13 Exhibit M, # 14 Exhibit N) (Acosta, Patricia) (Entered: 04/11/2008)
- 04/11/2008 193 MOTION to Amend *Complaint* by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc.. (Attachments: # 1 Exhibit A – Proposed First Amended Complaint, # 2 Exhibit B – Copy of Redline Version of the Proposed Amendment) (Acosta, Patricia) (Entered: 04/11/2008)
- 04/22/2008 197 REPLY to Response to 151 PARTIAL MOTION to Dismiss *for Mootness* filed by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Asay, Bridget) (Entered: 04/22/2008)
- 04/22/2008 198 RESPONSE in Opposition re 193 MOTION to Amend *Complaint* filed by William H. Sorrell, Jim

Douglas, Cynthia D. LaWare. (Asay, Bridget) (Entered: 04/22/2008)

- 04/28/2008 203 RESPONSE in Opposition to 168 CROSS-MOTION for Partial Summary Judgment – *Manufacturer Fee* filed by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Attachments: # 1 Memorandum in Support) (Asay, Bridget) (Text clarified 4/29/2008) (jmm) (Entered: 04/28/2008)
- 04/28/2008 204 RESPONSE to 170 Statement of Undisputed Facts filed by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Attachments: # 1 Moffatt Deposition Excerpts, # 2 Affidavit of Craig Jones, M.D., # 3 Jones Affidavit – Attachment A) (Asay, Bridget) (Text clarified 4/29/2008) (jmm) (Entered: 04/28/2008)
- 04/28/2008 205 CROSS-MOTION for Partial Summary Judgment – *Manufacturer Fee* by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Attachments: # 1 Memorandum in Support) (Asay, Bridget) (Entered: 04/28/2008)
- 04/28/2008 206 STATEMENT OF UNDISPUTED FACTS in Support of 205 CROSS-MOTION for Partial Summary Judgment – *Manufacturer Fee* by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Attachments:

# 1 Moffatt Deposition Excerpts,  
# 2 Affidavit of Craig Jones, M.D.,  
# 3 Jones Affidavit – Attachment A)  
(Asay, Bridget) (Text clarified  
4/29/2008) (jmm)  
(Entered: 04/28/2008)

04/29/2008 210 MINUTE ENTRY for proceedings held before Judge J. Garvan Murtha: Status Conference and Motions Hearing held 4/29/2008. Present were Robert Hemley, Esq. and Thomas Julin, Esq., for pltfs IMS Health, Inc., Verispan, LLC and Source Healthcare Analytics, Inc. (“the IMS pltfs”); Jeffrey Handwerker, Esq., Karen McAndrew, Esq. and Robert Weiner, Esq. for pltf Pharmaceutical Research and Manufacturers of America (“PhRMA”); and Kate Duffy, Esq., Bridget Asay, Esq. and David Cassetty, Esq. for dfts. Statements by counsel. ORDERED: Counsel to try to reach agreement as to outstanding discovery. 7 and 116 The IMS pltfs’ and PhRMA’s requests for judicial notice are DENIED as moot. 171 PhRMA’s Consented-to Motion to Amend Complaint is GRANTED. 193 The IMS pltfs’ Motion to Amend Complaint is DENIED without prejudice to filing an amended complaint that challenges the existing sections and language of the amended

statutory scheme. Additionally, the amended complaint shall not include the objected-to paragraphs which the Court explained are irrelevant to this litigation. The IMS pltfs and dfts should try to reach agreement on the filing of the amended complaint. In light of these rulings: 151 Dfts' Partial Motion to Dismiss for Mootness is DENIED as moot as it relates to PhRMA, and GRANTED as it relates to the IMS pltfs; 47 Dfts' Motion for Partial Summary Judgment against the IMS pltfs is DENIED as moot; and 82 Dfts' Motion for Partial Summary Judgment against PhRMA on claims related to the repealed portion of the statute is DENIED as moot. The Court shall issue a written decision on the remainder of dfts' motion which raises the question of whether the Tax Injunction Act deprives the Court of jurisdiction to hear PhRMA's challenge to the manufacturer fee. (Court Reporter: Coughlin) (kak) (Entered: 05/01/2008)

04/29/2008 221 AMENDED COMPLAINT against William Sorrell, Jim Douglas and Cynthia LaWare filed by Pharmaceutical Research and Manufacturers of America. (Attachments: # 1

Exhibit A, # 2 Exhibit B) (kak)  
(Entered: 05/15/2008)

- 05/14/2008 218 AGREED-TO MOTION to Amend *Complaint* by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc.. (Attachments: # 1 Exhibit A – Proposed Revised First Amended Complaint, # 2 Exhibit B – Red-lined Version of the Proposed Amendment) (Acosta, Patricia) (Entered: 05/14/2008)
- 05/14/2008 219 ORDER granting 212 PhRMA's Consented-To Motion for Extension of Time to File Reply re 203 Response in Opposition to Part II of 168 PhRMA's Motion for Partial Summary Judgment; PhRMA's reply shall be filed on or before 5/19/2008; ORDER granting 218 IMS pltf's' Consented-To Motion to File Revised First Amended Complaint. Signed by Judge J. Garvan Murtha on 5/14/2008. (This is a text only Order.) (kbl) (Entered: 05/14/2008)
- 05/14/2008 220 FIRST AMENDED COMPLAINT against William H. Sorrell, Jim Douglas and Cynthia D. LaWare filed by IMS Health Incorporated, Verispan, LLC and Source Healthcare Analytics, Inc.(kak) (Entered: 05/14/2008)

- 05/16/2008 229 MOTION for Protective Order by Pharmaceutical Research and Manufacturers of America. (McAndrew, Karen) (Entered: 05/16/2008)
- 05/19/2008 231 REPLY IN SUPPORT of Part II of 168 CROSS-MOTION for Partial Summary Judgment and RESPONSE IN OPPOSITION to Defendants' 205 Cross-Motion for Partial Summary Judgment – Manufacturer Fee filed by Pharmaceutical Research and Manufacturers of America. (Attachments: # 1 Exhibit A – Deposition of J. Slen, # 2 Exhibit B – Blueprint Strategic Plan, # 3 Exhibit C – Deposition of S. Moffat, # 4 Exhibit D – Declaration of M. Rosenthal) (Cohen, Linda) (Text clarified, link added 5/20/2008) (jmm) (Entered: 05/19/2008)
- 05/19/2008 233 RESPONSE to 206 Statement of Undisputed Facts in Support of 205 CROSS-MOTION for Partial Summary Judgment – Manufacturer Fee filed by Pharmaceutical Research and Manufacturers of America. (Cohen, Linda) (Text clarified, link added 5/20/2008) (jmm) (Entered: 05/19/2008)
- 05/28/2008 240 ORDER re: 229 Motion for Protective Order. The Court does not require a reply memorandum from

pltf PhRMA or oral argument.  
PhRMA's 229 Motion for Protective  
Order is DENIED. Signed by Judge  
J. Garvan Murtha on 5/28/2008.  
(This is a text only Order.) (kbl)  
(Entered: 05/28/2008)

- 05/29/2008 245 RESPONSE to Motion for Summary Judgment re 168 CROSS-MOTION for Partial Summary Judgment – 18 V.S.A. sec. 4631 filed by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Attachments: # 2 Exhibit Declaration of Dr. Kesselheim, # 3 Exhibit Declaration of Dr. Rosenthal, # 4 Exhibit Declaration of Dr. Wazana, # 5 Exhibit Declaration of Dr. Grande) (Asay, Bridget) (Additional attachment(s) added on 6/6/2008: # 6 Memorandum in Support (Corrected)) (jse). (Entered: 05/29/2008)
- 05/29/2008 246 RESPONSE re 170 Statement of Undisputed Facts, by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Attachments: # 1 Exhibit Kennedy Dep Excerpt, # 2 Exhibit McLean Dep Excerpt, # 3 Exhibit Pinckney Dep Excerpt) (Asay, Bridget) (Entered: 05/29/2008)
- 05/29/2008 247 MOTION for Summary Judgment *on Plaintiffs' First Amendment Claims Directed at 18 V.S.A. sec. 4631* by William H. Sorrell, Jim

Douglas, Cynthia D. LaWare.  
(Attachments: # 1 Memorandum  
in Support) (Asay, Bridget)  
(Entered: 05/29/2008)

- 05/29/2008 248 STATEMENT OF UNDISPUTED  
FACTS *in Redacted Form* by  
William H. Sorrell, Jim Douglas,  
Cynthia D. LaWare re: 247  
MOTION for Summary Judgment  
*on Plaintiffs' First Amendment  
Claims Directed at 18 V.S.A.  
sec. 4631.* (Asay, Bridget)  
(Entered: 05/29/2008)
- 05/29/2008 251 UNREDACTED STATEMENT OF  
UNDISPUTED FACTS in support  
of 247 MOTION FOR SUMMARY  
JUDGMENT on Pltfs First Amend-  
ment Counts Directed at 18 V.S.A.  
sec. 4631 (Attachments: # 1  
Attachment 1, # 2 Attachment 2,  
# 3 Attachment 3, # 4 Attachment 4,  
# 5 Attachment 5) (DOCUMENTS  
FILED UNDER SEAL) (kak)  
Text modified on 6/2/2008 (jse).  
(Entered: 05/30/2008)
- 06/02/2008 254 ANSWER to Amended Complaint of  
*IMS Plaintiffs* by William H. Sorrell.  
(Duffy, Kate) (Entered: 06/02/2008)
- 06/02/2008 255 ANSWER to Amended Complaint  
of *PhRMA* by William H. Sorrell,  
Jim Douglas, Cynthia D. LaWare.  
(Duffy, Kate) (Entered: 06/02/2008)

- 06/02/2008 256 ORDER granting 252 Consented-To Motion to File 251 Unredacted Statement of Undisputed Facts Under Seal. Signed by Judge J. Garvan Murtha on 6/2/2008. (This is a text only Order.) (kbl) (Entered: 06/02/2008)
- 06/02/2008 257 MOTION for Summary Judgment *on Commerce Clause and Preemption Counts* by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Attachments: # 1 Memorandum in Support) (Asay, Bridget) (Entered: 06/02/2008)
- 06/02/2008 258 STATEMENT OF UNDISPUTED FACTS by William H. Sorrell, Jim Douglas, Cynthia D. LaWare re: 257 MOTION for Summary Judgment *on Commerce Clause and Preemption Counts*. (Asay, Bridget) (Entered: 06/02/2008)
- 06/05/2008 264 REPLY to Response to 205 CROSS-MOTION for Partial Summary Judgment – *Manufacturer Fee* filed by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Attachments: # 1 Exhibit Deposition of Joshua Slen (Excerpts), # 2 Exhibit Deposition of Sharon Moffat (Excerpts), # 3 Exhibit Assessment of Authorized Generics (Excerpt), # 4 Exhibit Authorized Generics – Working Paper (Excerpt), # 5 Exhibit Transcript Status Conference 042908,

# 6 Exhibit PhRMA Req Admit  
(Excerpt) (Asay, Bridget)  
(Entered: 06/05/2008)

- 06/05/2008 265 REPLY re 233 Response to 206  
Statement of Undisputed Facts re:  
205 Cross-Motion for Summary  
Judgment – Manufacturer Fee, by  
William H. Sorrell, Jim Douglas,  
Cynthia D. LaWare. (Asay, Bridget)  
Docket text clarified on 6/6/2008  
(jse). (Entered: 06/05/2008)
- 06/17/2008 276 RULING: The Court finds that the  
TIA does not present a jurisdiction-  
al bar to Count 3 of PhRMA's 221  
Amended Complaint and the  
remainder of 82 MOTION for  
Partial Summary Judgment  
filed by William H. Sorrell, Jim  
Douglas, Cynthia D. LaWare is  
DENIED. Signed by Judge J.  
Garvan Murtha on 06/17/2008.  
(wjf) (Entered: 06/17/2008)
- 06/23/2008 290 MOTION in Limine *Seeking*  
*Judicial Notice of Certain Docu-*  
*ments Pursuant to the Doctrine*  
*of "Legislative Facts"* by William H.  
Sorrell, Jim Douglas, Cynthia D.  
LaWare. (Attachments: # 1  
Attachment 1, List of Docu-  
ments, # 2 Attachment 2,  
Citations for Findings) (Asay,  
Bridget) (Entered: 06/23/2008)

- 06/23/2008 298 REDACTED RESPONSE re 248 Statement of Undisputed Facts In Redacted Form re: 247 Motion for Summary Judgment on *PhRMA's First Amendment Counts* by Pharmaceutical Research and Manufacturers of America. (Attachments: # 1 Exhibit A, # 2 Certificate of Service) (Cohen, Linda) Docket text modified on 6/24/2008 (jse). (Entered: 06/23/2008)
- 06/23/2008 299 REPLY in Support re 168 CROSS-MOTION for Partial Summary Judgment and *OPPOSITION to Defendants' 247 Motion for Summary Judgment on First Amendment Claims* filed by Pharmaceutical Research and Manufacturers of America. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Exhibit F, # 7 Exhibit G, # 8 Exhibit H, # 9 Exhibit I, # 10 Exhibit J, # 11 Certificate of Service) (Cohen, Linda) Docket text clarified on 6/24/2008 (jse). (Entered: 06/23/2008)
- 06/23/2008 300 RESPONSE to Motion for Summary Judgment re 257 MOTION for Summary Judgment on *Commerce Clause and Preemption Counts* filed by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc.. (Julin, Thomas) (Entered: 06/23/2008)

- 06/23/2008 302 RESPONSE re 258 Statement of Undisputed Facts *in Support of Defendants' 257 Motion for Summary Judgment – Commerce Clause and Preemption Counts* by Pharmaceutical Research and Manufacturers of America. (Cohen, Linda) (jse). (Entered: 06/23/2008)
- 06/23/2008 303 RESPONSE to Motion for Summary Judgment re 257 MOTION for Summary Judgment *on Commerce Clause and Preemption Counts* filed by Pharmaceutical Research and Manufacturers of America. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Certificate of Service) (Cohen, Linda) (Entered: 06/23/2008)
- 06/23/2008 305 RESPONSE re 258 Statement of Undisputed Facts in Support of 257 Motion for Summary Judgment – Commerce Clause and Preemption Counts by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc.. (Attachments: # 1 Exhibit 1 – Jody Fisher Deposition (Excerpts), # 2 Exhibit 2 – Carol Livingston Deposition (Excerpts), # 3 Exhibit 3 – Hossam Sadek Deposition (Excerpts), # 4 Exhibit 4 – Defendants' Responses to IMS Health Incorporated, Verispan, LLC and Source Healthcare Analytics')

Requests for Admission) (Julin, Thomas) (Entered: 06/23/2008)

- 06/23/2008 306 RESPONSE to Motion for Summary Judgment re 247 MOTION for Summary Judgment *on Plaintiffs' First Amendment Claims Directed at 18 V.S.A. sec. 4631* filed by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc.. (Julin, Thomas) (Entered: 06/23/2008)
- 06/23/2008 307 RESPONSE re 248 Statement of Undisputed Facts *in Support of 247 Motion for Summary Judgment on First Amedment Counts* by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc.. (Attachments: # 1 Exhibit 1 – Carol Livingston Deposition (Excerpts), # 2 Exhibit 2 – Julin Letter to Duffy 4-10-08; Duffy Letter to Julin 4-15-08 and Julin Letter to Duffy 4-22-08, # 3 Exhibit 3 – LC 0009777, # 4 Exhibit 4 – Deborah Richter Deposition (Excerpts), # 5 Exhibit 5 – Carol Boerner Deposition (Excerpts), # 6 Exhibit 6 – Paul Harrington Deposition (Excerpts), # 7 Exhibit 7 – Madeleine Mongan Deposition (Excerpts), # 8 Exhibit 8 – Frank Landry Deposition (Excerpts), # 9 Exhibit 9 – Hossam Sadek Deposition (Excerpts), # 10 Exhibit 10 –

David Johnson Deposition (Excerpts), # 11 Exhibit 11 – Amanda Kennedy Deposition (Excerpts), # 12 Exhibit 12 – Richard Pinckney Deposition (Excerpts), # 13 Exhibit 13 – Steven Kappel Deposition (Excerpts), # 14 Exhibit 14 – Joshua Slen Deposition (Excerpts), # 15 Exhibit 15 – Sharon Moffatt Deposition (Excerpts), # 16 Exhibit 16 – Ashley Wazana Deposition (Excerpts), # 17 Exhibit 17 – Aaron S. Kesselheim Deposition (Excerpts), # 18 Exhibit 18 – Meredith Rosenthal Deposition (Excerpts), # 19 Exhibit 19 PART I OF III Shahram Ahari Deposition (Excerpts), # 20 Exhibit 19 PART II OF III Shahram Ahari Deposition (Excerpts), # 21 Exhibit 19 PART III of III Ahari Deposition Exhibit 6, # 22 Exhibit 20 – David T. Grande Deposition (Excerpts), # 23 Exhibit 21 – Second Declaration of Peter Barton Hutt) (Julin, Thomas) (Entered: 06/23/2008)

06/24/2008 309 CONSENTED-TO MOTION to Seal Response to Defts' 248 Statement of Undisputed Facts re: 247 MOTION for Summary Judgment on Plaintiffs' First Amendment Claims Directed at 18 V.S.A. sec. 4631 by Pharmaceutical Research and Manufacturers of America.(wjf) (Entered: 06/25/2008)

- 06/24/2008 310 UNREDACTED RESPONSE to Defts' 248 Statement of Undisputed Facts re: 247 MOTION for Summary Judgment on Plaintiffs' First Amendment Claims Directed at 18 V.S.A. sec. 4631 by Pharmaceutical Research and Manufacturers of America. (Attachments: # 1 Exhibit 1) (wjf) (Entered: 06/25/2008)
- 06/26/2008 316 ORDER granting 309 Consented-To Motion to Seal 310 PhRMA's Unredacted Response to Defendants' Statement of Undisputed Facts. Signed by Judge J. Garvan Murtha on 6/26/2008. (This is a text only Order.) (kbl) (Entered: 06/26/2008)
- 07/02/2008 332 MINUTE ENTRY for proceedings held before Judge J. Garvan Murtha: Motion Hearing held by telephone on 7/2/2008. Participating were Thomas Julin, Esq., Robert Hemley, Esq. and Matthew Byrne for pltfs IMS Health, Inc., Verispan, LLC and Source Healthcare Analytics, Inc.; Linda Cohen, Esq., Jeffrey Handwerker, Esq., Karen McAndrew, Esq. and Robert Weiner, Esq. for pltf Pharmaceutical Research and Manufacturers of America ("PhRMA"); and Kate Duffy, Esq., and David Cassetty, Esq. for dfts. Statements by counsel. ORDERED: 259 Motion

to Compel GRANTED in part. Atty. Cassetty informs Court and parties there was no purposeful destruction of the hard drive or email server. Court informs counsel that 7/11/2008 motion hearing may be postponed due to jury trial – they will be notified by 7/9/2008. If postponed, all pending motions, excluding summary judgment motions, will be heard at pretrial conference on 7/21/2008 unless the Court is able to arrange an earlier telephone conference. Summary judgment motions to be considered during trial. Trial memos due 7/9/2008. The following are due by 7/21/2008: (1) parties to confer and submit joint statement of undisputed facts; (2) each party shall file their separate disputed proposed findings of fact; (3) each party shall file a chart comparing the laws of NH, Maine & Vermont reflecting the March 2008 amendments. The statement of undisputed facts and proposed findings shall be filed electronically, and provided to chambers in WordPerfect format. (Court Reporter: Coughlin) (kak) (Entered: 07/03/2008)

07/03/2008 330 ORDER granting 327 PhRMA's Consented-To Motion to File Document Under Seal; granting 329 Dfts' Consented-To Motion for

Extension of Page Limits for Reply Memorandum. Signed by Judge J. Garvan Murtha on 7/3/2008. (This is a text only Order.) (kbl)  
(Entered: 07/03/2008)

- 07/03/2008 336 REPLY to Response to 257 MOTION for Summary Judgment *on Commerce Clause and Preemption Counts* filed by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Donofrio, Michael)  
(Entered: 07/03/2008)
- 07/03/2008 339 REPLY to Response to 247 MOTION for Summary Judgment *on Plaintiffs' First Amendment Claims Directed at 18 V.S.A. sec. 4631* filed by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Asay, Bridget)  
(Entered: 07/03/2008)
- 07/03/2008 340 REPLY to Response to 257 MOTION for Summary Judgment *on Commerce Clause and Preemption Counts re: IMS Plaintiffs' Opposition only* filed by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Asay, Bridget)  
(Entered: 07/03/2008)
- 07/08/2008 342 ORDER: The parties are informed that this case will be removed from the 7/11/2008 hearing calendar. Pending motions, excluding summary judgment motions, will be heard at the time of the pretrial

conference on 7/21/2008 at 10:00 a.m. in Brattleboro, Vt. Signed by Judge J. Garvan Murtha on 7/8/2008. (This is a text only Order.) (kbl) (Entered: 07/08/2008)

- 07/21/2008 369 STIPULATION AND ORDER re: Determination of PhRMA's Challenge to Section 20 of the Act, the Manufacturer Fee, on papers. Signed by Judge J. Garvan Murtha on 07/21/2008. (wjf) (Entered: 07/21/2008)
- 07/21/2008 375 MINUTE ENTRY for proceedings held before Judge J. Garvan Murtha: Final Pretrial Conference held on 7/21/2008. Participating were Thomas Julin, Esq., Robert Hemley, Esq. and Mark Ash, Esq. for pltfs IMS Health, Inc., Verispan, LLC and Source Healthcare Analytics, Inc.; Jeffrey Handwerker, Esq., Karen McAndrew, Esq., Robert Weiner, Esq. and Laura Van Druff, Esq. for Pharmaceutical Research and Manufacturers of America and Kate Duffy, Esq., Michael Donofrio, David Cassetty, Esq. and Bridget Asay, Esq. for dfts. Statements by counsel re: sealing of Wyeth exhibits and 290 Motion in Limine Seeking Judicial Notice of Certain Documents pursuant to the Doctrine of Legislative Facts; 293

Motion in Limine to Exclude Certain Testimony of Dr. Aaron Kesselheim; 301 Motion in Limine to Exclude Testimony of Legislative Witnesses; 358 Motion to Treat Dfts Violations of Rule 36 as Admissions or to Compel Compliance with the Rule; and 367 Motion for Appearance Pro Hac Vice. ORDERED: 367 Motion for Pro Hac Vice as to William Graham, Esq. for pltf PhRMA GRANTED. Court defers ruling on 290 Motion in Limine to Seeking Judicial Notice of Certain Documents. Counsel to file all documents and memoranda with regard to the sealing of Wyeth exhibits and 290 Motion in Limine on or before 4:00 p.m. on 7/24/2008. Memoranda shall be limited to not more than 10 pages. 301 Motion in Limine to Exclude Testimony of Legislative Witnesses GRANTED. 293 Motion in Limine to Exclude Certain Testimony of Dr. Kesselheim DENIED. Pltf may renew any objections as to specific questions at the time of hearing. 358 Motion to Treat Dfts Violations of Rule 36 as Admissions withdrawn by PhRMA. Dfts request that witnesses of pltf companies be sequestered GRANTED in part. A representative of each pltf may be present during all testimony. Joint

proposed findings of fact to be filed. Pltf's request for 4 hours for closing arguments DENIED. Dft to try to reschedule Dr. Rosenthal for time other than 1:00 p.m. 8/1/2008. (Court Reporter: Coughlin) (kak) (Entered: 07/22/2008)

07/23/2008 376 SUPPLEMENTAL BRIEF in Support of Part II of 168 CROSS-MOTION for Partial Summary Judgment and in Opposition to 205 CROSS-MOTION for Partial Summary Judgment – *Manufacturer Fee* by Pharmaceutical Research and Manufacturers of America. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibit 3, # 4 Exhibit 4) (Cohen, Linda) Docket text clarified on 7/23/2008 (jse). (Entered: 07/23/2008)

07/23/2008 379 SUPPLEMENTAL *Memorandum* re: 168 CROSS-MOTION for Partial Summary Judgment, 205 CROSS-MOTION for Partial Summary Judgment – *Manufacturer Fee* by William H. Sorrell, Jim Douglas, Cynthia D. LaWare.. (Attachments: # 1 Exhibit Jones Deposition Excerpts) (Asay, Bridget) (Entered: 07/23/2008)

- 07/24/2008 380 CONFIDENTIALITY AGREEMENT AND ORDER. Signed by Judge J. Garvan Murtha on 7/21/2008. (kak) (Entered: 07/24/2008)
- 07/24/2008 381 ORDER granting 371 PhRMA's Consented-To Motion to File Unredacted Findings of Fact and Conclusions of Law under seal. Signed by Judge J. Garvan Murtha on 7/24/2008. (This is a text only Order.) (kbl) (Entered: 07/24/2008)
- 07/28/200 386 MINUTE ENTRY for proceedings held before Judge J. Garvan Murtha: Day One of Court Trial held on 7/28/2008. Present in the courtroom were Robert Hemley, Esq., Thomas Julin, Esq. and Mark Ash, Esq. for pltfs IMS Health, Inc., Verispan, LLC and Source Healthcare Analytics, Inc.; Jeffrey Handwerker, Esq., Robert Weiner, Esq. and Karen McAndrew, Esq. for pltf Pharmaceutical Research and Manufacturers of America; Kate Duffy, Esq., Bridget Asay, Esq., David Cassetty, Esq. and Michael Donofrio, Esq. for dfts. Opening statements by counsel. The following witnesses, sworn by the clerk, were examined on behalf of the pltfs: Hossam Sadek, Jody Fisher, Carol Livingston and Andrew Cole, M.D. Court adjourned at 5:00 p.m. to continue on 7/29/2008 at 9:00

a.m. (Court Reporters: Coughlin and Booth – O'Brien Reporters)  
(kak) (Entered: 07/29/2008)

07/29/2008 387 MINUTE ENTRY for proceedings held before Judge J. Garvan Murtha: Day Two of Court Trial held on 7/29/2008. Present in the courtroom were Robert Hemley, Esq., Thomas Julin, Esq. and Mark Ash, Esq. for pltfs IMS Health, Inc., Verispan, LLC and Source Healthcare Analytics, Inc.; Jeffrey Handwerker, Esq., Robert Weiner, Esq. and Karen McAndrew, Esq. for pltf Pharmaceutical Research and Manufacturers of America; Kate Duffy, Esq., Bridget Asay, Esq., David Cassetty, Esq. and Michael Donofrio, Esq. for dfts. The following witnesses, sworn by the clerk, testified on behalf of the pltfs: Peter Hutt, Lori Reilly, Eugene Kolassa and Dr. Thomas Wharton. Court is adjourned at 5:00 p.m. to continue on 7/30/2008 at 9:00 a.m. (Court Reporters: Coughlin and Booth – O'Brien Reporters)  
(kak) (Entered: 07/30/2008)

07/30/2008 388 MINUTE ENTRY for proceedings held before Judge J. Garvan Murtha: Day Three of Court Trial held on 7/30/2008. Present in the courtroom were Robert Hemley, Esq., Thomas Julin, Esq. and Mark Ash, Esq. on behalf of pltfs IMS

Health, Inc., Verispan, LLC and Source Healthcare Analytics, Inc.; Jeffrey Handwerker, Esq., Robert Weiner, Esq. and Karen McAndrew, Esq. on behalf of pltf Pharmaceutical Research and Manufacturers of America; and Kate Duffy, Esq., Bridget Asay, Esq., David Cassetty, Esq. and Michael Donofrio, Esq. on behalf of dfts. Continuation of testimony of Dr. Thomas Wharton (previously sworn). The following witnesses, sworn by the clerk, testified on behalf of the pltfs: Jeffrey Robertson, Scott Tierney, Dr. Michael Turner and Randy Frankel. Taped (CD) deposition of Dr. Ken Ciongoli played into the record. The following witness, sworn by the clerk, testified on behalf of the dfts: Dr. Ashley Wazana. Court is adjourned at 5:00 p.m. to continue on 7/31/2008 at 9:00 a.m. (Court Reporters: Coughlin and O'Brien – O'Brien Reporters) (kak) (Entered: 07/31/2008)

07/31/2008 389 MINUTE ENTRY for proceedings held before Judge J. Garvan Murtha: Day Four of Court Trial held on 7/31/2008. Present in the courtroom were Robert Hemley, Esq., Thomas Julin, Esq. and Mark Ash, Esq. on behalf of pltfs IMS Health, Inc., Verispan, LLC and Source Healthcare Analytics, Inc.;

Jeffrey Handwerker, Esq., Robert Weiner, Esq. and Karen McAndrew, Esq. on behalf of pltf Pharmaceutical Research and Manufacturers of America; and Kate Duffy, Esq., Bridget Asay, Esq., David Cassetty, Esq. and Michael Donofrio, Esq. on behalf of dfts. Continuation of testimony of Randy Frankel (previously sworn). The following witnesses, sworn by the clerk, testified on behalf of the dfts: Dr. David Grande, Dr. Meredith Rosenthal (by videoconference) and Shahram Ahari. Court is adjourned at 3:55 p.m. to continue on 8/1/2008 at 9:00 a.m. (Court Reporters: Coughlin and O'Brien – O'Brien Reporters) (kak) (Entered: 08/01/2008)

08/01/2008 390 MINUTE ENTRY for proceedings held before Judge J. Garvan Murtha: Day Five of Court Trial held on 8/1/2008. Present in the courtroom were Robert Hemley, Esq., Thomas Julin, Esq. and Mark Ash, Esq. on behalf of pltfs IMS Health, Inc., Verispan, LLC and Source Healthcare Analytics, Inc.; Jeffrey Handwerker, Esq., Robert Weiner, Esq. and Karen McAndrew, Esq. on behalf of pltf Pharmaceutical Research and Manufacturers of America; and Kate Duffy, Esq., Bridget Asay, Esq., David Cassetty,

Esq. and Michael Donofrio, Esq. on behalf of dfts. The following witness, sworn by the clerk, testified on behalf of the dfts: Dr. Aaron Kesselheim. Closing arguments by counsel. Court takes matter under advisement. Parties shall file proposed findings of fact and legal memoranda by 9/15/2008. (Court Reporters: Coughlin and Booth – O'Brien Reporters) (kak) (Entered: 08/04/2008)

08/01/2008 396 LIST OF EXHIBITS of IMS Health Inc. admitted at Court Trial.(kak) (Entered: 08/08/2008)

08/01/2008 397 LIST OF EXHIBITS by Pharmaceutical Research and Manufacturers of America admitted during Court Trial.(kak) (Entered: 08/08/2008)

08/01/2008 398 LIST OF EXHIBITS by William H. Sorrell, Jim Douglas and Cynthia D. LaWare as admitted in Court Trial. (kak) Image replaced pursuant to Text Only Order 418 on 12/9/2008 (jlh). (Entered: 08/08/2008)

08/01/2008 399 JOINT EXHIBIT LIST by William H. Sorrell, Jim Douglas, Cynthia D. LaWare, Pharmaceutical Research and Manufacturers of America, IMS Health Incorporated, Verispan, LLC and Source Healthcare Analytics, Inc. as admitted

during Court Trial.(kak)  
(Entered: 08/08/2008)

- 09/29/2008 409 PROPOSED Findings of Fact by Pharmaceutical Research and Manufacturers of America, IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc.. (Julin, Thomas) (Entered: 09/29/2008)
- 09/29/2008 410 PROPOSED Findings of Fact by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc.. (Julin, Thomas) (Entered: 09/29/2008)
- 09/29/2008 412 POST TRIAL BRIEF/MEMORANDUM by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Duffy, Kate) (Entered: 09/29/2008)
- 09/29/2008 413 PROPOSED Findings of Fact by William H. Sorrell, Jim Douglas, Cynthia D. LaWare. (Duffy, Kate) (Entered: 09/29/2008)
- 12/01/2008 416 ORDER granting 415 Motion for Leave to File Supplemental Briefing. The parties may file supplemental memoranda limited to the three subjects suggested in plaintiffs' motion. The Court will be applying the *Central Hudson* analysis and will consider deference to the findings and material presented before the Vermont Legislature. Memoranda shall be

limited to no more than 10 pgs.  
and must be filed on or before  
12/15/2008. In the event the parties  
wish to file reply memoranda, they  
shall be limited to no more than 5  
pgs. and it must be filed on or  
before 12/31/2008. Signed by Judge  
J. Garvan Murtha on 12/1/2008.  
(This is a text only Order.) (kbl)  
(Entered: 12/01/2008)

- 12/09/2008 418 ORDER granting 417 Dfts'  
Consented-To Motion to Correct  
Exhibit List. The Clerk shall sub-  
stitute [417-3] for the image  
attached to 398 Dfts' List of  
Exhibits. Signed by Judge J.  
Garvan Murtha on 12/09/2008.  
(This is a text only Order.)  
(kbl) (Entered: 12/09/2008)
- 12/15/2008 420 SUPPLEMENTAL *BRIEF regard-*  
*ing First Circuit's Opinion in Ayotte*  
by Pharmaceutical Research and  
Manufacturers of America..  
(Attachments: # 1 Certificate  
of Service) (Cohen, Linda)  
(Entered: 12/15/2008)
- 12/15/2008 421 SUPPLEMENTAL *Brief Regarding*  
*First Circuit's Ruling in Ayotte* by  
William H. Sorrell, Jim Douglas,  
Cynthia D. LaWare.. (Asay, Bridget)  
(Entered: 12/15/2008)
- 12/15/2008 422 SUPPLEMENTAL *Memorandum*  
*Regarding IMS Health v. Ayotte* by

IMS Health Incorporated,  
Verispan, LLC, Source Healthcare  
Analytics, Inc . . . (Attachments:  
# 1 Exhibit Petition for Rehearing  
(IMS v. Ayotte)) (Acosta, Patricia)  
(Entered: 12/15/2008)

- 12/31/2008 423 SUPPLEMENTAL *Reply Brief  
Regarding First Circuit's Opinion  
in Ayotte* by Pharmaceutical  
Research and Manufacturers of  
America. (Cohen, Linda) Text  
clarified on 1/5/2009 (jlh).  
(Entered: 12/31/2008)
- 12/31/2008 424 SUPPLEMENTAL *Reply Brief  
Regarding First Circuit's Ruling  
in Ayotte* by William H. Sorrell,  
Jim Douglas, Cynthia D. LaWare.  
(Duffy, Kate) Text clarified  
on 1/5/2009 (jlh).  
(Entered: 12/31/2008)
- 12/31/2008 425 SUPPLEMENTAL *Publisher  
Plaintiffs Reply to State Memo re  
Ayotte* by IMS Health Incorporated,  
Verispan, LLC, Source Healthcare  
Analytics, Inc. (Julin, Thomas)  
Text clarified on 1/5/2009 (jlh).  
(Entered: 12/31/2008)
- 04/23/2009 430 MEMORANDUM OPINION AND  
ORDER: Plaintiffs 6, 61 motions  
for declaratory and injunctive relief  
as well as 168 summary judgment  
are DENIED. Defendants 205, 247  
and 257 motions for summary

judgment are DENIED as moot. Defendants 290 Motion in Limine Seeking Judicial Notice of Certain Documents Pursuant to the Doctrine of Legislative Facts is DENIED as moot. Signed by Judge J. Garvan Murtha on 4/23/2009. (kak) (Entered: 04/23/2009)

04/24/2009 431 JUDGMENT: pursuant to the Court's 430 Memorandum Opinion and Order, Plaintiffs' 6 and 61 motions for declaratory and injunctive relief as well as 168 summary judgment are DENIED. Defendants' 205, 247 and 257 motions for summary judgment are DENIED as moot. Defendants' 290 Motion in Limine Seeking Judicial Notice of Certain Documents Pursuant to the Doctrine of Legislative Facts is DENIED as moot. JUDGMENT is hereby entered for Defendants William Sorrell, Jim Douglas and Cynthia D. LaWare and against Plaintiffs IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc., a subsidiary of Walters Kluwer Health, Inc. and Pharmaceutical Research and Manufacturers of America. Signed by Deputy Clerk on 4/24/2009. (Attachments: # 1 Notice to Litigants – Notice of Appeal due 5/24/2009) (kak) (Entered: 04/24/2009)

- 05/04/2009 432 NOTICE OF CIVIL APPEAL as to 430 MEMORANDUM OPINION AND ORDER; 431 JUDGMENT by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc. Filing fee \$455. Paid R#4682002624. (gmg) (Entered: 05/04/2009)
- 05/05/2009 433 MOTION for Injunction *Pending Appeal* by IMS Health Incorporated, Verispan, LLC, Source Healthcare Analytics, Inc..(Julin, Thomas) Text clarified on 5/5/2009 (law) (Entered: 05/05/2009)
- 05/05/2009 434 NOTICE OF CROSS APPEAL as to 431 Judgment re: 430 Memorandum Opinion and Order on 6, 61 Motions for Declaratory and Injunctive Relief by Pharmaceutical Research and Manufacturers of America (Cohen, Linda) Filing Fee \$455 Paid: R#4682002632. Text clarified on 5/6/2009 (law). (Entered: 05/05/2009)
- 05/05/2009 435 JOINDER *in 433 Motion for Injunction Pending Appeal* by Pharmaceutical Research and Manufacturers of America.(Cohen, Linda) Text clarified on 5/6/2009 (jlh). (Entered: 05/05/2009)
- 05/22/2009 438 RESPONSE in Opposition re 433 MOTION for Injunction Pending Appeal filed by William H. Sorrell,

Jim Douglas, Cynthia D. LaWare.  
(Asay, Bridget) Text clarified on  
5/22/2009 (jlh). (Entered: 05/22/2009)

- 05/27/2009 439 REPLY to Response to 433  
MOTION for Injunction Pending  
Appeal filed by IMS Health Incorporated,  
Verispan, LLC, Source Healthcare Analytics,  
Inc.. (Julin, Thomas) (Entered: 05/27/2009)
- 05/27/2009 441 REPLY to Response to 433  
MOTION for Injunction Pending Appeal  
filed by Pharmaceutical Research and  
Manufacturers of America. (Cohen, Linda)  
(Entered: 05/27/2009)
- 06/05/2009 443 RULING ON 433 Motion  
for Permanent Injunction: The Court  
finds Plaintiffs have not satisfied  
the requirements for an injunction  
pending appeal under Fed. R. Civ. P.  
62(c). Plaintiffs' 433 Motion for  
Injunction Pending Appeal is DENIED.  
Signed by Judge J. Garvan Murtha on  
6/5/2009. (kak) (Entered: 06/05/2009)
- 06/18/2009 444 ORDER granting 442  
Joint Motion to Correct Party Names.  
Signed by Judge J. Garvan Murtha on  
6/18/2009. (This is a text only Order.)  
(kak) (Entered: 06/18/2009)
- 07/28/2009 448 ORDER of USCA as to  
432 Notice of Appeal filed by Source  
Healthcare Analytics, Inc., Verispan, LLC,

IMS Health Incorporated & 434  
Notice of Cross Appeal by Pharma-  
ceutical Research and Manufactur-  
ers of America. It is hereby  
ORDERED that a temporary stay  
is GRANTED until the motion for  
injunction pending appeal is heard  
by a three-judge motions panel.  
It is further ORDERED that  
Appellant's request to expedite  
oral argument on the motion for  
injunction is GRANTED. (gmg)  
(Entered: 07/28/2009)

08/24/2009 449 ORDER of USCA Circuit No. 09-  
1913-cv; 09-2056-cv as to 432 & 434  
Notice(s) of Appeal. It is ordered  
that Appellants' motion to expedite  
the appeal and amend the schedul-  
ing order is GRANTED; Appellees'  
brief filed by 9/1/2009; Amicus  
briefs in support of Appellees filed  
by 9/15/2009; Appellants reply  
briefs filed by 9/29/2009; the  
appeal shall be heard no earlier  
than week of 10/12/2009. (gmg)  
(Entered: 08/24/2009)

---

**RELEVANT DOCKET ENTRIES FOR  
THE UNITED STATES COURT OF APPEALS  
FOR THE SECOND CIRCUIT**

09-1913-cv

- 5/4/09 Copy of notice of appeal and district court docket entries on behalf of APPELLANTS INS Health Incorporated, Source Healthcare Analytics, Inc., Verispan, LLC, filed. [Entry date May 5 2009] [VC]
- 5/7/09 New Case Added: 09-2056-cv(CON) on behalf of APPELLANT Pharmaceutical Research and Manufactures of America, [Entry date May 20 2009] [VC]
- 6/4/09 Appellant IMS Health Incorporated, Appellant Verispan, LLC, Appellant Source Healthcare Analytics, Inc. motion for injunction pending appeal and to expedite oral argument on motion filed with proof of service. [Entry date Jun 4 2009] [ML]
- 6/8/09 Letter dated 06/05/2009 from Thomas R. Julin, Esq., informing that the district court entered the attached ruling denying the motion for injunction pending appeal from APPELLANT IMS Health Incorporated, Source Healthcare Analytics, Inc., Verispan, LLC, received. [Entry date Jun 8 2009] [ML]
- 6/15/09 Order FILED GRANTING motion for injunction pending appeal by Appellant IMS Health Incorporated, Appellant Verispan, LLC, Appellant Source Healthcare Analytics, Inc., endorsed on motion dated 6/4/2009, Order FILED

GRANTING motion to expedite oral argument on motion by Appellant IMS Health Incorporated, Appellant Verispan, LLC, Appellant Source Healthcare Analytics, Inc., endorsed on motion dated 6/4/2009. (before: RDS, CJ; by: JF) [Entry date Jun 15 2009] [ML]

- 6/16/09 Appellee William Sorrell, opposition to motion for injunction pending appeal filed with proof of service. [Entry date Jun 16 2009] [ML]
- 6/16/09 Appellant Pharmaceutical Research and Manufactures of America, joinder in emergency motion for injunction pending appeal filed with proof of service. [Entry date Jun 17 2009] [ML]
- 6/19/09 Appellant IMS Health Incorporated, Appellant Verispan, LLC, Appellant Source Healthcare Analytics, Inc., reply in support of emergency motion for injunction pending appeal filed with proof of service. [Entry date Jun 19 2009] [ML]
- 6/26/09 Order filed stating “Appellants IMS Health Incorporated, Verispan LLC, and Source Healthcare Analytics, Inc., through counsel, move for a preliminary injunction pending appeal. Appellant Pharmaceutical Research and Manufacturers of America joins in the motion, which Appellees oppose. Upon due consideration, it is hereby ORDERED that the motion is DENIED. Appellants have not demonstrated “a clear or substantial likelihood of success on the merits.” *Sussman v. Crawford*, 488 F.3d 136, 141 (2d Cir. 2007).

Briefing should proceed on an expedited basis to be determined by the Clerk's office. (before: BDP, RCW, CJJ, MGC, DJ; by: FP) [Entry date Jun 26 2009] [ML]

- 8/28/09 Set for argument on 10/13/09 (10am) [Entry date Aug 28 2009] [AV]
- 10/13/09 Case heard before panel: FEINBERG, LIVINGSTON, C.JJ. KOELTL, D.J. [Entry date Oct 13 2009] [AG]
- 11/23/10 OPINION, district court judgment reversed and remanded, FILED (Koeltl\*) [Entry date Nov 23 2010] [CM]
- 11/23/10 Judge Livingston dissents in a separate opinion, filed. [Entry date Nov 23 2010] [CM]
- 11/23/10 Judgment filed. [Entry date Nov 29 2010] [CM]
- 12/6/10 MOTION, to stay the mandate, on behalf of Appellee Jim Douglas, FILED. [Entry date Dec 6 2010] [CM]
- 12/29/10 ORDER, granting motion to stay the mandate pending resolution of a petition for writ of certiorari filed by Appellee Jim Douglas, by WF, DAL, KOELTL, FILED. [Entry date Dec 29 2010] [AG]
- 1/6/11 ORDER, Appellee William Sorrell, Appellee Robert Hofmann, Appellee Jim Douglas, motion for extension of time, granted, FILED. (DAL) [Entry date Jan 6 2011] [CM]
-

**RELEVANT DOCKET ENTRIES FOR  
THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF VERMONT**

**U.S. District Court**

**CIVIL DOCKET FOR CASE #: 1:07-cv-00220-jgm**

**Date Filed # Docket Text**

10/22/2007 1 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: # 1 Exhibit A# 2 Civil Cover Sheet)(law) (Entered: 10/22/2007)

---

**RELEVANT DOCKET ENTRIES FOR  
THE UNITED STATES COURT OF APPEALS  
FOR THE SECOND CIRCUIT**

**General Docket**

09-2056-cv

- 5/7/09 Copy of notice of appeal and district court docket entries on behalf of APPELLANT Pharmaceutical Research and Manufactures of America, filed. [Entry date May 20 2009] [VC]
- 5/20/09 The docket entries contained herein reference documents affecting the opening and the closing of the direct appeal. For a complete set of docket entries please refer to the lead docket number 09-1913-cv(L). [Entry date May 20 2009] [VC]
- 10/13/09 Case heard before panel: FEINBERG, LIVINGSTON, C.JJ. KOELTL, D.J. [Entry date Oct 13 2009] [AG]
- 11/23/10 OPINION, the district court judgment is Reversed and Remanded (KOELTL\*) [Entry date Nov 23 2010] [CM]
- 11/23/10 Judge Livingston dissents in a separate opinion, filed. [Entry date Nov 23 2010] [CM]
-

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

---

PHARMACEUTICAL	)	
RESEARCH AND	)	
MANUFACTURERS	)	
OF AMERICA,	)	Civil Action No.
	)	2:07-cv-00220-JGM
Plaintiff,	)	
	)	<b>CONSOLIDATED</b>
v.	)	<b>WITH</b> No.
	)	1:07-cv-00188-JGM
WILLIAM H. SORRELL,	)	(Filed Apr. 29, 2008)
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.	)	

---

**AMENDED COMPLAINT FOR  
DECLARATORY AND INJUNCTIVE RELIEF**

Plaintiff Pharmaceutical Research and Manufac-  
turers of America (“PhRMA”) alleges as follows:

## **INTRODUCTION**

1. In this action, PhRMA challenges certain provisions of Vt. Acts No. 80 (2007) (hereinafter “Act 80”), attached as Exhibit A, as amended by Vt. Acts No. 89 (2008) (hereinafter “Act 89”), attached as Exhibit B, because they violate the United States Constitution. Although Act 80, as amended by Act 89 (hereinafter collectively referred to as “the Vermont Act” or “the 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:
  - restrict communications by companies that use records containing prescriber-identifiable data for promotional purposes without the prior consent of the prescriber (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 rules (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 Drug 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. 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. Thus, under the Act, Vermont courts would be the arbiters of pharmaceutical manufacturers’ compliance with federal law and FDA regulations pertaining to prescription drug advertising. In so doing, the State would interfere with FDA’s careful, comprehensive, and complex regulation of such advertising. Thus, Vermont law conflicts with, and stands as an obstacle to, FDA regulation of

pharmaceutical marketing in violation of the Supremacy Clause.

5. The advertising restraint provision also 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. 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.

7. The prescription restraint provision restricts communications to doctors by pharmaceutical companies that use prescriber-identifiable data by pharmaceutical manufacturers unless the prescriber has consented. This provision fails directly to advance a substantial interest identified by the State, and is an impermissibly broad restriction on speech in violation of the First and Fourteenth Amendments.

8. The 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.

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

### **JURISDICTION AND VENUE**

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

11. 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**

12. 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>.

13. 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.

14. 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.

15. 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:

16. 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.

17. 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.

18. “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.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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).

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

25. 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.

26. None of these companies from which PhRMA members purchase prescriber-identifiable data is located in Vermont.

### The Advertising Restraint Provision

27. As amended by Act 89, 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 the requirements concerning drugs and devices and prescription drug advertising in federal law and regulations.” Act 89 § 5(c)(1), codified at 9 V.S.A. § 2466a(c)(1). Individual consumers may bring actions for violation of advertising restraint provision under the Consumer Fraud Act. *See id.*; *see also* 9 V.S.A. §§ 2461, 2451a(a).

28. PhRMA members are “manufacturer[s] of prescription drugs,” as the term is defined by State law. Act 80 § 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.

29. 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 80 § 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).

30. The FDA comprehensively regulates the advertising practices of PhRMA members. As described in the recent decision of the Third Circuit, *Pennsylvania Employee Benefit Trust Fund v. Zeneca, Inc.*, “the extent of [FDA’s] involvement in regulating prescription drug advertising is extensive and specific.” 499 F.3d 239, 251 (3d Cir. 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), *petition for cert. filed*, 76 U.S.L.W. 3349 (U.S. Dec. 18, 2007) (No. 07-822); 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”).

31. 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. *See, e.g.*, 21 C.F.R. §§ 202.1(e)(6)(xi), (xvii), 202.1(k); 121 Stat. at 823.

32. 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 Mar. 26, 2008); FDA Center for Drug Evaluation and Research, The CDER Handbook 49 (1998), *available at* <http://www.fda.gov/cder/handbook/index.htm> (last accessed Mar. 26, 2008).

33. 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.

34. 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).

35. FDA can and does determine whether advertising and labeling is false or misleading, *see, e.g.*, 21 U.S.C §§ 352(a), (n), 355(d), (e), and it has effective tools to enforce its determinations. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3,922, 3,968 (Jan. 24, 2006) (“FDA has a variety of enforcement options that allow it to make a calibrated response to suspected violations of the act’s information submission requirements.”); *see also* FDA, *Regulatory Procedures Manual* at 4-2 (Mar. 2007), *available at* [http://www.fda.gov/ora/compliance\\_ref/rpm/pdf/ch4.pdf](http://www.fda.gov/ora/compliance_ref/rpm/pdf/ch4.pdf) (last accessed Mar. 26, 2008) (“Regulatory Procedures Manual”) (“Also available to the agency are enforcement strategies which are based on the particular set of circumstances at hand and may include sequential or concurrent FDA enforcement actions such as recall, seizure, injunction, administrative detention, civil money penalties and/ or prosecution to achieve correction.”).

36. For example, FDA may convey its views regarding any advertisements it finds questionable

through warning and untitled letters. *See, e.g.*, Warning Letters and Untitled Letters to Pharmaceutical Companies 2007, <http://www.fda.gov/cder/warn/warn2007.htm>. Warning letters are FDA's "principal means of achieving prompt voluntary compliance with the federal Food, Drug, and Cosmetic Act," and are intended to spur dialogue between the FDA and the pharmaceutical company. Regulatory Procedures Manual at 4-2. Untitled letters "request" rather than "require" a response to the FDA. *Id.* at 4-25.

37. And, under the recently enacted FDAAA, FDA is authorized to require manufacturers to submit direct-to-consumer ("DTC") television advertisements up to 45 days prior to first use. 121 Stat. at 939 (amending 21 U.S.C. § 353b). FDA also may impose substantial civil penalties on those who disseminate or cause to be disseminated a DTC advertisement that is false or misleading. *Id.* at 940-41 (amending 21 U.S.C. § 333(g)).

38. Due to the FDA's "extensive and specific" regulation of prescription drug advertising, Vermont's attempt "to dictate the parameters of false and misleading advertising in the prescription drug context would pose an undue obstacle to both Congress's and the FDA's objectives in protecting the nation's prescription drug users." *Zeneca*, 499 F.3d at 251, 253.

39. And, 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.” Act 89 § 5(c)(1), codified at 9 V.S.A. § 2466a(c)(1). 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.

40. 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

41. 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 80 § 20, codified at 33 V.S.A. § 2004(a).

42. 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 chapter 91 of Title 18." Act 89 § 4(b), codified at 33 V.S.A. § 2004(b).

43. 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 80 § 14, codified at 18 V.S.A. § 4622(a)(1).

44. 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.

45. 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 80 § 14, codified at 18 V.S.A. § 4622(a)(1).

46. 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.

47. 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 80 § 14, codified at 18 V.S.A. § 4622(b). No pharmaceutical company or representative of the pharmaceutical industry is included in this process.

48. 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

49. As amended by Act 89, Section 17(d) of the Vermont Act, codified at 18 V.S.A. § 4631(d) (the “prescription restraint” provision), prohibits “pharmaceutical manufacturers and pharmaceutical marketers” from communicating with Vermont prescribers if they “use prescriber-identifiable data for marketing or promoting a prescription drug” unless the prescriber has consented to use of his or her identifying information. Act 89 § 3(d), codified at 18 V.S.A. § 4631(d).

50. 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 80 § 1(22).

51. 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 80 § 17(b)(5), codified at 18 V.S.A. § 4631(b)(5) (emphasis added).

52. By its terms, the definition of “marketing” in the Vermont Act includes “promotion.” Act 80 § 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.* § 17(b)(8), codified at 18 V.S.A. § 4631(b)(8) (emphasis added).

53. Any pharmaceutical manufacturer or marketer’s communications to or 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.

54. The Vermont Act deems a violation of Section 17(d) of the Act a violation of the State Consumer Fraud Act. *See* Act 89 § 5(a), codified at 9 V.S.A. § 2466a(a).

55. To limit the risk of liability under the Act, PhRMA members must assume a broad interpretation of the Act, which could require them to change their detailing, marketing, advertising, and scientific communications in Vermont, and could impose substantial additional costs, restrict their speech, and impede effective interactions with prescribers.

**PLAINTIFF'S CLAIMS FOR RELIEF****FIRST CLAIM FOR RELIEF**

(Declaratory/Injunctive Relief – Advertising  
Restraint Provision Is Preempted and  
Violates the Supremacy Clause)

56. PhRMA realleges and incorporates herein by reference paragraphs 1 through 55.

57. 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 law.

58. FDA has issued comprehensive, 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. 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).”). 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.

59. Vermont courts' adjudication of pharmaceutical manufacturers' compliance with federal law and FDA regulations pertaining to prescription drug advertising would interfere with FDA's careful, comprehensive, and complex regulation of prescription drug advertising.

60. It thus conflicts with, and 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.

## **SECOND CLAIM FOR RELIEF**

(Declaratory/Injunctive Relief – Advertising  
Restraint Provision Violates the Commerce Clause)

61. PhRMA realleges and incorporates herein by reference paragraphs 1 through 60.

62. 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 Vermont and disseminated predominantly outside of the state, so long as those

advertisements are also “printed, distributed, or sold” within the state.

63. 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.

64. 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.

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

### **THIRD CLAIM FOR RELIEF**

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

66. PhRMA realleges and incorporates herein by reference paragraphs 1 through 65.

67. 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.

68. 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.”

69. 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.

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

#### **FOURTH CLAIM FOR RELIEF**

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

71. PhRMA realleges and incorporates herein by reference paragraphs 1 through 70.

72. The prescription restraint provision burdens the lawful and non-misleading speech of PhRMA members by prohibiting them from communicating with Vermont prescribers for marketing or promotional purposes using prescriber-identifiable data without prescriber consent.

73. 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.

74. 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.

75. 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.

76. 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.

77. 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 Vermont Act's restraint of advertising, imposed by Section 21(c), is invalid;
- B. For a declaration that the manufacturer fee, created by Section 20, is invalid;
- C. For a declaration that the prescription restraint provision, set forth in Section 17(d), is invalid;
- D. For a permanent injunction enjoining Defendant Sorrell from enforcing the advertising restraint provision of the Act;
- E. For a permanent injunction enjoining Defendants Douglas and LaWare from enforcing the manufacturer fee provision of the Act;
- F. For a permanent injunction enjoining Defendant Sorrell from enforcing the prescription restraint provision of the Act;
- G. For such costs and reasonable attorneys' fees to which it might be entitled by law; and

H. For such other relief as this Court may deem just and appropriate.

Respectfully Submitted,

/s/ [Illegible]

---

Karen McAndrew  
Linda J. Cohen  
DINSE, KNAPP AND McANDREW, P.C.  
P.O. Box 988  
209 Battery Street  
Burlington, Vermont 05402-0988  
Phone: (802) 864-5751  
Fax: (802) 862-6409

Robert N. Weiner  
Jeffrey L. Handwerker  
ARNOLD & PORTER LLP  
555 Twelfth Street, N.W.  
Washington, D.C. 20004-1206  
Phone: (202) 942-5000  
Fax: (202) 942-5999

*Counsel for Plaintiff  
Pharmaceutical Research  
and Manufacturers of America*

Dated: May 14, 2008

---

IN THE  
UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF VERMONT

Case No. 1:07-cv-188 jgm & No. 1:07-cv-220  
(Consolidated)

IMS HEALTH INCORPORATED;	)	
VERISPAN, LLC;	)	
and SOURCE HEALTH-CARE ANALYTICS, INC.,	)	
a subsidiary of WOLTERS KLUWER, HEALTH INC.,	)	PRELIMINARY & PERMANENT INJUNCTIVE RELIEF SOUGHT BEFORE <u>JULY 1, 2009</u>
Plaintiffs,	)	
vs.	)	
WILLIAM H. SORRELL, as Attorney General of the State of Vermont,	)	(Filed May 14, 2008)
Defendant.	)	

Publisher Plaintiffs' Revised First Amended  
Complaint for Declaratory & Injunctive Relief

Thomas R. Julin,  
Patricia Acosta  
& Michelle Milberg  
Hunton & Williams LLP  
1111 Brickell Avenue –  
Suite 2500  
Miami, FL 33131  
305.810.2516 Fax 2460  
tjulin, pacosta, or  
mmilberg@hunton.com  
*Admitted pro hac vice*

Robert B. Hemley &  
Matthew B. Byrne  
Gravel & Shea, P.A.  
76 St. Paul Street  
7th Floor  
P.O. Box 369  
Burlington, VT 05402  
802.658.0220 Fax 1456  
rhemley, mbyrne  
@gravelshea.com

Mark Ash  
 Smith Anderson Blount  
 Dorsett Mitchell & Jernigan LLP  
 2500 Wachovia Capitol  
 Center (27601)  
 PO Box 2611  
 Raleigh, NC 27602-2611  
 919.821.1220 Fax 6800  
 mash@smithlaw.com  
*Admitted pro hac vice*

Attorneys for IMS Health Incorporated,  
 Verispan LLC & Source Healthcare Analytics, Inc.

TABLE OF CONTENTS

INTRODUCTION .....	1
JURISDICTION AND VENUE.....	4
THE PARTIES .....	5
OTHER COMMON FACTUAL ALLEGATIONS ....	5
Publishing Activities of IMS Health Incorporated .....	5
Publishing Activities of Verispan LLC.....	7
Publishing Activities of Source Healthcare Analytics, Inc.....	9
The Information at Issue: Prescriber-Identifiable Data .....	10
How the Prescription Information is Gathered & Published .....	11
History of the Prescription Restraint Law .....	14
The Prescription Restraint Law.....	16

Violations of the Law were Punishable by Severe Penalties .....	19
Damage Inflicted by the Law on the Plaintiffs & Others .....	20
The Initial Imminent Threat & Reasonable Fear of Enforcement.....	19
The Amendment to the Prescription Restraint Law .....	20
Violations of the Law, as Amended, are Punishable by Severe Penalties .....	23
Damage Inflicted by the Amended Law on the Plaintiffs & Others .....	23
The Imminent Threat & Reasonable Fear of Enforcement .....	24
Count I The Prescription Restraint Law, as Amended, Violates the First Amendment by Prohibiting the Plaintiffs' Commercial Speech.....	25
Count II The Prescription Restraint Law, as Amended, Violates the First Amendment by Prohibiting the Plaintiffs' Non-Commercial Speech.....	27
Count III The Prescription Restraint Law, as Amended, is Void for Vagueness & Overbreadth .....	30
Count IV The Prescription Restraint Law, as Amended, Violates the Commerce Clause .....	32
DEMAND FOR RELIEF .....	33

## INTRODUCTION

Plaintiffs, IMS Health Incorporated, Verispan, LLC, and Source Healthcare Analytics, Inc. (the “publisher plaintiffs”) 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”<sup>1</sup> or “the law”), as amended by Vt. Acts No. 89 (2008), unconstitutional and to preliminarily and permanently enjoin its enforcement. The law, as amended, 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, as amended, also violates the Commerce Clause of the United States Constitution by regulating transactions that take place wholly outside of Vermont.

2. The publisher plaintiffs are the world’s leading providers of information, research, and analysis

---

<sup>1</sup> 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.

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 safeguarded patient privacy.

3. In 2006, 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 publisher 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 publisher plaintiffs' 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 was to become effective on January 1, 2008.<sup>2</sup> Section 17 of Act 80 contains the provisions attacked in this amended 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 law, much like the New Hampshire law, will violate plaintiffs’ First Amendment rights without directly advancing any substantial governmental interest.

9. On February 22, 2008, the Vermont Legislature amended Section 17 of Vermont Act 80, codified as Vt. Stat. Ann. Tit. 18, §4631 (2007), by passage of H.750. The Governor of Vermont signed the bill into law on March 5, 2008, and it became Vermont Act 89 (2008).

---

<sup>2</sup> A copy of 2007 Vt. Acts No. 80, as enacted into law, is attached hereto as Exhibit A. A copy of the 2008 amendment to the law is attached as Exhibit B.

10. Section 7(a) of Act 89 (2008) provided that the act would take effect upon passage, but section 7(b) of Act 89 (2008) provided that the provisions of section 17 of Act 80 (2007), the Prescription Restraint Law “shall not be effective until July 1, 2009” with certain exceptions that would allow rulemaking under the law to proceed immediately.

11. 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 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 wellbeing of Vermont's citizens.

### JURISDICTION AND VENUE

12. 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.

13. 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

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

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

16. 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.

17. 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), as amended.

### OTHER COMMON FACTUAL ALLEGATIONS

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

#### Publishing Activities of IMS Health Incorporated

18. 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.

19. 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 attorneys general, 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).

20. 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 underserved 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 multi-faceted 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

21. 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.

22. 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).

23. 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.

24. 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.

25. 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

26. 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.

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

28. 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.

29. 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.

30. After retail pharmacies acquire prescription data, they then license, sell, or transfer the data (without disclosing the patient's identity) to publisher plaintiffs for two distinct purposes. First, in order to make a profit. Second, they license, sell, or transfer the information to the publisher plaintiffs 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.

31. The patient de-identified information that the publisher plaintiffs 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.

32. Currently, the publisher plaintiffs collectively acquire, aggregate and analyze information relating

to billions of prescription transactions per year throughout the United States.

33. 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.

34. 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.

35. 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

36. 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.

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

38. 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.<sup>3</sup> The publisher plaintiffs use the patient de-identified prescription data, together with the reference file information, to produce a variety of databases.

39. 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.

40. 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:

- 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;

---

<sup>3</sup> 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](http://www.ama-assn.org/go/prescribingdata).

- 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.

41. 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.

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

43. 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

44. 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 too much insight into prescriber behavior that often leads to inappropriate confrontation or coercion of prescribers about the products they prescribe.

45. 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.

46. 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.

47. 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.

48. 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 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 was thereafter amended to eliminate the disclosure requirement.

The Prescription Restraint Law

49. 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.

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

The Initial Imminent Threat &  
Reasonable Fear of Enforcement

51. 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.

52. As of August 29, 2007, the Attorney General had provided no assurances that the law would not be enforced as soon as it became effective.

53. Plaintiffs had 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

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

The Amendment to the Prescription Restraint Law

55. Six months after the publisher plaintiffs commenced this action on August 29, 2007, Vermont amended the Prescription Restraint Law through enactment of Vt. Acts No. 89 (2008). The Prescription Restraint Law, as amended, provides:

§ 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 dispensed in Vermont and written by a prescriber doing business 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

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. Pharmaceutical manufacturers and pharmaceutical marketers shall not sue prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents as provided in subsection (c) of this section.

(e) The prohibitions set forth in subsection (d) of this section shall not apply to the following:

(1) the sale, license, exchange for value, or use, 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 sale, license, exchange for value, or use 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.

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, as Amended,  
are Punishable by Severe Penalties

56. Section 5 of Vermont Act 89 (2008) amended the Consumer Fraud Act, 9 V.S.A. 2466a(a), to specify that a violation of 18 V.S.A. § 4631 is a violation of 9 V.S.A. § 2453 rather than a violation of the entire chapter. Section 2453(a), 9 V.S.A., specifies that “Unfair methods of competition in commerce, and unfair or deceptive practices in commerce, are hereby declared unlawful.” Section 2458, 9 V.S.A., authorizes the Attorney General, when he has reason to believe that any person is violating section 2453, to bring an action to enjoin such violations. It further authorizes the Attorney General to seek imposition of a civil penalty of not more than \$10,000 for each violation, an order for restitution of cash or goods on behalf of a consumer or a class of consumers, and an order requiring reimbursement to the State of Vermont for the fees incurred investigating and prosecuting.

57. 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 Amended  
Law on the Plaintiffs & Others

58. The Prescription Restraint Law, as amended, will impose 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.

59. If the publisher plaintiffs cannot use the information other than for purposes identified as permissible in the Prescription Restraint Law, neither the publisher plaintiffs 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, as amended.

60. 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. The law therefore will operate to freeze all or virtually all communication of prescriber identifiable information from the regulated records.

61. The amendment provides that the act shall become effective no later than July 1, 2009, 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 left unchanged the provision authorizing the Department and Office to 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

62. Since the amendment to the law, the publisher plaintiffs have resumed purchasing and selling prescription information showing the prescribing practices of prescribers doing business in Vermont and whose prescriptions are dispensed in Vermont. Plaintiffs have concrete plans to engage, after July 1, 2009, in activity proscribed by the law: purchasing and selling prescription information showing the prescribing practices of prescribers doing business in Vermont and whose prescriptions are dispensed in Vermont.

63. 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 July 1, 2009.

Count I

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

64. Plaintiffs re-allege paragraphs 1 through 63 and incorporate them herein by reference.

65. The Prescription Restraint Law, as amended, 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.

66. The Prescription Restraint Law, as amended, 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 used, sold, licensed or exchanged for value 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, as amended, 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.

67. The Prescription Restraint Law, as amended, 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, as amended. 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.

68. The Prescription Restraint Law, as amended, 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, as Amended,  
Violates the First Amendment by Restricting  
the Plaintiffs' Non-Commercial Speech

69. Plaintiffs reallege paragraphs 1 through 63 and incorporate them herein by reference.

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

71. "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.”

72. “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.”

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

74. 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.

75. When pharmacies and other entities with prescription information sell patient de-identified information to the publisher plaintiffs, 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.

76. 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.

77. 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.

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

79. The State of Vermont lacks a compelling justification for prohibiting noncommercial 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.

80. The Prescription Restraint Law, as amended, is not the least restrictive means of achieving the purpose of the Prescription Restraint Law, as amended.

81. In addition, the Prescription Restraint Law, as amended, 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.

82. The Prescription Restraint Law, as amended, 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 from 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.

83. The Prescription Restraint Law, as amended, therefore violates the First and Fourteenth Amendments of the United States Constitution facially and as it is applied to the noncommercial speech in which the publisher plaintiffs engage in the regular course of their businesses.

### Count III

#### The Prescription Restraint Law is Void for Vagueness & Overbreadth

84. Plaintiffs reallege paragraphs 1 through 63 and incorporate them herein by reference.

85. The Prescription Restraint Law, as amended, is vague and overbroad.

86. Section 4631(d), 18 Vt. Stat. Ann., provides that covered entities may not sell, license, exchange for value or permit others to use regulated records which include prescription information containing prescriber-identifiable data for marketing or promoting a prescription drug unless the prescriber has provided consent for the use of that information or the entity meets one of several specified exceptions. This section places responsibility on covered entities not to “permit others” to use regulated records, but it provides no guidance as to what is meant by that term or what acts are sufficient to satisfy the requirement.

87. 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 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 publisher plaintiffs, 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.

88. 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).

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. 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.

91. This law, as amended, 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.

92. The vagueness of the law, as amended, 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.

93. The vagueness of the Prescription Restraint Law, as amended, also is a matter of special concern for two additional reasons:

a. First, the Prescription Restraint Law, as amended, 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, as amended, imposes severe monetary penalties for violations. The severity of the sanctions may well cause speakers to remain silent rather than

communicate even arguably lawful words, ideas, and facts. As a practical matter, this increased deterrent effect, coupled with the “risk of discriminatory enforcement” of vague regulations, poses grave First Amendment concerns.

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

95. The Prescription Restraint Law, as amended, accordingly violates the First and Fourteenth Amendments for vagueness and overbreadth.

#### Count IV

##### The Prescription Restraint Law, as Amended, Violates the Dormant Commerce Clause

96. Plaintiffs reallege paragraphs 1 through 63 and incorporate them herein by reference.

97. The Prescription Restraint Law, as amended, impermissibly regulates conduct occurring wholly outside of Vermont.

98. The publisher plaintiffs 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 publisher plaintiffs is supplied by companies located outside

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

99. Accordingly, the Prescription Restraint Law, as amended, violates the dormant Commerce Clause of the United States Constitution.

#### DEMAND FOR RELIEF

Wherefore the plaintiffs demand:

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

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

C. A declaration that the Prescription Restraint Law, as amended, is unconstitutional, both facially and as applied because they regulate speech using such vague and overly broad terms that 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, as amended, violates the Dormant Commerce Clause of the United States Constitution by regulating transactions in commerce that take place wholly outside of the State of Vermont.

E. A permanent and preliminary injunction against the enforcement of the Prescription Restraint Law, as amended.

F. The costs and attorneys' fees that the plaintiffs have incurred in bringing this action, as is provided for by 42 U.S.C. § 1988.

G. 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,

Hunton & Williams LLP Gravel and Shea

<p>By <u>/s/ Thomas R. Julin</u>          Thomas R. Julin,          Patricia Acosta &amp;          Michelle Milberg  <i>Admitted Pro Hac Vice</i>          1111 Brickell Avenue –          Suite 2500          Miami, FL 33131          305.810.2516 Fax 2460          tjulin@hunton.com</p>	<p>By <u>/s/ Robert B. Hemley</u>          Robert B. Hemley          &amp; Matthew B. Byrne          76 St. Paul Street,          7th Floor          P.O. Box 369          Burlington, VT          05402-0369          802.658.0220 Fax 1456          rhemley or          mbyrne@gravelshea.com</p>
--	---

Attorneys for Plaintiffs

Smith Anderson Blount  
Dorsett Mitchell &  
Jernigan LLP

By /s/ Mark Ash

\_\_\_\_\_  
Mark Ash, *Admitted*

*Pro Hac Vice*

2500 Wachovia Capitol  
Center, P.O. Box 2611  
Raleigh, NC 27602-2611  
919.821.1220 Fax 6800  
mash@smithlaw.com

Co-Counsel for  
Verispan LLC

---

IN THE  
UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF VERMONT

IMS HEALTH INCORPORATED;	)	
VERISPAN, LLC; and SOURCE	)	
HEALTHCARE ANALYTICS,	)	
INC., a subsidiary of WOLTERS	)	
KLUWER, HEALTH INC.,	)	
Plaintiffs,	)	Case No.
vs.	)	1:07-cv-188-jgm
WILLIAM H. SORRELL,	)	
as Attorney General of	)	
the State of Vermont,	)	
Defendant.	)	

Publisher Plaintiffs' Supplemental  
Responses to Defendant's First  
Request for Production

\* \* \*

7. All correspondence between you and the AMA regarding contracts to obtain information about physicians, payments to the AMA for such information, and the AMA's Prescribing Data Restriction Program.

*Answer:* The parties have agreed to resolve the objections raised in plaintiffs' initial response to this document request by stipulating that the AMA's PDRP is not a less restrictive alternative to the Prescription Restraint Law under *Central Hudson*

and by agreeing that the plaintiffs will produce no documents responsive to this request.

\* \* \*

Hunton & Williams LLP	Gravel and Shea
By <u>/s/ Thomas R. Julin</u>	By <u>/s/ Robert B. Hemley</u>
Thomas R. Julin, Patricia Acosta & Michelle Milberg <i>Admitted Pro Hac Vice</i> 1111 Brickell Avenue – Suite 2500 Miami, FL 33131 305.810.2516 Fax 2460 tjulin@hunton.com	Robert B. Hemley & Matthew B. Byrne 76 St. Paul Street, 7th Floor P.O. Box 369 Burlington, VT 05402- 0369 802.658.0220 Fax 1456 rhemley or mbyrne@gravelshea.com

Attorneys for IMS Health Incorporated,  
Verispan LLC & Source Healthcare Analytics, Inc.

Smith Anderson Blount Dorsett  
Mitchell & Jernigan LLP

By /s/ Mark Ash  
Mark Ash  
*Admitted Pro Hac Vice*  
2500 Wachovia Capitol Center,  
P.O. Box 2611 Raleigh, NC  
27602-2611  
919.821.1220 Fax 6800  
mash@smithlaw.com

Co-Counsel for Verispan LLC

\* \* \*

---

UNITED STATES DISTRICT COURT  
DISTRICT OF VERMONT

---

IMS HEALTH INC., ET AL.	)	CASE NO: 1:07-CV-188
VS	)	TRIAL BY JURY
WILIAM SORRELL, ET AL	)	DAY 1, VOLUME 1

---

BEFORE: HONORABLE J. GARVAN MURTHA  
U.S. DISTRICT COURT JUDGE

APPEARANCES:

ROBERT B. HEMLEY, ESQUIRE  
GRAVEL & SHEA  
76 ST. PAUL STREET, 7TH FLOOR  
BURLINGTON, VERMONT 05402  
REPRESENTING IMS

THOMAS R. JULIN, ESQUIRE  
HUNTER & WILLIAMS, LLP  
1 BRICKNELL AVENUE, SUITE 2500  
MIAMI, FLORIDA 33131  
REPRESENTING THE IMS

KAREN MCANDREW, ESQUIRE  
DINSE, KNAPP & MCANDREW, P.C.  
P.O. BOX 988  
BURLINGTON, VERMONT 05402  
REPRESENTING PHARMACEUTICAL  
RESEARCH

(APPEARANCES CONTINUED TO NEXT PAGE)

\* \* \*

[73] HOSSAM SADEK, THE WITNESS, AFTER BEING DULY SWORN, WAS EXAMINED AND TESTIFIED AS FOLLOWS:

DIRECT EXAMINATION BY MR. JULIN:

Q. GOOD MORNING, MR. SADEK.

A. GOOD MORNING.

Q. COULD YOU PLEASE STATE YOUR NAME FOR THE RECORD?

A. HOSSAM SADEK.

Q. AND WHERE ARE YOU EMPLOYED?

THE COURT: WOULD YOU MIND SPELLING YOUR NAME, PLEASE?

A. H-O-S-S-A-M. LAST NAME IS SADEK, S-A-D-E-K.

THE COURT: THANK YOU.

Q. (BY MR. JULIN:) MR. SADEK, WHERE ARE YOU CURRENTLY EMPLOYED?

A. WITH IMS HEALTH.

Q. WHAT IS YOUR POSITION WITH IMS HEALTH?

[74] A. CURRENTLY I'M GENERAL MANAGER FOR BUSINESS LINE MANAGEMENT IN AMERICA'S REGION

\* \* \*

[75] Q. ALL RIGHT. THANK YOU. IMS HEALTH, CAN YOU GIVE THE COURT SOME BACKGROUND ON WHAT THAT COMPANY IS, WHAT ITS BUSINESS IS?

A. SURE. IMS HEALTH IS A HEALTH INFORMATION COMPANY. IT'S A PUBLICLY TRADED COMPANY. IT WAS CREATED IN 1954 AS AN INTERCONTINENTAL MARKETING SERVICES. AND WE OPERATE GLOBALLY IN ABOUT A HUNDRED COUNTRIES RIGHT NOW. AND WE PUBLISH INFORMATION ABOUT THE HEALTH CARE INDUSTRY TO DIFFERENT STAKEHOLDERS INCLUDING PHARMACEUTICAL AND BIOTECHNOLOGY COMPANIES, GOVERNMENT AGENCIES AS WELL AS A MULTITUDE OF OTHER USERS.

\* \* \*

[76] Q. THE PRESCRIBER INFORMATION, WHAT DOES THAT CONSIST OF? WHEN YOU GO TO SAY A CVS OR RITE AID AND SAY WE'D LIKE TO BUY INFORMATION FROM YOU WHAT TYPE OF INFORMATION DO THEY PROVIDE TO YOU?

A. WE COLLECT PRESCRIPTION INFORMATION THAT INCLUDES BASICALLY ON EACH PRESCRIPTION THAT WE RECEIVE THE DRUG THAT WAS DISPENSED, THE DAY THAT IT WAS DISPENSED AND THE AMOUNT THAT'S BEING GIVEN TO A PATIENT SOME INFORMATION ABOUT THE PRESCRIBERS THAT LIKE THEIR NAME AND AS WELL AS THE LOCATIONS OF

THE PHARMACY. SO THAT'S THE BASIC INFORMATION THAT WE COLLECT.

\* \* \*

[77] Q. NOW, LETS TALK ABOUT THE SUBSCRIBERS THAT YOU HAVE OR THE CUSTOMERS OR CLIENTS. WHO IS BUYING INFORMATION FROM IMS HEALTH?

A. IN GENERAL, AS I SAID, PHARMACEUTICAL COMPANIES, BIOTECHNOLOGY COMPANIES, FINANCIAL INSTITUTIONS, WHOLESALEERS, RETAILERS, IN SOME CASES PAYERS. THERE IS A LOT OF, THERE IS A LOT OF DIFFERENT STAKEHOLDERS THAT PURCHASE INFORMATION FROM US.

Q. NOW, WHEN I GO DOWN THE STREET AND I SEE THE BRATTLEBORO REFORMER I CAN PUT MY COIN IN THE SLOT AND I CAN BUY IT. DOES YOUR COMPANY OPERATE THE SAME WAY? WILL YOU SELL IT TO ANYONE WHO WANTS TO BUY IT?

A. WE WOULD SELL INFORMATION TO ANYONE WHO WANTS BUY IT.

[78] Q. AND WOULD THAT INCLUDE INSURANCE COMPANIES OR STATE GOVERNMENTS SUCH AS THE STATE OF VERMONT? IF THEY WANTED TO HAVE IT AND USE IT FOR THEIR PURPOSES COULD THEY DO THAT?

A. ABSOLUTELY.

Q. ALL RIGHT. NOW, WHEN YOU, WHEN YOU SELL THE INFORMATION TELL ME WHAT TYPE OF A TRANSACTION THAT IS? IS THERE A LICENSE INVOLVED IN THE SELLING OF THE INFORMATION OF THE COMPANIES?

A. YEAH. IT'S LICENSED TO THE USE OF THE INFORMATION.

Q. AND WHAT, WHAT SORT OF RESTRICTIONS ARE IMPOSED ON WHAT YOUR SUBSCRIBERS CAN DO WITH THE INFORMATION, IF ANY?

A. WELL, PART OF WHAT WE TRY TO DO, SINCE WE'RE DEALING WITH A KIND OF LIKE A LIMITED NUMBER OF SUBSCRIBERS, IS WE TRY TO PROTECT THE VALUE OF OUR INFORMATION. SO WE INCLUDE IN OUR LICENSING AGREEMENTS RESTRICTIONS ON SHARING OF OUR INFORMATION OUTSIDE OF THAT COMPANY TO PROTECT OUR RIGHTS TO SELL THAT INFORMATION TO OTHER PEOPLE, TO OTHER PARTIES.

Q. ALL RIGHT. NOW, AS FAR AS, AS ENTITIES AND INDIVIDUALS OTHER THAN THE MANUFACTURING INDUSTRY, AND OTHER THAN INSURERS AND STATE GOVERNMENTS ARE THERE, ARE THERE OTHERS IN THE ACADEMIC WORLD AND OTHER PLACES THAT

ARE ALSO INTERESTED IN IMS HEALTH INFORMATION?

A. YES. WE DO PROVIDE OUR INFORMATION, IN MOST CASES FREE OF CHARGE, TO A LOT OF ACADEMIC RESEARCHERS, UNIVERSITIES, EVEN NEWSPAPERS IN SOME CASES.

[79] Q. NOW, IS IMS HEALTH DATA USED IN SUPPORT OF RESEARCH, AND IF SO, CAN YOU GIVE ME SOME EXAMPLES OF THAT?

A. YEAH, ABSOLUTELY. OUR INFORMATION IS USED IN A LOT OF RESEARCH. AND I CAN GIVE YOU A COUPLE OF EXAMPLES. OUR INFORMATION WAS USED, FOR EXAMPLE, TO IDENTIFY OVERUSE OF ANTIBIOTICS IN CHILDREN, FOR EXAMPLE, AND TRY TO IDENTIFY WAYS AND PROGRAMS THAT COULD HELP RECTIFY THAT. AND THAT WAS A USE SPECIFIC TO PHYSICIAN LEVEL INFORMATION.

AND AS A RESULT OF THAT I THINK THE RESEARCHERS DESIGNED SOME PROGRAMS THAT WERE EFFECTIVE IN TERMS OF REDUCING THE OVER PRESCRIPTIONS OF ANTIBIOTICS AS A RESULT REDUCING THE NUMBER OF CASES WHERE YOU HAD BACTERIA THAT IS RESISTANT TO ANTIBIOTICS.

ANOTHER EXAMPLE I CAN GIVE YOU IS I THINK SOME, SOME RESEARCHERS USE OUR INFORMATION TO TRY TO SEE WHETHER THERE IS WIDE USE OF ANTHRAX PROPHYLACTIC

MEDICINES AFTER THE SCARES THAT HAPPENED IN 2001 AND TRY TO STUDY GENERIC DOWN TO THE PRESCRIBER LEVEL, THE PRESCRIBER LEVEL, THE WIDESPREAD USE OF THOSE ANTIBIOTICS LIKE CIPRO FOR EXAMPLE OUTSIDE OF THE AREAS WHERE THERE WAS A DETECTION OF SOME, SOME POTENTIAL CONTAMINATES.

Q. ARE THERE ANY OTHER EXAMPLES THAT JUST COME TO MIND?

A. SURE. DOCTOR CROSSMAN, FOR EXAMPLE, USED, AND SOME RESEARCHERS WITH HIM USED OUR INFORMATION, PHYSICIAN IDENTIFIABLE INFORMATION, TO TRY TO CREATE ALMOST LIKE A [80] SURVEILLANCE SYSTEM TO TRY TO PREDICT THE PREVALENCE OF DISEASE IN RURAL AREAS ACROSS THE COUNTRY WHERE THERE IS NO DATABASE THAT EXISTS TODAY THAT CAN ALLOW THEM TO DO THAT.

Q. NOW, DO YOU MAKE MONEY FROM CONVEYING INFORMATION TO RESEARCH PROJECTS LIKE THAT?

A. NO. MOST OF THAT INFORMATION IS PROVIDED FOR FREE.

\* \* \*

[82] Q. AND THEN IN TERMS OF INSURERS AND STATE GOVERNMENTS HOW WIDELY ARE THEY SUBSCRIBING TO YOUR SERVICES?

A. IN GENERAL WE DO HAVE INSURERS THAT SUBSCRIBE TO SOME OF OUR SERVICES STATE GOVERNMENTS I'M NOT ENTIRELY SURE. [83] BUT, FOR EXAMPLE, GOVERNMENTAL, LIKE FEDERAL GOVERNMENT AGENCIES I KNOW SUBSCRIBE TO OUR INFORMATION OR TO INFORMATION FROM OTHER HEALTH INFORMATION COMPANIES THAT ARE PRESENT.

Q. ARE THERE LAW ENFORCEMENT AGENCIES THAT, THAT ASK YOU FOR INFORMATION FROM TIME TO TIME?

A. YES, THEY DO. I KNOW, FOR EXAMPLE, THAT THE DEA SUBSCRIBED TO OUR PHYSICIAN IDENTIFIABLE INFORMATION TO CONDUCT SOME SURVEILLANCE ACTIVITY TO TRY TO FIND OUT INAPPROPRIATE PRESCRIBING OF CONTROLLED SUBSTANCES.

Q. NOW, I'M NOT SURE THAT YOU'VE COMPLETELY DESCRIBED WHAT ALL IS INVOLVED IN THE GATHERING OF THE INFORMATION. YOU GAVE US SOME IDEA. BUT IN TERMS OF THE NUMBER OF PHARMACIES THAT ARE OUT THERE, THE NUMBER OF PRESCRIPTIONS THAT ARE BEING WRITTEN, THE NUMBER OF DOCTORS, CAN YOU GIVE US SOME SENSE OF THE OVERALL SIZE OF WHAT YOU ARE DOING AND WHAT IT IS THAT YOU HAVE TO DO TO GATHER THAT INFORMATION?

A. SURE. WE COLLECT INFORMATION FROM ABOUT 36,000 RETAIL PHARMACIES.

THAT I THINK REPRESENTS ABOUT 70 PERCENT OF ALL THE PRESCRIPTIONS OUT THERE. IN ORDER OF MAGNITUDE WE PROCESS AROUND 60 MILLION PRESCRIPTIONS PER WEEK. AND ANNUALLY THAT GETS YOU TO SOME SORT OF LIKE 200 AND HALF, 3 BILLION PRESCRIPTIONS IF MY MATH WORKS CORRECTLY.

THAT INFORMATION IS ABOUT, YOU KNOW, 8,000 DIFFERENT PRODUCTS WITH DIFFERENT FORMS OF INSTRUMENTS. AND [84] IT'S ABOUT MORE THAN A MILLION PRESCRIBERS, I THINK A MILLION FOUR IS THE LATEST NUMBER THAT I HAVE IN MY HEAD ACROSS THE COUNTRY.

Q. ALL RIGHT NOW, WHEN YOU GET THIS INFORMATION IN TELL ME ABOUT THE PROCESS, WHAT IS IT NECESSARY TO DO TO THE INFORMATION BEFORE YOU SEND IT OUT TO SAY A PFIZER A MERCK?

A. WE, WE DO AN EXTENSIVE PROCESS OF RECEIVING THE INFORMATION, EDITING IT, MAKING SURE THAT IT IS GOOD INFORMATION. WE PUT THE INFORMATION IN DIFFERENT DATABASES AND WE USE VERY SOPHISTICATED STATISTICAL TECHNIQUES TO TRY TO PROVIDE VALUES FOR EACH PRODUCT OR PRESCRIBER FOR EACH TIME PERIOD. AND THEN THOSE INFORMATION ASSETS ARE PUT IN DIFFERENT SERVICES THAT ARE DIRECTLY

USABLE BY OUR PHARMA COMPANIES THAT WE PUBLISH TO.

Q. WHAT, WHAT IF ANYTHING DO YOU DO TO MAKE SURE THE INFORMATION YOU'RE GETTING FROM SAY CVS IS ACCURATE?

A. WE DO A LOT OF EDITING OF THE INFORMATION, A LOT OF VALIDATION OF THE INFORMATION WITH OTHER INFORMATION THAT WE'RE GETTING FROM OTHER SOURCES. SO WE USE, FOR EXAMPLE, SOME WHOLESALER INFORMATION TO GIVE US AN IDEA ABOUT THE SALES VOLUMES OF A SPECIFIC PRODUCT. WE DO VALIDATE THE PRODUCT NAMES THEMSELVES, THE PHARMACIES THAT ARE SENDING US THE INFORMATION, THE PHYSICIAN NAME AND ADDRESS AND SPECIALTY, WHICH DON'T NECESSARILY ALL COME ON THE PRESCRIPTION, BUT WE DO ENHANCE BACK WITH OTHER INFORMATION [85] THAT WE OBTAIN FROM THE DEA AND THE AMA AND SO ON

\* \* \*

[86] Q. DO YOU GET ANY INFORMATION DIRECTLY FROM THE STATE OF VERMONT?

A. I DON'T BELIEVE WE DO.

Q. AND DO YOU KNOW WHETHER YOU SELL ANY INFORMATION DIRECTLY INTO THE STATE OF VERMONT?

A. I DON'T THINK WE DO.

\* \* \*

[95] Q. AND SUBSTANTIALLY OF IMS'S REVENUES FROM ITS U.S. OPERATIONS COME FROM THE SALES TO THE PHARMACEUTICAL INDUSTRY; CORRECT?

A. IT'S A VERY LARGE PORTION, YES.

Q. SUBSTANTIALLY ALL?

A. UM, YEAH, THAT SOUNDS RIGHT

\* \* \*

[114] THE WITNESS: WELL, THIS IS MARKED COMPILATION OF NON-COMMERCIAL USES OF IMS DATA.

Q. (BY MS. DUFFY:) RIGHT. AND IT INDICATES THAT THERE ARE QUITE A FEW JOURNALISTS AND FINANCIAL ANALYSTS ON THERE; RIGHT?

A. UM, WHAT I'M LOOKING AT SO FAR IS LIKE PHARMACEUTICAL COMPANIES AND RESEARCHERS. SO I CAN CONTINUE LOOKING. THERE ARE SOME PUBLICATIONS HERE LIKE USA TODAY AND SO ON.

Q. AND IF YOU LOOK AT THE RIGHT IT DOESN'T INDICATE THE EXACT TYPE OF DATA THAT'S BEING USED DOES IT?

A. IT TALKS TO THE TYPE OF DATA USED BY SCRIPTS OR GLOBAL DATA AND SO ON OF SALES DATA.

Q. BUT IT DOESN'T INDICATE ON THERE THAT ANY FINANCIAL WALL STREET ANALYSTS OR JOURNALISTS USED PRESCRIBER-IDENTIFIABLE DATA DOES IT?

A. I'M NOT SEEING AN INDICATION OF THAT, NO.

\* \* \*

[124] Q. AND THIS IS A DOCUMENT THAT'S PROVIDED TO YOUR POTENTIAL CUSTOMERS ABOUT WHAT YOU THINK YOUR PRODUCTS ARE CAPABLE OF DOING; CORRECT?

A. IT'S A PROMOTIONAL PIECE.

Q. NOW, I'D ASK IF YOU WOULD TURN TO PAGE 2094

A. YES

Q. AND IF YOU WOULD LOOK UNDER THE RESULTS THERE'S THREE BULLET POINTS. AND IMS TELLS ITS POTENTIAL CUSTOMERS THAT PRESCRIBER-IDENTIFIABLE DATA CAN BE USED TO EFFECTIVELY COACH YOUR REPRESENTATIVES ON HIGH RETURN ON INVESTMENT PROMOTIONAL PRACTICES THAT DRIVE INCREASE IN PRESCRIPTION VOLUME; CORRECT?

A. AGAIN, AS I SAID PREVIOUSLY, THE INFORMATION THAT WE HAVE IN ITS VARIOUS FORMS IS USED TO PROMOTE PHARMACEUTICAL [125] PRODUCTS. AND IT'S USED TO HELP PHARMA COMPANIES TO PROMOTE THOSE PRODUCTS THAT ARE APPROVED WITH THOSE MESSAGES THAT ARE APPROVED IN THE MARKETPLACE.

Q. IS THAT A YES, MR. SADEK?

A. I BELIEVE IT'S A YES

Q. AND IF YOU TURN TO THE NEXT PAGE, 2095. YOU'VE INDICATED THAT THIS CAN HELP PROVIDE ANSWERS TO IMPORTANT QUESTIONS LIKE ARE WE ALLOCATING DETAILS, SAMPLES AND CME EFFORTS PROPERLY IN KEY CUSTOMER SEGMENTS; RIGHT?

A. YEAH. AGAIN, BACK TO MY EXAMPLE THAT I WAS GIVING BEFORE, THE ANSWER TO YOUR QUESTION IS YES, IT'S THERE. BUT BACK TO MY, THE ANSWER THAT I WAS GIVING BEFORE THE, THE PHARMACEUTICAL COMPANY HAS A POOL OF DOCTORS THAT THEY NEED TO FIGURE OUT WHETHER THESE DOCTORS ARE GOING TO USE THEIR PRODUCTS THAT THEY HAVE TO DELIVER THEIR INFORMATION TO EDUCATE THEM ABOUT THE USE OF THEIR PRODUCTS. SO ALL OF THIS INFORMATION IS USED TO HELP THE PHARMA COMPANIES UNDERSTAND THAT THEY DON'T NEED TO CALL AT A MILLION DOCTORS. THEY NEED TO

CALL ON THE 50,000 AND WHAT THE PROFILE OF THOSE 50,000 DOCTORS ARE SO THEY DON'T WASTE THEIR TIME AND PROVIDE INFORMATION THAT IS RELEVANT TO THEM.

Q. AND IT ALSO PERMITS PHARMACEUTICALS TO DETERMINE WHETHER OR NOT THEY ARE ALLOCATING THE PARTICULAR DETAIL SAMPLES, CONTINUING MEDICAL EDUCATION EFFORTS ON THEIR KEY SEGMENTS, WHICH ARE THEIR HIGH PRESCRIBERS; RIGHT?

[126] A. YEAH. IT COULD BE HIGH PRESCRIBERS OR EVEN LOW PRESCRIBERS. IT COULD BE HIGH PRESCRIBERS OR LOW PRESCRIBERS BECAUSE LOW PRESCRIBERS COULD BE AN INDICATION THAT THE DOCTOR IS UNDERPRESCRIBING.

Q. AND IT COULD BE THAT THEY WOULD GO THERE THOUGH AS A SALES REPRESENTATIVES BECAUSE THEY SEE AN OPPORTUNITY FOR ADDITIONAL SALES?

A. FOR POTENTIALLY GETTING MORE DOCTORS TO USE THEIR PRODUCTS.

Q. AND ADDITIONAL SALES?

A. POTENTIALLY.

Q. NOW, IF YOU TURN TO PAGE 2098. WE'RE TALKING ABOUT PRESCRIBING DYNAMICS. AND IT'S INDICATED THERE THAT PRESCRIBER-IDENTIFIABLE DATA IS USED TO

IDENTIFY PRESCRIBERS WITH HIGH SWITCH VOLUMES. AND THAT CAN BE USED TO ADJUST MESSAGING; RIGHT?

A. CORRECT.

Q. AND YOU ALSO INDICATE THAT DETERMINING MESSAGE EFFECTIVENESS ON TERRITORY PERFORMANCE IS HELPFUL TO CAPTURE NEW AND REFILL BUSINESS; RIGHT?

A. UM, THAT'S WHAT IT SAYS. I'M NOT EXACTLY SURE WHAT THAT MEANS, BUT THAT'S WHAT IT SAYS.

Q. AND ON THE NEXT PAGE IT HELPS YOU ANSWER THE CRITICAL QUESTION OF WHAT IS MY PRODUCT SWITCH RATE WITH HIGH OPPORTUNITY PRESCRIBERS; RIGHT?

[127] A. WHERE ARE YOU, IN THE MIDDLE OF THE PAGE?

Q. NO. IF YOU LOOK AT THE SIDE IT SAYS, FOR ANSWERS TO CRITICAL QUESTIONS. AND IT'S THE THIRD BULLET POINT. WHAT IS MY PRODUCT SWITCH RATE WITH HIGH OPPORTUNITY PRESCRIBERS?

A. YEAH, AGAIN, WHAT THAT, WHAT THAT MEANS IS THAT WHATEVER THE COMPANY DETERMINED TO BE THE PRESCRIBERS THAT THEY THINK ARE APPROPRIATE FOR THEIR PRODUCTS OR THAT ARE PRESCRIBING THEIR PRODUCTS THIS HELPS THEM IDENTIFY

WHICH DOCTORS ARE SWITCHING AWAY FROM THEIR PRODUCTS TO OTHER BRANDS, FOR EXAMPLE.

Q. AND IDENTIFY WHICH ARE THE HIGH OPPORTUNITY PRESCRIBERS; RIGHT?

A. UM, YEAH YOU DON'T NECESSARILY NEED TO GET TO THIS TO DETERMINE THAT. BUT, AGAIN, AS I SAID, IT'S A MULTITUDE OF INFORMATION THAT IS USED TO MAKE THAT STATEMENT.

Q. BUT THAT IS WHAT IMS'S MARKETING MATERIALS SAYS; CORRECT?

A. YES.

Q. OKAY. NOW, HOW ABOUT THE NEXT PAGE, IT TALKS ABOUT TARGETING. TARGETING IS TARGETING A PARTICULAR SEGMENT OF A POPULATION SO IF YOU IDENTIFY DOCTORS AND YOU IDENTIFY THEM INTO RANKING SAY ON THE VOLUME THAT YOU WOULD THEN TARGET A PARTICULAR SEGMENT; CORRECT? THAT'S WHAT TARGETING IS?

A. UM, IN GENERAL.

Q. OKAY. PROBABLY NOT THE BEST DESCRIPTION I'LL ADMIT BUT [128] CLOSE ENOUGH –

A. CLOSE ENOUGH.

Q. – FOR US LAWYER TYPES.

AND UNDER THE RESULTS IT INDICATES THAT PRESCRIBER-IDENTIFIABLE DATA CAN BE USED FOR TARGETING TO REACT INSTANTLY AND ADJUST TO MARKETPLACE ACTIVITY. RE-DIRECTING SALES AND PROMOTIONAL ACTIVITIES TO THOSE TARGETS WITH THE HIGHEST POTENTIAL. IDENTIFY HIGH AND LOW WRITERS OF YOUR PRODUCT. SHIFT DETAILING EFFORTS TO INCREASE BRAND MARKET SHARE; RIGHT?

A. YES.

Q. AND IT ALSO INDICATES UNDER VALUE DRIVERS THAT THIS IS USED TO MAXIMIZE THE REVENUE PER CALL AND THE SCRIPT PER DETAIL DUE TO BETTER INFORMATION?

A. CORRECT.

Q. AND IT PROVIDES EARLY REVERSAL OF NEGATIVE TRENDS BY SUPERIOR SPEED TO INCITE AND INFORMATION?

A. CORRECT.

Q. AND IT ALSO PROVIDES INFORMATION THAT WOULD ANSWER THE QUESTION, IS MY SALES FORCE TARGETING THE HIGHEST POTENTIAL PRESCRIBERS, ARE KEY PRESCRIBERS ACCEPTING MY MARKETING MESSAGE; RIGHT?

A. YES.

Q. IF YOU'LL TURN TO PAGE 2106. THIS IS A MODULE THAT DEALS WITH LAUNCH MONITORING?

[129] A. YES.

Q. AND IMS INDICATES THAT PRESCRIBER-IDENTIFIABLE DATA CAN BE USED FOR LAUNCH MONITORING TO MAXIMIZE THE RETURN ON INVESTMENT OF YOUR PROMOTIONAL DETAILING, EDUCATION AND SAMPLING EFFORTS TO IMPROVE PROFITABILITY?

A. YES. IN THE LAUNCH PHASE YOU ARE REALLY TRYING TO MAXIMIZE THE RETURN OF YOUR OVERALL INVESTMENT IN A PRODUCT THAT YOU SPENT BILLIONS OF DOLLARS ON.

Q. AND YOU ARE ALSO LOOKING TO DEFEND AGAINST COMPETITIVE PRODUCT LAUNCHES BY IDENTIFYING PRESCRIBER SHIFTS AS PRESCRIPTION ACTIVITY BEGINS ALLOWING FOR QUICK ADJUSTMENT TO THE PLAN OF ACTION?

A. YES.

Q. AND IF YOU TURN TO PAGE 2110. THIS DISCUSSES THE USE OF PRESCRIBER-IDENTIFIABLE DATA FOR SEGMENTATIONS. AND PERHAPS I'LL JUST ASK YOU TO DESCRIBE WHAT SEGMENTATION IS RATHER THAN BUTCHERING MY UNDERSTANDING OF IT.

A. SEGMENTATION IS REALLY TRYING TO, THE DIFFERENCE BETWEEN TRYING TO DEAL WITH A MILLION DOLLARS AS A MILLION DOCTORS OR AS A MILLION INDIVIDUAL POINTS. SOMEWHERE IN THE MIDDLE IS TO TRY TO GROUP THE DOCTORS INTO SEGMENTS OR GROUPS THAT HAVE SIMILAR CHARACTERISTICS.

Q. AND IN IMS'S MARKETING MATERIALS IT SAYS THE PRESCRIBER-IDENTIFIABLE DATA CAN BE USED FOR SEGMENTATION AND THE RESULTS OF THAT WOULD BE TO DEVELOP THE MOST [130] EFFECTIVE PROMOTIONAL STRATEGIES FOR EACH SEGMENT BY TRACKING THE ADOPTION RATE OF YOUR PRODUCTS VERSUS THE COMPETITOR; RIGHT?

A. THAT'S ONE ASPECT OF IT. I THINK THE UNDERSTANDING IS YOU ARE DEVELOPING SEGMENTS IN ORDER TO DO SOMETHING WITH THE SEGMENTS.

Q. RIGHT.

A. AND THE INFORMATION ALLOWS YOU TO UNDERSTAND HOW TO DEVELOP THE SEGMENTS AND EXACTLY HOW TO GO ABOUT, YOU KNOW, TRACKING WHAT'S HAPPENING WITH EACH ONE OF THE SEGMENTS.

Q. AND, IN FACT, THE DOCUMENT INDICATES THAT ONE OF THE USES IS THAT YOU CAN UNDERSTAND THE OPTIMAL SAMPLING

LEVEL REQUIRED TO DRIVE YOUR PRODUCT'S MARKET SHARE WITHIN EACH OF YOUR TARGETED SEGMENTS; RIGHT?

A. CAN YOU POINT ME TO THAT?

Q. THAT'S THE SECOND BULLET POINT UNDER RESULTS.

A. UNDER RESULTS? POTENTIALLY, YEAH.

Q. AND UNDER THE VALUES DRIVER SECTION IT INDICATES THAT USING PRESCRIBER-IDENTIFIABLE DATA FOR SEGMENTATION WILL HELP MAXIMIZE THE REVENUE PER SALES CALL IN THE SCRIPT FOR DETAIL; RIGHT?

A. RIGHT.

Q. AND PERMIT YOU TO MESSAGE WITH CONFIDENCE GIVEN THE PRESCRIBER'S PROFILE?

A. YUP. ARE WE DONE WITH THIS EXHIBIT?

\* \* \*

[132] Q. IF YOU TURN TO PAGE, WHAT'S IDENTIFIED AS THREE. AND, IM SORRY, I DON'T HAVE A MORE SPECIFIC NUMBER THAN THAT. IT SAYS THAT RESEARCH HAS SHOWN THAT WINNING JUST ONE MORE PRESCRIPTION PER WEEK FROM EACH PRESCRIBER YIELDS AN ANNUAL GAIN OF 52 MILLION IN SALES; RIGHT?

[133] A. THAT'S WHAT IT SAYS. I DON'T KNOW WHAT THAT RESEARCH IS BASED ON.

Q. WELL THIS IS AN IMS DOCUMENT; RIGHT?

A. FROM 1995, YES.

\* \* \*

[135] Q. AND IT SAYS, KNOWLEDGE IS WHAT ANSWERS A REP'S TWO MOST IMPORTANT QUESTIONS. ONE, HOW MUCH AM I GETTING PAID. AND, TWO, WHAT DO I NEED TO MAKE MORE MONEY. SO THAT'S FAIR TO SAY THAT THOSE ARE THE TWO AT LEAST VERY IMPORTANT QUESTIONS FACING SALES REPRESENTATIVES?

A. THOSE ARE LISTED HERE, YES.

Q. AND SO THAT'S A YES?

A. YES.

Q. AND YOU'VE INDICATED THAT IF, FOR EXAMPLE, A REP SEES THAT HIS PROJECTED SALES SHOWS HIS QUOTA WON'T BE MET HE NEEDS TO KNOW WHICH DOCTORS TO VISIT MORE FREQUENTLY OR LESS FREQUENTLY, WHICH PROMOTIONS TO DELIVER MORE OFTEN OR LESS OFTEN, AND WHETHER THERE'S A COMPETITOR ISSUE, AND WHAT IS THE, WHAT THE RIGHT MESSAGE SHOULD BE; CORRECT?

A. YES.

Q. OKAY. AND IF YOU LOOK AT THE CUSTOMIZATION CASE STUDY THAT'S BELOW IT INDICATES THERE THAT THE CONTENT FORMAT TIMING AND DELIVERY OF DATA TO INDIVIDUAL SALES REPS HELPED ONE TOP PHARMA COMPANY INCREASE ITS MARKETING SHARE BY 86 PERCENT; RIGHT?

A. YUP.

\* \* \*

[136] Q. RIGHT. BUT, IN FACT, THE AGREEMENT THAT YOU ENTER INTO WITH PHARMACEUTICAL COMPANIES PROHIBIT THEM FROM SHARING THAT DATA AND ACTUALLY SITTING DOWN AND EDUCATING THE DOCTOR WITH THAT DATA; RIGHT?

A. WE PROHIBIT THEM FROM DISCLOSING THE DATA TO ANY THIRD PARTIES. AND I GUESS THAT WOULD INCLUDE DOCTORS BECAUSE, AGAIN, WE'RE TRYING TO PROTECT THE VALUE OF THE INFORMATION.

Q. AND SO IF A PHARMACEUTICAL COMPANY PUBLISHED THAT INFORMATION TO A DOCTOR IT WOULD BE IN BREACH OF ITS CONTRACT WITH YOU?

MR. HANDWERKER: OBJECTION, YOUR HONOR. LEGAL CONCLUSION.

THE COURT: OBJECTION IS OVER-  
RULED. IF YOU CAN ANSWER IT.

[137] THE WITNESS: UM –

THE COURT: YOU CAN ANSWER IT.

THE WITNESS: IT WOULD BE IN  
BREACH OF –

Q. (BY MS. DUFFY:) IT'S A CONTRACTUAL  
ARRANGEMENT WITH YOU WHICH PROVIDES  
IT CANNOT DISCLOSE THE INFORMATION TO  
ANY THIRD PARTY INCLUDING DOCTORS?

A. I BELIEVE IT WOULD BE.

\* \* \*

---

UNITED STATES DISTRICT COURT  
DISTRICT OF VERMONT

-----  
IMS HEALTH, INC., ET AL.

vs.

CASE NO: 1:07-CV-188

WILLIAM SORRELL, ET AL.,  
-----

PROCEEDINGS BEFORE  
HONORABLE J. GARVAN MURTHA  
TRIAL DAY #1 – AFTERNOON SESSION  
taken on Monday, July 28th, 2008,  
United States District Court  
Brattleboro, Vermont.

APPEARANCES:

ON BEHALF OF THE IMS HEALTH, INC.:

ROBERT B. HEMLEY, ESQUIRE

Gravel & Shea

76 St. Paul Street, 7th Floor

Burlington, Vermont 05402

ON BEHALF OF THE IMS HEALTH, INC.:

THOMAS R JULIN, ESQUIRE

Hunter & Williams, LLP

1111 Brickell Avenue, Suite 2500

Miami, Florida 33131

ON BEHALF OF PHARMACEUTICAL RESEARCH:

KAREN McANDREW, ESQUIRE

Dinse, Knapp & McAndrew, P.C.

P.O. Box 988

Burlington, Vermont 05402

(APPEARANCES CONT. ON NEXT PAGE)

\* \* \*

[143] DIRECT EXAMINATION OF JODY FISHER  
BY ATTORNEY ASH:

Q. Mr. Fisher, would you please state your full name for the record?

A. Jody Fisher.

Q. And where do you live?

A. I live in Voorhees, New Jersey.

Q. Where do you work?

A. I work for Verispan, LLC.

Q. What is your position at Verispan?

A. My position is Vice President, Product [144] Management.

\* \* \*

[145] Q. Does Verispan publish reports and analyses that are used by pharmaceutical companies?

A. Yes.

Q. Are its reports and analyses also used by governmental agencies?

A. Yes.

Q. Are its reports and analyses used by researchers and others?

A. Yes.

Q. Is it fair to say, however, that the majority of Verispan's business is directed towards the pharmaceutical industry?

A. Absolutely.

Q. Are you able to estimate for us the [146] percentage of Verispan's business that is connected one way or another to pharmaceutical marketing, and I'm including physician identifiable as well as nonphysician identifiable?

A. I would say about 80 to 90 percent of our business.

Q. So, the overwhelming majority of Verispan's business it sounds like is directed one way or another to pharmaceutical marketing issues?

A. Yes.

\* \* \*

[148] Q. Thank you. Can you tell the Court also the approximate number of patients, individual patients, whose prescription information is contained in the Verispan data base?

A. Through the course of the data base, we've been able to track the activities of over two hundred [149] million, about three hundred million, obviously some of have passed away and some were born in the interim but it's about two hundred million patients, through the course of the productive use of the data

base on an per annum basis, just over a hundred million.

Q. Okay. For the patient information that's in the data base, is that patient information personally identifiable so that, for example, if you wanted to check on your own history, is a patient able to be identified in the Verispan data base?

A. There's no patient identifiable information in the data base. And it's a resected question. If I wanted to go find Jody Fisher's information and I desired to do it, I couldn't do it.

\* \* \*

[150] Q. With respect to Vermont prescriber [151] identifiable information, does any of the information of that type in Verispan data base come to Verispan directly from Vermont or does it pass through some intermediary like the headquarters of CVS?

A. There is always an intermediary involved. We don't get any information directly from the State of Vermont.

\* \* \*

Q. The process of stripping away the patient identifiable information, where does that occur?

A. That occurs outside of Verispan firewalls, [152] electronic firewalls. It is an encryption process that actually we have patented which takes all of the information that would be charged under HIPAA and

strips off all of the information using an algorithm. I think it's called an MD5 Hash Algorithm, and what we do is we encrypt the information, strip out all of the identifiable information, and replace it with the serial linking code. That linking code is several digits long. It's about in its native form about 39 digits long actually and what we do is we strip off the information, replace it with this linking code, so that every time an entity comes into the data base, it's replaced with the same code. So, you can follow an individual over time, but you have no idea who that individual actually is.

Q. I want to explore with you just for a minute or so back to the types of customers that Verispan has. I think you indicated that there are certain governmental entities or agencies that are customers; is that fair?

A. That's correct.

Q. And with respect to the pharmaceutical companies that are customers, does Verispan provide data from its data base to generic pharmaceutical companies?

[153] A. Yes.

Q. And does Verispan also supply its analyses and publications to branded pharmaceutical companies?

A. Yes.

\* \* \*

Q. Would you then just briefly describe for the Court, once Verispan receives data from CVS or Rite Aid or any of the other 40 or so suppliers, what does Verispan do with that data in general before it then provides reports and analyses to customers?

A. Well, the data in its native state is actually quite raw and not really completely useful. What we have to do is we have to relate that to useful information. So, what we do is take some of the codes that we receive, for example, to identify a specific drug, would you look at something called an NDC11 code, and we would have a big list of whatever all the NDC – active NDC11 codes were, and we would be able to match what drug was being prescribed based on the [154] NDC11 code to something that somebody would be able to look at and determine to be more useful. We do that typically with – so that's one of the P's, the product. I call it the four P's. The four P's are the product; the payer, so who's in fact paying for the medication; the pharmacy, so who is dispensing the medication; and also the prescriber. So, those are the four P's. And we have a way of decoding all four of the P's and that's how we turn the data into a more usable, publishable form.

\* \* \*

[155] Q. Okay. So, with respect to the information that's in the Verispan data base, and let's focus on what's at issue in this case, the prescriber identifiable information, what is the factual information about prescribers that is in the data base?

A. Well, so one would know who the prescriber was, the identity of the prescriber. You could look further on the claim to determine what the drug was that was actually being supplied, in what form, what strength, how many days the doctor issued the medication for, how many pills or how much liquid or suspension that they provided to the patient.

Additionally, just because of the some of the information that we have about the doctor, you also know about the doctor's specialty; you also know if the doctor – where the doctor's address is, where the doctor is principally doing business.

\* \* \*

[159] Q. You've already explained that you don't keep patient identifiable information in your data base.

A. Yes.

Q. All right. Can you just briefly explain this notion of the longitudinal data and how it is in particular that that information can be useful to pharmaceutical companies in marketing?

A. So, we talked about the four P's a little bit earlier. We talked about the product, the prescriber, the payer and the pharmacy. We like to think that we do add the dimension of the fifth P, which is the D identified patient, and what we do is as I alluded before we strip off all the HIPAA offending information and receive a linking code that would be able to determine a specific entity was traveling throughout our data base.

[160] Q. By identity, we mean Mark Ash has traveled from Vermont to California and back to North Carolina and I get prescriptions, am I the entity you're referring to?

A. Yes. The person would be the entity that I'm referring to, and that person would get the code, I'm not going to rattle of 39 digits, let's just say it's code 12345, and every time that entity or individual came into our data set, that person would get the same linking code, which means that we don't know who that person is, but our ability to track that person over time and determine behaviors is intact and retained.

Q. And can we connect that person, that un-identifiable person, 12345, with particular prescribers who write prescriptions for patient 12345?

A. So, the common way that the data is used is to really link up any of the five P's together at the end of the day, and so if you're using the patient entity and you're linking that to the prescriber, that's one potential use of the data.

\* \* \*

[167] Q. You've used the term in some of your sworn testimony that the information that Verispan has is like a scoreboard. Can you explain what you mean when you talk about the information in the Verispan data base being a scoreboard?

A. Well, I've always thought of it as a [168] scoreboard because it's really a reflection of what's happening, if you consider – I realize this is being a bit colloquial, but if you consider the marketplace a

game that for profit companies are taking on, our data really shows them what is happening in the marketplace. So, it's essentially the scoreboard that the pharmaceutical companies use to measure how their drugs are performing within the marketplace.

\* \* \*

[171] Q. Has the CDC, the Centers For Disease Control, prescribed to Verispan reports?

A. They have received our information.

Q. Can you give an example of what use the CDC has made based on your knowledge of CDC use?

A. Common use, I attributed to the delivery of this particular solution. What we did was the CDC determined that there were a couple of drugs during the flu season that were what one would term older generation flu medications, and they put out a bulletin to physicians which indicated that perhaps these weren't the drugs that we want to be using to treat flu and obviously flu is highly communicable, it's virulent in how it's communicated between [172] individuals, and so this was very time-sensitive information. And what they were interested in knowing from us was really the uptake of those drugs, whether or not subsequent to revealing or creating this message point, whether there were still some doctors who were a bit slow in determining and still using those medications. And so we were able to provide some insight.

Q. And was that information provided to the CDC, was at the doctor identifiable level?

A. Yes.

Q. What use, if any, does the FDA make of Verispan doctor identifiable information?

A. They are interested in seeing how any two medications are actually used together. So, we make use of not only the doctor level, the product level, so those are two of the P's, but also the patient level because in theory a patient can be taking any two medications, in particular if they're seeing multiple doctors, one doctor may not know what the other doctor is specifically providing. Maybe the patient didn't discuss that with him or her or whatever, and the result is what the FDA has asked us to help them out with is to determine exactly what the possibility or the probability that any two [173] medications are being taken and prescribed by multiple doctors or individual doctors.

Q. And, again, was the information that the FDA subscribed to, was that at the doctor identifiable level?

A. They have access to the prescriber level information.

\* \* \*

[184] Q. You could use that data to gauge the effect of a particular sales call, I go see Dr. Smith?

A. Verispan wouldn't.

Q. No. Verispan's data?

A. Verispan's data, right. And I'm not doing any type of that analysis, but . . .

Q. You're just supplying the data?

A. That's right.

\* \* \*

[188] Q. Okay. So, this product is a unique tool that connects surveyed patient attitudes and perceptions with their actual prescription fills by using Verispan claims data?

A. It does.

Q. Okay. What claims data does Verispan use?

A. So, the way this product works is that we work with a company called Health Track who is referred to in the marketing material, and Health Track maintains a patient identifiable portal where patients actually opt in, meaning they give Health Track and subsequent users permission to use information that they report within the portal. What happens is the information is encrypted prior to coming to Verispan using our proprietary technology as we discussed before, and it's matched in the aggregate to the activity of matched patients in our data set, and then we report both from what the patient actually did to what the doctor – were also getting information from the physicians as to what's happening [189] at that point of care. Contact as well. And we marry it all together to discuss something that we actually call in the document the medical moment of truth.

Q. And so when you're saying matched, you're taking the identifier you have for the patient and

matching it up with the surveyed results from the outside company?

A. Yes.

Q. And as a result, you're able to use this product and you market this product to the pharmaceutical companies to answer such questions as to what was and was not discussed during the doctor's appointment?

A. Yes.

Q. What did patient's learn about your brand?

A. Yes.

Q. What was the impact of specific messages on patient fill rates?

A. That's right.

Q. Did patients fill or not fill the prescriptions and why?

A. Yes.

Q. And the Brand Sig gives the pharmaceutical companies information they need to develop targeted messages that have been proven to impact prescription-[190]filling behavior, correct?

A. That's right.

\* \* \*

Q. And it allows them to – the pharmaceutical companies to measure the impact of promotional changes on prescription filling and refilling?

A. Potentially, yes.

Q. And you market for that purpose, not just potentially?

A. Yes.

\* \* \*

[191] Q. Now, you said you offered an opinion that using prescriber identifiable data would keep marketing costs down. Do you know if marketing [192] budgets have decreased since Verispan went into the business of selling prescriber identifiable data?

A. Well, if we just take a look – I don't know if budgets – I don't know what's happened to budgets. I do know what's happened to spend, and we do maintain promotional audits which track spend; and at the very least if you look at those, what we're reporting, that year in and year out, they do increase.

\* \* \*

[195] THE COURT: So, when you say you they cannot reveal the data, they can't go to a doctor and say you've been prescribing such and such a medication in the past month –

THE WITNESS: We don't permit that.

\* \* \*

[196] Q. Would you state your name for the record?

A. Carol Livingston, L-I-V-I-N-G-S-T-O-N.

Q. And where are you employed?

A. I'm employed by Source Health Care Analytics.

\* \* \*

[197] Q. And maybe you could answer the Judge's question about whether your data can be used generally by sales representatives when they're going to doctors, can they give them information about what other doctors are doing?

A. No. We would not allow that to occur. It is our expectation that a sales rep uses that only as directional information, and they should not be sharing anything specific with a doctor or another doctor that is represented in that material.

\* \* \*

[212] Q. So, the information that's included in the Source Launch Trac includes counts and quantity for the pharmaceutical that's dispensed?

A. Correct.

Q. And then dollars for that transaction?

A. Yes. Right.

Q. Okay. And it describes, by viewing this information on a weekly basis, field sales representatives

can see quick feedback to determine the impact of their sales calls in order to tailor their message appropriately?

A. Yes.

Q. And that's the value you're describing this product gives to the pharmaceutical companies?

A. It's a tool that allows them to remessage if they need to.

Q. They can look at the data, and if the physicians on whom they're calling aren't writing enough of their prescriptions, they can alter their – they can alter their message or tailor their message appropriately to try and drive those sales in a better [213] way?

ATTORNEY HANDWERKER: Objection, Your Honor.

A. Yes.

\* \* \*

[217] Q. Do you agree with the statement that prescribing trends do not happen in a vacuum, so it's essential that representatives leverage reports to understand prescribing cause and effect across all products within a given therapeutic market?

A. I'm assuming you're reading from some of our marketing material.

Q. I am.

A. That's what our marketers say it does. I don't disagree that we enable pharmaceutical companies to drive their profits.

\* \* \*

[221] Q. If you would look at the second page of it, did Source Health Care determine that the industry spends eight billion dollars annually on detailing?

A. They must have. I couldn't validate that.

Q. Okay. Do you have any reason to doubt the number in this report?

A. No.

\* \* \*

[225] Q. So, this is a description of the total U. S. market dollar trend. Again, this is for the whole pharmaceutical industry in the U. S.?

A. Yes

Q. Okay. And at the bottom, it says the source, NDC Pharmaceutical Suite Data Phast Integrated, that's one of your products?

A. That's our audit, yes.

Q. Okay. So, this is information that your company generated?

A. Correct.

Q. And that's shows from '99 to 2004, so over the six-year period, it shows a five-year, I guess that's an aggregate, or an average increase of 10.9 percent?

A. That's what it says.

Q. Okay. And if you look at the next page, it has two fewer years, and this refers to TRx trends, is that total prescriptions?

A. Total prescriptions.

Q. And for years 2001 through 2004, the growth is 2 percent, 3 percent and 2 percent, for an average of 2 1/2 percent?

A. Yes.

[226] Q. Okay. So, if we look at 2001 to 2004 on the prior page, it goes from a hundred and eighty-two billion dollars to two hundred fifty-one billion dollars with a much more modest increase in the actual number of prescriptions, correct?

A. Right.

Q. So, does that suggest that the average prescription price for 2001 to 2004 increased?

A. It does suggest that. I just don't know if there's other components, but it does suggest that.

\* \* \*

[230] Q. We've already discussed, you discussed with Mr. Julin, that Source Health Care does not

permit pharmaceutical companies to discuss the provider level data with the prescribers, correct?

A. That's correct.

\* \* \*

Q. And the sales representatives cannot discuss that with patients either, correct?

A. That didn't cross my mind. No.

Q. Let's say the guy who lives across the street from me happens to be a detailer.

A. Okay.

Q. I want to know what my doctor is prescriber [231] and I know he knows, because he's buying from one of you guys.

A. He should not be telling you.

\* \* \*

[233] DIRECT EXAMINATION OF ANDREW JAMES COLE, M.D. BY ATTORNEY HEMLEY:

Q. Would you state your name once again for the record, please?

A. Andrew James Cole.

ATTORNEY HEMLEY: And, Judge, we have provided the Court and counsel with what is a Joint Exhibit Number 8. It's Dr. Cole's resume, which the parties have agreed may be admitted into evidence.

THE COURT: All right. So, 8 is admitted.  
(Joint Exhibit 8 was admitted into evidence.)

BY ATTORNEY HEMLEY:.

Q. And with that, Doctor, I'm not going to ask you to go through all thirty pages, but I would like to tell the Court a bit about yourself. Tell us where you are working and how long have you been working, first of all.

A. I'm a neurologist by training. I went to College of Medical School at Dartmouth. Did my training in Montreal, and I've been on the faculty at Mass. General and Boston and Harvard Medical School since 1992 where I came to start and direct an [234] epilepsy service, which I do to this day.

\* \* \*

[235] Q. How does a generic drug differ, if at all, from a patented drug?

A. The rules surrounding the development and marketing of generic drugs essentially descend from the Hatch-Waxman Act which outline the basic guidelines and then regulatory actions that were taken by the FDA to codify these.

So, essentially a generic drug has to meet two major criteria to be approved. It has to meet a criteria called chemo equivalence and has to meet a criteria of bioequivalence.

Chemo equivalence is essentially saying the active ingredient in the generic drug is identical to

the parent structure, the chemical structure is identical.

Bioequivalence refers to the ability of that [236] drug to enter into the bloodstream and be metabolized and distributed in the body, and there are rules around bioequivalence which creates a range of values from slightly below to slightly above the parent compound, which I will elaborate on in a minute.

Bioequivalence you might imagine is identical to chemo equivalence, except it turns out that is not the case. So, even though the active ingredient is identical, the way it's packaged, the shape of the pill, the size of the pill, the filler materials, the dyes, the coatings, the other things that are used to deliver the active ingredient may differ between generics and those lead to a difference in the way the medication is absorbed and distributed in the body. So, this can lead to a difference in bioavailability.

The rules around bioequivalence, they're fairly well described – well, they're extremely well described, precisely described by the FDA, and essentially a simple view of them is a generic drug to be approved using an abbreviated new drug application, an ANDA, must be either between the range of 85, excuse me, 80 and 125 percent bioavailable compared to the parent compound.

\* \* \*

[237] Q. Okay. With that in mind, what are some of the considerations that you face as a physician, especially a physician treating epilepsy patients, when thinking about substituting a generic for a patented medicine?

A. Well, there are a number of issues. Let me see if I can elaborate them. The first issue is whereas this 80 to 125 bioequivalence rules might sound like it defines a reasonably narrow range and that may be the case in some compounds, in certain disease states, patients are exquisitely sensitive to the blood level that they obtain, and a range between 80 and 125 might be excessive for a given patient. So, at the low end of the range, a patient might not [238] get a full therapeutic effect, and my area that might result in the appearance of a seizure; and at the high end of the range, they might develop toxication or toxic side effects from the medication.

As I said, in many disease states, in some disease states anyway, the difference between being at the low end and the high end of the bioequivalence range may not be very clinically meaningful. In other disease states, it may be extremely meaningful and epilepsy happens to fall in the latter category.

\* \* \*

[246] Q. With the limitations of evidence-based medicine in mind, what then is in your judgment the proper way for a physician confronted with a particular problem to make the judgment for a particular patient as to which medication to prescribe?

A. Well, I think – I mean I think that’s what we’re trained and paid to do is make these judgments using all the available information, and the available information includes published evidence, personal and – personal experience and the experience of others who you work with and communicate with, information that you receive from publications, from journals, from meetings, from conferences, from the INH, from manufacturers, and all of this information gets integrated in a fashion that allows you to try to make the best choice – and I would add to that, information from the FDA, that allows you to try to make the best choice for any given patient in the face of what is inevitably incomplete information.

We’re always making therapeutic decisions with incomplete information and we have to take the available information, weight it, balance it, using [247] the guidelines that I’ve outlined, and experience is an important one, try to be sure we’re not unduly influenced by our own anecdotal experience and that we reach out more broadly and try to hear about the experience of others and be sure that we’re not seeing through a very unusual lens and put all that information in the form of a recommendation to a given patient. So, it’s an integrative process.

Q. Are you trained among other things as a professional to integrate the information that you receive from the pharmaceutical manufacturing companies, either directly or indirectly, into this analysis having in mind the source of the information?

A. Absolutely. I mean the fact of the matter is that most information about a compound that is available in the published literature and in the packaged label comes from the pharmaceutical industry. They're the ones that do the registration studies. They're the ones that collect the data, not interpret it, but filter it, present it to the agency, the FDA, and to the medical community.

So, the basic information base about most new drugs comes from the industry under a highly regulated and, I think, effective system. In addition, additional information aftermarket or after [248] registration or licensing, use the term of your preference, also comes from industry. Industry learns about things that happen with their drugs sometimes more quickly than any individual physician, because they're in a position to receive feedback about side effects, about unusual situations where the drug is particularly efficacious, about dosing, and they're in a position to collate that feedback and again integrate it in a way that no individual physician is positioned to do. And of course once they have such information, if they choose to distribute it or promulgate it, that can be a valuable source of information.

But I think we look at the information from every place it comes from, whether it's from a colleague or a publication or a pharmaceutical rep or a pharmaceutical executive or a colleague in the pharmaceutical industry, and we analyze as professionals that information in the context of its source with all the limitations that those sources impose.

There are, of course, biases among academic publishers as well as among pharmaceutical companies and we have to take those into account as we read the papers.

[249] Q. Do you think you and your patients would be disadvantaged if the full information from pharmaceuticals was curtailed or altered in some fashion?

A. I do. I think they can often bring information that may eventually make its way into the literature and into the public domain. They can bring that information more rapidly and more efficiently to my attention and to my colleagues' attention that would be likely to happen by a passive information from information diffusion that would otherwise take place.

Q. In your experience, is there pressure brought to bear by the government and insurance companies to prescribe generics simply because of the costs?

A. Well, I would say in my experience and my perception, the answer to your question is yes. We see this directly with insurance companies in the form of tiering of copayments. So, insurance companies will take anticonvulsants, they don't do it with anti-convulsants often, let's say antihypertensive drugs, and there will be what they call tier 1 drugs, and a tier 2 bunch of drugs and a tier 3 bunch of drugs, and the patient pays more out of pocket for the [250] higher tier drugs. It's a way to influence behavior, patient behavior, prescriber behavior to choose the

most economical agents that meets the need. So that's an overt and explicit pressure.

There are other pressures, however, for example, Medicaid in Massachusetts, requires prior authorization for the use of certain anticonvulsant drugs that happen to be in a higher priced category. My perception is that this is done to try to influence physicians to not use these agents which are more expensive. Now, there may be other rationales for prior authorization, and I'm not an expert on what Medicaid's thinking is on this, but my perception and my experience is that the message that we receive loud and clear from the government and payer perspective is try to control costs, use cheaper agents when possible, try to factor that into your thinking and make trade-offs to accomplish that goal of lower costs. That seems to be a primary emphasis.

Q. Thank you. I'm going to shift topics here for a moment and I'm going to ask you if when you do make a prescription or prescribing decision you expect that your decision will be kept secret from your colleagues or from the world at large?

A. Do I expect that?

[251] Q. Yes.

A. No, I don't expect that. It's quite clear using the systems that are available in modern medicine that these decisions are widely available. The patient submits the prescription to a pharmacy. Of course, they see the information. The pharmacy submits the

material to the insurer who is going to paid for it. The insurer sees the information. The hospital on whose computer I wrote the prescription analyzes my prescribing behavior and everyone else's from time to time, so they see the information.

The formulary committee at the hospital that decides which drugs might be available on our standard list of medicines at my particular hospital is continually reviewing physician prescribing practices to determine whether their formulary matches up well with what people are wanting to use and whether there are certain agents whose use might be discouraged by changing the formulary. Utilization review kinds of activities that look broadly at practices and whether they're consistent with various guidelines look at data about my prescribing habits and all my colleagues prescribing habits every day.

So, any hope that my information about or information about my prescribing behavior would [252] somehow be privileged or secret is – there's no basis for such a hope in the modern medical system, and I'm also well aware that pharmaceutical companies become aware of my prescribing habits, albeit, without the patient's name attached, and that information is useful to them and ultimately I think it's useful to me.

\* \* \*

[256] Q. I'm going to switch subjects again and I'm going to ask you whether in your practice, you

have had occasion to meet with so-called detailers from pharmaceutical companies?

A. Yes, I have.

Q. And have you understood that there was a requirement imposed on you to meet with them?

A. No. There's no requirement that I meet with anybody.

Q. Have you been free to ask any detailer with whom you did not want to meet to leave or refuse to meet with them?

A. Yes, I am free to do that.

Q. Okay. In your meetings with the detailers, have you found them generally to be informed about the pharmaceutical products they came to talk about?

A. Yes.

Q. Have you found them to behave in a professional manner?

A. Yes.

Q. What sorts of information have the detailers provided? You need not be specific with regards to [257] the details of a particular drug, but in general, what sorts of information do they provide to you?

A. Well, detailers provide summaries of clinical studies. They provide summaries of indications and contraindications. That's information that's generally

easily available in the PDR or on the internet and various reference sources.

They also may provide information about such things as formulation, what size tablets available, is there anything special for children, if there's a chewable tablet instead of a capsule that can be sprinkled on the cereal. Things that might be available out there if I go digging for them, but this makes it easy for me to appreciate.

They also provide early warnings to me of potential problems. For example, information about the risk of fetal abnormalities in the children of woman who are taking antiseizure medicines. When it became apparent that one particular compound had an elevated risk, that manufacturer had their sales force out there talking to physicians about the fact that perhaps their drug was not the most appropriate choice for young women when alternatives that appeared safer were available.

So, those kinds of early warning signs, on [258] occasion, rare, thank God, when a problem arises with a drug, that leads at least not to a recall, but at least to a level of concern and a warning, I've had the experience of representatives coming and telling me about that often before I heard it somewhere else. So, they can serve as an early warning system for problems and alerting people and the appropriate people, the people that happen to be using those drugs, about these problems arising.

Finally, the world that we all live in is – we’re confronted with a market – I think someone may have used this term this morning, we’ve confronted with a marketplace of ideas and a marketplace of data; and as I said earlier, the more sources I get data from, the more likely it is for me to make an informed and complete decision.

And hearing the representatives of several different manufacturers, I’ll use the word tout, I’m not sure that’s the right word, tout or discuss their products with me, allows me to evaluate competing claims more thoroughly and more completely than I might if I didn’t hear that information. So, it allows me to make better choices I think.

Q. In your experience, have the detailers appeared to you to be aware of the specialty in which [259] you practice?

A. Detailers that visit me are aware of the specialty in which I practice because the sign on the door says Mass. General Epilepsy Service, so it’s not hard, but I think, I think it’s a problem in some parts of the medical word. For example, if one walked into a general neurologist’s office, there would be no way to know from the sign of the door, I can say this from my experience, because I’ve walked in general neurologist’s offices, it says, Neurology Associates, specializing in adult neurology. There’s no way to tell whether that doctor takes care of patients with stroke, Parkinson’s disease, dementia, with multiple sclerosis, with epilepsy, whether he has a disproportionate

number in one domain or another. There's no way to know that from the sign of general neurology on the wall. It's pretty easy to tell when the sign says epilepsy on the wall that you take care of epilepsy patient.

Q. From your experience with the detailers, have they stayed within the boundaries of the approved FDA label information?

A. From my experience, they've stayed frustratingly within the boundaries. The guidelines from the companies of the detailers that I hear from [260] are so strict, that it's actual difficult to sometimes get what would be useful information because they're simply not allowed to talk about it.

Q. From time to time have you become aware that representatives of drug companies leave behind tokens like pens or –

A. Yeah, they leave pens and pads and they used to leave pizzas. They do.

Q. Have any of your prescribing decisions ever been affected by the fact that someone left you such an item?

A. I don't think so. I'll say absolutely not. I have a nice pen of my own. I bought it.

\* \* \*

[268] Q. The fact that the pharmacy, the insurer, anybody at the hospital happens to see the

patient's name doesn't remove the privacy rights, correct?

A. It doesn't remove the privacy rights from the pharmacy or the insurer, but it does – but the information is no longer private from those people. It doesn't remove their obligation to not distribute the envelopes. I think that's what you're getting at.

Q. Correct. The patient still maintains the privacy right notwithstanding the fact that some other people see it?

A. Well, the privacy right where everyone can [269] see it isn't much of a privacy rights, is it?

Q. I don't think we're talking about everyone, are we?

A. Well, it just depends on how big our universe is. I'm not trying to argue with you. I'm just trying to understand what you're asking me so I can try to respond to your question. I'm not sure I follow it. I don't think that the fact that some parties, for example, the payers, see the patients's name, deprives that patient a general right to privacy, I agree with you on that.

\* \* \*

[275] Q. But really for the patients for whom are you prescribing chronic medication, which is the reason why you're concerned about the bioavailability, we're not talking about an acute situation?

A. That's correct.

Q. That's only an issue with chronic, that's for a disease state that affects approximately 1 percent of the population?

A. That's a fair estimate, yes.

\* \* \*

[277] Q. But the 1 percent of the population suffering from epilepsy for which you treat the chronic condition and you wish to avoid a generic substitution, there are mechanisms for insuring that the branded medication is dispensed, correct?

A. Well, there are mechanisms for insuring it, and it's in more than the 1 percent that I treat. There are mechanisms for insuring it in patients with any condition for which this might be an issue. If the implication is it's only an issue in the one percent that I see, I would disagree with that, but there is a mechanism for insuring dispensing of a brand name drug, although that mechanism is sometimes cumbersome and varies from state to state.

\* \* \*

---

UNITED STATES DISTRICT COURT  
DISTRICT OF VERMONT

---

IMS HEALTH INC., ET AL	)	CASE NO:
VS	)	1:07-CV-188
WILLIAM SORRELL, ET AL	)	TRIAL BY COURT
	)	DAY 2 – VOLUME 1

---

BEFORE: HONORABLE J. GARVAN MURTHA  
U.S. DISTRICT COURT JUDGE

APPEARANCES:

MARK A. ASH, ESQUIRE  
SMITH, ANDERSON, BLOUNT,  
DORSETT, MITCHELL & JERNIGAN  
P.O. BOX 2611  
RALEIGH, NC 27601  
REPRESENTING IMS

ROBERT B. HEMLEY, ESQUIRE  
GRAVEL & SHEA  
76 ST. PAUL STREET, 7TH FLOOR  
BURLINGTON, VERMONT 05402  
REPRESENTING IMS

THOMAS R. JULIN, ESQUIRE  
HUNTON & WILLIAMS, LLP  
1111 BRICKELL AVENUE, SUITE 2500  
MIAMI, FLORIDA 33131  
REPRESENTING THE IMS

(APPEARANCES CONTINUED TO NEXT PAGE)

\* \* \*

[284] PETER B. HUTT, THE WITNESS, AFTER  
[285] BEING DULY SWORN, WAS EXAMINED AND  
TESTIFIED AS FOLLOWS:

DIRECT EXAMINATION BY MR. JULIN:

Q. GOOD MORNING, MR. HUTT. WOULD  
YOU PLEASE STATE YOUR NAME FOR THE  
RECORD?

A. MY NAME IS PETER BARTON HUTT.

Q. WHERE ARE YOU PRESENTLY EM-  
PLOYED?

A. I'M EMPLOYED AT COVINGTON AND  
BURLING A LAW FIRM IN WASHINGTON, DC.

Q. THANK YOU. YOU'VE HAD, YOU'VE  
DONE SOME WORK FOR THE FOOD AND DRUG  
ADMINISTRATION OF THE UNITED STATES; IS  
THAT CORRECT?

A. YES.

Q. AND CAN YOU PLEASE TELL THE  
COURT WHAT WORK YOU HAVE DONE WITH  
THE FDA?

A. WELL, DURING 1971 TO 1975 I SERVED  
AS CHIEF COUNCIL TO THE FOOD AND DRUG  
ADMINISTRATION.

Q. AND SINCE THAT TIME HAS YOUR  
PRACTICE BEEN IN THE AREA OF FOOD AND  
DRUG LAW?

A. ACTUALLY, BEFORE AND SINCE.

\* \* \*

[298] Q. AND WHAT THE COMPETING SOCIETAL INTERESTS IN THE TWO ASPECTS OF THE HATCH-WAXMAN ACT?

A. ON THE ONE HAND IT WAS NECESSARY TO EXTEND THE PATENT TERM BECAUSE THE SHORTER THE PATENT TERM, EFFECTIVE PATENT LIFE I'M TALKING NOW, NOT THE 20 YEAR TERM, BUT THE SHORTER THE EFFECTIVE PATENT LIFE THE HIGHER DRUG PRICES MUST BE CHARGED IN ORDER TO RECOUP THE TREMENDOUS INVESTMENT NECESSARY IN ORDER TO OBTAIN APPROVAL OF A NEW DRUG APPLICATION.

SO THE LONGER PATENT, EFFECTIVE PATENT LIFE, THE 11 AND A HALF YEARS ALLOWS PEOPLE TO RECOUP THAT TREMENDOUS INVESTMENT. AND, YOUR HONOR, THE INVESTMENT TODAY IS ABOUT \$2 BILLION IN ORDER TO OBTAIN THE, ALL THE DATA NECESSARY TO OBTAIN APPROVAL FOR A NEW DRUG APPLICATION.

NOW, ON THE OTHER HAND, THE SOONER A GENERIC DRUG [299] GETS ON THE MARKET THAT DRIVES DOWN THE PRICE OF THAT PARTICULAR DRUG. AND, THEREFORE, IT'S IN THE INTERESTS OF CONSUMERS AND THE COUNTRY TO HAVE LOWER DRUG PRICES AS SOON

AS IS REASONABLY POSSIBLE. AND THE BALANCE IS, AND IT'S HARD TO STRIKE THIS BALANCE, BETWEEN NOT LETTING GENERIC DRUGS ON THE MARKET TOO FAST BECAUSE THEN YOU WOULD DRIVE THE BRAND NAMED PHARMACEUTICAL INDUSTRY OUT OF THE BUSINESS AND NOT ON THE OTHER HAND, LETTING IT GO ON TOO LONG SO THAT YOU HAVE UNNECESSARILY HIGH PRICES FOR TOO LONG. THAT IS THE BALANCE.

\* \* \*

[303] Q. ALL RIGHT. AND THEN AS FAR AS THE SALES REPRESENTATIVES, OBVIOUSLY THIS CASE IS ABOUT SALES REPRESENTATIVES VISITING DOCTORS. TO WHAT EXTENT DOES THE FDA ENFORCE REGULATIONS AGAINST WHAT SALES REPRESENTATIVES CAN DO IN TERMS OF THEIR COMMUNICATIONS WITH PRESCRIBERS?

A. FDA UNEQUIVOCALLY STATES THAT NO SALES REPRESENTATIVE, INDEED NO REPRESENTATIVE OF ANY PHARMACEUTICAL COMPANY, CAN MAKE A REPRESENTATION ORALLY OR IN WRITING TO A PHYSICIAN THAT IN ANY WAY DEVIATES FROM THE APPROVED LABELING AND ADVERTISING.

Q. AND IS THERE A FAIR AND BALANCE REQUIREMENT IN TERMS OF COMMUNICATIONS WITH PRESCRIBERS?

A. WELL, THERE ARE, THERE ARE TWO OR THREE REQUIREMENTS.

Q. THANK YOU.

A. FIRST, EVERYTHING THAT IS PROVIDED TO A PHYSICIAN MUST NOT BE, IT IS PROHIBITED TO BE FALSE OR MISLEADING IN ANY PARTICULAR. AND THAT'S THE EXACT STATUTORY PHRASE. FALSE OR MISLEADING IN ANY PARTICULAR. SECOND, FOR PRESCRIPTION DRUGS FDA REQUIRES FAIR BALANCE. THAT IS FAIR BALANCE BETWEEN WHAT IS SAID OR WRITTEN ABOUT EFFECTIVENESS AND ABOUT SAFETY. NO ONE CAN JUST EMPHASIZE THE EFFECTIVENESS. THEY MUST ALSO GIVE EQUAL EMPHASIS AND IMPORTANCE TO THE [304] SAFETY CONSIDERATIONS.

AND THIRD, THERE MUST ALWAYS BE WHAT IS EUPHEMISTICALLY CALLED A BRIEF STATEMENT. IT IS NOT VERY BRIEF. BUT IT IS A FULL STATEMENT OF ALL THAT IS KNOWN ABOUT THE SIDE EFFECTS OF THE DRUG.

\* \* \*

[306] Q. WELL, THERE ARE THOUSANDS AND THOUSANDS OF SALES REPRESENTATIVES OUT THERE. HOW CAN THE FDA ENFORCE SUCH A REQUIREMENT?

A. FDA DOES NOT REQUIRE THAT THEY BE TAPE RECORDED. I ASSURE YOU OF THAT. WHAT HAPPENS IS TWO OR THREE THINGS.

FIRST, SOMETIMES A SALES REPRESENTATIVE WILL IMPROPERLY USE, LET US SAY, HOME-MADE DETAILING MATERIALS. THOSE ARE DOCUMENTS THAT FDA CAN OBTAIN.

SECOND, IF ORAL STATEMENTS ARE MADE IN NUMEROUS [307] TIMES A PHYSICIAN WILL, IF HE OR SHE BELIEVES THAT THEY ARE IMPROPER, WILL INFORM FDA. AND, THIRD, AND THIS IS FAR AND AWAY THE MOST IMPORTANT, THIS IS A HIGHLY COMPETITIVE INDUSTRY. SO THAT IF I GO IN AND DETAIL A DOCTOR TODAY AND YOU COME IN FOR A COMPETITOR TOMORROW YOU WILL ASK WHAT I SAID. AND IF YOU FIND OUT THAT I HAVE GONE BEYOND THE PACKAGE INSERT THE FIRST THING YOU WILL DO IS WRITE A LETTER TO FDA AND INFORM THE AGENCY. THAT IS COMMON. AND IT'S A REMARKABLE STATISTIC BUT, YOUR HONOR, WE ESTIMATE IN PRACTICING FOOD AND DRUG LAW THAT 80 PERCENT OF FDA ENFORCEMENT ACTION IS TAKEN AS A RESULT OF COMPETITOR COMPLAINTS.

Q. THANK YOU. NOW, COMPLAINTS ARE ONE THING, BUT ENFORCEMENT IS ANOTHER. WHAT SORT OF POWERS DOES THE FDA HAVE TO GIVE SOME TEETH TO THESE, THESE, TO ITS ENFORCEMENT POWERS?

A. FDA HAS BOTH INFORMAL AND FORMAL ENFORCEMENT POWER. INFORMALLY THE MOST COMMON METHOD IS TO ISSUE

WHAT IS CALLED A WARNING LETTER. AND FDA ISSUES A SUBSTANTIAL NUMBER OF WARNING LETTERS ABOUT ADVERTISING AND LABELING STATING THAT A COMPANY HAS GONE BEYOND WHAT FDA BELIEVES IS PERMISSIBLE, PARTICULARLY IN THE AREA OF COMPARATIVE CLAIMS.

IF I WERE TO COMPARE MY DRUG TO YOURS, MR. JULIN, FDA REQUIRES, FOR EXAMPLE, THAT THERE BE TWO ADEQUATE AND WELL CONTROLLED CLINICAL TRIALS BEFORE I CAN MAKE THAT [308] CLAIM. AND, THEREFORE, THEY WILL ISSUE WARNING LETTERS FREQUENTLY IF I WERE TO DO THAT. THAT IS THE MOST COMMON FORM OF INFORMAL FDA ACTION.

NOW, ON THE FORMAL SIDE THERE ARE THREE TYPES OF PENALTIES OR WHAT YOU MIGHT CALL JUDICIAL ACTION WHERE IT IS ACTUALLY THE DEPARTMENT OF JUSTICE THAT BRINGS ENFORCEMENT ACTION ON BEHALF OF FDA IN THE COURTS.

FIRST, FDA CAN REQUEST SEIZURE OF PRODUCT. IT IS AN UNUSUAL PROCEDURE, YOUR HONOR. IT IS AN IN REM ADMIRALTY TYPE OF PROCEDURE WHERE THE U.S. MARSHAL ACTUALLY GOES OUT AND TAKES POSSESSION OF THE OFFENDING PRODUCT IF IT'S SAY MISLABELED. THAT'S THE FIRST ACTION THAT CAN BE TAKEN. IT'S A CIVIL ACTION.

THE SECOND IS AN INJUNCTION, WHICH IS, OF COURSE, A WELL-KNOWN TYPE OF ACTION. AND THE THIRD IS CRIMINAL PROSECUTION OF BOTH THE RESPONSIBLE INDIVIDUALS AND THE COMPANY.

\* \* \*

[309] Q. ALL RIGHT. WE'VE HEARD SOME ABOUT ACADEMIC DETAILING, COUNTER DETAILING, INSURERS, SOMETIMES STATES AND MEDICAID MEDICARE FOLKS GOING OUT TO DOCTORS AND THEMSELVES ENGAGING IN DEALING IN DETAILING SUGGESTING THAT DOCTORS SHOULD [310] PRESCRIBE PERHAPS LOWER COST DRUGS. DOES THE FDA REGULATE THAT PROCESS AT ALL?

A. NO, IT DOES NOT.

Q. AND THEN IN TERMS OF, AND SO THERE'S NO FAIR BALANCE REQUIREMENT AS FAR AS ACADEMIC DETAILERS IS CONCERNED?

A. THERE IS NO REQUIREMENT OF ANY TYPE.

\* \* \*

[313] Q. OKAY. AND DO YOU AGREE WITH DR. KESSELHEIM'S OPINION?

A. I DO NOT.

Q. AND WHY DO YOU DISAGREE WITH HIS OPINION?

A. FIRST, ONE MUST GO BACK TO THE PARADIME THAT YOU [314] PRESENTED EARLIER OF 11 AND A HALF YEARS WITHIN WHICH TO RECOUP A \$2 BILLION INVESTMENT. IF YOU SLOW DOWN THE INTRODUCTION OF NEW DRUGS THAT WILL NECESSARILY FORCE UP THE PRICE BECAUSE YOU WILL HAVE A, ONLY A FIXED AMOUNT OF TIME IN ORDER TO RECOUP YOUR INVESTMENT. IF YOU CAN'T SELL THOSE DRUGS AT A NORMAL PACE AND INTRODUCE THEM AT A NORMAL RATE, AND MUST INSTEAD DO IT AT A SLOWER RATE, YOU HAVE TO HAVE HIGHER PRICES OR YOU'RE GOING TO LOSE MONEY.

\* \* \*

[315] Q. NOW, DO YOU HAVE AN OPINION AS TO WHETHER ACT 80, AS IT HAS BEEN AMENDED IN 2008, WILL IT DRIVE COSTS UP, DRIVE COSTS DOWN OR HAVE NO EFFECT WHATSOEVER?

A. THE PHARMACEUTICAL INDUSTRY CAN ONLY EXIST IF IT MAKES A PROFIT. AND TO THE EXTENT THAT SOMEONE TRIES TO SLOW THE INTRODUCTION OF DRUGS AND TO IN EFFECT SHIFT TO GENERIC DRUGS, ONE OF TWO THINGS IS GOING TO HAPPEN. EITHER THE PRICE OF DRUGS WILL GO UP OR THE INTRODUCTION OF NEW DRUGS WILL GO DOWN, I.E., INDUSTRY WILL HAVE LESS MONEY TO INVEST [316] INTO THE DEVELOPMENT OF

SAFE AND EFFECTIVE NEW DRUGS THAT FRANKLY REPRESENT THE WHOLE FUTURE OF HEALTH CARE IN THIS COUNTRY.

Q. LET ME ASK YOU WHETHER YOU HAVE AN OPINION AS TO THE IMPACT THAT THIS LAW WILL HAVE ON THE QUALITY OF CARE FOR PATIENTS AND PATIENT SAFETY.

A. I THINK IT WILL, IT WILL HARM PATIENT HEALTH AND IT WILL HARM IT BECAUSE PATIENTS LIKE MYSELF WHO NEED NEW DRUGS IN ORDER TO ADDRESS COMMON MEDICAL PROBLEMS WILL BE DENIED THOSE DRUGS WHEN THEY COULD BE TREMENDOUSLY HELPFUL TO THEIR HEALTH.

\* \* \*

[323] Q. NOW, YOU INDICATED YOU READ THE STATUTE. AND THERE IS A FINDING 5 OF THE STATUTE SAYS THAT FDA HAS A LIMITED LEGAL ABILITY TO ENFORCE THE REQUIREMENT OF FAIR BALANCE. DO YOU SEE THAT?

A. YES, I DO.

Q. IS THAT ACCURATE?

A. THAT IS INACCURATE.

Q. AND WHY IS THAT INACCURATE?

A. WELL, IT IS INACCURATE BECAUSE FDA FIRST HAS MAJOR RESOURCES THAT ARE BEING SUBSTANTIALLY INCREASED THIS YEAR

TO ENFORCE THE LAW. AND, SECOND, THAT THE AGENCY HAS UNPARALLELED ENFORCEMENT POWER IN THE STATUTE. I, I DO NOT UNDERSTAND HOW ONE COULD SAY THAT FDA HAS LIMITED LEGAL ABILITY WHEN IT HAS THE STRONGEST CRIMINAL ENFORCEMENT POWER IN THE HISTORY OF THIS COUNTRY.

\* \* \*

[333] Q. WELL, WE TALKED A MOMENT AGO ABOUT THERE BEING DISPUTE OVER THIS NUMBER. AND ARE YOU AWARE OF THE LITERATURE THAT CRITIQUES SOME OF THESE STUDIES THAT HAVE REACHED THE FIGURE YOU ARE TALKING ABOUT?

A. OH, YES. YES, I AM.

Q. SO LET ME SHOW YOU WHAT'S BEEN MARKED FOR IDENTIFICATION AS STATE'S 1183.

A. YES.

Q. COULD YOU TELL US WHAT THAT DOCUMENT IS, SIR?

[334] A. IT IS A REPRINT OF AN ARTICLE FROM THE JOURNAL OF HEALTH ECONOMICS.

Q. AND ARE YOU FAMILIAR WITH THIS ARTICLE?

A. NO, I AM NOT.

Q. I WOULD LIKE TO DIRECT YOUR ATTENTION TO THE FIRST PARAGRAPH UNDER WHERE IT SAYS, EXTRAORDINARY CLAIMS REQUIRE EXTRAORDINARY EVIDENCE, WHICH DESCRIBES THIS AS AN ARTICLE SUGGESTING SOME CRITIQUES OF THE STUDY THAT WAS DONE BY DEMAZZI ET AL IN 2003?

A. YES.

Q. AND THIS, THIS ARTICLE REPORTS THAT THE DEMAZZI STUDY IS BASED PRIMARILY ON CONFIDENTIAL PROPRIETY DATA PROVIDED BY PHARMACEUTICAL COMPANIES TO THE TUFT CENTER FOR THE STUDY OF DRUG DEVELOPMENT, A RESEARCH CENTER THAT RECEIVES SIGNIFICANT UNRESTRICTED GRANTS FROM PHARMACEUTICAL COMPANIES.

DO YOU HAVE ANY REASON TO DISAGREE WITH THE STATEMENT, THEIR EVALUATION OF THE STUDY IS BASED ON CONFIDENTIAL AND PROPRIETARY DATA?

A. MY UNDERSTANDING IS THAT IT WAS ALSO BASED ON DATA THAT WAS PUBLICLY AVAILABLE IN COMPANY REPORTS AS WELL.

Q. SO IN YOUR VIEW IT'S A COMBINATION OF PROPRIETARY DATA?

A. YES.

Q. AND PUBLIC DATA?

[335] AND YOU WOULD AGREE THAT TO THE EXTENT THE STUDY IS BASED ON A CONFIDENTIAL AND PROPRIETARY DATA, IT CANNOT BE REPLICATED BY OTHER RESEARCHERS. ISN'T THAT RIGHT?

A. NO. THAT IS NOT CORRECT BECAUSE THE GENERAL ACCOUNTING OFFICE RAN ITS OWN STUDY AND USED THE SAME TYPES OF DATA AND ARRIVED AT THE SAME, YOU KNOW, AREA OF COST.

\* \* \*

[346] Q. SO IF A GOVERNMENT PROGRAM SUCCEEDS IN SHIFTING PRESCRIBING COSTS, PRESCRIBING PRACTICES TOWARD GREATER USE OF GENERICS THAT WILL REDUCE THE COST PAID OUT FOR PRESCRIPTION DRUGS?

A. THERE'S NO QUESTION ABOUT THAT. AND IT WILL RESULT IN EITHER HIGHER PRICES ON THE NAMED BRAND DRUG OR AND WHAT I FEAR, AND WHAT I THINK IS THE WORST RESULT IS IT WILL RESULT IN A REDUCTION OF INVESTMENT IN NEW DRUGS AND THAT MEANS FEWER MEDICATIONS FOR ALL OF US.

\* \* \*

[362] LORI REILLY, THE WITNESS, AFTER BEING DULY SWORN, WAS EXAMINED AND TESTIFIED AS FOLLOWS:

DIRECT EXAMINATION BY MR. HAND-  
WERKER:

Q. GOOD MORNING.

A. GOOD MORNING.

Q. YOU'VE INTRODUCED YOURSELF SO  
COULD YOU PLEASE, MISS REILLY, DESCRIBE  
WHAT YOU DO FOR A LIVING?

A. SURE. I AM VICE PRESIDENT FOR THE  
PHARMACEUTICAL RESEARCH AND MANUFAC-  
TURERS OF AMERICA. I AM THE VICE PRESI-  
DENT FOR POLICY THERE WHICH IS A  
DIVISION WITHIN PHRMA. I MANAGE ABOUT  
SEVEN PEOPLE THAT WORK ON A VARIETY  
ISSUES EVERYTHING FROM FDA INCLUDING  
DIRECT CONSUMER ADVERTISING AND MAR-  
KETING TO ISSUES RELATED TO COMPARATIVE  
EFFECTIVENESS, INTELLECTUAL PROPERTY  
POLICY ISSUES, THE VALUE OF MEDICINE,  
INNOVATION, HEALTH CARE QUALITY, AND  
THE LIKE.

Q. HOW LONG HAVE YOU BEEN EM-  
PLOYED BY PHRMA?

A. JUST SHORT OF EIGHT YEARS.

\* \* \*

[396] Q. - MORE CLOSELY. IF YOU TAKE A  
LOOK AT FINDING NUMBER 6 WHICH SAYS, THE  
PUBLIC HEALTH IS ILLSERVED BY THE MAS-  
SIVE IMBALANCE IN INFORMATION PRESENT-  
ED TO DOCTORS AND OTHER PRESCRIBERS.

IS THAT, DO YOU HAVE ANY INFORMATION THAT IS CONTRARY TO THAT FINDING?

A. WELL, I'M PRESUMING BY HOW I'M READING THAT THAT THEY ARE ASSOCIATING THE IMBALANCE WITH INFORMATION FROM PHARMACEUTICAL COMPANIES. CERTAINLY FROM INFORMATION AVAILABLE IN SURVEY DATA AND THE LIKE PHYSICIANS ARE PRESENTED WITH INFORMATION FROM A VARIETY OF SOURCES. THEY UNDERTAKE CONTINUING MEDICAL EDUCATION. THEY ARE SUBJECT TO [397] COUNTER DETAILING BY INSURERS AND OFTENTIME PUBLIC PAYERS AS WELL. THEY ARE SUBJECT TO FORMULARIES AS WELL. IN FACT, ACCORDING TO ONE STUDY ABOUT A THIRD OF DOCTORS DON'T EVEN TALK TO PATIENTS WHEN A GIVEN MEDICATION ISN'T COVERED IN A PATIENT'S FORMULARY. THEY TALK TO PEERS. THEY ASSESS INFORMATION THAT PATIENTS BRING IN. WE'RE IN A REVOLUTION OF SORTS WHERE PATIENTS WILL OFTENTIMES DO THEIR OWN RESEARCH AND BRING IN THE INFORMATION.

SO CERTAINLY THERE'S A NUMBER OF DATA POINTS THAT ARE PRESENTED TO DOCTORS. I WOULD ALSO SAY THAT GIVEN THE HIGH GENERIC USE RATE OF ALMOST 68 PERCENT THAT CERTAINLY DOCTORS ARE BEING PERSUADED BY OTHER MECHANISMS TO INCUR SUCH A HIGH GENERIC USE RATE.

---

UNITED STATES DISTRICT COURT  
DISTRICT OF VERMONT

-----  
IMS HEALTH, INC., ET AL.,  
vs. CASE NO. 1:07-CV-188  
WILLIAM SORRELL, ET AL.,  
-----

PROCEEDINGS BEFORE HONORABLE  
J. GARVAN MURTHA  
TRIAL DAY #2 – AFTERNOON SESSION

taken on Tuesday, July 29th, 2008,  
United States District Court  
Brattleboro, Vermont.

APPEARANCES:

ON BEHALF OF THE IMS HEALTH, INC.:

ROBERT B. HEMLEY, ESQUIRE  
Gravel & Shea  
76 St. Paul Street, 7th Floor  
Burlington, Vermont 05402

ON BEHALF OF THE IMS HEALTH, INC.:

THOMAS R JULIN, ESQUIRE  
Hunter & Williams, LLP  
111 Brickell Avenue, Suite 2500  
Miami, Florida 33131

ON BEHALF OF PHARMACEUTICAL RESEARCH:

KAREN McANDREW, ESQUIRE

Dinse, Knapp & McAndrew, P.C.

P.O. Box 988

Burlington, Vermont 05402

(APPEARANCES CONT. ON NEXT PAGE)

\* \* \*

[419] DIRECT EXAMINATION OF EUGENE  
KOLASSA, Ph.D.

BY ATTORNEY HANDWERKER:

Q. Good afternoon.

A. Good afternoon.

Q. Could you please introduce yourself to the Court and tell Judge Murtha where you're from and what you do for a living?

A. Sure. My name is Eugene Kolassa. People call me Mick. I live in Oxford, Mississippi. I'm a CEO and Managing Partner of Medical Marketing Economics, a firm that consults with pharmaceutical and health care companies. I'm also adjunct professor of pharmaceutical marketing at the University of Mississippi, formerly full-time faculty at the University. Additionally, I'm adjunct professor of pharmaceutical business at the University of the Sciences in Philadelphia.

\* \* \*

[434] Q. Is it accurate to say that pharmaceutical sales representatives or pharmaceutical companies use [435] prescriber-identifiable data to tailor the messages that they provide to physicians?

A. No.

Q. In your opinion, Dr. Kolassa, do prescribers obtain valuable information from detailers?

A. Oh, yes.

Q. And if a prescriber does not receive or does not perceive that he or she is receiving valuable information from detailers, what typically happens?

A. Okay. Typically the prescriber won't see them anymore; certainly won't provide them with the same access that those that provide good information.

Q. And do prescribers in your experience control the amount of time that they spend with detailers, if any?

A. Yes, that's totally under their control.

Q. And in your experience, do pharmaceutical sales representatives honor requests by prescribers that they not be detailed?

A. In my experience, most do, yes.

Q. And why is it that?

A. Well, if – just in marketing in general, if a customer has said I'm not interested, don't talk to me, then that's a pretty clear signal that they don't want

to be bothered and to go back would just [436] aggravate the situation.

\* \* \*

[455] Q. Besides marketing and promotion, are there any other uses for prescriber-identifiable data?

A. There's a number of other uses.

Q. And what are those?

A. The one that I was most impressed with was a firm that used it to identify – a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product and they would use that to notify the DEA and other authorities of potential problems.

\* \* \*

[458] Q. All right. Dr. Kolassa, I've handed you what's previously been marked as Joint Exhibit 4 which is a copy of Vermont Act 80?

A. Are you familiar with the findings in Section 1 of the Act.

A. Yes, I am.

Q. Okay. I would like to review a few of those with you. I recognize that you may have opinions about some of the others, but I want to focus on some key ones here.

Beginning with Finding 4 which reads, “The marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that brand name companies invest in expensive pharmaceutical [459] marketing campaigns to doctors. The one-sided nature of the marketing leads to doctors prescribing drugs based on inaccurate 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.”

Do you agree with that finding?

A. No, I don't.

Q. Why not?

A. Well, because the marketplace for ideas on medicines is much more than one-sided. You know, having presented information to physicians, that's definitely a two-sided conversation.

More importantly, the marketplace for pharmaceuticals is quite competitive; and if a manufacturer goes and provides information, again, that by law needs to be fair and balanced and provide the negatives as well as the positives, even if it is not done that way, the competitor sales representative will be in there to deliver a counter message, you know, very quickly.

There are also other sources of information that are commonly used. Peers are the most important influence on physicians. We have got payers playing a

[460] bigger role all the time in terms of providing information to physicians. So, it's not at all one-sided.

Q. What role do payers play in providing information to physicians?

A. A bigger role all the time. It's amazing what's happened in just the last couple of years in terms of the amount of information provided by payers, insurers that will send scientific documents to physicians, will call when physicians are prescribing too much or too little of a product and provide them with information.

Blue Cross/Blue Shield of New Jersey is providing PBAs for electronic prescribing so that when a physician prescribes a product there is immediately a message on there about alternatives. Payers are playing a huge role.

Q. And those alternatives, are they typically generics or lower cost brand drugs?

A. Typically generics or lower cost brand drugs, yes.

Q. And do payers in your experience have a commercial incentive to encourage use of lower cost prescription drugs?

A. Payers succeed by not paying, so, yes, the [461] less they pay the more successful they are.

\* \* \*

[470] Q. Just a few final questions, Dr. Kolassa. In your opinion, would the Vermont Act restrictions on the use of prescriber-identifiable data apply even when the data would not lead to lower health care costs?

A. Certainly.

Q. And do the Act's restrictions on prescriber-identifiable data apply even where a brand name drug has no generic equivalent?

A. Yes.

Q. Do the Vermont Act's restrictions, in your view, on prescriber-identifiable data apply even where [471] a brand name drug is not the most expensive treatment?

A. Yes.

Q. And do the Vermont Act's prescription on prescriber-identifiable data apply even where the brand name drug would actually reduce medical costs for a patient?

A. Yes.

Q. And in your opinion, Dr. Kolassa, will the Vermont Act stop pharmaceutical companies from marketing their drugs in Vermont?

A. No.

Q. Why not?

A. Without physician-identifiable data, they'll continue to market less efficiently, probably no more less effectively, but certainly less efficiently. There will be more sales calls that result in talking to physicians that aren't interested in the product. There will be opportunities missed with physicians that could find the new product useful, could find the information, new information useful and important, but they won't get it because the company was unaware that the physician used that drug.

Q. And, Dr. Kolassa, based on your thirty years experience in the pharmaceutical industry and your knowledge of pharmaceutical marketing, are you aware [472] of any empirical evidence at all that links restrictions on prescriber-identifiable data with increased or decreased health care costs?

A. No.

Q. And are you aware of any empirical evidence at all that links restrictions on prescriber-identifiable data with improvement in public health?

A. No.

Q. And are you aware of any empirical evidence at all that links restrictions on prescriber-identifiable data with improved privacy for prescribers?

A. No.

\* \* \*

[473] Q. Dr. Kolassa, are you aware of how prescriber-identifiable data are used by pharmaceutical

companies or others to implement risk [474] mitigation strategies?

A. Certainly, and it's part of a large process that again. Identifying physicians that are regular prescribers, even occasional prescribers, of a product, sales representatives can visit them, talk about that experience, understanding if they've experienced any side effects, provide information on warnings of potential side effects. And because many of the risk management programs, risk mitigation programs, require documentation to be able to quickly identify those physicians that need those materials and get them to them, that's quite important.

\* \* \*

[482] Q. And you also became the Associate Director for the Center of Pharmaceutical Marketing and Management?

A. Soon after returning, yes.

Q. And the Center is funded by pharmaceutical and medical device companies or sponsor it?

A. Some funding came from there.

Q. Now, you're currently the CEO of Medical Marketing Economics?

A. Yes.

Q. And the vast majority of your clients are from the pharmaceutical industry?

A. That is correct.

Q. And you've represented pharmaceutical manufacturers in litigation?

A. Yes, I have.

\* \* \*

[483] Q. That's okay. And you're being paid today for your services?

A. Yes.

Q. And you've been paid for preparing your report and appearing at deposition?

A. Yes.

Q. And you were paid \$850 an hour?

A. Correct.

\* \* \*

[488] Q. Now, the amount of money spent promoting a drug is not reflected in the price that's charged for that drug, is it?

A. No, it isn't.

\* \* \*

[496] Q. Now, it's your opinion that Act 80 will not protect prescriber privacy?

A. Correct.

Q. And that's based on the fact that government and insurance companies have access to that information?

A. And nonmarketing aspects of the pharmaceutical companies would as well.

Q. Because of the exemptions in the act?

A. Correct.

\* \* \*

[497] Q. Okay. And that doesn't mean that the patient's privacy right is eviscerated?

\* \* \*

A. I would say that my insurance company by looking at my medical records can find out different things and may choose to intervene. Now, whether the degree to which that has to do with privacy, I know for a fact that they are using – insurance companies are using physician-identifiable information to call physicians to try to get them to comply with, with formularies, try to get them to change their prescribing in a way that may or may not be in the patient's best interests.

\* \* \*

[508] Q. And do insurance companies in your experience detail generic drugs?

A. They are doing so at a greater rate all the time, yes.

Q. And do academics in your experience detail generic drugs?

A. Well, academic detailing is the term that's used. It's also called counter-detailing, to have people

talk about, generally professionals, quite often pharmacists, come in, talk to physicians, play the same role as the sales representative, usually to promote the use of generics or alternative products.

\* \* \*

[509] DIRECT EXAMINATION THOMAS WHARTON, M.D.

BY ATTORNEY ASH:

Q. Dr. Wharton, where do you live?

A. In Exeter, New Hampshire.

Q. And what field of medicine do you practice in?

A. Cardiology.

Q. And how long have you been practicing in the field of cardiology?

A. 31 years.

Q. Sorry?

A. 31 years.

Q. And has that been entirely New Hampshire or have you practiced in any other states?

A. I trained in Boston in cardiology, and then I practiced in Boston until 1991 and moved to New Hampshire then and have been at Exeter ever since.

\* \* \*

[512] Q. Over the course of your career, your 31-year career, have you observed a sort of increasing trend towards transparency in the field of medicine?

A. Absolutely. Transparency is the name of the game. There is more and more public reporting of outcomes on the internet. On the Web MD – I don't mean the Web MD. Healthcarereportcards.com, you can look at the outcomes in many different areas for any [513] hospital you choose.

Q. In connection with treating your cardiology patients, I assume you write prescriptions?

A. Of course.

Q. And can you estimate the number of prescriptions that you write on a weekly basis?

A. Probably 75, including new and refills.

Q. You submitted a declaration in this case; do you recall that?

A. Yes.

Q. And in your declaration, in paragraph 13, you speak to some degree about the complexity of the prescription-writing process. Could you just describe in a very general way and briefly the complexities that you face as a cardiologist in writing prescriptions?

A. Well, first of all, one has to know the diagnosis of the patient and what the appropriate medications are, and most complex patients require five, six

medications. For each medication, one has to choose from a vast variety of medicines, even classes, to pick which is the medicine that is most likely to have the most efficacy with the least side effects in the particular patient, considering all of the other medications and their interactions, the age [514] of the patient, the patient's renal function, the patient's previous history of adverse reactions to medications and so forth. So, this is a daily task every time we encounter a patient.

Q. Is there a source that you can go to so that no matter what is ailing your patient, for example, can you go to a guideline and pick from column A, column B, and column C with precision and is that all that is involved in the prescribing process? In other words, is the guideline the be all and end all for treating your patients?

A. No. Of course not. There are general directions. Even the guidelines themselves say that these are only suggestions as to appropriate care or recommendations, but care must be individualized by the individual physician in the individual patient considering all factors. The patient's economic state, the patient's insurance coverage, these are all factors that have to enter into it in addition to the medical considerations that I've just listed.

Q. In a laymen's way, would it be fair to say that the prescribing process requires you to put the best interest of the patient first?

A. Yes, emphatically, and the doctor's ethical obligation to his patient is paramount.

\* \* \*

[523] Q. Thank you. Let's move on to another topic then. Do you consider yourself to have any sort of obligation to stay current on the developments in pharmaceuticals?

A. We have a sacred trust to stay current in a sense. We're dealing with people's lives and the public health.

Q. And how do you personally – what are the various sources that you personally look to to honor that sacred trust?

A. There are many peer-reviewed medical and cardiology journals that we all subscribe to and try to read, but there's thousands of pages published every month and it's impossible to keep up. There are national conventions that we all go to and, in fact, we have to to keep our credentialing at the hospital and our state license.

[524] There are all kinds of sources on the internet that will mail you the current information on the areas that you're interested in, and these are not pharmaceutical sources. There is the Medical Letter. And then of course there are our interactions with the representatives from the pharmaceutical industry.

Q. So, one of the sources that you personally make reference to are sales representatives; is that fair?

A. That's fair.

Q. But it's just one of the several that you listed?

A. Yes.

Q. Now, of all the sources that you listed, the medical journals, the web sites, the conventions, the meetings, the others that you mentioned, is there any one of those sources that in your experience is so authoritative that, without question, when you read something or you hear something in one of these sources, that you automatically go and prescribe the medication that is discussed in that source?

A. No.

Q. Why not?

A. Because the medical science is incredibly complex and one must consider all of the available [525] evidence before one makes a decision not just one particular piece of evidence.

\* \* \*

Q. Does the medical world, if you will, then ultimately rely on you in treating your patients to be in effect something of a gatekeeper to determine what is in the best interests of your patient?

A. Yes.

Q. And you fulfill that sacred trust, I take [526] it, by reviewing a wide variety of sources of information?

A. Yes, the sources that I mentioned, and I'm sure there are others.

Q. Let's transition here to your interactions with pharmaceutical sales representatives. How frequently do you in your practice meet with them?

A. We meet with them for lunch between one and two times a week, depending upon our schedules, in addition to which, a lot of reps come to the office, leave samples, and a secretary will give me a sheet to sign so that they'll leave samples, but I don't directly meet with the drug rep.

Q. Is it actually required that you meet with a pharmaceutical representative to receive samples?

A. No.

Q. And can you just explain that briefly?

A. I don't know what the official regulation is, but we receive samples all the time just by signing on a pad of paper that the rep has given the secretary to give to us, it takes about two seconds, and we get the samples we need.

\* \* \*

[527] Q. And in your own dealing with pharmaceutical representatives, is a glossy brochure sufficient for you to make a decision to treat a given patient with a [528] particular pharmaceutical?

A. Well, no, of course not. We hardly look at them any more than most of us look at ads in magazines as we're reading the magazine. I might be caught over something, but we're not going to make a decision on how to treat – on what we want to buy if it's a significant item on the basis of an ad that we read in the magazine. What we do pay attention to is the articles from the peer-reviewed literature that the drug reps invariably bring to discuss.

Q. All right. Again, I think we've already established you were not here for the openings. During the openings, the State made reference to legislative – testimony before the legislature by a couple of doctors, Dr. Boerner and Dr. Landry. Have you had a chance to review the testimony of Dr. Boerner and Dr. Landry before the legislature?

A. Yes, I have.

Q. And Dr. Boerner testified, and, Your Honor, this is at page 57 of the transcript for Friday, April 13, 2007, before the State of Vermont, it's in the legislative record, and she says, her testimony beginning at line 5, quote, a good rep is absolutely invaluable, because when you're in the hinterlands, where are you going to get your information about [529] what's going on with drugs? It's the drug rep. They'll come in and they say, we have a new drug, you know, X drug does this, our drug does X plus Y, so you can see why it's a good idea for your patients. You know, you can learn from them, and oftentimes they'll help you out. Do you agree or do you disagree with

Dr. Boerner's testimony before the Legislature about the helpfulness of sales rep?

A. I completely agree.

Q. Now, Dr. Landry testified – and, Your Honor, this is – I'm going to be reading from page 28 of his testimony on April 20, Friday, April 20, beginning at line 4, quote, as long as the free market exists, my concept is we need to teach other physicians how to interact with the pharmaceutical industry, not necessarily shut them out, because there are things they do well and they help us with education. So, there's lots of positives that they do and we need to have a better relationship with them to say how does this work, you know, but I think the reality is we have to find a way to be balanced and unbiased as best we can in doing that. So, I think it's not an all or none shut them out.

Do you agree or disagree with Dr. Landry [530] that there are positives in what your discussions have been over the years with pharmaceutical reps?

A. I completely agree.

Q. Now, have you noticed, let's say, over the past ten to fifteen years any changes in the strategies or techniques that the sales representatives are using with you in marketing the various competing products that they market to your practice?

Q. Absolutely. The entire field –

Q. Can you describe that, please?

A. The entire field of medicine has gone more and more toward evidence-based medicine, which means that we practice not according to what we think will work, but according to what has been proven to work scientifically, and this evidence comes from articles in peer-reviewed respected medical journals.

More and more, the reps are trained in this evidence and bring this evidence to us to discuss. In the old days, perhaps there were inappropriate complaints, I should not say complaints, but claims made about medications that were not perhaps substantiated, such as Darvon is better than aspirin or something. I'm talking about 20 plus years ago.

Perhaps as recently as ten years ago, I [531] would occasionally find a rep or have a rep come to me and say, Dr. Wharton, I told you about this product; I gave you lunch; you haven't prescribed it; what's wrong. And of course that offended me and all I had to do is say, don't come back anymore, thank you very much, and the problem was solved. I haven't seen that happening in perhaps the last decade.

Q. You raised a point I was going to ask you about. I'll just go ahead and cover it. Is a sales representative entitled to come into your office, or do you have some control over that?

A. They're invited to come into our office. They make appointments or we make appointments with them.

Q. But if you don't want them there, or if, I think, to use a phrase that Mr. Julin used in his examination or opening statement, if they're just giving you a bunch of malarkey, what do you do?

A. We don't see them anymore. It's as easy as that, either a particular rep or a particular company if we've had some adverse experiences. I must say we haven't had these types of adverse experiences in the past many, many years.

Q. When a sales representative comes into you – well, first of all, do sales representatives come [532] to you from competitor companies in each class for the classes of medicines that your patients receive?

A. Absolutely. When they know that we prescribe a particular class, we see reps from virtually every company.

Q. And will the representative from company A for a given class, occasionally compare or let's say counter detail you with respect to what you might have heard from the rep from company B?

A. Yes.

Q. Okay. And is that a common experience?

A. It's a very common experience, and they don't say, this other company is lying, they rather say, well, my drug has an advantage in this niche of patients where the other drug is perhaps weaker. For example, my drug doesn't affect the way Coumadin thins your blood and this other drug does, and that

makes management more complex; that's true and that's important information.

Q. And how common is it that the representatives you're dealing with, whether it's for company A, B, C or Z, how common is it that they bring peer reviewed or other scientific literature?

A. They virtually always bring something. Sometimes we've seen it before. Very often it's [533] something brand new. Very often it's something that we're quite familiar with. Other times it's important stuff that some of us have missed.

Q. Do you understand – I mean, does the sales representatives, you know, say for Lipitor, does he or she hide the fact that he's working for a company that sells Lipitor, it's like stealth marketing?

A. No. Of course not. They wear a little Lipitor tag and give out Lipitor pens and so forth.

Q. Or umbrellas or golf things?

A. Well, usually it's only a pen and a sandwich.

Q. Have you ever written a prescription based on the receipt of one of these gifts?

A. Of course not.

Q. Why not?

A. Why would anyone expect a respected scientist, physician to have some trinket with a drug logo

influence how they treat a patient? I don't understand why one would even think that could be possible.

Q. Well, if a sales representative thinks it's possible, I mean do you, do you make decisions based on subliminal messages, if you will, connoted by a pen or an umbrella?

[534] A. Well, we would like to think that we don't. I would say absolutely not, but perhaps somebody else could prove that subliminal influences do influence people, in which case the subliminal influences would cancel each other out, because we have pens from every single drug company, so . . .

Q. Yeah, right. Dr. Wharton, in this particular case, we're mostly focused not just on detailing generally, but on the use of doctor-identifiable information.

At some point in your career as a cardiologist, did you become aware that one or more of the representatives meeting with you actually had access to your prescription writing history and practices?

A. Yes.

Q. And how did that, how did that make you feel; what was your reaction when you first learned that?

A. The events that I mentioned from decades ago, Dr. Wharton, they would say, why aren't you prescribing more of my product, initially offended me

because I felt what right do they have to know how I'm treating my patients.

But then I learned that they do not have [535] access to patient-identifiable data, which would be a violation of doctor-patient relationship, and then I thought that this may be – may mean that I don't waste my time being marketed by – for drugs that I don't use and that to be targeted for classes of drugs that I'm interested in might be a good thing. So, I changed my mind completely years ago on that subject.

Q. And in the field of cardiologists, are there differences in the types of practices, if you will?

We've heard from a Dr. Cole that there are differences among neurology practices. Are there differences within cardiology so that your patient population or what you do may be different from somebody else's?

A. Yes. Many differences. There are general cardiologists. Noninvasive cardiologists that read ECHO tests, nuclear tests, CT scans. Invasive cardiologists that do catheterizations. Interventional cardiologists that do stents. Electrophysiologists that do all kinds of electrical procedures to the heart and implant these Dick Cheney type ICD devices, electrical procedures with catheters, I would add, to heart patients, including implanting the Dick Cheney type ICD defibrillator devices that shock patients back to life when they [536] have cardiac arrest. Each of these specialties is different, each of these specialties have their own areas of expertise, and most of these you

can achieve subspecialty boards in the particular subspecialty.

Q. So, are you finding from the – from your own experience that because the representatives know you're prescribing history, that they don't often try to market you something that is of no particular interest to you or what are you finding in that regard?

A. It's very rare that somebody would come by with a medication that we're not interested in.

Q. Yeah.

A. For example, we never are marketed for diabetic drugs, because we don't treat diabetes. We leave that to the internists. Other cardiology groups, particularly in the hinterlands, might. We don't ever be marketed for sleeping pills or antidepressants, for example, because we simply don't use them even though cardiology patients sometimes have insomnia and can't sleep.

Q. I wanted to move to a related topic. In your declaration, you indicate that there are a variety of examples of situations where a pharmaceutical representative has brought to your [537] attention some new innovative product or perhaps an application for an older product and you testified about some of these examples in Maine and New Hampshire. But in your recent, more recent experience, is there a circumstance with a me-too drug, and I'm going to just try to cut through it here, a me-too drug, Bestolic or something like that, that you've had experience

with, and could you relate that briefly to the Court and, if at all, how a sales rep influenced your conduct?

A. Yes. This is all recent information about this new beta blocker. Beta blockers are very common heart drugs that have been used for decades. They block the effect of adrenaline on the heart. They improve survival in heart attack patients. They improve angina. They are imperative drugs to use in heart patients if they can tolerate them. However, they are not well tolerated in many patients. They cause fatigue, depression, lethargy, inability to exercise as well, asthma if they have lung disease, and impotence.

Q. And was Bestolic approximately the seventeenth beta blocker in its category?

A. Right.

Q. And so what was brought to your attention [538] about Bestolic that caught your attention?

A. We all use four or five beta blockers out of the sixteen or seventeen and we're not really interested when a new one hits the market. So, no one of my group looked at Bestolic until the drug rep came and talked to us about how it is really a different sort of beta blocker essentially without any of those bad side effects that I mentioned. So that many people who should be on a beta blocker for their heart health who couldn't take them now may be able to take them.

In the old days, for example, the beta blocker, Inderal, the slogan was Inderal ends it all in reference

to impotence. Bestolic interestingly acts on the nitric oxide pathways in the blood vessel wall to dilate vessels, and the bottom line is that's the same pathway that Viagra uses. Now, they can't market it has a new Viagra, but they can say that they don't see impotence with this particular drug as one single example or patients with lung disease can take it now because they don't wheeze.

So, this is a very important non-me-too beta blocker that we learned of the advantages of first by a drug rep marketing it to us only in the matter of a month or two ago.

[539] Q. In your deposition in this case, you testified briefly about another new drug, which I think is actually an entirely new class if I understand correctly, and it's called Tekturna, is that a hypertension related treatment?

A. Yes.

Q. And was that a medication or new class that was brought to your attention by a sales representative?

A. No. No. But we learned more about the drug from that sort of meeting.

Q. Okay. Well, then just briefly tell the Court what it was that the sales representative brought to your attention that influenced your thinking about Tekturna?

A. Well, Tekturna is a very important new class of drugs for hypertension that acts on the renal metabolic pathways, something they've been looking for for twenty years. It's now available, but it has complex interactions with other kinds of drugs that the patients are already taking, ace inhibitors, ARBs, spironolactone-type drugs. It was very confusing.

The drug rep brought a medical scientist from Boston to explain to us the detailed chemistry of how this drug works in the kidney versus how the other [540] drugs work in the kidney and how they interact, so our level of understanding was augmented tremendously in terms of how to use this new and important drug from a Boston researcher, not part of the drug company, but obviously getting an honorarium for making a visit to us.

Q. Okay. Dr. Wharton, there are many other examples, I take it, that you could, if we had just two weeks of time, we could talk about with the Court, is that fair?

A. A great many.

Q. Now, let me just list a few of them and just ask if we were to take the time, are these other drugs situations where a pharmaceutical representative either brought the drug to your attention or brought an issue to your or a partner's attention in an educational and helpful way? Lovaza, which is a fish oil, Inspra and Coumadin, are those other – or the Coumadin-Crestor interactions, are those situations where pharmaceutical representatives brought to your attention

useful educational information that have helped your patients?

A. They all are. Yes.

Q. Okay. Now, what about Vytorin? I understand Vytorin has been a very heavily detailed or [541] marketed product. Is that something that you regularly prescribe?

A. Vytorin is probably more heavily marketed than Lipitor, but it hasn't displaced Lipitor. It's a combination of medications that I decided not to prescribe even though it's heavily marketed, and in fact it is now going out of vogue by recent studies.

Q. Okay. And did you adopt Vytorin simply because you had some free lunches, I take it, where a Vytorin representative came and talked?

A. I didn't adopt it. That was the thing. We had lots of free lunches and we were talking about Vytorin versus other statins, and they weren't able to convince us and so we did not adopt it.

Q. And did that representative of Vytorin offer you literature to try to persuade you, but despite that, you decided not to use it?

A. The literature was persuasive in that it did lower cholesterol. What was not persuasive is did it improve outcomes. There's no literature on that.

Q. So, you exercised your own independent medical judgment on behalf of your patients, I take it, not to use Vytorin despite several lunches?

A. Absolutely.

Q. Okay. Another issue that's come up in this [542] case is whether this legislation that we're talking about and the use of prescriber-identifiable information will reduce costs, and you have already spoken about this a little bit.

From your experience as a cardiologist, is the cost per pill the true measure of the cost of taking care of and improving the health of your patient and, if not, can you explain that?

A. No, of course not. It should be self-evident that the cost of anything that's used over the long term is not determined simply by the initial cost. A car that's cheap but gets worse gas mileage and and has a worse repair record may be more expensive in the long run and this is especially true with medications.

For example, an ace inhibitor that is generic that lowers blood pressure may be cheaper at the outset than an ace inhibitor that's branded but gets into the blood vessel wall and lowers heart attack, stroke, death and diabetes. Readmission for heart attack is awfully expensive.

So, in the long run, the branded or previously branded Altace would cost more per pill, but is arguably much better for patients not only in terms of medical care but in terms of long-term costs.

[543] Q. Thank you. Another issue is privacy. Do you – first, what are the various players in the

medical market, if you will, who to your knowledge have access to your prescription writing information?

A. The patient. The patient's doctor. I already tell the patient's doctor what I'm doing.

Q. When you say you tell the patient's doctor –

A. What I'm doing.

Q. – you're talking about a primary care or do you mean –

A. Right, the primary care physician. We're usually consultants and they're usually followed by a primary care physician, and when we treat, we say here is how we're treating. The patient's family. The insurance companies, they know exactly what we're prescribing. The pharmacies. Government agencies. I'm sure Medicare does. And ultimately scientists doing studies on populations.

Q. Do you personally have any expectation of privacy given the various players in the medical community or in the insurance community who have access to your prescription writing practices?

A. No, I do not. In fact, I expect transparency; and as I have said before, much of our [544] very important outcomes in terms of many areas of our care are becoming publicly available on the internet?

Q. Have you had the experience of insurance companies putting pressure on you or other doctors in your practice to use one drug instead of another drug?

A. Virtually several times a day we get that pressure. It's a nuisance.

Q. Okay. And has an insurance company ever suggested that your patients be prescribed a more expensive medication?

A. If the insurance company –

Q. I mean per pill.

A. Yeah. If the insurance company – I'm not talking about the list price over the counter, but rather what the insurance company gets the medication for. They may have a deal with Lipitor and not with Crestor, for example. But, for example, a patient who does not get to goal with say a generic Simvastatin and we've switched to Crestor, we have to write the insurance company a letter why to justify our upgrading from a generic to a branded drug and we do, but it's a nuisance.

\* \* \*

---

UNITED STATES DISTRICT COURT  
DISTRICT OF VERMONT

---

IMS HEALTH INC., ET AL	)	CASE NO: 1:07-CV-188
VS	)	TRIAL BY COURT
WILLIAM SORRELL, ET AL	)	DAY 3 – VOLUME 1

---

BEFORE: HONORABLE J. GARVAN MURTHA  
U.S. DISTRICT COURT JUDGE

APPEARANCES:

MARK A. ASH, ESQUIRE  
SMITH, ANDERSON, BLOUNT, DORSETT,  
MITCHELL & JERNIGAN  
P.O. BOX 2611  
RALEIGH, NORTH CAROLINA 27601  
REPRESENTING IMS

ROBERT B. HEMLEY, ESQUIRE  
GRAVEL & SHEA  
76 ST. PAUL STREET, 7TH FLOOR  
BURLINGTON, VERMONT 05402  
REPRESENTING IMS

THOMAS R. JULIN, ESQUIRE  
HUNTER & WILLIAMS, LLP  
111 BRICKNELL AVENUE, SUITE 2500  
MIAMI, FLORIDA 33131  
REPRESENTING IMS

(APPEARANCES CONTINUED ON NEXT PAGE)

\* \* \*

DATE: JULY 30, 2008

\* \* \*

[557] AND YOU'RE AWARE THAT IN VERMONT UNDER THE STATUTE INVOLVED IN THIS CASE, UNLIKE NEW HAMPSHIRE, PRESCRIBERS CAN CHOOSE TO PERMIT THEIR PRESCRIBER DATA TO BE RELEASED TO THE MARKETERS?

A. YES.

Q. SO ANY DOCTOR WHO FEELS THE SAME WAY YOU DO ABOUT THE USE OF THE DATA CAN CHOSE TO HAVE THEIR DATA RE-LEASED IN THIS STATE?

A. IF THEY FEEL THE SAME WAY THAT I DO ABOUT THEIR OWN PERSONAL DATA THEY MAY NOT NECESSARILY FEEL THE SAME WAY I DO ABOUT TRANSPARENCY IN GENERAL.

Q. FOR INSTANCE, IF YOU WERE TO PRACTICE ON THIS SIDE OF THE CONNECTICUT RIVER YOU COULD RELEASE YOUR DATA IN VERMONT UNLIKE IN NEW HAMPSHIRE?

A. YES, I COULD.

Q. AND UNDER THE VERMONT LAW THE SALES REPRESENTATIVES CAN STILL MARKET THEIR PRODUCTS; CORRECT?

A. YES.

Q. AND THERE'S NOTHING IN THE VERMONT LAW THAT WOULD PREVENT YOU FROM HAVING YOUR ONCE OR TWICE WEEKLY MEETINGS, THE ROUND TABLES DISCUSSIONS WITH

THE PHYSICIANS IN YOUR PRACTICE AND THE SALES REPRESENTATIVES; CORRECT?

[558] A. THAT'S CORRECT.

Q. NOW, IN THE COURSE OF THOSE MEETINGS WOULD SALES REPRESENTATIVES BE ABLE TO FIGURE OUT FAIRLY QUICKLY WHAT TYPE OF PRACTICE YOU HAVE, WHAT TYPE OF MEDICATIONS YOU WERE INTERESTED IN?

A. ONCE THEY VISITED US. BUT WE MIGHT REQUIRE EXTRA VISITS BY, FOR EXAMPLE, REPRESENTATIVE OF DIABETIC DRUG COMPANIES OR SALINE PILLS OR PSYCHIATRIC AGENTS, THAT MIGHT BE A WASTE OF TIME.

Q. SURE. AND YOU CAN LET THEM KNOW THAT PRETTY QUICKLY, I DON'T NEED TO SEE YOU, I DON'T PRESCRIBE DIABETIC DRUGS?

A. YES.

Q. SO THAT'S A SITUATION THAT COULD RESOLVE ITSELF IN SOME AMOUNT OF TIME?

A. EXCEPT THAT USUALLY WHEN THEY MAKE THE APPOINTMENT THEY DON'T TALK ABOUT WHICH OF THE SEVERAL DRUGS THEY HAVE THAT THEY ARE GOING TO TALK ABOUT. SO WE SEE A REPRESENTATIVE FROM COMPANY X OR Y AND WE DON'T KNOW WHAT DRUGS WILL BE COMING UP.

Q. THAT'S PERHAPS A CONVERSATION THAT YOU COULD HAVE AT THE TIME THE APPOINTMENT IS MADE ISN'T IT?

A. THE SECRETARIES HANDLE THE APPOINTMENTS SO WE WOULD NOT NECESSARILY LOOK INTO THAT WHILE WE'RE BUSY TAKING CARE OF PATIENTS.

Q. YOUR SECRETARY COULDN'T ASK WHAT THEY INTENDED TO [559] DISCUSS WITH YOU?

A. THEY COULD.

\* \* \*

[560] Q. AND YOU'RE AWARE THAT THE PRESCRIBER LEVEL DATA CANNOT BE REVEALED TO THE PHYSICIANS BY THE SALES REPRESENTATIVES?

A. I'M NOT SURE WHAT THE QUESTION MEANS.

Q. ARE YOU AWARE THAT THE SALES REPRESENTATIVES CAN'T DISCUSS THAT DATA WITH YOU?

A. OH, WITH ME? WITH EVERYONE? I KNOW THEY ARE DISCOURAGED FROM THAT. I WILL SOMETIMES ASK THEM, WHAT DO YOU HAVE ON ME FOR MY DATA. AND THEY WILL ALLUDE TO THAT IN A GENERAL WAY BUT NOT TALK ABOUT SPECIFICS.

Q. AND THEY'VE NEVER TALKED TO YOU ABOUT SPECIFICS; CORRECT?

A. AS I SAID YESTERDAY SOMETIMES THEY HAVE ATTEMPTED TO. THEY HAVEN'T SAID IT, FOR EXAMPLE, THEY HAVE SAID IT IN 5 YEARS PAST, WHY AREN'T YOU PRESCRIBING MY PRODUCT. AND I SAID, WELL, I ALREADY TOLD YOU AND I DON'T APPRECIATE THAT QUESTION. IT'S ALMOST AS IF YOU'RE MAKING ME FEEL OBLIGATED TO PRESCRIBE THE PRODUCT BECAUSE WE'VE TALKED ABOUT IT. SO YOU DON'T HAVE TO COME BACK ANY MORE. THANK YOU VERY MUCH.

\* \* \*

[561] Q. THE CLIENTS WHO RETAINED YOU TO OFFER YOUR OPINIONS IN THIS LITIGATION TODAY ARE THE HEALTH INFORMATION COMPANIES?

A. YES.

Q. ARE YOU AWARE THAT YOUR CLIENTS, THE HEALTH INFORMATION COMPANIES, PROHIBIT THEIR CLIENTS, THE PHARMACEUTICAL MANUFACTURERS, FROM REVEALING THE DATA TO THIRD PARTIES SUCH AS PRESCRIBERS? DID THEY TELL YOU THAT WHEN THEY HIRED YOU?

A. I CANNOT – LET ME THINK. LET ME TRY TO REMEMBER. YES, THE DATA IS PROPRIETARY, PRIVATE. I'M AWARE OF THAT.

Q. AND IT'S CONFIDENTIAL?

A. YES.

\* \* \*

[563] Q. SO IS YOUR TESTIMONY STILL THAT UNLESS THERE'S AN OBVIOUS BENEFIT AND AN OBVIOUS LOW RISK A LOT OF US PHYSICIANS TEND TO WAIT A WHILE UNTIL THE DRUG IS RELEASED UNTIL WE START PRESCRIBING?

A. YES. AND THAT WAS THE INTENT OF WHAT I MEANT TO TELL YOU IN MY ANSWER JUST NOW. THAT EACH DRUG IS DIFFERENT. AND TALKING IN GENERAL VERSUS TALKING IN SPECIFIC ARE TWO DIFFERENT THINGS.

\* \* \*

[567] Q. AND SO THAT WAS THE EXAMPLE, AN EXAMPLE YOU GAVE THAT DESPITE THE EFFORTS OF THE VITORN SALES PEOPLE YOU WEREN'T INFLUENCED AND DIDN'T PRESCRIBE THE DRUG?

A. THAT'S CORRECT.

Q. BUT YOU'RE AWARE THAT IT SOLD APPROXIMATELY 1.9 BILLION DOLLARS IN 2006?

A. YES.

Q. AND IN 2007 SOLD ABOUT 2.78 BILLION DOLLARS?

A. I'LL TAKE YOUR WORD FOR IT. I'M NOT SURPRISED.

Q. BUT 2008 IT'S NOT DOING SO WELL IS IT?

A. EXACTLY. OTHER DOCTORS PERHAPS ARE THINKING MORE LIKE I WAS THINKING INITIALLY. IT'S NOT CAUSING HARM. BUT THE DOCTORS RESPONDED TO IT BECAUSE FOR TWO VERY GOOD REASONS. ONE, IT LOWERED CHOLESTEROL VERY DRAMATICALLY. AND, NUMBER TWO, TO GET ONE PILL INSTEAD OF TWO IT MEANT THE PATIENT HAD ONE CO-PAY INSTEAD OF TWO AND MORE COMPLIANCE. THESE ARE THE ARGUMENTS IN FAVOR OF VITORN. AND THIS IS WHY MANY DOCTORS ACCEPTED IT I THINK BECAUSE THESE, BECAUSE OF THESE OTHER FACTORS.

Q. BUT IT'S NOT BEING PRESCRIBED VERY HEAVILY NOW; CORRECT?

[568] A. THAT'S CORRECT. A STUDY CAME OUT THAT SHOWED THAT ADDING ZATIA SIMVASTATIN DIDN'T SEEM TO IMPROVE THE THICKNESS OR THE PLAQUE IN THE COROTID ARTERIES LIKE THEY THOUGHT IT MIGHT AND OTHER STATINS HAVE BEEN SHOWN TO DO. NO NEGATIVE EFFECT, BUT THE LACK OF THE BENEFIT THAT WAS EXPECTED.

Q. AND A BENEFIT THAT'S AVAILABLE FROM OTHER DRUGS?

A. THAT'S CORRECT. THE BENEFIT IS A POOR SURROGATE IN A SMALL STUDY FOR OUTCOMES SUCH AS HEART ATTACK OR STROKE BUT NEVER THE LESS IT WAS A SIGN THAT MAYBE THE ZATIA WASN'T AS GOOD AS THE EQUIVALENT STATIN DOSE.

\* \* \*

[571] JEFFREY ROBERTSON, THE WITNESS, AFTER BEING DULY SWORN, WAS EXAMINED AND TESTIFIED AS FOLLOWS:

DIRECT EXAMINATION BY MISS MCKEARIN:

Q. JEFF, YOU TEND TO SPEAK SOFTLY SO CAN YOU MAKE SURE YOU'RE CLOSE ENOUGH TO THE MICROPHONE SO EVERYONE CAN HEAR YOU?

A. SURE.

Q. YOU'RE EMPLOYED BY WYETH?

A. YES.

Q. AND IS WYETH A MEMBER COMPANY OF PHARMA?

A. YES, IT IS.

Q. ONE OF THE PLAINTIFFS IN THIS CASE? WHAT IS WYETH'S BUSINESS?

[572] A. RESEARCH, MANUFACTURING AND SALES OF PHARMACEUTICALS.

Q. WHAT'S YOUR CURRENT POSITION WITH WYETH?

A. I'M THE ASSISTANT VICE PRESIDENT OF SALES PLANNING AND INCITES.

\* \* \*

[594] Q. WE'VE HEARD SOME REFERENCE HERE TO DEAR DOCTOR LETTERS. CAN YOU TELL US BRIEFLY WHAT DEAR DOCTOR LETTERS ARE?

A. UM, SO FOR WYETH DEAR DOCTOR LETTERS ARE TYPICALLY USED IF THERE'S SOME SIGNIFICANT OR MATERIAL OR URGENT CHANGE IN THE FACTS OF ONE OF OUR PRODUCTS, A NEW STUDY, A NEW INDICATION, A NEW WARNING THAT WE THINK IS IMPORTANT TO GET NEW INFORMATION OUT TO, TO A LARGE NUMBER OF HEALTH CARE PROVIDERS.

Q. DOES WYETH USE PRESCRIBER-IDENTIFIABLE DATA IN CONNECTION WITH DEAR DOCTOR LETTERS?

A. UM, TYPICALLY WYETH GOES PRETTY BROAD AND FAST. SO IF THERE'S NEW INFORMATION ABOUT A WYETH PRODUCT WE HAVE A SYSTEM THAT GETS SORT OF A BLAST OF INFORMATION OUT TO A VERY BROAD GROUP OF HEALTH CARE PROVIDERS.

FOLLOWING THAT THEN OUR REPRESENTATIVES ARE ALSO PROVIDED A COPY OF THAT

LETTER. AND THEN AS THEY INTERACT WITH THE HEALTH CARE PROVIDERS THEY CALL ON THEY GIVE A FOLLOW-UP OF THAT INFORMATION. AND THAT SPECIALLY LIKE, THAT'S PARTICULARLY HELPFUL WHERE WE KNOW THAT A PHYSICIAN HAS A PARTICULAR INTEREST IN A THERAPEUTIC AREA SO THAT WE'RE CERTAIN THAT THAT PHYSICIAN RECEIVES THAT INFORMATION.

Q. SO THE SALES REPS FOLLOW-UP THEN AFTER YOUR, WHAT YOU CALL YOUR BROAD AND FAST DISTRIBUTION?

[595] A. YES. SO, AGAIN, TO THE EXTENT THAT PRESCRIBER-IDENTIFIABLE DATA WE USE IN THE CALL PLANNING PROCESS THEN THOSE REPRESENTATIVES ALSO KNOW WHICH PHYSICIANS WOULD BE MOST INTERESTED IN THIS NEW INFORMATION IN THE DEAR DOCTOR LETTER.

\* \* \*

[599] Q. AND, IN FACT, THE SALES PEOPLE ARE COMPENSATED, IN PART, BASED ON THE VOLUME OF PRESCRIPTIONS THAT THEIR CUSTOMERS GENERATE; CORRECT?

A. UM, SALES REPRESENTATIVES ARE IN PART COMPENSATED ON MANY MEASURES, GOAL ATTAINMENT BEING ONE OF THEM.

\* \* \*

[600] Q. THE GOAL EXPRESSED IN THE NUMBER OF PRESCRIPTIONS?

A. YEAH, GENERALLY. YES.

\* \* \*

Q. AND IF THEY ACHIEVE OR EXCEED THAT GOAL THEY MAKE MORE MONEY?

A. THAT'S CORRECT.

\* \* \*

[603] Q. IN FACT, IT WAS A - WYETH PRESCRIBER LEVEL DATA ISN'T USED BY ANYONE BESIDES THE SALES FORCE; CORRECT?

A. UM, THE BRAIN TEAMS DO IT. BUT GENERALLY THAT'S THE USES, THE MARKETING TEAMS, THE BRAIN TEAMS AND THE SALE FORMS.

Q. THE BRAIN TEAMS, THEIR FUNCTION IS THE MARKETING FUNCTION?

A. YES.

\* \* \*

[605] Q. SO FOR INSTANCE YOU WOULD KNOW NOT JUST WHETHER A WYETH PRODUCT FOR A PARTICULAR DISEASE STATE WAS PRESCRIBED, BUT YOU WOULD KNOW WHAT COMPETITOR PRODUCTS WERE PRESCRIBED WEEK TO WEEK?

A. YES.

Q. SO A SALES REPRESENTATIVE COULD LOOK AT THAT DATA AFTER MAKING A SALES CALL OR TWO AND SEE WHETHER THERE'S ANY CHANGE IN THE RATIO BETWEEN THE PRODUCT THAT YOUR SALES PERSON'S PROMOTING AND WHAT COMPETITORS ARE WRITING; CORRECT?

A. THEY COULD SEE WHAT THE PHYSICIAN HAS, HAS USED FOR THE PRODUCTS WITHIN THAT CATEGORY, YES.

\* \* \*

[610] Q. SO IN YOUR CONFLICT OF INTEREST POLICY YOU PROHIBIT WYETH EMPLOYEES, INCLUDING SALES REPRESENTATIVES, FROM ACCEPTING GIFTS?

A. THERE'S A, IT GOES ON TO SAY THAT IT DOESN'T UM, DOES NOT INCLUDE OCCASIONAL LOCAL ENTERTAINMENT OR GIFTS OF [611] NOMINAL VALUE.

Q. SO THERE'S, THERE'S SOME LIMITATIONS THERE AND SOME RESTRICTIONS THAT A WYETH EMPLOYEE CAN ACCEPT SOME NOMINAL VALUE GIFTS OR?

A. YES.

Q. BUT OTHERWISE THE CONCERN THAT WYETH HAS IS THAT ACCEPTING GIFTS COULD IMPROPERLY INFLUENCE AN EMPLOYEE?

A. THAT'S THE POLICY.

\* \* \*

[615] DIRECT EXAMINATION BY MR. HEMLEY:

Q. GOOD MORNING, MR. TIERNEY.

A. GOOD MORNING.

Q. MR. TIERNEY, NO REFLECTION ON BRATTLEBORO, YOUR HONOR, BUT MR. TIERNEY CHOSE TO GO HOME AND COME BACK RATHER THAN SPEND THE EVENING.

A. NO REFLECTION. I USED TO LIVE HERE SO, NOT BRATTLEBORO BUT –

THE COURT: I'LL GIVE HIS TESTIMONY WHATEVER WEIGHT IT DESERVES.

THE WITNESS: I USED TO LIVE HERE, YOUR HONOR.

MR. HEMLEY: BORN AND RAISED IN BROWNSVILLE, YOUR HONOR.

THE COURT: ALL RIGHT.

[616] Q. JUST STATE YOUR NAME ONCE AGAIN FOR THE RECORD, PLEASE?

A. SCOTT JAMES TIERNEY.

Q. AND WOULD YOU TELL US WHERE YOU WORK?

A. CVS CARE MARK.

Q. WHAT IS THE BUSINESS OF CVS CARE MARK?

A. CVS CARE MARK IS THE LARGEST PROVIDER OF PRESCRIPTIONS AND RELATED HEALTH SERVICES IN THE NATION.

Q. WHAT IS YOUR RESPONSIBILITY THERE AT THE PRESENT TIME?

A. I AM THE DIRECTOR OF MANAGE CARE OPERATIONS.

Q. AND BEFORE I ASK YOU TO TELL US WHAT DUTIES THAT ENTAILS, TELL US, IF YOU WOULD, HOW LONG HAVE YOU WORKED FOR CVS?

A. EIGHTEEN YEARS.

Q. WHAT ARE YOUR PRESENT DUTIES?

A. I OVERSEE THE RELATIONSHIPS WITH OUR DATA VENDERS. AND I OVERSEE THE COMMUNICATION OF DATA BETWEEN OUR PHARMACIES AND OUR PAYERS.

Q. TELL US A LITTLE BIT ABOUT THE RELATIONSHIPS THAT CVS HAS WITH DATA VENDERS INCLUDING A DESCRIPTION OF WHAT A DATA VENDER IS.

A. OUR DATA VENDERS INCLUDE IMS HEALTH, VARISPAN, WALTER SKLORE. THE DATA VENDERS, OF COURSE, WE USE THEM

FOR ANALYSIS AND AGGREGATION OF DATA,  
SOME CONSULTING SERVICES.

Q. AND DO YOU PROVIDE THOSE COMPANIES WITH INFORMATION, DATA INFORMATION YOURSELVES?

[617] A. YES, WE DO.

Q. WHAT SORT OF DATA DO YOU PROVIDE TO THEM?

A. WE PROVIDE VARIOUS ELEMENTS, YOU KNOW, IT WOULD – PRESCRIBER LEVEL DATA, DRUG LEVEL DATA, PLANE LEVEL DATA, DEIDENTIFIED PATIENT DATE.

\* \* \*

[618] Q. TELL US A BIT ABOUT WHAT KIND OF PROCESSING AND EDITING OF THE COLLECTED DATA OCCURS IN WOONSOCKET?

A. ONCE WE, ONCE WE, ONCE WE PULL OUR DATA FROM OUR STORES NIGHTLY IT GETS MERGED WITH OTHER RELEVANT DATA TO GET DISSEMINATED THROUGHOUT THE ORGANIZATION, FOR INVENTORY, FOR PHARMACY MERCHANDIZING, FINANCIAL SYSTEMS, WHAT HAVE YOU. ARE YOU ASKING RELATIVE TO WHAT IT DOES WITH OUR DATA VENDERS OR JUST IN GENERAL?

Q. WELL, I'M INTERESTED IN KNOWING BEFORE IT GOES OUT TO ORGANIZATIONS LIKE IMS, VARISPAN AND WALTER SKLURE,

WHETHER ANY EFFORT IS MADE TO EDIT THE DATA TO ENCRYPT IT, TO PROTECT INFORMATION SUCH AS THAT?

A. YES. WE DON'T DISSEMINATE OUR DATA TO ANYONE ELSE BUT [619] TO THE DATA VENDERS THAT I MENTIONED EARLIER. SO WE GO THROUGH A PROCESS WHEREBY WE DO, OF COURSE, EDIT THE DATA THAT IS SENT TO THEM. IT CERTAINLY DOESN'T REPRESENT OUR WHOLE BREADTH OF DATA AND WE ARE COMPELLED VIA HIPPA TO DEIDENTIFY PATIENT LEVEL DATA, WHICH WE DO. AND WE FOLLOW THOSE RULES.

Q. DO YOU TAKE OTHER STEPS TO PROTECT CONFIDENTIALITY, FOR EXAMPLE, WHEN DATA IS ORIGINATING FOR A PATIENT WHO LIVES IN A LOCATION WHICH HAS LESS THAN A CERTAIN NUMBER OF PEOPLE?

A. SURE. THERE ARE SPECIFIC HIPPA REGULATIONS THAT REQUIRE US TO ENSURE THAT IF THE ZIP CODE CONTAINS LESS THAN, I'M GOING BY MEMORY HERE, MAYBE 80,000, 50,000 PEOPLE, WE ARE REQUIRED TO ENCRYPT THAT. IF PATIENTS ARE OVER A CERTAIN AGE WE HAVE TO DEIDENTIFY THEIR DATE OF BIRTH. RX NUMBERS, ANYTHING RELATED TO THE SCRIPT, WE HAVE TO DEIDENTIFY AND, OF COURSE, THE PATIENT LEVEL INFORMATION WE DO AS WELL.

Q. ONCE THE INFORMATION HAS BEEN EDITED IN THE FASHION THAT YOU HAVE DESCRIBED IS IT THEN SENT TO THE THREE DATA VENDERS YOU'VE DESCRIBED IMS, VARISPAN AND WALTER SKLURE?

A. YES, IT IS. EACH VENDER HAS AN ENCRYPTION PROCESS THAT THEY'VE ASKED US TO EMPLOY. AND IT HAS GONE THROUGH RIGOROUS REVIEW BY OUR LEGAL DEPARTMENT TO ENSURE THAT THEIR HIPPA PRIVACY OFFICE AND EXPERTS HAVE SIGNED OFF ON THAT PROCESS.

\* \* \*

[620] Q. AND EXPLAIN TO THE COURT, IF YOU WOULD, THE REASONS WHY CVS DETERMINED TO SELL THE DATA THAT IT PROVIDES TO THE DATA VENDERS?

A. WELL, OF COURSE, WE GET FINANCIAL COMPENSATION FOR IT. AND WE GET BENEFIT FROM THE DATA IN TERMS OF LEVERAGING OR USING THE DATA TO IMPROVE OUR QUALITY OF CARE AND OUR COSTS TO DISPENSE. WE FEEL AS THOUGH IT PROVIDES A BETTER PRODUCT, GIVES US INCITE TO COMPETITOR INFORMATION, AGGREGATED COMPETITOR INFORMATION, MARKET SHARE INFORMATION.

Q. DOES CVS ALSO CONSIDER ITSELF TO BE PART OF A HEALTH CARE DYNAMIC OR HEALTH CARE PROVIDER?

A. DO WE CONSIDER OURSELVES TO BE PART OF THAT?

Q. YES.

A. ABSOLUTELY. WE'RE THE LARGEST PROVIDER OF PRESCRIPTIONS IN HEALTH CARE IN THE NATION, OF COURSE.

Q. AND TO BE CLEAR AMONG THE INFORMATION THAT YOU ARE [621] PROVIDING TO THE DATA PROVIDERS, TO THE DATA VENDERS RATHER, IS PRESCRIBER IDENTIFYING INFORMATION; CORRECT?

A. YES, THAT'S CORRECT.

Q. IF YOU AT CVS BELIEVED THAT THIS INFORMATION THAT YOU WERE PROVIDING TO THE DATA VENDERS RESULTED IN AN ADVERSE IMPACT IN EITHER COST OR HEALTH CONSEQUENCES TO THE PATIENTS AND TO THE PEOPLE WHO ARE BENEFITING FROM THE PRESCRIPTIONS WOULD CVS CONTINUE TO SELL THE DATA?

A. ABSOLUTELY NOT. OUR BUSINESS IS HEALTH CARE. AND PATIENT PRIVACY AND PRESCRIBER PRIVACY IS OF UTMOST CONCERN.

Q. ARE YOU AWARE IN YOUR POSSESSION OF ANY COMPLAINTS HAVING BEEN MADE TO CVS BY DOCTORS CONCERNING THE SALE

OF THE PRESCRIBER-IDENTIFYING INFORMATION?

A. NO, I HAVE NOT.

Q. ARE YOU, IN YOUR POSITION AT CVS, AWARE OF ANY COMPLAINTS HAVING BEEN MADE TO CVS BY DOCTORS CONCERNING ANY CLAIMED INVASION OF PRIVACY OR A VIOLATION OF THEIR PRIVACY INTERESTS?

A. NO, I AM NOT.

\* \* \*

[623] Q. SO LET ME JUST WALK THROUGH AGAIN THIS PROCESS OF THE PRESCRIPTION BEING FILLED AND THE INFORMATION BEING ENTERED. YOU SAID IT STARTS WITH THE PATIENT WALKING INTO A PHARMACY?

A. CORRECT.

Q. THAT HAPPENS IN VERMONT; RIGHT?

A. SURE.

Q. IT COULD HAPPEN MAYBE DOWN THE STREET FROM HERE?

A. ABSOLUTELY.

Q. THE TECHNICIAN IN VERMONT ENTERS INFORMATION INTO A COMPUTER IN VERMONT?

A. SURE.

Q. THE PRESCRIPTION GETS FILLED IN VERMONT?

A. YES.

Q. PRESCRIPTION GETS PICKED UP IN VERMONT?

[624] A. SURE. NOW WE COULD HAVE A CUSTOMER IN VERMONT THAT HAS MAIL ORDER TOO. AND THAT GETS FILLED AT ONE OF OUR MAIL ORDER FACILITIES.

Q. SO IT COULD BE MAILED TO THEIR HOME?

A. IT COULD BE MAILED TO THEIR HOME.

Q. VERMONT LAW REGULATES PRETTY MUCH EVERY STEP OF THAT PROCESS DOESN'T IT?

A. I DON'T KNOW IF I COULD ANSWER ALL THAT, BUT I ASSUME IT DOES.

Q. WELL, YOU'D AGREE, WOULDN'T YOU, THAT THE STATE'S REGULATIONS FOR PHARMACIES GOVERN, FOR EXAMPLE, THE MANNER IN WHICH A PRESCRIPTION MAY BE RECEIVED?

A. YEAH, THE PHARMACY, THE VERMONT PHARMACY, BOARD OF PHARMACY, YES, THAT'S TRUE.

Q. AND IT REGULATES THE INFORMATION THAT HAS TO BE IN THE PRESCRIPTION RECORD?

A. SURE.

Q. AND IT REQUIRES THAT INFORMATION BE MAINTAINED BY THE VERMONT PHARMACY FOR A PARTICULAR PERIOD OF TIME ABOUT ITS PRESCRIPTION RECORDS?

A. SURE.

Q. AND I BELIEVE YOU STATED IN YOUR DECLARATION IN THIS CASE THAT CVS COMPLIES WITH STATE AND FEDERAL LAWS THAT PROTECT CONFIDENTIALITY OF INFORMATION IN PRESCRIPTION DRUG RECORDS?

[625] A. WE ASPIRE TO DO THAT. YES, WE DO.

Q. AND THAT'S BECAUSE STATE LAW DOES IN FACT REGULATE THE CONFIDENTIALITY OF INFORMATION IN PRESCRIPTION DRUG RECORDS?

A. AS DOES FEDERAL LAW, YEAH.

\* \* \*

[626] Q. I'M NOT SURE THAT WAS MY QUESTION. MY QUESTION WAS WHETHER OR NOT YOU PROVIDE INFORMATION TO DOCTORS TO LET [627] THEM KNOW THAT THEIR INFORMATION IS SOLD TO DATA VENDERS?

A. I'M NOT AWARE TO DOCTORS, NO.

\* \* \*

Q. AS A PART OF THE HEALTH CARE DELIVERY SYSTEM DOES CVS BELIEVE THAT THE DELIVERY OF THIS INFORMATION, THIS DATA, IS OF BENEFIT TO THE PATIENTS THAT IT SERVES?

A. ABSOLUTELY. YOU KNOW, A DATA DRIVEN INFRASTRUCTURE IMPROVES QUALITY OF CARE, IT REDUCES HEALTH CARE COSTS, SURE.

Q. DOES CVS BELIEVE THAT TRANSPARENCY AS TO THE PRESCRIBING HABITS OF THE DOCTORS THAT THE DATA [628] COMMUNICATIONS TO, ULTIMATELY TO THE PHARMACEUTICAL INDUSTRY IS ALSO A BENEFIT TO THE PATIENTS?

A. YES.

\* \* \*

Q. SO THE BELIEF THAT IT'S OF BENEFIT TO THE PATIENT, BOTH IN TERMS OF THE NATURE OF THE DATA AND THE TRANSPARENCY THAT IT AFFORDS TO THE SYSTEM, IS ANOTHER REASON WHY CVS HAS CHOSEN TO MARKET THIS DATA?

A. OF COURSE, YES.

\* \* \*

[629] Q. SO YOUR TESTIMONY JUST NOW IS ABOUT TRANSPARENCY, BUT I BELIEVE YOUR TESTIMONY EARLIER WAS THAT CVS ONLY SELLS DATA TO THE THREE DATA VENDERS THAT ARE THE PLAINTIFFS IN THIS CASE?

A. I'M NOT SURE I UNDERSTAND THE QUESTION. TRANSPARENCY IN WHAT RESPECT?

Q. IF YOU COULD JUST RESPOND TO THE QUESTION. WAS IT NOT YOUR TESTIMONY EARLIER THAT CVS ONLY SELLS PRESCRIBER-IDENTIFIABLE DATA TO THE THREE DATA VENDERS THAT ARE PLAINTIFFS IN THIS CASE?

A. SURE.

\* \* \*

[635] Q. WOULD YOU PLEASE STATE YOUR NAME FOR THE RECORD?

A. IT'S MICHAEL ANDREW TURNER.

Q. AND WHERE ARE YOU EMPLOYED?

A. I WORK AT THE POLITICAL AND ECONOMIC RESEARCH COUNCIL, WHICH IS A NON-PROFIT NON-PARTISAN POLICY RESEARCH ORGANIZATION THAT FOCUSES PRIMARILY ON ISSUES PERTAINING TO INFORMATION POLICY IN THE MARKETS.

\* \* \*

[644] Q. YEAH. NOW, WHAT I'D LIKE TO, I'D LIKE TO BRING YOU INTO THIS CASE AND TO ASK YOU ABOUT WHETHER AS A POLITICAL ECONOMIST THERE ARE GENERALLY ACCEPTED METHODOLOGIES THAT ARE USED TO DETERMINE THE IMPACT OF A PROPOSED STATUTE WHICH WOULD LIMIT THE DISSEMINATION OF INFORMATION.

A. THERE ARE.

Q. AND WHAT, WHAT GENERALLY ACCEPTED METHODOLOGIES EXIST IN THAT FIELD?

A. WELL, THE GENERAL APPROACH WOULD BE THE WIDELY ACCEPTED BODY OF RULES THAT ARE APPLIED FOR TESTING THEORY AGAINST EVIDENCE. AND THOSE RULES COLLECTIVELY ARE KNOWN AS THE [645] SCIENTIFIC METHOD OR THE POSITIVIST APPROACH

\* \* \*

[652] Q. NOW, YOU HEARD ME TALKING ABOUT JOINT EXHIBITS 1, 2 AND [653] 3, THE LEGISLATIVE RECORD IN THIS CASE. HAVE YOU HAD AN OPPORTUNITY TO REVIEW THE DOCUMENTS THAT WERE BEFORE THE VERMONT LEGISLATURE IN THE COURSE OF ITS CONSIDERATION OF THIS LAW THAT WE'RE CHALLENGING HERE TODAY?

A. I HAVE, YES.

Q. AND IN REVIEWING THAT DID YOU DETERMINE WHETHER THE VERMONT LEGISLATURE APPLIED ANYTHING APPROACHING THE METHODOLOGY THAT YOU HAVE SUGGESTED WOULD BE APPROPRIATE TO APPLY TO DETERMINE A RELIABLE PREDICTION OF THE IMPACT THAT THE LAW THAT WE'RE CHALLENGING WOULD HAVE ON EITHER THE COST OR HEALTH CARE OR QUALITY OF HEALTH CARE IN VERMONT?

A. WELL, AS I SUGGESTED EARLIER, I THINK THE STATE OF VERMONT DID A FINE JOB IN COMING UP WITH A GENERAL THEORY. THEY CERTAINLY EXAMINED SOME LITERATURE. BUT IT WAS A BASIC BACKGROUND RESEARCH. IT WAS NEVER FORMULIZED.

I WOULD AGREE WITH THE GENTLEMAN FROM PHRMA THAT WHAT'S PROBABLY MOST NOTABLE IN THE RECORD IS NOT SO MUCH THAT WAS INCLUDED IT'S WHAT'S EXCLUDED. IT SEEMS THAT THEY, THERE WAS A CONCLUSION THAT WAS DRIVING THE WHOLE SEARCH FOR LITERATURE. THE LITERATURE THAT'S INCLUDED DOESN'T INCLUDE ANY EMPIRICAL ANALYSIS OF PRESCRIBER-IDENTIFIABLE DATA AND ITS RELATIONS TO HEALTH CARE COSTS OR HEALTH CARE OUTCOME, OR HEALTH OUTCOMES. IT IN FACT SOME OF THE STATE'S OWN, AT LEAST ONE OF THE STATE'S OWN WITNESSES SAYS AS MUCH.

IT DOESN'T INCLUDE EVEN REALLY RELIABLE PROXY [654] VARIABLES. SO IN TERMS OF WHETHER THERE WAS AN ATTEMPT TO APPLY THIS APPROACH, NO, NOT AT ALL.

Q. WERE THERE, YOU'VE DESCRIBED SOME OF WHAT, I THINK YOU'RE SAYING THE FAILINGS OF THE LEGISLATIVE RECORD IN TERMS OF APPLYING A METHODOLOGY SUCH AS THAT THAT YOU'VE SUGGESTED. ARE THERE OTHERS, AND I DON'T NEED YOU TO GET INTO ALL OF THE SPECIFICS OF IT, BUT ARE THERE SOME OTHER ASPECTS OF WHAT YOU WOULD RECOMMEND THAT THEY DO THAT THE LEGISLATURE DID NOT DO IN THIS INSTANCE?

A. WELL, IT'S CLEAR FROM MY REVIEW OF THE RESEARCH THAT WAS CONSIDERED THAT THE RESEARCH IS NOT BASED ON RANDOM SELECTION. THAT THE ASSERTIONS MADE IN SOME CASES ARE UNSUBSTANTIATED. THERE ARE CONTRADICTORY ASSERTIONS MADE. IN SOME CASES, YOU KNOW, AND TYPICALLY, FOR EXAMPLE, IN ACADEMIA IF I RELEASE A REPORT, A THEORY I CAN EXPECT THAT THERE MIGHT BE A RESPONSE, SOME CRITICISM IN ANOTHER JOURNAL. AND IF I'M A RESPONSIBLE SOCIAL SCIENCE RESEARCHER I WOULD TAKE THAT CONSTRUCTIVE CRITICISM TO HEART. AND THEN I MAY MAKE THE SUGGESTED ADJUSTMENTS TO MY THEORY AND

RERUN MY TESTS AND SHARE THOSE RESULTS.

AND THIS WAS ALLOWED FOR UP TO THE POINT WHERE THE ADJUSTMENTS WERE MADE AND THE SAME RESULTS ADHERED. AND THAT WAS JUST CONVENIENTLY IGNORED. SO THERE SEEMS TO BE A BIAS IN WHAT WAS PRESENTED, WHAT WAS EXAMINED AND WEIGHTS ATTACHED TO CERTAIN OUTCOMES.

[655] DRUGS THAT WERE EXAMINED WERE DRUGS THAT WERE KNOWN TO BE HARMFUL, YOU KNOW, VIOXX, SHOCKING THAT IT WAS FOUND TO BE HARMFUL. BUT NO DRUGS THAT HAVE SIGNIFICANT THERAPEUTIC BENEFITS WERE EVER EXAMINED IN TERMS OF THE IMPACT OF THE USE OF PRESCRIBER-IDENTIFIED DATA IN DETAILING.

SO THERE WAS A SELECTION BIAS IN THE CASES. THERE WERE SELECTION BIAS ACTUALLY IN THE SAMPLES. THERE WAS ONE SURVEY OF PHYSICIANS THAT WAS PRESENTED TO BROUGHT EVIDENCE OF THE IMPACT OF PRESCRIBER-IDENTIFIABLE DATA ON PRESCRIBER BEHAVIOR, WHICH I SUGGESTED WOULD BE A PROXY MEASURE. AND, IN FACT, THIS INCLUDED AN IMPRESSIVE 29 SURVEYS INCLUDED IN THEIR SURVEY OF SURVEYS. BUT THE REALITY IS OF THOSE 29 ONLY SIX ACTUALLY SPOKE TO PRESCRIBER BEHAVIOR. AND OF THOSE SIX, THREE CONCLUDED THAT THE

BEN, THERE WERE BENEFITS FROM PRESCRIBING THOSE DRUGS. ONE THAT TALKED ABOUT DRUGS OUT OF THE FORMULARIES, IN FACT, SUGGESTED THERE WAS SIGNIFICANT THERAPEUTIC ADVANCES.

OF THE REMAINING THREE ONE HAD A SAMPLE OF 22 WHICH IS STATISTICALLY INSIGNIFICANT. ONE WAS FROM THE NETHERLANDS IN 1982. AND THAT WAS, IN FACT, THE ONE THAT HAD NEGATIVE CONSEQUENCES. THE NONRATIONAL PRESCRIBING BEHAVIOR CAME FROM A STUDY OF PRESCRIPTIONS IN THE NETHERLANDS OF 1982. SO YOUR ABILITY TO GENERALIZE FROM A DIFFERENT PLACE IN A DIFFERENT ERA TO THE UNITED STATES OF [656] TODAY IS DUBIOUS AT BEST.

AND THEN, FINALLY, THE THIRD ONE HAD BASICALLY A AMBIGUOUS OUTCOME SO IN CASES WERE HARMS DEMONSTRATED, IN NO CASES WERE PRICE IMPACTS DEMONSTRATED AND IN NO CASES WERE HEALTH QUALITY OUTCOMES WAS DEMONSTRATED TO BE NEGATIVE.

SO IT REMAINS UNCLEAR TO ME, PARTICULARLY IN THIS CASE WHERE WHAT WAS REALLY THE FOCUS OF THAT ANALYSIS WAS GIFTS AND TRAVEL EXPENSES AND PERKS AND NOT AT ALL DETAILING HOW THOSE RESULTS COULD BE EXTENDED TO SOMETHING THAT WASN'T EVEN ANALYZED AND THE RESULTS OF

WHICH ACTUALLY, YOU KNOW, ARE COUNTER TO WHAT IS REPORTED. SO, YOU KNOW, I FOUND SIGNIFICANT MISINTERPRETATIONS AND MISLEADING CONCLUSIONS DRAWN ON THAT RESEARCH.

\* \* \*

Q. DOCTOR TURNER, IMS COMMISSIONED A STUDY TO ANALYZE WHAT THE IMPACT OF PRESCRIBER-IDENTIFIABLE DATA WOULD BE, THE ADVANCE ON PRESCRIBER-IDENTIFIABLE DATA WOULD BE ON THE [657] HEALTH CARE SYSTEM?

A. THAT'S PARTIALLY CORRECT, YES.

Q. AND, IN FACT, IMS PUT OUT AN RFP REQUESTING PEOPLE TO ADVISE THEM WHAT KIND OF METHODOLOGY THEY WOULD USE AND IF THEY WERE TO CONDUCT SUCH A STUDY?

A. THAT'S RIGHT.

Q. OKAY. AND PERK RESPONDED TO THAT RFP?

A. THAT'S CORRECT.

Q. AND INITIALLY IT WAS FOCUSING ON, THE QUESTIONS THAT WERE POSED WERE FOCUSING ON PRIVACY QUESTIONS; CORRECT?

A. WELL, AT THE TIME THAT THE RFP WAS ISSUED THE CONCERN WAS WITH LEGISLATIVE DEVELOPMENTS IN THE STATE OF NEW HAMPSHIRE.

Q. BUT AT SOME POINT IMS ADVISED YOU THAT THEY WANTED TO FOCUS MORE ON THE ECONOMIC OR THE POTENTIAL ECONOMIC CONSEQUENCES OF ANY RESTRICTIONS ON THE USE OF PRESCRIBER-IDENTIFIABLE DATA?

A. THAT'S CORRECT.

Q. AND YOU REVISED YOUR RFP, YOU RESPONDED TO THAT REVISED RFP?

A. THAT'S ALSO CORRECT.

Q. AND YOU PROPOSED A METHODOLOGY TO CONDUCT ORIGINAL QUANTITATIVE AND QUALITATIVE AND RESEARCH TO ADDRESS THE QUESTIONS THAT WERE BEING POSED TO YOU BY IMS?

A. THAT'S RIGHT.

[658] Q. AND YOU, IN ORDER TO BE ABLE TO DO SUCH A STUDY PERK WOULD NEED ACCESS TO PROPRIETARY DATA; CORRECT?

A. WITH THE METHODOLOGY WE OFFERED WE SUGGESTED WE WOULD LIKE CERTAIN PROPRIETARY DATA SETS. THAT'S RIGHT.

Q. RIGHT. YOU TOLD THEM YOU WANTED INFORMATION FROM IMS ITSELF ABOUT THE

COSTS OF DEVELOPING AND MAINTAINING THEIR DATABASES?

A. YES.

Q. AND YOU WANTED INFORMATION FROM THEM ON THE SHARE OF THE REVENUES FOR THEIR COMPANY THAT RESULT FROM PRESCRIBER-IDENTIFIABLE DATA?

A. THAT'S CORRECT.

Q. AND YOU WANTED A PORTFOLIO OF ALL OF THEIR CUSTOMERS?

A. YES.

Q. AND YOU ALSO WANTED THAT INFORMATION FROM OTHER COMPANIES WITHIN THE INDUSTRY NOT JUST ONE HEALTH INFORMATION ORGANIZATION?

A. YES. IT'S HELPFUL TO BENCHMARK, THAT'S RIGHT.

Q. AND YOU ALSO SAID THAT YOU WOULD NEED ACCESS TO INFORMATION FROM PHARMACEUTICAL COMPANIES?

A. THAT'S RIGHT.

Q. YOU WOULD WANT TO KNOW WHAT THEIR ANNUAL EXPENDITURES WERE ON PRESCRIBER-IDENTIFIABLE DATA?

A. AMONG OTHER THINGS, THAT'S RIGHT.

Q. YOU WANTED TO BE ABLE TO DO A DETAILED OVERVIEW OF HOW [659] THEY USED PRESCRIBER-IDENTIFIABLE DATA?

A. YES.

Q. SO YOU WOULD, YOU WOULD BE ABLE TO INTERVIEW THEM TO GET AN UNDERSTANDING OF THEIR PRACTICES TO PREVENT ABUSES OF THE USE OF PRESCRIBER-IDENTIFIABLE DATA?

A. THAT'S CORRECT.

Q. AND IN ADDITION TO WANTING TO DO INTERVIEWS YOU ALSO WANTED TO DO SOME SURVEY RESEARCH WITH PHARMACEUTICAL COMPANIES?

A. YES, THAT'S RIGHT.

Q. AND YOU ALSO WANTED TO DO SOME CASE STUDIES?

A. CORRECT.

Q. AND YOU PROPOSED TO DO ALL OF THIS IN ABOUT 13 WEEKS?

A. YUP, THAT'S RIGHT.

Q. AND IT ENDED UP, YOU ENDED UP ACTUALLY CONDUCTING SOME OR YOU ENDED UP PRODUCING A DOCUMENT IN RESPONSE TO THE RFP; CORRECT?

A. I DID, YES, INDEED.

Q. AND THAT TOOK MORE THAN 13 WEEKS THOUGH DIDN'T IT?

A. IT DID. AND IT'S WITH ALL THINGS THAT YOU CAN PROVIDE AN ESTIMATE AND THEN REALITY PROVIDES CONSTRAINTS.

Q. ABSOLUTELY. I CAN MORE THAN UNDERSTAND THAT.

AND YOU ALSO PROPOSED A BUDGET THAT WOULD BE NEEDED IN ORDER TO PERFORM THIS ANALYSIS?

A. CORRECT. THAT'S TYPICALLY PART OF OUR PROPOSAL.

[660] Q. AND I THINK ULTIMATELY YOU WERE PAID ABOUT A HUNDRED AND 50 THOUSAND DOLLARS?

A. UM, I THINK IT WAS AROUND A HUNDRED AND 40, BUT I COULD BE WRONG.

Q. A HUNDRED AND 40, A HUNDRED AND 50, IN THAT RANGE?

A. SURE.

\* \* \*

[669] Q. NOW, WHEN, WHEN IMS CAME TO YOU AND ASKED YOU TO DO THIS WORK DID YOU FIND THAT THERE HAD BEEN ANY STUDY UNDERTAKEN ON THE USE OF PRESCRIBER-IDENTIFIABLE DATA ANYWHERE ACROSS THE UNITED STATES?

A. ACROSS THE UNITED STATES, NO. AS I MENTIONED THE ONLY ONE, THE ONLY EMPIRICAL STUDY THAT HAD ACTUALLY LOOKED AT THE USE OF PRESCRIBER-IDENTIFIABLE DATA IN DETAILING AND ITS IMPACT ON HEALTH COSTS WAS THAT DONE BY PAUL GUDENDORPH IN SASKATCHEWAN WHICH I CONSIDERED TO BE A MORE RELEVANT CASE IN TERMS OF INSTITUTION SIMILARITY, CULTURAL SIMILARITY – TO MORE RELEVANT CASE IN TERMS OF INSTITUTION SIMILARITIES AND CULTURAL SIMILARITIES TO CONTEMPORARY UNITED STATES THAN I WOULD, FOR INSTANCE, A STUDY FROM THE NETHERLANDS IN 1982.

Q. AND SO, SO YOUR ORGANIZATION, PERK, WAS THE FIRST [670] ORGANIZATION IN THE UNITED STATES REALLY TO EVEN UNDERTAKE ANY SORT OF AN EVALUATION OF THE IMPACT OF THE USE OF PRESCRIBER-IDENTIFIABLE DATA ON THE COSTS OR QUALITY OF HEALTH CARE IN THE UNITED STATES; IS THAT CORRECT?

A. IN A SYSTEMATIC FASHION, THAT'S CORRECT.

\* \* \*

[672] Q. (BY MR. JULIN:) MISS DUFFY ASKED YOU ABOUT COMPELLING INFORMATION FROM PHARMACEUTICAL COMPANIES. AT THE TIME THAT YOU WERE RETAINED BY

IMS TO PREPARE THE STUDY DID YOU HAVE ANY ABILITY TO COMPEL PHARMACEUTICAL COMPANIES TO COOPERATE WITH YOU IN THE PERFORMANCE OF THE STUDY THAT IMS HAD ASKED YOU TO UNDERTAKE?

A. NO. I MEAN NO.

Q. AND THEN THE STATE IN THIS CASE OF COURSE ARE YOU AWARE THAT THEY HAVE, THE STATE HAS SUBPOENAED MANY DIFFERENT PHARMACEUTICAL COMPANIES TO COMPEL THEM TO TESTIFY IN THIS CASE?

A. I'M AWARE OF THAT, YES.

Q. NOW, IN TERMS OF THE TYPE OF INFORMATION THAT MIGHT BE USEFUL IN EVALUATING THE IMPACT OF A STATUTE LIKE THIS ON THE, ON THE COST AND QUALITY OF HEALTH CARE, WHAT TYPES OF INFORMATION WOULD AN ECONOMIST LIKE YOURSELF BE INTERESTED IN OBTAINING FROM PHARMACEUTICAL COMPANIES?

A. WELL, THIS GOES BACK TO THE METHODOLOGY THAT I DEVELOPED IN THE APPAREL INDUSTRY. THE FIRST QUESTION YOU HAD ASKED IS WHAT WOULD YOU DO IF YOU WEREN'T ABLE TO ACCESS THIS DATA. HOW WOULD YOU ADJUST YOUR MARKETING STRATEGIES AND HOW WOULD THAT IMPACT YOUR COST STRUCTURE.

Q. RIGHT. AND HAVE YOU HAD AN OPPORTUNITY TO REVIEW WHETHER THE STATE OBTAINED FROM THE PHARMACEUTICAL COMPANIES OR ASKED THE PHARMACEUTICAL COMPANIES ABOUT WHAT THEY WOULD [673] DO IN RESPONSE TO THE ENACTMENT OF A STATUTE LIKE THIS IF IT WERE UPHELD?

A. YES. I HAD AN OPPORTUNITY TO REVIEW THOSE MATERIALS.

Q. AND WHAT DID YOU FIND IN THAT REGARD?

A. THAT IN NOT A SINGLE INSTANCE WERE ANY OF THE QUESTIONS THAT I SUGGESTED ASKED EVER BY THE STATE.

Q. THAT THE STATE DID NOT ASK THE PHARMACEUTICAL COMPANIES WHAT THEIR REACTION WOULD BE TO THIS STATUTE IF IT WERE UPHELD, WHAT STEPS THAT THEY WOULD TAKE?

A. THAT'S CORRECT. THOSE QUESTIONS WERE ASKED ACTUALLY BY COUNSEL FOR THE PLAINTIFF.

Q. AND THE, AND DID YOU SEE WHAT THE RESPONSES WERE IN THAT?

A. I DID.

Q. AND WHAT WERE THE RESPONSES?

A. THEIR RESPONSES WERE CONSENSUS,  
CONSISTENT AND UNEQUIVOCAL THAT IF  
THERE WERE A DATA RESTRICTION THEY  
WOULD HAVE TO INCREASE DETAILING NOT  
DECREASE DETAILING AND THAT COSTS  
WOULD GO UP AND NOT GO DOWN

\* \* \*

[676] ATTORNEY JULIN: Our next wit-  
ness, your Honor, is a video deposition of Dr. Ken  
Ciongoli of Burlington, Vermont.

\* \* \*

[680] (Videotaped transcript of Dr. Ciongoli  
viewed.)

\* \* \*

---

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF VERMONT

-----  
 IMS HEALTH INCORPORATED; )  
 VERISPAN, LLC; and SOURCE )  
 HEALTHCARE ANALYTICS, INC., )  
 a Subsidiary of WOLTERS )  
 KLUWER HEALTH, INC. ) 1:07-cv-00188

v. )

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

-----  
 PHARMACEUTICAL RESEARCH )  
 AND MANUFACTURERS OF )  
 AMERICA )

v. )

WILLIAM H. SORRELL, in his )  
 official capacity as Attorney )  
 General of the State of Vermont; ) 1:07-cv-00220  
 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 )

-----  
 DEPOSITION OF  
 A. KENNETH CIONGOLI, M.D.  
 Taken on May 16, 2008, at 1:03 PM  
 At the Offices of Gravel & Shea  
 Burlington, Vermont

## Appearances:

ROBERT HEMLEY, ESQ., of the firm of Gravel & Shea, P.O. Box 369, Burlington, Vermont; on behalf of IMS, Verispan and Wolters Kluwer.

DAVID CASSETTY, ESQ., Assistant Attorney General, 109 State Street, Montpelier, Vermont.

LAURA VAN DRUFF, ESQ., of the firm of Arnold & Porter, 555 Twelfth Street, NW, Washington, DC 20004-1206; on behalf of PhRMA.

VIDEO OPERATOR: James O'Hanlon, Moonlight Video

REPORTER: Sherri L. Bessery, RMR, CRR

DEPOS UNLIMITED, INC.

P.O. Box 4595

Burlington, Vermont 05406-4595

(802) 658-1188

depos@together.net

\* \* \*

[7] Q. In the course of your work as a neurologist have you had occasion from time to time to meet with so-called detailers or pharmaceutical marketing representatives?

A. Yes, I have.

Q. How often do you routinely meet with them?

A. Four to six times, approximately, half a dozen times a week.

Q. Do you find these detailers to be informed about the products that they are selling?

A. Yes, I do.

Q. Do you understand when you meet with them that they are representatives of pharmaceutical companies trying to sell you products?

A. Absolutely.

Q. How does your understanding of their position affect your evaluation of the information that they provide you with?

A. Well I understand that, that they are presenting a best case scenario to me about what they're trying to get me to use. I understand completely and they know that I [8] understand it. And so they, therefore, will usually focus the message and make it a best case scenario, and also tell me about the adverse effects of, important adverse effects of their products, because they would prefer that I know about them in advance rather than discover them through the use in a patient.

Q. Do the detailers with whom you meet seem to be aware of the area of your practice –

A. Yes.

Q. – and specialization?

A. Yes, they know of exactly what kind of patients I see and what medicines I use.

Q. Do you find that their awareness in this regard allows them to focus on the areas in which you

are interested and not to deviate into areas in which you have no interest?

A. Yes. They know that access to me is limited, and that they have five, at the very most ten minutes, to present what they have to present and they don't waste time presenting extraneous things.

Q. In the course of your meetings with the detailers do they provide you with research about the products?

A. Yes, they do. They sometimes present published papers, evidence-based results provided to them by the company that they represent.

[9] Q. Do they provide you with information about what has been approved to be placed on their label by the FDA?

A. Yes.

Q. Do you find that they restrict themselves to the information that they have been permitted by law to disclose to you?

A. Yes. It's my understanding they're not permitted to discuss off-label uses. And even if I were to ask ask, they refuse to, and have in the past, refused to discuss off-label uses of their medications.

Q. As a physician, do you have other sources of information besides what the detailers tell you to assist you in the evaluation of the information that they provide?

A. Yes. I as well as almost all physicians learn about medicines from the literature, from conferences, from colleagues, grand rounds, and they represent just one more source of information.

Q. Do you find that the information you receive from the detailers is helpful to you in the practice of medicine?

A. Yes, it is helpful, particularly since they know my prescribing tendencies and practices, and so therefore they can focus whatever they might perceive as a deficiency on my part or something that I'm not doing [10] that they think other people are doing, so it's very helpful to me.

Q. Do you think that your decisions as to which medications to prescribe are informed to any extent by the information that the detailers provide?

A. Not really. I make up my mind based upon almost all of the other things that I've told you about, and then after I've used them for a short period of time, based upon experience.

Q. Do you think that if you were deprived of the information the detailers give to you, that would make your decisions better or worse?

MR. CASSETTY: Objection. Lack of foundation.

A. I believe that, as I've said, that they are one more source of information. But they're a very focused source, and I think it's very useful for me to hear the

bullets that they have about their medicine over and over again. It certainly doesn't hurt me to have that kind of repetition. And also to evaluate the claims that they make.

Q. Have you ever been influenced by information that you've been given by a detailer to make what you consider to be an inappropriate decision as to the medication you would prescribe?

A. Never.

[11] Q. Do detailers from time to time offer you tokens in the nature of pens and pads or a meal or something like that?

A. Yes. Detailers frequently bring pens and cups and occasionally lunch to the office.

Q. Does the delivery of these in any way influence your decision as to the prescriptions you would provide to a patient?

A. I mean of course not. I mean to think that a doctor would treat a patient with a specific medicine because someone gave him a pen or a cup or even lunch is just, is just not only improbable, it's unbelievable.

Q. Do you find that information relating to new drugs that have been introduced by a pharmaceutical company is of particular help to you?

A. Yeah, it is of particular help because, because the claims are focused early on. They tell, they tell us,

as I said before, the best case scenario of what they think their drug can do for us, and I find that useful.

Q. What's the thought process that you go through in deciding what medication to prescribe for a patient?

A. Well as an experienced physician, first thing I do is group the patient by disease type, and then perhaps by age, and then by gender. Because all those things matter in terms of which medicines you produce – you prescribe. [12] And, and at this point in my career I, I just think of the drug that would seem to fit those categories best and prescribe it.

Q. Has any sales representative ever influenced you to make an inappropriate prescribing decision?

A. No.

Q. Do detailers provide you with samples of drugs that they're selling?

A. They provide our office with samples, yes.

Q. Does the provision of those samples influence you to prescribe the drug for which the sample is given?

A. No. No. We use those samples for patients that cannot afford the drug that I'm prescribing, and it's very convenient for a lot of patients because the medicines can be very expensive.

Q. Okay. Do you ever give a patient a drug for which a sample is given independent of feeling that that's the appropriate drug for the particular patient?

A. No.

Q. Do detailers tell you information about generic drugs?

A. No.

Q. Where then do you get information as to available generics?

A. Well drugs become generic after they've lost their [13] patent, which takes five, eight, sometimes longer than that, years; sometimes longer than that. And so I've learned what I need to know about those drugs by using them during that period of time.

Q. In your practice have you found that generics are always appropriate substitutes for drugs that have still retained their patent?

A. I have found they are not always appropriate, and there are a couple of conditions, epilepsy being the most, the best example. And the reason is that, as I think you know, generics are bound by the 80-125 rule, which means that they have to have the same bioavailability within 80 percent to 125 percent as a brand name drug. But that difference is significant, particularly in patients with epilepsy. A small change like that can, can induce a seizure.

So therefore, the generics by law are permitted to have different fillers, different shapes, different

covers, and that changes the bioavailability, now within the range that we talked about, but that range is too big for epilepsy. So it has been said that if we could start an epileptic patient on a generic and keep them on that generic, then we could adjust the medicine so that it worked. But the problem is that the pharmacists frequently get different generics from different [14] companies that have different 80-125 characteristics, and so therefore you can't trust it, because a seizure can be deadly. Someone could have a car accident, bicycle accident, fall and break their necks or something, break another bone on the street.

So, so I and almost all neurologists that I know will write brand only for epileptic patients. And pain medicines are similar. There are many generics in the field of pain that patients will just tell you don't work the way the brands do. And when they do tell us that, then I write brand only.

\* \* \*

Q. I want to ask you some questions about the privacy interest that is at issue in this case. Do you expect that when you write a prescription, your prescription choice will be made available for review by government?

A. Yes, I do.

Q. How about by researchers?

A. Yes.

Q. And how about by insurance companies or other payers?

[15] A. Yes.

Q. Do you have any objection to this?

A. No.

Q. Why not?

A. Well I really have no claim to privacy with this information. I expect and receive letters from the insurance companies and from the state government, federal government, about Medicaid, Medicare, suggesting that I use a different drug, usually a generic that's less expensive. And so I know that, that they have a legitimate interest in what I'm prescribing, and therefore I expect them to have that information.

Q. How do you feel that the sharing of information to include sharing with pharmaceutical companies about your prescribing practices and the prescribing practices of other physicians improves the quality of medical care?

A. We have a saying in medicine, information is power. And the more you know, or anyone knows, the better decisions can be made. So if I learn, for example, through this process that I am an outlier, that for example in a certain kind of Parkinson's disease I am not prescribing one kind of drug the way my colleagues are, it's exceptionally beneficial for me to know that so I can try to understand why I have strayed, so

to speak, or vice versa. So it's very valuable for me to know, [16] have that information.

Q. Have you ever had the experience of being contacted by a pharmaceutical company which has knowledge that you have prescribed one of its products in order to inform you about some problem with the product or some concern with the product?

A. Yes. We get from time to time mailings from pharmaceutical companies telling us about a side effect that's come up after larger numbers of patients have been treated and to look for it, and of course that obviously very beneficial for us to know.

Q. Have you reviewed what is known as Act 80, the Act that is at issue in this case?

A. Yes, I have.

Q. Do you think that Act 80 is necessary to protect your privacy?

A. No, I do not think so, because I, as I've said, I do not have a privacy interest in this matter.

Q. Do you think that Act 80 in restricting the flow of information to manufacturers is helpful or harmful to the delivery of medical services to Vermonters?

A. I think it's harmful because it ruins one, one chain of, or branch of education, educational information that I get that I've explained how and why it's useful. And so restricting that serves no purpose as far as I can [17] see.

Q. Do you find that the government contacts have a different interest with respect to the drugs that you use than the manufacturers?

A. Yes. The manufacturers are part of the medical treatment team, which means we're trying to get the very best results for our patients. They have a, obviously have a monetary interest, but their other, their major interest for that monetary interest is that their drugs work and don't hurt people. And so they help me to do a better job with my patients.

The governments, on the other hand, have a purely, as I see it, economic interest; they solely are interested in, in having me prescribe the cheapest drugs for the, for the interests of the State budget, et cetera.

\* \* \*

Q. Yes, I'll try to. The question is whether you have a view as to whether the pharmaceutical companies having information about your prescribing practices helps [18] them identify the drugs with which to approach you?

A. There's no question. To just use a couple of examples, multiple sclerosis there are five drugs that are routinely used and they know which one I'm using, and if they want me to use a different one, they will tailor their message to try to convince me, and that's very useful.

And similarly with migraine, there are seven first line drugs, and it's useful for them to know what

I do, because if they want me to do something differently, they have to convince me or show me some data which, which would make me review it, my practice.

Q. Do you have an opinion as to whether your patients are better served the more information you are given?

A. The more information that I have from all of the sources that I have clearly benefit my patients in terms of end result.

Q. Do you have a view as to whether the detailers present any danger at all to you that you will misprescribe based on their message?

A. I, I cannot conceive of one. As I have said before at some point, the encounter between a physician and a detailer is not an encounter of peers. They know that and the physicians know that. We are far broadly, more broadly educated than they are. They are expert in [19] one drug in a phamacopia that is six inches thick, and we know that and we know they're trying to sell us. But they are experts, and therefore their information is useful. But it, it does not direct what I do. I mean the sum total of my experience and everything else I know is what directs. And unless their drugs work and are useful to me, I don't use them.

\* \* \*

[28] Q. Now you said that the information you receive from the sales representatives includes

published papers, evidence-based studies, and FDA approved labeling information?

A. Yes.

Q. A detailer can provide you with all of that information without regard to the use of prescriber-identifiable data, isn't that correct?

A. I'm sorry, what do you – you mean they could give me that information without telling me who writes for what or what I write for, is that what you're asking?

Q. I'm asking without, without them even knowing what you're writing.

A. Yes.

Q. Would you agree that the sales representatives are particularly helpful with regard to newly approved drugs?

A. Yes.

Q. Okay. And would you agree that once you have established a track record with your patients with certain medications, there's little a detailer could tell you that would overcome your personal experience with that medication?

[29] A. Yes. With one exception, that if I were the only one of my peers using it, that would be very useful for me to know, then I'd have to find out why.

\* \* \*

[31] Q. You offered the opinion that you do not have a right to privacy in your prescription history?

A. I do not expect it, nor do I think it helps me or my patients in any way to have that, my information private.

Q. And that opinion is based on the fact that insurers and other entities that pay for prescriptions, such as state governments and federal governments, have access to that information?

A. Yes.

Q. You agree that patients have a right of privacy in their medical information?

A. Yes.

Q. And you understand that insurers and other payors, including state government and federal government, have access to the patient's information?

A. Well they have a legitimate access to it because they're paying the bills, so they have the legitimate right to know what's being prescribed so that they can then input in that and try to, have an economic interest in trying to get us to do, to prescribe something less expensive.

\* \* \*

[32] Q. The question was simply the fact that insurance companies, state government and federal government obtain [33] patients' medical information

does not eliminate the patients' right to confidentiality?

A. No.

Q. Do you agree or disagree?

A. It does not.

\* \* \*

Q. And your opinion is that sales representatives for pharmaceutical companies are, should be allowed to tailor their message to physicians and other prescribers by using prescriber-identifiable data?

A. Yes.

Q. And that helps the representatives to try to convince prescribers to prescribe the products that the sales representative is promoting?

A. The ultimate benefit is to me, and to my patient ultimately. The more that I know, they know about me, the more information that I will have, which will help me make a better decision about my patient. So I cannot see any interest in, in my claiming a personal privacy for that information. It's, it serves nothing as far as I can see. Serves no purpose except to limit the amount of information I will ultimately get.

\* \* \*

[35] Q. How does the access to prescriber-identifiable data, how does the limitation on the access of prescriber-identifiable data prevent the sales

representative from presenting you with published papers, evidence-based studies, or FDA approved information?

A. It does not. But it does prevent them from tailoring a message. They won't know as much about me and so they will approach me as a generic neurologist and, and present to me more general information that really doesn't necessarily apply to me. By them knowing what my practice parameters are, they can focus their message and save us both time and give me more valuable information. So it does not hurt me in any way, nor does it violate my privacy in my opinion for them to know my practice patterns. I think it helps me.

Now if I were prescribing illegal drugs of course I mean I, I would feel differently about that. But since I'm not, I don't – I mean people who prescribe pain medicines there's a problem with the overuse, I could see where they would be against something like this. But for the overwhelming majority of us, I see nothing but, but a gain for them to know how I practice medicine.

\* \* \*

[36] Q. In the course of questioning by Mr. Cassetty you made reference to a study by a Dr. Avorn which you [37] mentioned was 25 years old or so.

A. Yes.

Q. I simply want to ask you whether in your experience the detailers have changed their approach as comparing now to 25 years ago? And if so, in what way?

A. It's a very, very different experience. 25 years ago it was largely local and social and people who sold anticold medicines would come in to say hello. I don't know what their advantage was to do that, but it was, it was more of a social thing than, than the kind of focused information now.

What's changed is that, is the type of detailer. I think they're all college graduates; I'm not sure that's a prerequisite, but it seems to be. They're all relatively young people. And I'm just reviewing some of the faces in my mind. I mean I – all intelligent and, and they seem to know exactly what I need and want and they just provide it to me within five minutes or ten at most, and that's not the way it existed before.

So when Dr. Avorn was commenting, he was commenting on a totally different universe. And even in his study, at least it's reported in the material that I reviewed, he did have some positive things to say about detailing, although he had some negatives ones to say as well. Even then 25 years ago he thought that there was some [38] advantage to detailing.

\* \* \*

---

[676] July 30, 2008

AFTERNOON SESSION

\* \* \*

[680] Q. Good afternoon, Doctor. I would just like to start by introducing you to the Court. Would you give us your name, again?

A. My name is Ashley Wazana.

Q. And are you a medical doctor?

A. Yes.

Q. What is your specialty?

A. I am a psychiatrist.

\* \* \*

[692] Q. Let's switch topics, then, and talk a bit about your research expertise. Have you done work over the course of your professional career researching the relationship between doctors and the pharmaceutical industry?

A. Yes, I have.

Q. When did you begin researching this area?

A. It would be in around nineteen-eighty – sorry – 1998, 1997. And that was when I was practicing doing my residency training in Montreal at McGill University and had come from McMaster University in which that environment was quite, being quite critical look – had made the quite critical look at [693] the impact of the association between

physicians and pharmaceutical industry, and trained us quite rigorously about the evidence to that matter and given us certain attitudes, offered certain approaches about how to proceed in our training, and came to an environment in McGill where the approaches were quite divided. And some physicians did and some physicians didn't feel there was a concern about this particular interaction.

So I was actually, it was suggested to me by my supervisor of my in-patient rotation to actually look up the literature. And so I proceeded to do a systematic review of the literature for this academic presentation, and which the chairman of the department said was of rigorous enough value that he thought I should submit it for publication. And that's how my interests began, or, I believe, at least my formal research interest began.

\* \* \*

[696] Q. Were the results of your research published in a peer review journal?

A. Yes, they were published in the "Journal of the American Medical Association," which I specifically chose, not just because it was peer reviewed, but it was also a journal that was being accessed not only by physicians, but by policymakers. And I was very fortunate to [697] have it published because it gave us enormous coverage at the level of policy that was really the key issue that I was trying to address.

\* \* \*

[701] Q. And maybe you could spell out what kind – first, what was the general conclusion about the impact on doctors' conduct?

A. That it had an impact on the conduct of physicians, on the behavior of physicians.

Q. And is that impact positive or negative?

[702] A. And that would be negative, except for as I have stated in that paper, there's one, with the exception of one particular outcome. Which was in a particular study with a pharmaceutical representative and the physician presenter gave rounds on the treatment for a particular illness, Lyme disease. Residents who attended the rounds and residents who didn't attend the rounds were asked afterwards whether and what they would do to treat a specific presentation of that illness, sort of less complicated ones and more complicated ones. And an interesting thing is that, certainly for the complicated presentation of Lyme disease, the residents who had attended those rounds were more likely to actually prescribe the appropriate treatment for the refractory sort of complicated presentation more than those who hadn't attended. However, when it came to sort of bread-and-butter uncomplicated presentations of Lyme disease, they had the same sort of reflex to prescribed IV administrated sort of complicated antibiotic regimen, when a simpler regimen would have [703] been as appropriate. So, actually, none of the residents who attended the talk were able to give the appropriate treatment for that noncomplicated presentation.

So, for the exception of that particular talk, that particular study, all the other ones look at things like decreased prescribing of generic medication, non-rational prescribing choices, addition of medication to hospital formulary of equal or lesser efficacy, and as well as rapid prescribing of medication, rapid and early prescribing.

Q. So the examples you have just given of examples of –

A. These are considered negative outcomes.

Q. When you use the term “negative outcome” or negative influence, are you using your own definition or is that a definition supplied by the literature?

A. No. Those are the ones that the literature considers. Nonrational prescribing of an alternative is, I have medication of the brand medication instead of a generic, when a less-expensive alternative is available. Additions of medication, hospital formulary, even if [704] it's a medication with no increased benefit. These are now considered to be positive outcomes. And these are – really, in essence, one has to appreciate the, a systematic overview is not there to overlay a judgment on the literature as much as a synthesis of the literature.

So, this is a collation of the, of the outcomes that had been identified from all these individual studies all summarized into one paper.

\* \* \*

[722] Q. And then what, Doctor, is your opinion on whether doctors are in fact influenced by interactions with the pharmaceutical industry?

A. Consistent with the conclusions from my systematic overview, I think there's evidence to show that it has an influence, not only on the attitudes of the physicians, on the knowledge of the physicians as well as on their practice.

Q. And would you describe that as a positive or a negative influence?

[723] A. I would say a concerning influence. So, negative and concerning influence. And that's the tone of the paper that was, I think, at issue here in terms of the systematic review.

\* \* \*

[755] Q. (By Atty. McAndrew) You cannot offer any testimony, can you, on how the use of the prohibition on the use of prescriber-identifiable data might impact medical outcomes; can you?

A. Not directly.

Q. And you can't offer any testimony on how a [756] prohibition on the use of prescriber-identifiable data might impact health care costs in the state of Vermont?

A. Not directly.

Q. So it's fair to conclude that you cannot offer this Court any information about the possible effects

of Act 80 or about prescriber-identifiable data; is that correct?

ATTORNEY ASAY: Objection, your Honor. I think it's a question for the Court to decide whether the witness's testimony supports or does not support data.

THE COURT: Objection is overruled.

ATTORNEY MCANDREW: Okay. I would like to have –

THE COURT: I don't know if you want him to answer the question?

Q. (By Atty. McAndrew) I'm sorry. What was the answer to that question?

A. Can you repeat the question, please?

Q. Is it fair to conclude that you cannot offer this Court any information about the possible effects of Act 80 or about prescriber-identifiable data?

A. The possible effects, I can certainly; not the [757] certain effects.

Q. But you don't know what Act 80 is; do you?

A. No. Okay.

Q. And you don't have any information about prescriber-identifiable data?

A. No.

\* \* \*

[763] Q. And then, lastly, Ms. McAndrew also asked if you had any information that was relevant to Act 80, so one thinks what the Plaintiffs have offered in this case is testimony from a couple of doctors who have said that Act 80 is not likely to succeed because doctors are not influenced by marketing. And, based on your research and expertise, is it your view that doctor are influenced by marketing?

A. I think the evidence is clear that doctors are influenced by marketing above and beyond their [764] awareness and their belief that that occurs.

\* \* \*

[768] Q. Dr. Wazana, I am Tom Julin. I represent IMS Health and all the other health information companies or publishers.

You mentioned that a study could be designed by roping off a certain geographic area and then studying – and then isolating the prescribers within that area from sales representatives who are using prescriber-identifiable information; is that correct?

A. Actually, the design was the other way around. Is that you would make sure that you would have the terrain where there would be no prescriber-identifiable data, and then you [769] would actually circumscribe an area where it would be available.

Q. All right.

A. It's the subtlety that's important.

Q. What's the subtlety that's important?

A. The subtlety is, it's harder if you have a small population that is not supposed to be exposed, to be protected from what is – and contaminated from what is considered the exposure than the other way around, which is having a whole population that is unexposed and then having a small circumscribed population which is exposed. I mean, these are basics of epidemiological designs about exposures.

Q. So you would want to compare similar geographical areas, is that what you are talking about?

A. Yes. Populations that would have – in essence, randomly assigned. You wouldn't necessarily look for controlled or populations with similar factors; you actually do that after the fact. At first you just randomly assign exposure or not exposure to parts of a region which is considered homogeneous. Then, [770] in a secondary analysis, you actually try to see whether your randomization worked by examining the reviews of physicians, the population and such.

Q. And I then I think you also mentioned you would want a wash-out period; what did you mean by that?

A. A wash-out period just means that you want to make sure that whatever it is you are observing as an in fact of your particular exposure or lack of exposure is not because of what was prior to happening. Which means that in the context of if you are talking about the influence of prescriber-identifiable data on the patterns of detailing by the pharmaceutical representatives and on the patterns of prescribing

by physicians, you would have to let elapse a period of time significantly long enough that physicians wouldn't be considering using new information, new medication, without that, with information from pharmaceutical representatives that was not assisted by prescriber-identifiable data.

So you would have, probably, if you are talking about the cycle of medication, an [771] introduction to the market. You could look at maybe five years of a period where you would be washing out that effect. Then you could look down the line with particular medications that are being introduced in the market, what would be the particular prescribing patterns, the costs for particular conditions, the distribution by physicians and by exposure and, you know, then establish that.

\* \* \*

RANDOLPH FRANKEL, Sworn

DIRECT EXAMINATION BY ATTORNEY  
JULIN

Q. Mr. Frankel, would you have a drink first?

A. I will pour first and ask later.

THE COURT: It's only water.

(Laughter.)

A. I won't express my disappointment. Thank you.

[772] Q. Would you, then, state your name for the record, please?

A. Randolph Frankel.

Q. Where, sir, are you employed?

A. I am employed by IMS Health.

Q. And what is your position with IMS Health?

A. I'm a Vice President of External Affairs.

\* \* \*

[791] Q. How, then, would you be able to do that? You have doctors that are prescribing presumably whatever they feel to be the appropriate drugs for the patients that they are seeing; how would a pharmacy benefits manager for a large employer for a large insurer go about managing what doctors are prescribing, particularly if you didn't agree with the decision the doctors were making?

A. Well, we saw an opportunity to the data. There were a number of large therapeutic categories that had multiple drugs in that category. And, while they are all different, they also have a lot of similarities.

We also recognize the fact that, and I would have to say in this case that I was the one who came up with this and managed the function, that doctors aren't aware of the cost of the drugs. So, we created the situation where with the help of the Medical Advisory Board, cardinal rule number one in managed

care, I hope – I hope because I’m subject to it – you don’t want to hurt anybody; you want to be able to deal with things in a way that can optimize the use of [792] drugs and even inform physicians so that patient care improves, or where you reduce costs, but you don’t want to do it at the expense of harming someone.

So, what we would do is we had pharmacists who would call patients and the essence of the message was: Doctor, we know you prescribed drug A, but if you had known that drug B was 25 percent less expensive than drug A, would you still have done it?

Q. I think you said pharmacists who called patients?

A. I’m sorry. Doctors; they called doctors.

And then, because of the Medical Advisory Board, we would try to remind doctors, we’d say: Oh, by the way, we recognize you never want to do this if your patient is taking other drugs it might interact with or if they are over a certain age where it’s contraindicated, or any of these other areas where it might hurt someone. But all else being equal, if those things exist, would you still have prescribed the more expensive drug?

And we found that doctors were very [793] cooperative and would authorize the pharmacist on the phone to change the prescriptions. We would then send a letter to the patient: Your doctor authorized this because it will save some money, and you, too,

will save some money on your co-pays. But, if you have had a problem with it, here's a an 800 number you can call. And, if they did have a problem, we would reverse the whole thing.

Q. So, is it correct that you would use prescriber-identifiable data in essence to respect the viewpoint of new clients who were representing directly to the doctors –

A. Yes, yes.

Q. – to the doctors to attempt to influence them to maybe look at what you regarded as better decisions, perhaps, not what the – the pharmacy benefits manager thought to be the best decisions for the doctor's patients; is that correct?

A. There's no way to change behavior if you don't know who you are talking about. So provider level data was a part of every program we used, and this was just a few of many drug review utilizations.

[794] We would look historically for patterns of abuse, and we would look at what we thought would be overuse, and we would send letters with data and literature to the doctors we thought were overusing it without the name of the doctor. There was no way to create that intervention. We used Medical Advisory Boards to make sure it was truthful, it was accurate, it was well-substantiated. And, in the end, it was the doctor's choice.

\* \* \*

[798] Q. Yes. I was going to ask you whether states, in managing their Medicare and Medicaid programs, they provide coverage for pharmaceutical products for those individuals who have Medicaid and Medicare claims, do they use this type of methodology of managing their pharmaceutical product costs that you have just described for us?

A. Yes. In fact, I must confess, and I'm pleased to say it, and the state of Vermont is really a pioneer in many of these areas and has used [799] a lot of elements, some of which I did help pioneer, many of which are relatively new but, yes, most states use a PBM mechanism as part of management.

Q. Now, if a state like the state of Vermont has a Medicaid/Medicare program and it perceives that doctors are making bad decisions, let's say, because of the influence of the pharmaceutical manufacturers, is there a way that it can use its pharmacy benefits manager or its formulary to try to improve the prescribing practices of the doctors?

A. Yes. Absolutely. That's part of the function.

\* \* \*

---

UNITED STATES DISTRICT COURT  
DISTRICT OF VERMONT

---

IMS HEALTH, INC., ET AL )  
VS )  
WILLIAM SORRELL, ET AL )

CASE NO: 1:07-CV-188  
COURT TRIAL  
DAY 4 – VOLUME 1

---

BEFORE: HONORABLE J. GARVAN MURTHA  
U.S. DISTRICT COURT JUDGE

APPEARANCES:

MARK A. ASH, ESQUIRE  
SMITH, ANDERSON, BLOUNT,  
DORSETT, MITCHELL & JERNIGAN, LLP  
P.O. BOX 2611  
RALEIGH, NORTH CAROLINA 27601  
REPRESENTING IMS

ROBERT B. HEMLEY, ESQUIRE  
GRAVEL & SHEA  
76 ST. PAUL STREET, 7TH FLOOR  
BURLINGTON, VERMONT 05402  
REPRESENTING IMS

THOMAS R. JULIN, ESQUIRE  
HUNTON & WILLIAMS, LLP  
1111 BRICKELL AVENUE, SUITE 2500  
MIAMI, FLORIDA 33131  
REPRESENTING IMS

(APPEARANCES CONTINUED ON NEXT PAGE)

\* \* \*

[828] YOU'VE ALSO SAID THAT PRESCRIBER-IDENTIFIABLE DATA CAN BE USED TO IDENTIFY EARLY ADOPTERS OF PRESCRIPTION DRUGS?

A. YES

\* \* \*

Q. EXCUSE ME. BY IDENTIFYING EARLY ADOPTERS PHARMACEUTICAL COMPANIES CAN ACCELERATE THE ADOPTION OF A NEW DRUG?

A. YES THEY CAN.

Q. AND THAT HELPS A PHARMACEUTICAL MANUFACTURER SELL MORE [829] OF ITS PRODUCTS?

A. OVERTIME IT ALSO MEETS THE DEMANDS OF PHYSICIANS FOR INFORMATION WHO ARE INCLINED TO PRESCRIBE THESE DRUGS EARLY ON. THIS IS A, AGAIN, THIS IS ANOTHER ISSUE OF, AND IT GOES BACK SOME TIME AGO, EARLY ADOPTION IS SOMETHING THAT CAME OUT OF A NATURALLY OCCURRING SITUATION.

Q. AND YOU -

A. I'M NOT FINISHED, PLEASE. THE THE THERE HAVE BEEN DRUGS THAT HAVE BEEN LAUNCHED WHERE DOCTORS HAVE BEEN VERY UPSET WITH THE PHARMACEUTICAL INDUSTRY FOR NOT HAVING PROVIDED THE

INFORMATION QUICKLY. AND AS A RESULT THE PHARMACEUTICAL COMPANIES IDENTIFIED WHO THESE PEOPLE WERE TO BE SURE THAT BEFORE THEY LAUNCH A PRODUCT THESE EARLY ADOPTERS WOULD HAVE ALL THE INFORMATION SO THEY WOULDN'T BE EMBARRASSED BY PATIENTS WHO WALK IN AND SAY I WANT SOMETHING OR I HEARD ABOUT SOMETHING AND THE DOCTOR WOULD NOT KNOW ABOUT IT.

\* \* \*

[830] Q. NOW, IN YOUR EXPERIENCE DETAILING DOES AFFECT WHAT DRUGS ARE PRESCRIBED BY PHYSICIANS AND NURSES?

A. YES.

Q. AND THE USE OF PRESCRIBER-IDENTIFIABLE DATA INCREASES THE NUMBER OF PRESCRIPTIONS WRITTEN BY PRESCRIBERS FOR PARTICULAR DRUGS BEING MARKETED?

A. WELL, IT FACILITATES THE FLOW OF INFORMATION AND THAT INCREASES FAMILIARITY. AND, THEREFORE, A DOCTOR IS MUCH MORE LIKELY TO PRESCRIBE SOMETHING THEY UNDERSTAND AND ARE COMFORTABLE WITH THAN SOMETHING THEY DON'T UNDERSTAND.

Q. AND THAT INCREASES THE NUMBERS OF PRESCRIPTIONS?

A. YES.

\* \* \*

[832] Q. AND YOU DID THAT BECAUSE THERE WAS NO ONE HOLY GRAIL OR SILVER BULLET THAT'S GOING TO, YOU KNOW, CONTAIN HEALTH CARE COSTS FOREVER, RIGHT?

A. THERE IS NOTHING IN MY ESTIMATION THAT WILL EVER CONTAIN HEALTHCARE COSTS. ALL YOU CAN DO IS MANAGE IT AND RATIONALIZE IT SO YOU GET THE GREATEST VALUE OUT OF IT. HEALTH CARE COSTS WILL GO UP NO MATTER WHAT WE DO.

\* \* \*

[834] Q. NOW, IMS HAS PHARMACIES ENCRYPT THE INFORMATION ABOUT PATIENTS AT THE PHARMACY BEFORE IT'S SENT TO IMS; CORRECT?

A. THAT'S CORRECT.

Q. AND THEN IMS ASSIGNS A NUMBER TO THE PATIENT SO THAT YOU CAN FOLLOW INFORMATION ABOUT THE PATIENT WITHOUT ACTUALLY KNOWING THE PATIENT'S IDENTITY; IS THAT CORRECT?

A. THAT IS THE END RESULT OF SEVERAL ENCRYPTION METHODOLOGIES. AND THERE ARE SEVERAL INTERMEDIARIES THAT ARE INVOLVED THAT BREAK THIS APART SO THAT PATIENT PRIVACY IS COMPLETELY PROTECTED.

[835] Q. AND A PATIENT IS ASSIGNED A NUMBER SO THAT YOU CAN KNOW INFORMATION ABOUT THE PATIENT WITHOUT KNOWING THEIR NAME?

A. THAT'S CORRECT.

Q. AND IMS COULD ASK PHARMACIES TO ENCRYPT THE NAME OF PHYSICIANS WHO, WHO OPT OUT OF THE, THE PROGRAM? IF THEY SAY I DON'T WANT TO SELL MY DATA, AND THEY SAY I'M OPTING OUT, IMS COULD ASK PHARMACIES TO PROVIDE THAT INFORMATION BUT IN AN ENCRYPTED FORMAT?

A. WE CAN ONLY ASK BECAUSE IT'S THE PHARMACY THAT MAKES THE DECISION. THEY'VE TOLD US UNDER THE CONDITIONS OF THIS LAW THEY PROBABLY WOULDN'T TAKE THAT CHANCE AND JUST WOULDN'T SELL IT TO US.

\* \* \*

[840] Q. BUT WITHIN THE SAME THERAPEUTIC CLASS IN MOST CASES GENERIC DRUGS HAVE THE SAME THERAPEUTIC VALUE FOR PATIENTS. THAT'S WHAT YOU SAID IN YOUR DEPOSITION?

A. MOST, YES. I WOULD SAY IN MOST CASES.

\* \* \*

Q. THERE'S NOTHING IN ACT 80 THAT PREVENTS A PRESCRIBER FROM PRESCRIBING

A PATENT PROTECTED DRUG IF THAT'S THE BEST TREATMENT FOR A PATIENT?

A. NO. THIS, THIS ACT 80 IS MEANT, IS SIMPLY MEANT TO SLOW THE DISSEMINATION OF INFORMATION ABOUT NEWER DRUGS.

\* \* \*

[844] Q. AND YOU KNOW THAT VERMONT HAS ALREADY MADE SIGNIFICANT EFFORTS TO REDUCE HEALTH CARE COSTS DON'T YOU?

A. I THINK IT'S PROBABLY ONE OF IF NOT THE LEADING STATE IN THE NATION.

Q. WE'VE DONE QUITE A FEW THINGS. WE'VE DONE GIFT DISCLOSURE, RIGHT?

A. YES, 25 DOLLARS AND UP.

Q. RIGHT. WE HAVE A PREFERRED DRUG LIST?

A. YOU DO, BUT I DON'T KNOW HOW WELL IT WORKS. I MEAN I CAN'T SPEAK TO THAT.

Q. RIGHT. BUT WE DO HAVE ONE?

A. YES, YOU DO.

Q. AND WE MAY THINK IT'S PRETTY GOOD?

A. I AM NOT ARGUING WITH YOU.

Q. OKAY. AND WE ALSO HAVE A MANDATORY GENERIC SUBSTITUTION LAW?

A. YES, YOU DO. ALTHOUGH, AS A STATE, YOUR SUBSTITUTION RATE IS WORSE THAN SOME OF YOUR NEIGHBORING STATES.

Q. INDICATING THAT THERE IS ROOM FOR CONTINUED USE OF GENERIC DRUGS?

A. MAYBE CONTINUING MEDICAL EDUCATION.

Q. RIGHT. OR MAYBE ACT 80.

ACADEMIC DETAILING IS SOMETHING THAT VERMONT IS [845] DOING?

A. NO. YOU STARTED.

Q. RIGHT?

A. YOU HAVE NOT REALLY HAD A CHANCE TO SEE HOW IT WORKS.

Q. AND ACADEMIC DETAILING IS PRETTY EXPENSIVE ISN'T IT?

A. IT IS EXPENSIVE AND IT IS A DIFFICULT PROCESS TO MANAGE.

\* \* \*

Q. BUT IN DOING ACADEMIC DETAILING YOU'RE LOOKING AT BEST EVIDENCE, IN OTHER WORDS, HOPEFULLY CONTROLLED STUDIES, HEAD TO HEAD STUDIES YOU DON'T HAVE AS MUCH OF THAT WHEN A DRUG IS FIRST APPROVED DO YOU?

A. WELL, YOU'VE GOT TWO QUESTIONS IMBEDDED IN THAT QUESTION. NUMBER ONE IS DO YOU, DOES ACADEMIC DETAILING NECESSARILY MEAN THAT YOU HAVE TO – YOU CAN ONLY MAKE A RECOMMENDATION BASED ON A LOT OF HISTORY. YOU COULD USE ACADEMIC DETAILING TO SUGGEST TO DOCTORS THAT IF A NEW DRUG, A METHODOLOGY FOR DEALING WITH NEW DRUGS. THERE ISN'T A CLEAR BENEFIT, PERHAPS IT MIGHT BE USEFUL TO WAIT. YOU [846] MIGHT USE IT TO CHANGE BEHAVIOR AS OPPOSED TO PRESENT DATA. AND IT WOULD HAVE AN IMPACT ON THE UTILIZATION OF NEW DRUGS.

YOU IN THE STATE HAVE SAID DOCTORS SEEM TO JUMP TOO QUICKLY ON NEW DRUGS. WELL, THAT'S TRAINING AND MEDICAL EDUCATION.

Q. WELL, DON'T WE WANT TO WAIT WITH ACADEMIC DETAILING TO SEE WHAT THE EVIDENCE SHOWS BEFORE WE MAKE CERTAIN RECOMMENDATIONS ABOUT WHAT THE TREATMENT SHOULD BE?

A. THAT COULD BE A PART OF IT. BUT ACADEMIC DETAILING IS A CONDUIT FOR INFORMATION TO DOCTORS FROM A SOURCE THEY TRUST. NOT UNLIKE THE PHARMACEUTICAL INDUSTRY, BECAUSE MOST DOCTORS DO TRUST THAT, FOR GOOD REASON. SO YOU CAN GO IN AND DO ANYTHING YOU WANT WITH

THAT, THAT COMMUNICATIONS CHANNEL. SOME OF IT WOULD BE TO SHOW DATA. THAT WOULD BE MOST USEFUL, AND SOME OF IT MIGHT BE TO EDUCATE ON DIAGNOSIS. SOME OF IT COULD BE TO EDUCATE ON PRACTICES REGARDING NEW DRUGS.

Q. SURE, LIFE-STYLE CHANGES OR ALL KINDS OF THINGS. BUT IN TERMS OF BEING ABLE TO SPEAK ABOUT NEW DRUGS YOU WANT EVIDENCE BEFORE YOU START SAYING THIS IS GOOD OR THIS IS BAD AND IN ORDER TO GET THAT EVIDENCE YOU NEED, YOU NEED SOME TIME. YOU CAN'T, THE DRUG COMES OUT THE FIRST DAY YOU DON'T KNOW, IN FACT, WE KNOW THAT MANY DRUGS ARE WITHDRAWN FROM THE MARKET BECAUSE OF THE SERIOUS SAFETY RISKS RIGHT?

A. NUMBER ONE YOU'RE SAYING YOU NEED EVIDENCE. AND YOUR, [847] YOU SEEM TO BE IGNORING THE FACT THAT YOU'VE GOT A 14 YEAR PROCESS. THOUSANDS OF PEOPLE IN DOUBLE BLIND CLINICAL TRIALS AND FDA, SEVERAL FDA REVIEW BOARDS AND THE FDA APPROVAL BEHIND IT. AND FORMULARIES THAT COVER PROBABLY, YOUR HONOR, 70 PERCENT OF THE UNITED STATES. MANAGED CARE PLANS COVER ABOUT 70 PERCENT OF THE PEOPLE IN THIS COUNTRY. THEY ALL HAVE FORMULARIES WITH MEDICAL EXPERTS. THEY REVIEW THE DATA, THEY LOOK AT NEW PRODUCTS. AND IF YOU GO AROUND THE COUNTRY

YOU'LL FIND THAT MOST NEW PRODUCTS, NOT ALL, GET ON A FORMULARY BUT WITH STIPULATIONS. SO THERE ARE WAYS TO MANAGE NEW DRUGS BASED ON EVIDENCE BECAUSE IT COMES TO YOU WITH THE NEW DRUG.

\* \* \*

[848] Q. AND WE HAVE A FORMULARY IN VERMONT; CORRECT?

A. YES, YOU DO.

Q. AND SO THEY MAY WELL BE DOING THAT. BUT WHAT WE'RE TALKING ABOUT IS ACADEMIC DETAILING?

A. YOU AND I MAY HAVE A DIFFERENT DEFINITION OF ACADEMIC DETAILING. BECAUSE ACADEMIC DETAILING HAS NO SUCH DEFINITION. YOU CAN DO ANYTHING YOU WANT WITH IT. IT IS ABOUT PROVIDING A RATIONAL FRAME WORK FOR THE UTILIZATION OF DRUGS FROM A GOVERNMENT SOURCE WITH A COST PERSPECTIVE. A LOT OF WHAT HAPPENS IN THIS COUNTRY, AND WE'VE ALL GOT ROLES. THE PHARMACEUTICAL INDUSTRY SPEND BILLIONS OF [849] DOLLARS TO DEVELOP A DRUG AND THEN THEY BRING THE ATTRIBUTES OF THOSE DRUGS TO THE MARKET TO GET TO THE PATIENTS WHO COULD BENEFIT. THEY TALK ABOUT QUALITY. THEY FOCUS ON THE UTILITY. THEY DON'T FOCUS ON COST.

THEN YOU HAVE MANAGED CARE FOCUSING ON COST. AND I WOULD HAVE TO SAY THEY DON'T FOCUS NEARLY AS MUCH ON QUALITY. SO YOU'VE GOT THESE DIFFERENT INTERESTS. AND THE MORE INTERESTS, FRANKLY, THAT YOU HAVE, AND I PERSONALLY CAN'T WAIT FOR CONSUMERS TO GET INVOLVED, BUT THE MORE INTERESTS WE HAVE AND THE MORE INFORMATION THE BETTER THEY ARE.

SO YOU WOULD BE COMMUNICATING THROUGH ACADEMIC DETAILING A GOVERNMENT PERSPECTIVE ON THE COST AND QUALITY ISSUES OF DRUGS AND ADD IT TO THE MIX.

\* \* \*

[850] THE COURT: WHO DOES THAT?

THE WITNESS: IT WAS A DOCTOR OR A PHARMACIST TALKING TO A DOCTOR.

NOW, IN THE OUTPATIENT ENVIRONMENT IT WOULD BE PROHIBITIVELY EXPENSIVE TO HIRE DOCTORS TO GO OUT AND TALK WITH DOCTORS. SO DR. AVORN, AND THIS HAPPENED IN MEDCO IN THE EARLY '90'S. WE ACTUALLY HIRED HIM TO TRY IT IN THE OUTPATIENT ENVIRONMENT. AND SO HE HAD NEVER DONE IT BEFORE. HE BASICALLY IDENTIFIED THE AREAS WHERE THERE MIGHT BE SOME OPPORTUNITY FOR IMPROVEMENT. AND WE HELPED HIM DEVELOP THE MATERIALS. THEY LOOKED

JUST LIKE BROCHURES FROM PHARMACEUTICAL COMPANIES, BUT ARE DONE BY A PAIR. AND THE [851] PHARMACIST WOULD GO OUT AND SHOW THEM THEIR DATA, EXPLAIN TO THEM THE COSTS AND ECONOMICS OF THE ISSUE AND ASK THEM TO TRY, WHERE APPROPRIATE, DON'T DO ANY HARM, WHERE APPROPRIATE, TO USE MORE OF THE LOWER COST DRUGS. AND THEY MEASURED THAT.

NOW WHAT'S HAPPENED IS THERE ARE MORE AND MORE OF THOSE SITUATIONS IDENTIFIED. AND SO ACADEMIC DETAILING HAS THIS CONNOTATION OF CUTTING COSTS. BUT THERE'S NO REASON WHY IT CAN'T IMPROVE BEHAVIOR, IMPROVE DIAGNOSIS OR INCREASE THE UTILIZATION OF DRUGS WHERE IT'S APPROPRIATE BECAUSE THERE ARE PLENTY OF AREAS WHERE A DRUG WOULD SAVE OTHER COSTS.

SO THERE IS NO SOLID DEFINITION. BUT IT IS A PROCESS THROUGH A PAYER PERSPECTIVE OF TALKING TO DOCTORS ABOUT THEIR PRESCRIBING PATTERNS AND ADDING THE COST TO THE PICTURE.

\* \* \*

[853] Q. SO YOU'RE AWARE THAT VERMONT HAS A MULTI-PAYER DATABASE; RIGHT?

A. I BELIEVE YOU HAVE STARTED TO DEVELOP A MULTI-PAYER DATABASE. DO YOU HAVE IT UP AND RUNNING?

Q. ACTUALLY, WE'VE HAD IT FOR A NUMBER OF YEARS. AND THAT MULTI-PAYER DATABASE HAS PRESCRIBER-IDENTIFIABLE DATA IN IT THAT COULD BE USED FOR THE ACADEMIC DETAILING PROGRAM.

A. I THINK THAT'S GREAT.

[854] Q. UMHUM. AND SO THEY WOULDN'T NEED TO PURCHASE DATA TO DO THAT. AND, IN FACT, THERE'S AN EXEMPTION UNDER THE ACT FOR USING THIS KIND OF DATA FOR THESE PURPOSES.

A. WELL NOW I UNDERSTAND WHY YOU DIDN'T, THE STATE DIDN'T ACCEPT OUR OFFER OF DATA.

\* \* \*

[863] Q. AND THEN AS FAR AS THE ACADEMIC DETAILING IS CONCERNED, NOW ACADEMIC DETAILING HAS NOT ALWAYS BEEN CALLED ACADEMIC HAS IT?

A. IT'S CALLED COUNTER DETAILING.

Q. COUNTER DETAILING. AND THOSE ACADEMIC DETAILING PROGRAMS, SUCH AS WE SEE IN VERMONT TODAY, THEY ARE OFTEN THE SAME THING AS COUNTER DETAILING IN THE SENSE THAT THEY HAVE THEIR OWN

PARTICULAR POINT OF VIEW, THEY ARE FUNDED BY A GOVERNMENT AGENCY, FOR EXAMPLE, THAT PAYS FOR THE COST OF DRUGS AND IS INTERESTED IN REDUCING THE DRUGS; IS THAT CORRECT?

A. YES. AND THAT'S PART OF MY CONCERN WITH ACADEMIC DETAILING. I DON'T SUGGEST IT SHOULDN'T BE DONE. BUT WHOSE GOING TO PLAY GOD IN THIS SITUATION? WHOSE GOING TO DECIDE THEY ARE THE FDA AND HOW TO REGULATE AND WHAT MESSAGE IS APPROPRIATE AND WHERE IS THE BALANCING INFORMATION.

SO I DON'T, I MEAN THE OLD DRUGS ARE NOT SAFER [864] THAN NEW DRUGS. YOU JUST KNOW MORE ABOUT THEM. THE FACT IS THAT NEW DRUGS ARE TESTED IN A LARGER POPULATION SO AS - THAN THEY USED TO BE. SO WE KNOW MUCH MORE ABOUT NEW DRUGS TODAY THAN WE DID EARLIER. AND BACK THEN DRUGS WERE TAKEN OFF THE MARKET.

NUMBER TWO, ALL THE OLD DRUGS WE WANT TO USE TODAY WERE ONCE NEW DRUGS. YOU WON'T PREVENT PEOPLE FROM GETTING HURT BY DELAYING THINGS NECESSARILY BECAUSE YOU USUALLY, IT'S A FUNCTION OF HOW MANY PATIENTS TAKE A DRUG. IN A POPULATION OF 5,000 IN A STUDY YOU'LL PICK UP A CERTAIN NUMBER OF ADVERSE REACTIONS. IN 10 THOUSAND YOU'LL PICK UP MORE. SO

YOU MAY GET TO THAT 10 THOUSAND NUMBER LATER IF YOU DELAY THE DISSEMINATION OF INFORMATION, BUT EVENTUALLY YOU'LL – ALL THESE THINGS BECOME KNOWN.

\* \* \*

[865] THE COURT: I HAVE ONE MORE QUESTION AGAIN. I KNOW YOU COVERED IT, BUT EXPLAIN WHAT A FORMULARY IS.

THE WITNESS: THANK YOU. I'LL BE GLAD TO.

THE COURT: OR WHAT THE PROCESS IS.

THE WITNESS: A FORMULARY –

THE COURT: AND HOW DO YOU SPELL IT?

A. F-O-R-M-U-L-A-R-Y.

YOU HAVE A PREFERRED DRUG LIST HERE IN THE STATE. THAT'S ESSENTIALLY A FORMULARY. IT IS A LIST OF DRUGS THAT ARE RECOMMENDED BY THE ENTITY THAT MANAGES IT. AND IT'S RECOMMENDED ON A NUMBER OF BASES. NUMBER ONE, MEDICAL NECESSITY. I MENTIONED YESTERDAY, YOUR HONOR, THAT YOU START BY LOOKING AT ANY, EVERY DRUG THERE IS AND SAY WHICH ONES ARE ABSOLUTELY ESSENTIAL. THEY MUST BE ON THE FORMULARY. AND WHICH ONES HAVE

ABSOLUTELY NO SAVING GRACE OF ANY KIND AND THEY ARE TAKEN OFF THE FORMULARY.

IF YOU'RE OFF THE FORMULARY YOU WON'T BE REIMBURSED FOR IT. A DOCTOR CAN PRESCRIBE IT, A PATIENT CAN TAKE IT, BUT THERE WILL BE NO REIMBURSEMENT.

AND THEN WITHIN THAT RANGE OF WHAT IS COVERED UNDER THE FORMULARY THEY'VE DEVELOPED OVER THE YEARS DIFFERENT WAYS OF ENCOURAGING APPROPRIATE USE. FOR EXAMPLE, NEWER DRUGS MIGHT BE A MUCH HIGHER CO-PAY. SO YOU CAN HAVE IT BUT YOU BETTER WANT IT BECAUSE IT'S A LOT MORE EXPENSIVE.

[866] AND THE OLDER DRUGS, LIKE GENERICS OR OTHER DRUGS THAT MAY BE PREFERRED, WOULD HAVE A MUCH LOWER CO-PAY. AND THAT WOULD BE AN ALTERNATIVE TO RESTRICTING SPEECH RIGHT THERE. YOU'D BE SLOWING DOWN THE USE. BUT THERE'S AN APPEAL PROCESS, IF YOU WILL, BECAUSE IF A PATIENT REALLY NEEDS IT THEY CAN GET IT. AND ALSO THE PHARMACEUTICAL INDUSTRY IF A PATIENT REALLY NEEDED IT, THE CO-PAY WAS TOO HIGH, YOU COULD GO FOR AN ASSISTANCE PROGRAM WITH ALMOST ANY PHARMACEUTICAL COMPANY AND THEY WOULD PROBABLY PROVIDE YOU SOME OF IT FOR FREE. SO THERE ARE WAYS TO DEAL WITH, WITH THAT THAT DON'T REQUIRE RESTRICTING SPEECH.

THEN THEY HAVE, WITHIN THOSE CO-PAYS THEY HAVE PREFERRED DRUGS WITHIN CLASSES. SO IF THERE ARE FIVE DRUGS THAT HAVE THE SAME MECHANISM OF ACTION, YOU NEGOTIATE WITH THE MANUFACTURERS. THE ONE WHO GIVES YOU THE BEST PRICE GET THE PREFERRED RATING. AND THAT PREFERRED RATING MEANS THAT IT'S A LOWER CO-PAY.

THE COURT: AND ORGANIZATIONS THAT DO THAT INCLUDE MEDCO AND –

THE WITNESS: EVERY MANAGED CARE ORGANIZATION IN THE COUNTRY, UNITED HEALTH CARES OF THE WORLD PBM'S WHICH ARE OFTEN HIRED BY MANAGED CARE ORGANIZATIONS JUST TO DO THE DRUG. THEY DO IT EVERY HOSPITAL IN THE COUNTRY DOES IT. THE FEDERAL GOVERNMENT HAS A FORMULARY FOR MEDICARE PART D SO THIS IS A COMMON PRACTICE AND A TOOL TO MANAGE [867] UTILIZATION THAT DOES NOT IMPEDE SPEECH.

THE COURT: AND VERMONT, WHAT DOES IT HAVE?

THE WITNESS: THEY HAVE A PREFERRED DRUG LIST.

THE COURT: THROUGH WHOM?

THE WITNESS: EXCUSE ME?

THE COURT: IN OTHER WORDS, THROUGH WHOM? HOW IS IT ADMINISTERED, IF YOU KNOW?

THE WITNESS: THEY CAN PROBABLY ANSWER THE QUESTION BETTER. BUT IT'S MED MATRIX I BELIEVE. AND I THINK THAT'S A NON-PROFIT ORGANIZATION FROM MASSACHUSETTS. AM I CORRECT?

MS. DUFFY: IT'S THROUGH THE OFFICE OF VERMONT HEALTH ACCESS.

THE COURT: AND IT GOES TO WHOM? WHO KNOWS ABOUT THIS?

MS. DUFFY: WELL, THE DATA IS AVAILABLE IN THE MULTI-PAYER DATABASE, BUT THEY ACT AS ANY OTHER SORT OF INSURER OR THIRD PARTY. THEY HAVE THE DATA.

THE COURT: SO IT'S AVAILABLE TO –

MS. DUFFY: IT'S AVAILABLE TO THEM.

THE COURT: – ANYBODY?

MS. DUFFY: I'M SORRY?

THE COURT: IT'S AVAILABLE TO ANYBODY I GUESS?

MS. DUFFY: WELL, IT'S AVAILABLE TO THEM BECAUSE THEY HAVE A CONTRACTUAL RELATIONSHIP. BECAUSE THEY ARE [868] PAYING FOR THE, FOR EXAMPLE, OVA DOES THIS

FOR ITS MEDICARE AND MEDICAID CLIENTS. SO BECAUSE THEY ARE GETTING IT THROUGH MEDICAID THEY ARE, THEY ARE MANAGING THOSE COSTS. AND ESSENTIALLY THE CLAIMS ARE BEING PROCESSED THROUGH THEM. SO JUST AS AN INSURANCE COMPANY WOULD GET CLAIMS INFORMATION OVA GETS CLAIM INFORMATION AND MANAGES THEIR COSTS THROUGH A FORMULARY.

THE WITNESS: AND THESE FORMULARIES ARE VERY EFFECTIVE. THEY HAVE A GREAT DEAL OF INFLUENCE ON UTILIZATION IN THIS COUNTRY SEVEN OUT OF 10 PRESCRIPTIONS ARE WRITTEN ANNUALLY FOR GENERICS FOR EXAMPLE.

THE COURT: I'M SORRY?

THE WITNESS: OF ALL OF THE PRESCRIPTIONS IN THE COUNTRY 70 PERCENT OF THEM ARE ALREADY WRITTEN FOR GENERICS BECAUSE OF ALL THESE FORMULARIES AND REIMBURSEMENT METHODOLOGIES. IT'S IN THE BRAND AREA WHERE THEY CHOOSE APPROPRIATENESS, THEY BASICALLY TIE A CO-PAY TO IT AS A WAY TO ENCOURAGE OR DISUADE THE USE OF A DRUG. AND IT'S HIGHLY EFFECTIVE. AND YOU CAN SEE PRODUCTS THAT DON'T GET ON FORMULARIES ARE VIRTUALLY WIPED OUT SO IF IT'S ON A FORMULARY IT'S BECAUSE IT'S BEEN – THE EVIDENCE HAS BEEN PRESENTED THAT IT'S SAFE AND

EFFECTIVE, THE FORMULARY COMMITTEE HAS REVIEWED IT AND ITS APPROPRIATENESS AND WHERE IT COULD BE USED AND WHERE IT SHOULDN'T

IF THERE ARE AREAS WHERE IT SHOULDN'T THEY PRIOR [869] AUTHORIZE IT. THEN THEY HAVE THE DATA THAT COMES IN ON A REGULAR BASIS WITH YOUR RETROSPECTIVE REVIEW AND YOU FIND DOCTORS WHO AREN'T FOLLOWING IT. AND THEY MAKE PHONECALLS TO EDUCATE THEM. AND THEN THEY OFTEN SOME OF THEM DO CONTINUING MEDICAL EDUCATION AS PART OF THEIR PRACTICE. SO THAT THE BEST PRACTICES AND GUIDELINES ARE FOLLOWED. BECAUSE IN THIS COUNTRY THERE'S A LANDMARK GRANT STUDY IN 2003 ABOUT ADULT CARE. 56 PERCENT OF ADULTS WITH A CHRONIC ILLNESS ARE LIKELY TO BE TREATED ACCORDING TO BEST PRACTICES. WHEN YOU LOOK AT CHILDREN IT'S 48 PERCENT. SO THERE'S A LOT OF NEED FOR EDUCATION ON THE QUALITY SIDE AS WELL.

Q. (BY MR. JULIN:) AND MR., MR. FRANKEL, IF I COULD ASK YOU ONE MORE QUESTION TO CLARIFY THE NATURE OF WHOSE PAYING FOR CLAIMS. IN A STATE IT IS BASICALLY A INSURER, IS IT NOT, FOR CLAIMS THAT COME IN THROUGH BOTH THE MEDICAID PROGRAM THAT EXISTS FOR LOW INCOME INDIVIDUALS, AND FOR THE MEDICARE PROGRAM NOW

THROUGH PART D. WHICH PROVIDES FOR A PHARMACEUTICAL BENEFIT FOR ELDERLY PEOPLE WHO ARE QUALIFIED UNDER MEDICARE; IS THAT CORRECT?

A. YES.

Q. SO –

A. THE MISSING POPULATION IS THE UNINSURED FRANKLY. AND THAT'S WHERE THERE IS, THERE ARE NO COST CONTROLS. AND THE STATE COULD CREATE A PROGRAM FOR THE UNINSURED TO GIVE THEM [870] ACCESS TO LOWER COST PLANS.

Q. RIGHT. BUT JUST SO THAT WE'RE CLEAR, BASICALLY THE STATE OF VERMONT ACTS AS AN INSURANCE COMPANY, IT'S PAYING CLAIMS FOR PATIENTS THAT NEED PHARMACEUTICAL PRODUCTS THROUGH MEDICARE PART D AND THROUGH THE MEDICAID PROGRAM, THE STATE USES ITS OWN PHARMACY BENEFITS MANAGEMENT PROGRAM TO CONTAIN THE COSTS AND IT USES A FORMULARY, THAT PHARMACY BENEFITS MANAGER USED A FORMULARY TO SELECT THE DRUGS AND USES A DRUG UTILIZATION REVIEW BOARD OF EXPERTS WHO SELECT THOSE DRUGS AND REQUIRE PRIOR APPROVAL FOR ALL OF THOSE DRUGS, ALL OF THAT IS DONE ON BEHALF OF THE STATE NOW, IS THAT CORRECT?

A. THAT'S MY UNDERSTANDING.

Q. JUST LIKE INSURANCE COMPANIES ARE DOING THAT?

A. YES, THAT'S MY UNDERSTANDING.

Q. AND IF THE STATE STILL BELIEVES THAT THERE IS SOME WASTE TAKING PLACE, SOME BAD DECISIONS BEING MADE BY PRESCRIBERS, CAN THEY DO THINGS WITHIN THEIR FORMULARY STRUCTURE OR THEIR PBM STRUCTURE IN ORDER TO INSURE THAT THAT WASTE, THOSE BAD DECISIONS ARE ELIMINATED?

A. THE TYPICAL METHOD IS DRUG, RETROSPECTIVE REVIEWS MEANING YOU GO INTO THE DATA AND YOU FIND OVERUSE OF A CERTAIN DRUG YOU THEN BREAK IT DOWN TO WHICH DOCTORS ARE OVERUSING IT. AND THEN YOU SEND THE DOCTOR A REPORT SHOWING THEM THEIR DATA WE DID THAT AT MEDCO AS WELL. AND THAT [871] WAS VERY EFFECTIVE.

\* \* \*

[890] DAVID GRANDE, THE WITNESS, AFTER BEING DULY SWORN, WAS EXAMINED AND TESTIFIED AS FOLLOWS:

DIRECT EXAMINATION BY MISS DUFFY:

Q. GOOD MORNING, DR. GRANDE.

A. GOOD MORNING.

Q. COULD YOU TELL THE COURT WHERE YOU WORK?

A. THE UNIVERSITY OF PENNSYLVANIA.

Q. AND HAVE YOU BEEN RETAINED BY VERMONT TO OFFER OPINIONS ON THE USE OF PRESCRIBER-IDENTIFIABLE DATA IN PHARMACEUTICAL MARKETING AND THE POTENTIAL IMPACT OF ACT 80?

A. YES.

\* \* \*

[898] Q. AND, DOCTOR, HAVE YOU DONE AN EMPERIC STUDY TO ASSESS [899] THE IMPACT OF PRESCRIBER-IDENTIFIABLE DATA ON PHYSICIAN PRESCRIBING PRACTICES?

A. NO, I HAVE NOT.

Q. WHY NOT?

A. WELL, I THINK THAT THE PRACTICE OF USING PRESCRIBER-IDENTIFIABLE DATA IN PHARMACEUTICAL – IS SO DEEPLY IMBEDDED IN PHARMACEUTICAL MARKETING TODAY THAT IT'S DIFFICULT TO SEPARATE THE EFFECTS OF PRESCRIBER-IDENTIFIABLE DATA FROM THE ENTERPRISE OF PHARMACEUTICAL MARKETING MORE GENERALLY.

I THINK WHEN, WHEN THE LAW WAS PASSED IN NEW HAMPSHIRE I HAD DISCUSSIONS WITH SEVERAL INDIVIDUALS ABOUT

THE IDEA OF BEGINNING TO EVALUATE THE IMPACT OF THAT LAW BECAUSE THAT WAS REALLY THE FIRST OPPORTUNITY TO REALLY SEE WHAT WOULD HAPPEN WHEN YOU, WHEN YOU SEPARATE THE ISSUES.

Q. WHY DO YOU SAY IT WAS THE FIRST OPPORTUNITY TO EXPLORE THE ISSUE?

A. BECAUSE IN ORDER TO DO A WELL DESIGNED RESEARCH STUDY ONE HAS TO BE ABLE TO ISOLATE THE EFFECTS OF WHATEVER THE ISSUE IS THAT YOUR, THAT YOU ARE INTERESTED IN.

AND THE WAY THAT PHARMACEUTICAL MARKETING OCCURS TODAY, AND THE WAY DATA IS USED IN A VERY WIDESPREAD FASHION, MAKES IT VERY DIFFICULT TO DESIGN A STUDY WHERE YOU COULD SPECIFICALLY LOOK AT THE EFFECTS OF PRESCRIBER-IDENTIFIABLE DATA.

\* \* \*

[903] Q. HOW CAN PRESCRIBER-IDENTIFIABLE DATA BE USED TO DEVELOP AND TAILOR A MESSAGE?

A. WELL, I THINK, YOU KNOW, YOU HAVE PHYSICIANS MAKING PRESCRIBING DECISIONS WHERE THERE'S MULTIPLE THERAPEUTIC OPTIONS. AND WHEN A SALES REP VISITS A PHYSICIAN ULTIMATELY THEIR GOAL IS TO

ENCOURAGE THE PHYSICIAN TO PRESCRIBE MORE OF THEIR PRODUCT.

AND SO THEY WILL COME IN WITH A PARTICULAR SET OF MESSAGES. AND IF THEY KNOW WHAT THE CURRENT, WHAT THE PHYSICIAN'S CURRENT PRESCRIBING BEHAVIORS ARE THEY CAN CRAFT THEIR MARKETING MESSAGE IN A WAY THAT CONTRASTS THEIR PRODUCT WITH WHAT THE PHYSICIAN IS CURRENTLY PRESCRIBING.

WHETHER OR NOT THEY MAKE THAT, THAT COMPARISON [904] DIRECTLY AND EXPLICITLY OR NOT THEY COULD BE, THEY COULD TALK VERY MUCH ABOUT CERTAIN ASPECTS OF THEIR PRODUCT WITH THE PHYSICIAN KNOWING WHAT THEIR CURRENT BEHAVIORS ARE AND USE THAT IN A WAY TO REALLY TRY TO PUSH THE PHYSICIAN'S BEHAVIOR TOWARD THEIR PRODUCT.

Q. SO IF A REP KNEW THAT A PHYSICIAN WAS PRESCRIBING A COMPETITOR'S PRODUCT WHAT INFORMATION WOULD THAT PROVIDE TO THE SALES REP THAT MIGHT BE USEFUL IN TAILORING THE MESSAGE?

A. WELL, FOR EXAMPLE, IF THE SALES REP IS MARKETING A PRODUCT THAT, AS IN MOST CASES, HAS A SLIGHTLY DIFFERENT SIDE EFFECT PROFILE, THEY COULD CHOSE A PARTICULAR SIDE EFFECT WHERE THE TWO

PRODUCTS DIFFER AND CHOOSE TO FOCUS THE CONVERSATION ON THAT

Q. AND DO YOU KNOW WHETHER OR NOT THEY WOULD FOCUS SPECIFICALLY ON THE COMPETITOR'S PRODUCT?

A. AT TIMES THEY MIGHT IF, IF THEY HAVE DIRECT COMPARATIVE STUDIES. AT OTHER TIMES THEY MAY NOT NEED TO. THEY KNOW WHAT THE PHYSICIAN IS PRESCRIBING. AND, THEREFORE, THEY COULD TALK ABOUT THE SIDE EFFECTS OF WHATEVER PRODUCT THEY ARE PROMOTING AND, AND TALK MORE ABOUT THE ONES THAT THEY KNOW THAT CONTRAST WELL WITH THE COMPETITOR'S PRODUCT WITHOUT MAKING ANY DIRECT PRODUCT CLAIMS AT ALL.

AND THE PHYSICIAN CAN COME TO THEIR OWN CONCLUSION AT THAT POINT BASED ON THIS INFORMATION THAT HAS BEEN PROVIDED IN WHAT I VIEW IS A SELECTIVE MANNER.

\* \* \*

[908] Q. DOCTOR, BASED UPON YOUR RESEARCH HAVE YOU FORMED AN OPINION TO A REASONABLE DEGREE OF CERTAINTY ABOUT THE IMPACT THAT PRESCRIBER-IDENTIFIABLE DATA HAS ON MEDICAL PROFESSIONALISM?

A. YES.

Q. AND WHAT IS THAT OPINION?

A. MY OPINION IS THAT THE AVAILABILITY OF PRESCRIBER-IDENTIFIABLE DATA AMPLIFIES THE INFLUENCE THAT [909] MARKETING HAS ON PHYSICIAN PRACTICE. AND THE GREATER THAT INFLUENCE IS THE MORE LIKELY THE PRIVACY OF PATIENT WELFARE IS LIKELY TO BE COMPROMISED WHICH IS ONE OF THE FUNDAMENTAL TENANTS OF MEDICAL PROFESSIONALISM.

SECONDLY, REGARDLESS OF THE ACTUAL IMPACT, PATIENTS PERCEPTIONS ABOUT WHETHER OR NOT THEIR INTERESTS ARE BEING PUT FIRST ARE JUST AS IMPORTANT. BECAUSE THOSE ARE IMPORTANT WITH RESPECT TO WHETHER OR NOT PATIENTS FEEL LIKE THEIR INTERESTS ARE BEING PUT FIRST AND THEY CAN TRUST THE HEALTHCARE SYSTEM.

I BELIEVE THAT WHEN YOU INTRODUCE PRESCRIBER-IDENTIFIABLE DATA INTO THE DOCTOR PATIENT RELATIONSHIP THAT THE PRESENCE OF THAT DATA WILL MAKE PATIENTS ONLY FEEL MORE ANXIOUS ABOUT WHETHER OR NOT IN FACT THEIR INTERESTS ARE BEING PUT FIRST OR WHETHER IT'S TRULY MARKETING INTERESTS THAT IS BEGINNING TO OVERRIDE THEIR OWN.

Q. AND, DOCTOR, HAVE YOU FORMED AN OPINION TO A REASONABLE DEGREE OF CERTAINLY ABOUT THE IMPACT THAT ACT 80 WILL

LIKELY HAVE ON THESE ISSUES OF MEDICAL PROFESSIONALISM?

A. YES

Q. AND WHAT IS THAT OPINION?

A. WELL I BELIEVE THAT IT ENHANCES THE OPPORTUNITIES FOR A GREATER LEVEL OF MEDICAL PROFESSIONALISM IN THE PRACTICE OF MEDICINE.

Q. AND HOW IS THAT?

[910] A. IT REDUCES THE LEVEL OF UN-DUE INFLUENCE FROM COMMERCIAL INTERESTS IN THE DOCTOR PATIENT RELATIONSHIP.

\* \* \*

CROSS EXAMINATION BY MR. ASH

Q. DR. GRANDE, WE JUST MET I THINK MAYBE 30 MINUTES AGO. MY NAME IS MARK ASH

YOU DID NOT TESTIFY BEFORE THE LEGISLATURE IN CONNECTION WITH ACT 80; IS THAT RIGHT?

A. CORRECT

Q. AND YOU'VE TALKED THIS MORNING ON DIRECT ABOUT PATIENT PERCEPTIONS. IS IT FAIR TO SAY THAT YOU'VE NOT CONDUCTED ANY STUDY WHATSOEVER, ANY SCIENTIFIC STUDY WHATSOEVER ABOUT PATIENT

PERCEPTIONS OF THE USE OF DOCTOR IDENTIFIABLE INFORMATION?

A. I HAVE NOT.

\* \* \*

[913] Q. OKAY. NOW, YOU'RE AWARE FROM YOUR READING OF THE LITERATURE THAT THERE ARE A VARIETY OF OTHER HEALTH-CARE RELATED INTERESTS THAT DO USE PRESCRIBER-IDENTIFIABLE DATA?

A. YES.

Q. FOR EXAMPLE, INSURANCE COMPANIES, YOU KNOW THAT THEY USE IT?

A. YES.

Q. HAVE YOU READ DR. BARNER'S TESTIMONY BEFORE THE VERMONT LEGISLATURE ABOUT HER EXPERIENCE WITH INSURANCE COMPANIES AND THE EFFECTS THAT SHE EXPERIENCES WHEN SHE WANTS TO PRESCRIBE A MEDICATION THAT SHE THINKS IS IN THE BEST INTERESTS OF A PATIENT AND HOW THE INSURANCE COMPANIES DEAL WITH HER? HAVE YOU READ THAT?

A. NO.

MR. ASH: YOUR HONOR, I'M GOING TO READ FROM DR. [914] BARNER'S TESTIMONY BEFORE THE LEGISLATURE ON FRIDAY, APRIL 13, 2007. AND I ONLY HAVE ONE COPY OF THIS.

I'LL READ IT AND I'LL LET YOU THEN LOOK AT IT TO MAKE SURE I'VE FAIRLY READ IT, DOCTOR.

IT SAYS, BASICALLY WHEN A DOCTOR PRESCRIBES FOR A PATIENT YOU WOULD LIKE TO THINK THAT THE DOCTOR TAKES THE BEST DRUG FOR YOU AND HOPEFULLY THAT'S WHAT THE DOCTOR CAN DO. BUT THE FIRST THING YOU HAVE TO LOOK AT IS OH, WHAT'S YOUR INSURANCE. SO WE HAVE TO LOOK AT A LIST OF DRUGS THAT THEIR INSURANCE WILL ALLOW THEM TO HAVE. SO THAT'S THE FIRST PAINFUL THING THAT A DOCTOR HAS TO DO WHEN THEY ARE MAKING A DRUG, A DECISION TO PUT A PATIENT ON A DRUG. AND THEN YOU CAN, IF YOU CHECK THE LIST YOU WRITE THE PRESCRIPTION. IF IT'S A DRUG PLAN EVEN IF A PATIENT IS BEGGING YOU, PLEASE DON'T MAKE ME, PLEASE DON'T PUT ME ON THE THIRD TIER DRUGS, YOU KNOW, THAT KIND OF STUFF. SO IT'S A PAIN IN THE DERIARE ANYWAY TO DO PRESCRIBING THESE DAYS. IT'S NO LONGER WHAT'S THE BEST THING FOR THE PATIENT. IT'S WHAT THEIR HEALTH PLAN WILL LET YOU DO FOR THEM. TAKE A SECOND TO READ THAT. IT'S UP HERE.

HAVE YOU HAD A CHANCE READ IT?

A. YES.

Q. DID I READ IT FAIRLY?

A. YES.

Q. HAVE YOU EXPERIENCED THAT KIND OF PRESSURE FROM [915] INSURANCE COMPANIES THAT WILL ACTIVELY DISAGREE WITH THE PRESCRIPTION THAT I WANT TO WRITE AND THAT YOU FELT IS TO THE DETRIMENT OF A PATIENT THE WAY DR. BARNER TESTIFIED TO THE LEGISLATURE?

A. I'VE HAD THE EXPERIENCE OF RECEIVING WRITTEN LETTERS STATING THAT A CERTAIN PATIENT'S FORMULARY COVERS A CERTAIN MEDICATION AND THAT THE FORMULARY DOES NOT AND IF I PRESCRIBE THAT MEDICATION IT WON'T BE COVERED AS PART OF THEIR INSURANCE. THERE'S NO PROHIBITION ON PRESCRIBING THE PATIENT ANOTHER MEDICATION.

\* \* \*

Q. OKAY. NOW, YOU'RE AWARE THAT, WE'VE HEARD ABOUT [916] PHARMACY BENEFIT MANAGERS, SO CALLED PBM'S, YOU'RE AWARE THAT THEY USE PRESCRIBER-IDENTIFIABLE INFORMATION?

A. YES.

Q. YOU'RE AWARE THAT HEALTH MANAGEMENT ORGANIZATIONS USE SUCH INFORMATION?

A. DEFINE WHAT YOU MEAN BY HEALTH MANAGEMENT ORGANIZATIONS.

Q. YOU DON'T KNOW WHAT A MANAGED CARE, HMO IS?

A. HEALTH MAINTENANCE ORGANIZATION.

Q. I'M SORRY?

A. YES.

Q. I'M FROM NORTH CAROLINA.

A. OKAY.

Q. MEDICARE, YOU'RE AWARE THAT THE GOVERNMENT USES DOCTOR IDENTIFIABLE INFORMATION?

A. YES.

Q. YOU'RE AWARE THAT MEDICAID AND THAT FORMULARIES AND ACADEMIC DETAILERS, THEY ALL USE DOCTOR IDENTIFIABLE INFORMATION?

A. YES.

Q. AND YOU'RE AWARE THAT THIS LAW WOULD PROHIBIT ONE VOICE AND ONE VOICE ONLY FROM USING IT AND THAT'S PHARMACEUTICAL COMPANIES; IS THAT RIGHT?

A. MY UNDERSTANDING OF THE LAW IS THAT IT PROHIBITS MARKETING USES OF THE DATA.

\* \* \*

[917] Q. WELL, IN THAT REGARD IF THE PHYSICIAN DOESN'T WANT TO HEAR THEY DO WHAT YOU DO, THEY JUST SHUT THE DOOR, RIGHT?

A. THEY COULD.

Q. OKAY. BUT, IN FACT, A VERY LARGE NUMBER OF PHYSICIANS OPEN THE DOOR TO PHARMACEUTICAL REPRESENTATIVES SO THEY CAN HEAR THE MESSAGE ABOUT WHATEVER THAT PHARMACEUTICAL [918] REPRESENTATIVE CARES TO TALK TO THEM ABOUT, IS THAT FAIR?

A. I THINK THERE'S SOME OTHER INCENTIVES PROVIDED TO MAKE THAT ENCOUNTER HAPPEN.

Q. MY SIMPLE QUESTION IS THIS, FROM YOUR READING, FROM YOUR EXPERIENCE, HAVE YOU LEARNED THAT DOCTORS, MANY DOCTORS OPEN THEIR DOORS AND VOLUNTARILY LET SALES REPRESENTATIVES COME IN?

A. YES

Q. AND YOU'VE LEARNED THAT SOME DOCTORS, AND YOU'RE ONE OF THEM, WHO

VOLUNTARILY CLOSES THE DOOR WITHOUT THE BENEFIT OF ANY LAW, ANY LEGISLATION IN PENNSYLVANIA TO GIVE YOU THAT RIGHT?

A. YES.

\* \* \*

[923] Q. BUT, IN FACT, EVEN AT THE TIME THAT YOU STILL SAW DETAILERS YOU DON'T BELIEVE OR YOU CANNOT IDENTIFY FOR US TODAY A SINGLE INCIDENT OR A SINGLE PATIENT FOR WHOM YOU PRESCRIBED A MEDICATION WHERE YOU BELIEVED THAT THAT PRESCRIPTION WAS INAPPROPRIATE FOR THE PATIENT?

A. WELL, I THINK THAT THE WHOLE NATURE OF THE WAY INFLUENCE ARISES IS THAT IT'S AN UNCONSCIOUS INFLUENCE. SO I THINK IT WOULD BE AN EXCEPTIONAL CIRCUMSTANCE WHERE YOU WOULD ACTUALLY RECALL MAKING A DECISION THAT IN RETROSPECT YOU THINK WAS CONTRARY TO THE PATIENT'S INTERESTS.

Q. SO I THINK THE ANSWER TO THE QUESTION IS, NO, YOU DO NOT RECALL MAKING AN INAPPROPRIATE DECISION AT THE POINT IN TIME THAT YOU SAW DETAILERS? IS THAT WHAT YOUR ANSWER IS? NO?

A. I DON'T RECALL A SPECIFIC PATIENT.

\* \* \*

[927] Q. OKAY. YOU YOURSELF IN YOUR OWN PRACTICE PRESCRIBE BRANDED DRUGS ON SOME OCCASIONS EVEN WHEN A GENERIC IS AVAILABLE FOR YOUR PATIENTS; IS THAT RIGHT?

A. YES.

\* \* \*

[940] Q. NOW, WE HEARD SOME TESTIMONY FROM DR. CAROL BARNER AT THE LEGISLATURE. AND SHE SAID DURING HER TESTIMONY IT IS [941] DISGUSTING AND REALLY DEMEANING WHEN A DRUG REP CAN SAY, WELL, YOU SAY NICE THINGS TO MY FACE, BUT I KNOW YOU ARE NOT USING MY PRODUCT. HELLO. THEY ARE IN MY OFFICE AND THEY ARE ACCUSING ME OF LYING. LOVELY. THEY, THE DRUG REP WILL SAY, WELL, I KNOW WHAT YOU ARE DOING AND WHY AREN'T YOU USING MY PRODUCT. I'M A 5-FOOT 4 LADY. SOME OF THESE DRUG REPS, YOU KNOW, CAN BE, IT'S INTIMIDATING. WHY AREN'T YOU BLA, BLA, BLA, BLA. IT'S ANOTHER LAYER OF THE HORROR OF PRACTICING MEDICINE THESE DAYS AND IT SHOULDN'T BE THAT WAY. TO HAVE DRUG REPS COME IN AND TELLING ME I'M NOT DOING WHAT THEY WANT ME TO DO AND THEY CAN PROVE IT IS NASTY.

IS THAT CONSISTENT WITH SOME OF THE, WHAT YOU'VE HEARD ABOUT PEOPLE'S, DOCTOR'S FEELINGS ABOUT THE USE OF PRESCRIBER-IDENTIFIABLE DATA?

A. I THINK THAT IT'S A, THAT PHYSICIANS – MANY PHYSICIANS THAT I'VE TALKED TO WERE UNAWARE THAT SALES REPRESENTATIVES HAD THEIR PRESCRIBING DATA. AND I THINK THAT IT MADE THEM FEEL WHEN THEY DID FIND OUT THEY WERE FIRST SHOCKED AND SURPRISED. AND, SECONDLY, I THINK IT MADE THEM FEEL THAT IT WAS A, I DON'T HAVE A GREAT WORD OTHER THAN TO SAY SORT OF A UNDERHANDED WAY TO INFLUENCE THEM.

\* \* \*

---

## INDEX

	Page
WITNESS:	
MEREDITH ROSENTHAL, Ph.D. DIRECT EXAMINATION BY ATTY. DUFFY	943
CROSS-EXAMINATION BY ATTY. HANDWERKER	964
SHAHRAM AHARI DIRECT EXAMINATION BY ATTY. CASSETTY	972
CROSS-EXAMINATION BY ATTY. ASH	1028
REDIRECT EXAMINATION BY ATTY. CASSETTY	1055

## EXHIBITS

Exhibit No.	Page
Joint Exh. 6	943
Joint Exh. 14	973
Exh. 1205	986

[2] Q. Good afternoon, Dr. Rosenthal. Would you please introduce yourself for the Court and tell the Court where you work?

A. My name is Meredith P. Rosenthal. I'm an Associate Professor of Health, Economics and Policy at the Harvard School of Public Health.

\* \* \*

[954] And does that summarize the [955] calculation that you did?

A. So once I had the number of prescriptions that are single-source, multi-source, and generic, then I can implement this estimate. Which is to say, if I take one percent of those single-source prescriptions, one percent of those single-source prescriptions would be .03 million. So essentially 30,000 prescriptions. There are three million single-source prescriptions, approximately. So I take one percent of those. And then to that one percent I apply the difference in price between a generic and a brand-name drug. That difference in this case is about seventy dollars. And it's based on the average cost of a brand-name drug versus the average cost of a generic drug. From there I can calculate the total proximate savings which yield about two million dollars, 2.01 million dollars to be precise.

Q. So a 2.01 million dollar savings for every percentage increase in generic prescribing; is that correct?

A. For every reduction in single-source prescribing, which because of the generic [956] substitution rate in Vermont is 97.7 percent, is virtually the same thing as a one percent increase in generic prescribing.

\* \* \*

[964] Q. I'm just going to cut right through this and make this short.

You have no opinion, correct, that the cost savings that you just identified could be achieved by restricting prescriber-identifiable data, correct?

A. I believe that there's not enough evidence to make a substantive opinion about that point.

Q. You have no opinion that the cost savings that you identified in response to Ms. Duffy's questions could be achieved by a restriction on prescriber-identifiable data; correct?

A. That's correct.

Q. And you have no opinion about whether a restriction on prescriber-identifiable data could achieve improved public health; correct?

A. Let me just clarify, if I may?

I have expressed the opinion in my published work that promotion affects sales.

[965] I do not have an opinion about the specific effect of prescriber-identifiable data.

Q. That's right. You have no opinion about whether a restriction on prescriber-identifiable data could improve public health; right?

A. That's correct.

Q. And you have no opinion about whether a restriction on prescriber-identifiable data would protect prescriber privacy; correct?

A. I do not have an opinion about privacy. No.

Q. And, at the time you formed your opinions in this case, you had not read the act that's at issue in this litigation; is that right?

A. That's correct.

Q. And you had not read the findings in that act; is that correct?

A. That's correct.

Q. And you have no opinion about whether the act that's at issue in this case would lead to increased use of generic drugs; correct?

A. That's correct. That's correct.

\* \* \*

[972] SHAHRAM AHARI, Sworn

\* \* \*

[973] Q. And what did you do with that degree after graduating?

A. My first real employment after university was working as a sales rep for Eli Lilly in New York City.

Q. As a sales rep, what products did you promote?

A. I sold Prozac and Zyprexa.

\* \* \*

[988] Q. As a salesperson, how would you use that [989] prescriber-level data to gain access to high

prescribers, or those doctors with high potential to prescribe new products?

A. Well, again, as I said, the number of prescriptions and the potential to being influenced were the two primary factors that we used to determine who are priority targets are. The first criteria are simply a base selection of those physicians who have the greatest number of prescriptions they write in a given time period.

In other words, say, for example, the top ten writers of antidepressants within the borough of Brooklyn. And then another competing criteria would be those that have either the greatest potential increase in writing more of the drug of my choice, Prozac. In other words, who among those ten physicians has – hasn't shown specific allegiance to a competitor and has shown the potential for increasing the amount of shares of Prozac or prescriptions of Prozac.

Those two factors get weighed and balanced, and we determine who among that then section, cross-section of those doctors are [990] our potential clients, are target clients; the people whom we will dedicate most of our time and resources in trying to persuade.

\* \* \*

Q. Were you allowed to discuss their prescribing [991] patterns with them after entering their office?

A. No, actually, we were told never to bring the computer into the office, to dismiss any conversations

or deflect any conversations regarding this data, and to understate its value to our prescribing practices. This is one of the reasons why I felt dishonest about the nature of our job, or uncomfortable about the nature of our job.

\* \* \*

[999] Q. Do you use prescriber-level data for tailoring messages?

A. Absolutely. We use it, as well. The physician-prescriber data is used as tailoring in a variety of difference circumstances. But perhaps the most common is in determining what our competitors or what competing medications our client uses. Once we know that information, we can specifically deliver our presentation of our drug to place it in the best possible light with regard to that competitor.

For example, when selling Prozac to a physician who prefers Effexor, another antidepressant which has a particularly short [1000] half-life, I would come in, never mention Effexor by name, but tout Prozac's high – long half-life and say this is a positive thing. I walk away, never mentioning Effexor. The physician feels that I have made an uncanny coincidental comparison. And I have the most impact in the time that I have to present with the physician.

That process, unfortunately, delivers a very skewed perspective of what's otherwise – what should be objective information. That parallax is one of the

reasons why I actually left pharmaceutical marketing.

Again, it was, based on my experience both as an undergraduate science major and as a graduate student familiar with evidence-based practices, it's horribly disconcerting to see how that information can be distorted. Factually, it's true. But, in the manner of presentation, leaves a very skewed, distorted presentation of the data

\* \* \*

[1002] Q. And, in your opinion experience, is the focus of the District Manager on moving and improving sales results rather than education?

[1003] A. Yes. We never received a bonus for educating our physicians. Our prime incentive was how many prescriptions we can get our physicians to write in that time frame.

\* \* \*

[1007] Q. And how would you, how would you look – how do you know what the competitor is doing?

A. We would, of course, use the physician-prescriber data to see what the physician's drug of choice is. And the interesting thing about this again is that physicians usually regard this information as confidential; they don't really wish to tell the drug rep about this. So we pretend that we don't know and again make all our comparisons seemingly coincidental.

\* \* \*

[1020] Q. I think you discussed a couple of different uses of prescriber-level data for the marketing of pharmaceutical drugs. Can you recount the different ways in which the sales representative could make use of prescriber-level data?

A. Sure. There are basically four ways that I can think of at the top of my head in which this information is used at the tactical and strategic level by the sales rep.

The first, again, is identifying and prioritizing our target clients.

[1021] The second is tailoring our presentation to the best effect against our target's preferred drug of choice. In other words, tailoring it towards our competitors.

The third is evaluating how effective our sales practices are, whether or not the journal article has made an impact on our physician's prescribing or if the dinner made an impact on our physician that's prescribing.

The fourth we haven't gone into, but is probably worth mentioning, is to hold the physician accountable to. And this is where there is the greatest potential friction between the drug rep and physician.

The idea that we can keep track of what the physician is prescribing is a remarkably useful tool for our sales practices. There is something in the field which we call positive indifference; that is in essence the doctor acquiescing to whatever point we make or

acquiescing to use our product for whatever population we are asking for simply to placate us and get us out of their office as quickly as possible. Well, [1022] when they do that, we actually have data that we can hold them accountable to in the subsequent encounter.

For example, if Dr. Jones agrees to use Prozac for the next five patients that come in with depression/anxiety, and I suspect he is saying that just to get me out of his office, I can come back at a later point in time and say: Dr. Jones, have you been doing it? And I have the data to verify that. And I can effectively charm, harass, mention it, guilt him; a variety of different social tactics to employ.

\* \* \*

---

UNITED STATES DISTRICT COURT  
DISTRICT OF VERMONT

---

IMS HEALTH, INC., ET AL	)	CASE NO: 1:07-CV-188
VS	)	COURT TRIAL
WILLIAM SORRELL, ET AL	)	DAY 5 – VOLUME 1

---

BEFORE: HONORABLE J. GARVAN MURTHA  
U.S. DISTRICT COURT JUDGE

APPEARANCES:

MARK A. ASH, ESQUIRE  
SMITH, ANDERSON, BLOUNT, DORSETT,  
MITCHELL & JERNIGAN, LLP  
P.O. BOX 2611  
RALEIGH, NORTH CAROLINA 27601  
REPRESENTING IMS

ROBERT B. HEMLEY, ESQUIRE  
GRAVEL & SHEA  
76 ST. PAUL STREET, 7TH FLOOR  
BURLINGTON, VERMONT 05402  
REPRESENTING IMS

THOMAS R. JULIN, ESQUIRE  
HUNTON & WILLIAMS, LLP  
1111 BRICKELL AVENUE, SUITE 2500  
MIAMI, FLORIDA 33131  
REPRESENTING IMS

(APPEARANCES CONTINUED ON NEXT PAGE)

\* \* \*

[1066] AARON KESSELHEIM, THE WITNESS, AFTER BEING DULY SWORN, WAS EXAMINED AND TESTIFIED AS FOLLOWS:

DIRECT EXAMINATION BY MR. CASSETTY.

\* \* \*

[1067] Q. AND WHAT DEGREES DID YOU RECEIVE FROM THE UNIVERSITY OF PENNSYLVANIA?

A. MEDICAL AND LAW DEGREES.

Q. AND DO YOU HAVE ANY OTHER DEGREES?

A. I HAVE A MASTER'S IN PUBLIC HEALTH.

Q. AND WHEN DID YOU GET THAT?

[1068] A. IN 2007 FROM THE HARVARD SCHOOL OF PUBLIC HEALTH.

Q. AND ARE YOU LICENSED TO PRACTICE LAW?

A. I AM. I'M A MEMBER OF THE BAR IN THE STATE OF NEW YORK.

Q. AND ARE YOU LICENSED TO PRACTICE MEDICINE?

A. I AM LICENSED IN THE STATE OF MASSACHUSETTS.

Q. AND DO YOU PRACTICE MEDICINE IN MASSACHUSETTS?

A. I DO.

Q. DO YOU HAVE ANY BOARD CERTIFICATIONS?

A. I'M BOARD CERTIFIED IN INTERNAL MEDICINE.

Q. AND WHERE DO YOU PRACTICE MEDICINE?

A. I PRACTICE AT BRIGHAM AND WOMAN'S PRIMARILY AND OCCASIONALLY AT FAULKNER HOSPITAL WHICH IS A LOCAL COMMUNITY HOSPITAL AS WELL.

Q. THAT'S A HOSPITAL BASED PRACTICE?

A. YES. IT'S A – I HAVE BOTH A PRIMARY CARE PRACTICE WHERE I TAKE CARE OF A PANEL OF PRIMARY CARE PATIENTS AND I ALSO ATTEND ON THE GENERAL MEDICINE SERVICE.

Q. WHAT DOES IT MEAN THAT YOU ATTEND ON THE GENERAL MEDICINE SERVICE?

A. I TAKE CARE OF PATIENTS WHO ARE ADMITTED TO THE HOSPITAL.

Q. AND DO YOU HAVE ANY ACADEMIC APPOINTMENTS?

A. I'M APPOINTED AS AN INSTRUCTOR OF MEDICINE AT HARVARD MEDICAL SCHOOL.

[1069] Q. YOU TEACH MEDICAL STUDENTS?

A. I TEACH MEDICAL STUDENTS, RESIDENTS AND SCHOOL OF PUBLIC HEALTH STUDENTS.

Q. DO YOU HAVE ANY RESEARCH AFFILIATIONS?

A. I, I DO RESEARCH AT HARVARD MEDICAL SCHOOL AND BRIGHAM AND WOMAN'S HOSPITAL.

Q. AND WHAT AREAS OF RESEARCH ARE YOU ENGAGED IN?

A. I PRIMARILY FOCUS ON MATTERS RELATED TO DRUG POLICY AND IMPROVING PRESCRIPTION DRUG PRACTICES AND ISSUES RELATED TO REGULATORY AND OTHER LEGAL ISSUES THAT IMPACT DRUG COSTS AND DRUG DEVELOPMENT.

\* \* \*

[1070] Q. AND WHAT AFFECT DO YOU THINK RESTRICTING THE USE OF PRESCRIBER LEVEL DATA IN PHARMACEUTICAL, MARKETING WILL HAVE ON PUBLIC HEALTH?

A. I THINK THAT PHARMACEUTICAL MARKETING PRACTICES HAVE A [1071] VERY STRONG IMPACT ON PHYSICIANS PRESCRIBING HABITS. AND THIS DATA HELPS PHARMACEUTICAL SALES REPRESENTATIVES ATTUNE

THEIR MESSAGES FOR THE HIGHEST ADVERTISING IN PROMOTIONAL AFFECT. AND REMOVING THAT ASPECT OF THE SALES PITCH FROM THE DISCUSSIONS BETWEEN PHARMACEUTICAL SALES REPRESENTATIVES AND PHYSICIANS WILL HELP PREVENT INAPPROPRIATE USE OR OVER PRESCRIPTION OF DRUGS IN PATIENTS WHOM THEY ARE NOT INDICATED OR FOR CONDITIONS WHERE THEY MIGHT NOT, THE DATA MIGHT NOT SUPPORT THEIR USE.

Q. ONE OF THE FINDINGS OF THE VERMONT LEGISLATURE WAS THAT NEWLY APPROVED DRUGS ARE NOT NECESSARILY BETTER THAN EXISTING DRUGS. DO YOU HAVE AN OPINION REGARDING THAT STATEMENT?

A. I MEAN I THINK THAT THAT'S WELL UNDERSTOOD TO BE THE CASE. FOR A MANUFACTURER OR A SPONSOR TO GET A DRUG APPROVED BY THE FDA THEY DO NOT HAVE TO SHOW THAT IT'S BETTER THAN OR EVEN EQUIVALENT TO DRUGS ON THE MARKET. ALL THEY HAVE TO DO IS SHOW THAT IT IS MORE EFFECTIVE THAN PLACEBO IN A TRIAL, A SMALL TRIAL OF A LIMITED NUMBER OF PATIENTS, MOST OF WHOM ARE – LACK OTHER CO-MORBIDITIES OR OTHER DRUGS THAT THEY ARE TAKING THAT MIGHT INTERACT WITH THE DRUG. SO THERE ARE A NUMBER OF DRUGS AND NEW DRUGS THAT ARE PUT OUT

ON THE MARKET THAT ARE NOT NECESSARILY BETTER THAN EXISTING DRUGS.

\* \* \*

[1072] Q. – THE CORRECT TERM? DO YOU PRESCRIBE PROTON PUMP INHIBITORS?

A. I DO VERY FREQUENTLY.

Q. IS NEXIUM A PROTON PUMP INHIBITOR?

A. IT IS.

Q. IS THAT A PATENT PROTECTED DRUG THAT OFFERS A THERAPEUTIC BENEFIT OVER EXISTING MEDICATION?

A. NO. WELL, IT IS A PATENT PROTECTED DRUG. AND IT IS MORE EXPENSIVE THAN OTHER PROTON PUMP INHIBITORS ON THE MARKET. BUT IT OFFERS THOUGH THERAPEUTIC BENEFIT OVER PROTON PUMP INHIBITORS THAT HAVE BEEN ON THE MARKET FOR LONGER PERIODS OF TIME AND ARE CURRENTLY LESS EXPENSIVE BECAUSE THEY, THEIR PATENT HAS EXPIRED.

Q. SO THERE ARE PROTON PUMP INHIBITORS THAT ARE AVAILABLE IN GENERIC FORM?

A. YES.

Q. IS THERE ANY THERAPEUTIC REASON THAT YOU WOULD PRESCRIBE NEXIUM FOR ONE OF YOUR PATIENTS INSTEAD OF A GENERIC?

A. NO. IN, IN ALL CASES I PRESCRIBE THE GENERIC PRILOSEC BECAUSE I'M NOT CONVINCED THAT NEXIUM IS ANY BETTER THAN, THAN PRILOSEC. THERE MIGHT BE, I, YOU KNOW, A VERY RARE CASE WHERE A PATIENT MIGHT BE, INDIVIDUALLY HAVE A REACTION TO, AN ADVERSE REACTION TO PRILOSEC OR AN ALLERGIC REACTION [1073] OR SOMETHING LIKE THAT IN WHICH CASE I MIGHT THEN CONSIDER PRESCRIBING NEXIUM AS AN ALTERNATIVE. BUT THERE'S NO REASON FOR IT TO BE PRESCRIBED AS A FIRST, FIRST DRUG FOR THE VAST MAJORITY OF MY PATIENTS.

Q. AND DO YOU KNOW WHETHER NEXIUM IS BEING PRESCRIBED AS THE FIRST DRUG OF CHOICE FOR PATIENTS SIMILAR TO YOURS?

A. YES, ITS, ITS A VERY HIGHLY PRESCRIBED DRUG. AND ITS VERY PROFITABLE FOR ITS MANUFACTURER. AND IN MANY CASES I WILL RECEIVE REFERRALS FROM THE GASTROLOGY CLINIC WHERE THE GASTROLOGIST STARTED THE PATIENTS ON, ON NEXIUM WITHOUT FIRST GIVING A TRIAL OF PRILOSEC. SO I SEE IT IN PRACTICE ALL THE TIME.

Q. NOW, THERE ARE NEWLY APPROVED DRUGS WHICH DO OFFER THERAPEUTIC IMPROVEMENTS OVER EXISTING DRUGS?

A. OH, CERTAINLY.

Q. WE'VE HEARD SOME TESTIMONY, WE HEARD A LOT OF TESTIMONY ACTUALLY ABOUT STATINS. ARE YOU FAMILIAR WITH THAT LINE OF MEDICATION?

A. YES.

Q. AND WHAT ARE THOSE USED FOR?

A. TO LOWER CHOLESTEROL.

Q. AND WE'VE HEARD THAT LIPITOR WAS NOT THE FIRST OR SECOND STATIN THAT CAME ON THE MARKET. IS THAT ACCURATE?

A. THAT'S ACCURATE.

Q. AND THAT LIPITOR REPRESENTS A THERAPEUTIC IMPROVEMENT [1074] OVER THE PREDECESSOR STATINS?

A. WELL, I MEAN THERE ARE, THERE ARE STUDIES THAT SHOW THAT IN A VERY, AND AGAIN IN A VERY LIMITED SEGMENT OF THE POPULATION PATIENTS WHO ARE, HAVE HAD A MYOCARDIAL INFARCTION IN THE PAST AND ARE AT VERY HIGH RISK FOR HAVING ANOTHER ONE THAT LIPITOR CAN PROVIDE LOWERING OF THE CHOLESTEROL TO LEVELS THAT THOSE SORT OF INDIVIDUAL PATIENTS REQUIRE WITH THOSE RISK FACTORS. AND IN THOSE CIRCUMSTANCES LIPITOR HAS SHOWN TO BE AN IMPROVEMENT OVER THE OTHER CHOLESTEROL MEDICATIONS ON THE MARKET. BUT FOR THE MAJORITY OF PATIENTS

WHO REQUIRE A MEDICATION TO LOWER THEIR CHOLESTEROL LIPITOR IS NOT SHOWN TO BE ANY IMPROVEMENT OVER OTHER AVAILABLE STATIN MEDICATIONS.

Q. AND THE OTHER STATIN MEDICATIONS THAT OFFER THE SAME THERAPEUTIC BENEFIT FOR THE MAJORITY PATIENTS, ARE THOSE AVAILABLE IN GENERIC?

A. YES, SOME OF THOSE ARE IN GENERIC FORM AND LESS EXPENSIVE.

Q. LIPITOR HAS BEEN A SUCCESSFUL DRUG?

A. YES. ITS A MULTI-BILLION DOLLAR A YEAR PRODUCT.

Q. ITS ONE OF THE TOP PRESCRIBED DRUGS IN THE COUNTRY?

A. ITS ONE OF THE TOP PRESCRIBED DRUGS IN THE WORLD.

\* \* \*

[1081] Q. DO YOU HAVE AN OPINION WHETHER NEWLY APPROVED DRUGS CAN PRESENT INCREASED RISKS?

A. WELL, NEWLY APPROVED DRUGS, IT'S, AGAIN, HAS BEEN, HAS BEEN SHOWN IN MULTIPLE STUDIES CAN PRESENT INCREASED RISKS TO PATIENTS BECAUSE WHEN A DRUG IS APPROVED IT IS USUALLY APPROVED ON THE

BASIS OF PRELIMINARY STUDIES IN A RELATIVELY SMALL SUBSET OF PATIENTS WHO MAY NOT LOOK LIKE THE PATIENTS WHO ULTIMATELY RECEIVE THE DRUG IN TERMS OF POTENTIALLY OTHER PRESCRIPTIONS THEY ARE RECEIVING OR OTHER DISEASES THEY MIGHT HAVE.

THE STUDIES THAT ARE DONE IN LEADING UP TO THE APPROVAL OF A DRUG ARE USUALLY DONE IN RELATIVELY HEALTHIER PATIENTS WHO HAVE FEWER CO-MORBIDITIES AND FEWER CO-PRESCRIPTIONS AND IN A LIMITED, AGAIN, AS SORT OF A SMALL SUBSET OF PATIENTS, NOT IN THE MILLIONS AND MILLIONS OF PATIENTS WHO MIGHT RECEIVE A DRUG AFTER IT IS ON THE MARKET.

AND WHEN A DRUG IS APPROVED IT ALSO CAN BE [1082] APPROVED ON THE BASIS OF SURROGATE MARKERS WHERE IT'S SHOWN TO LOWER LDL CHOLESTEROL BUT WE MIGHT NOT KNOW WHAT IT'S ULTIMATE AFFECT IS ON THE FINAL OUTCOMES OF HEART ATTACKS OR STROKES.

AND SO FOR ALL THESE REASONS WHEN A NEW DRUG IS PUT ON THE MARKET THERE ARE A NUMBER OF THINGS ABOUT THE SAFETY OF THE DRUG THAT ARE YET TO BE KNOWN. AND IN THE YEARS AFTER A DRUG IS APPROVED THOSE NEW SAFETY CONCERNS CAN COME OUT AND CAN SOMETIMES, IN THE

WORSE CASE SCENARIO, CAN THEN LEAD TO THE DRUG THEN BEING WITHDRAWN FROM THE MARKET BUT THEN CAN ALSO ADJUST THE WAY THE PHYSICIANS UNDERSTAND HOW TO USE THE DRUG.

Q. ONE OF THE MORE HIGHLY PUBLICIZED WITHDRAWALS RECENTLY WAS THE MEDICATION VIOXX. ARE YOU FAMILIAR WITH THAT?

A. YES

Q. AND I BELIEVE YOU DISCUSSED THAT IN YOUR ORIGINAL REPORT?

A. YES

Q. WHAT INDICATIONS – WHEN VIOXX CAME OUT WHAT WAS THE INDICATION FOR THAT DRUG?

A. I BELIEVE IT WAS A, IT WAS APPROVED FOR PAIN CONTROL. BUT THE STUDIES THAT WERE DONE SHOWED THAT THE BENEFIT THAT VIOXX PROVIDED WAS IN POTENTIALLY LIMITING GASTROINTESTINAL BLEEDS IN PATIENTS WHO HAVE THE NEED FOR PAIN CONTROL.

IT WAS, IT'S IN A CLASS OF DRUGS CALLED [1083] NONSTEROIDAL ANTIINFLAMMATORY DRUGS THAT ARE USED FOR PAIN CONTROL AND THE STUDIES DIDN'T SHOW THAT IT HAD ANY SUBSTANTIAL BENEFIT IN PAIN CONTROL

THAN THESE OTHER DRUGS. BUT IT DID HAVE THIS ONE SORT OF PARTICULAR SUBSET OF PATIENTS IN WHICH IT MIGHT BE USEFUL.

Q. NOW, NONSTEROIDAL ANTIINFLAMMATORY DRUGS, THOSE ARE NORMAL ENSEDS?

A. LIKE MOTRIN OR IBUPROFEN WHICH YOU CAN BUY OVER THE COUNTER.

Q. SO VIOXX IS IN THE SAME CATEGORY AS IBUPROFEN?

A. YES.

Q. AND IBUPROFEN WAS SHOWN TO BE EQUALLY EFFECTIVE THERAPEUTICALLY FOR CONTROLLING PAIN?

A. YES. I DON'T THINK – I DON'T THINK IT UM, IBUPROFEN WAS SHOWN OR THE NON-STEROIDAL ANTIINFLAMMATORY DRUGS WERE SHOWN IN THE ORIGINAL STUDIES TO BE JUST AS EFFECTIVE IN CONTROLLING PAIN AS VIOXX.

Q. BUT THE ENSEDS CAN CAUSE –

A. YES. ONE OF THE KNOWN SIDE EFFECTS OF ENSEDS IS THAT THEY CAN CAUSE GI BLEEDS.

Q. AND SO VIOXX WOULD BE APPROPRIATE FOR A PATIENT WHO NEEDED THE PAIN RELIEF BUT WAS AT RISK FOR GASTROINTESTINAL BLEEDING?

A. EITHER HIGH RISK FOR OR HAD A HISTORY OF GASTROINTESTINAL BLEEDS.

[1084] Q. WAS THE DRUG PRESCRIBED APPROPRIATELY TO THAT POPULATION?

A. NO, THE DRUG WAS FAR OVER PRESCRIBED AND USED AS IN PATIENTS WHO WERE NOT AT THAT INCREASED RISK. AND SOON BECAME A BLOCK BUSTER PRODUCT USED IN MANY, MANY PATIENTS ACROSS THE COUNTRY.

Q. DO YOU KNOW WHETHER VIOXX WAS A MORE EXPENSIVE MEDICATION THAN IBUPROFEN?

A. YES. VIOXX WAS A MUCH MORE EXPENSIVE MEDICATION. IT COSTS MULTIPLE DOLLARS A PILL. WHEREAS IBUPROFEN YOU CAN BUY LARGE BOTTLES OF IT OVER THE COUNTER FOR THE SAME AMOUNT OF MONEY.

Q. AND DID VIOXX PRESENT AN INCREASED RISK OVER IBUPROFEN?

A. WELL, IT TURNS OUT IN ULTIMATELY SOME OF THE - THE, THE PRE-APPROVAL STUDIES ACTUALLY PREDICTED THIS AS WELL, BUT AS WE SOON FOUND OUT AFTER THE DRUG WAS ON THE MARKET IT UM, WAS ASSOCIATED WITH INCREASED RISK OF MYOCARDIAL INFARCTIONS, HEART ATTACKS AND OTHER CARDIOVASCULAR OUTCOMES, BAD CARDIOVASCULAR OUTCOMES MUCH MORE SO THAN MOTRIN OR IBUPROFEN.

Q. AND ARE THOSE RISKS THAT PATIENTS WHO ARE NOT AT HIGH RISK FOR A GASTROINTESTINAL BLEED NEEDED TO BE EXPOSED TO?

A. NO. A PATIENT WHO WAS NOT DERIVING THE THEORETICAL BENEFITS FROM VIOXX WOULD THEREFORE BE RECEIVING THE SAME AMOUNT OF PAIN CONTROL BUT BEING EXPOSED TO THESE ELEVATED [1085] RISKS THAT VIOXX HAD OVER ENSEDS AND PAYING MORE MONEY FOR THEM AT THE SAME TIME.

Q. WHAT'S A BLACK BOX WARNING?

A. ITS THE STRONGEST WARNING THAT THE FDA CAN PROVIDE TO PHYSICIANS AND PATIENTS ABOUT RISKS ASSOCIATED WITH A DRUG.

Q. AND ARE YOU FAMILIAR WITH, ARE THERE ANY STUDIES ABOUT THE TIMING OF THE ISSUANCE OF BLACK BOX WARNINGS?

A. THERE IS A GOOD STUDY DONE JUST A FEW YEARS AGO THAT TOOK A LOOK AT NEWLY APPROVED DRUGS OVER THE LAST COUPLE OF DECADES AND FOUND THAT THESE BLACK BOX WARNINGS WERE USUALLY ADDED TO THE LABEL ABOUT A PRODUCT IN THE, IN THE FIRST FEW YEARS AFTER THE PRODUCT WAS APPROVED.

Q. SO BLACK BOX WARNINGS, IS IT FAIR TO SAY, ARE MORE FREQUENTLY ASSOCIATED

WITH DRUGS WHILE THEY ARE STILL WITHIN THEIR PATENT PROTECTION PERIOD?

A. YES. NEWLY APPROVED – BLACK BOX WARNINGS ARE MORE FREQUENTLY ASSOCIATED WITH – THE ADDITION OF A BLACK BOX WARNING IS MORE FREQUENTLY ASSOCIATED WITH A NEWLY APPROVED PRODUCT THAT IS PATENT PROTECTED.

Q. AND WHAT'S THE NEXT STEP AFTER A, FOR A MORE SEVERE PROBLEM THAN WOULD WARRANT A BLACK BOX WARNING?

A. THERE ISN'T ONE. THE FDA WILL JUST REQUEST THAT THE DRUG BE WITHDRAWN FROM THE MARKET.

Q. AND THAT HAPPENS ON OCCASION?

A. YES, THAT HAPPENS TOO THAT – THAT HAS HAPPENED IN [1086] MORE, UNFORTUNATELY MORE FREQUENTLY THAN, THAN YOU WOULD LIKE BUT USUALLY TENDS TO, AGAIN, THE SAME STUDIES FIND THAT THAT SORT OF WITHDRAWAL FROM MARKET USUALLY TENDS TO HAPPEN IN THE FIRST FEW YEARS AFTER A DRUG IS APPROVED.

\* \* \*

[1091] Q. NOW, REVIEWING THE LITERATURE, IS THAT AN EXAMPLE OF EVIDENCE BASED MEDICINE?

A. THAT'S WHAT WE TRY TO PROMOTE, YES.

Q. AND IS ACADEMIC DETAILING LIMITED TO THE PROFESSION OF GENERIC MEDICATIONS OVER BRANDED MEDICATIONS?

A. NO. WE TRY TO LOOK AT ALL THE AVAILABLE TREATMENTS BOTH PHARMACOLOGIC AND NON-PHARMACOLOGIC FOR A PARTICULAR CONDITION AND LOOK AT WHAT THE LITERATURE SHOWS AND TRY TO HELP GUIDE PHYSICIANS IN THEIR MANAGEMENT OF PATIENTS. AND, YOU KNOW, IF A, CERTAINLY IF A GENERIC DRUG WORKS – IF WE FIND THAT A GENERIC DRUG WORKS JUST AS GOOD AS A BRAND NAME [1092] DRUG AND IS AVAILABLE FOR LESS MONEY WE WILL, YOU KNOW, INCLUDE THAT AS PART OF OUR LITERATURE. BUT, YOU KNOW, IF WE FIND THAT THE EVIDENCE SUPPORTS USE OF A BRAND NAMED DRUG AND THAT THE COST OF THE DRUG AND THE BENEFITS OF THE DRUG OUTWEIGH THE RISKS OF IT, AND ARE IN SUBSTANTIAL APPROVEMENT, YOU KNOW, IF THAT'S WHAT THE LITERATURE SHOWS AND WHAT THE DATA SHOWS THAT'S WHAT WE'LL RECOMMEND.

Q. AND IS IT ALWAYS – ARE YOUR RECOMMENDATIONS ALWAYS THE USE OF MEDICATIONS?

A. NO. SOMETIMES WE'LL, YOU KNOW, SUGGEST LIFE-STYLE MANAGEMENT, DIET,

YOU KNOW, DIFFERENT CHANGES THAT PHYSICIANS CAN RECOMMEND TO THEIR PATIENTS IN TERMS OF IMPROVING THEIR DIET. AND, YOU KNOW, THERE ARE STUDIES THAT SHOW DIFFERENT DIET WAYS OF CONTROLLING BLOOD PRESSURE AND THEN WE'LL, YOU KNOW, PRESENT THAT INFORMATION TO THEM AS WELL.

Q. SORT OF THINGS LIKE DIET, EXERCISE, PERHAPS FOR PSYCHIATRIC CONDITIONS THERE MAY BE SOMETHING OTHER THAN THERAPEUTIC?

A. COUNSELING, RIGHT. EAT YOUR WHEATIES, ALL THAT STUFF.

Q. NOW, DO YOU UNDERSTAND THE VERMONT LAW TO BE DESIGNED TO SLOW THE UPTAKE OF NEW MEDICATIONS?

A. NO. I – THE VERMONT LAW WILL – THE REASON THAT I THINK THAT THE VERMONT LAW IS A GOOD IDEA IS THAT IT WILL HELP SLOW THE OVER PRESCRIPTION AND OVER USE OF NEW [1093] MEDICATIONS.

Q. DOES IT PREVENT THE APPROPRIATE USE OF NEW MEDICATIONS?

A. IT SHOULDN'T, NO.

Q. AND HOW, HOW, HOW DOES THAT MECHANISM WORK IN YOUR OPINION?

A. WELL, YOU KNOW, WHEN A NEW DRUG COMES ON THE MARKET PHYSICIANS WILL FIND OUT ABOUT THAT PRODUCT THROUGH A NUMBER OF MECHANISMS INCLUDING CONFERENCES AND INTERACTIONS WITH THEIR COLLEAGUES, AS WELL AS THROUGH VISITS FROM REPRESENTATIVES FROM THE COMPANY. AND THE VERMONT LAW DOESN'T PREVENT THE PHARMACEUTICAL MANUFACTURER FROM SENDING REPRESENTATIVES TO PHYSICIANS AND HELPING TEACH THEM ABOUT A NEW DRUG THAT'S ON THE MARKET.

ALL IT, ALL IT DOES IS PREVENT THEM FROM USING INSIDE INFORMATION TO TRY TO HELP GUIDE THE PROMOTIONAL AND ADVERTISING ASPECTS OF THAT MESSAGE TO BE AS, AS STRONGLY – TO MOVE PRESCRIPTION PRACTICES, YOU KNOW, TO HELP THE PROMOTION OF IT GUIDE THE PRESCRIPTION PRACTICES. IT DOESN'T HELP – IT DOESN'T PREVENT INFORMATION OR THE KNOWLEDGE ABOUT THE DRUG FROM GETTING OUT.

Q. SO, IF A NEW DRUG COMES ON THE MARKET AND GETS APPROVED BY THE FOOD AND DRUG ADMINISTRATION AND IT PRESENTS A BREAKTHROUGH, IT, IT CAN TREAT OR CURE A CONDITION THAT IS CURRENTLY, LETS SAY A DRUG COMES ON THE MARKET THAT CAN REVERSE THE EFFECT OF MULTIPLE SCLEROSIS, WOULD THE VERMONT [1094] LAW

PREVENT THE UP-TAKE OF SUCH A MEDICATION?

A. NOT AT ALL. I THINK THAT – THE NEUROLOGISTS WHO TREAT MULTIPLE SCLEROSIS WILL KNOW, FIRST OF ALL THEY’LL LEARN ABOUT THE DRUG FROM COLLEAGUES AND FROM KNOWLEDGE ABOUT THE, ABOUT THEIR FIELD OF PRACTICE AS THE DRUG, POTENTIALLY AS THE DRUG IS IN DEVELOPMENT AND AS THE DRUG IS UNDER CONSIDERATION FROM THE FDA, AND THE FDA ADVISORY COMMITTEE REPORT BECOMES PUBLIC AND, YOU KNOW, I THINK THAT PEOPLE WHO TREAT THAT CONDITION WILL HAVE AN UNDERSTANDING OF WHAT THE, OF, YOU KNOW, AVAILABLE NEW DRUGS. AND THEN IF THE PHARMACEUTICAL MANUFACTURER ALSO WANTS TO SEND REPRESENTATIVES TO PHYSICIAN’S OFFICES TO EDUCATE THEM ABOUT THE FACT THAT THIS NEW DRUG IS ON THE MARKET THE VERMONT LAW WOULDN’T PREVENT THEM FROM DOING THAT AT ALL.

\* \* \*

[1095] Q. DO YOU GET INFORMATION FROM PHARMACEUTICAL SALES PEOPLE?

A. NO OUR PRACTICE DOESN’T ALLOW PHARMACEUTICAL SALES PEOPLE FROM INTERACTING WITH PHYSICIANS.

Q. AND HAVE YOU FOUND THAT THAT HAS STUNTED YOUR KNOWLEDGE OF NEW MEDICATIONS?

A. NO I FEEL LIKE – I TRY AS BEST I CAN TO STAY ABREAST OF THE MEDICATIONS THAT ARE ON THE MARKET.

Q. DO YOU FEEL THAT THE COLLEAGUES THAT MEET WITH SALES PEOPLE ARE BETTER INFORMED THAN YOU ARE?

A. NO.

Q. SO THE USE OF PRESCRIBER LEVEL DATA IN YOUR OPINION CAN ACCELERATE THE NATURAL PROGRESSION OF A DRUG'S UP-TAKE?

[1096] A. NO. THE USE OF PRESCRIBER LEVEL DATA – WELL I MEAN THE USE OF PRESCRIBER LEVEL DATA CAN OVER ACCELERATE IT. I THINK IF A DRUG IS MEANT TO BE PRESCRIBED IN A CERTAIN POPULATION AND HAS CERTAIN INDICATIONS THAT IT WILL, IT WILL – THE UP-TAKE OF THAT PRODUCT WILL OCCUR AS IT SHOULD. AND THE PRESCRIBER LEVEL DATA IS USED EXCLUSIVELY FOR, TO, FOR MARKETING AND PROMOTIONAL REASONS AND TO TRY TO, AND TO TRY TO OVER INFLUENCE PHYSICIAN'S PRESCRIBING PRACTICES AND CAN BE DETRIMENTAL IN THAT IT CAN LEAD TO OVER PRESCRIPTION AND OVER ACCELERATION OF A NEW DRUG'S UP-TAKE.

Q. AND SO ONCE ONE OF THOSE RISKS WOULD BE WHAT WE DISCUSSED EARLIER WITH VIOXX?

A. SURE. I THINK THE EXAMPLE OF VIOXX IS A GOOD ONE WHERE, YOU KNOW, DETAILERS WENT TO PHYSICIAN'S OFFICES ARMED WITH THIS INFORMATION ABOUT THE NON-STEROIDAL DRUGS THAT THEY PRESCRIBED AND TALKED TO THEM ABOUT THE PAIN CONTROL. BENEFITS OF VIOXX AND, YOU KNOW, USED THIS INFORMATION TO HELP TAILOR THEIR MESSAGES. AND WHAT WE SAW WAS A – AND DUE TO THAT PROCESS, AS WELL AS A NUMBER OF OTHER PROCESSES, UM, THAT, YOU KNOW, ARE INVOLVED IN THE PROMOTIONAL PROCESS, WHAT WE SAW WAS A LARGE OVEREXPANSION OF THE USE OF VIOXX AFTER IT WAS OUT ON THE MARKET.

SO THAT ULTIMATELY, YOU KNOW, A FEW YEARS LATER WHEN THESE REPORTS OF THE CARDIOVASCULAR SIDE EFFECTS ULTIMATELY WERE MADE PUBLIC AND BECAME WIDESPREAD AND [1097] ULTIMATELY VIOXX WAS WITHDRAWN FROM THE MARKET MANY MORE PATIENTS HAD BEEN EXPOSED TO THIS PRODUCT THAN WOULD OTHERWISE BE.

Q. DID BAYCOL EXPERIENCE A SIMILAR PHENOMENON?

A. SURE. BAYCOL IS A CHOLESTEROL LOWERING DRUG THAT UM, WAS SIMILARLY

ASSOCIATED WITH, WITH ADVERSE AND FATAL EVENTS AND WAS APPROVED AND VERY DETERMINEDLY PROMOTED BY ITS MANUFACTURER AND OVERUSED AND ULTIMATELY WHEN THE, YOU KNOW, THE REPORTS OF MORTALITY WERE MADE PUBLIC UM, AND IT WAS WITHDRAWN FROM THE MARKET MANY MORE PATIENTS WERE EXPOSED TO THESE RISKS AND SUFFERED THESE DAMAGES THAN, THAN SHOULD HAVE BEEN.

Q. AND THAT WAS A CHOLESTEROL LOWERING DRUG YOU SAID SO THAT WAS A DRUG FOR WHICH THERE WAS NUMEROUS ALTERNATIVES THAT COULD HAVE BEEN PRESCRIBED?

A. YES. THIS WAS NOT THE FIRST CHOLESTEROL LOWERING DRUG. IT WAS, YOU KNOW, FOURTH OR FIFTH. AND THERE WERE, AGAIN, NUMEROUS ALTERNATIVES THAT, AS YOU SAID, THERE WERE NUMEROUS ALTERNATIVES THAT HAVE BEEN PRESCRIBED IN ITS PLACE. BUT, YOU KNOW, THE DRUG WAS PROMOTED AND THAT LED TO AN OVEREXPANSION OF USE OF THE PRODUCT.

Q. AND AN OVEREXPANSION WOULD ALSO APPLY TO THE CALCIUM CHANNEL BLOCKERS THAT WERE STUDIED IN THE ALLHAT, THE NIH ALLHAT STUDY?

A. YES. BACK IN THE 1990'S WHEN CALCIUM CHANNEL BLOCKERS [1098] WERE PATENT PROTECTED AND HAD RECENTLY BEEN PUT

OUT ON THE MARKET THERE WAS A CONCERTED EFFORT TO PROMOTE THESE PRODUCTS. AND THEY WERE – SO REPRESENTATIVES IN PHYSICIAN'S OFFICES HELPED LEAD TO AN EXPANSION OF THE USE OF CALCIUM CHANNEL BLOCKERS AS A FIRST LINE THERAPY FOR HIGH BLOOD PRESSURE WHEN THE GUIDELINES INDICATED THAT HYDROCHLOROTHIAZIDE, WHICH IS THE DIURETIC, WAS THE MORE REASONABLE CHOICE FOR A FIRST LINE AGENT.

\* \* \*

[1100] Q. NOW, WAS THERE ANY STUDIES OR ANY DETERMINATIONS MADE ON WHAT THE COSTS OF THE USE OF THOSE CALCIUM CHANNEL BLOCKERS INSTEAD OF THE DIURETICS REPRESENT?

A. ONE STUDY SHOWED THAT THOSE, THAT THE OVERUSE OF CALCIUM CHANNEL BLOCKERS FROM THE LATE 1990'S WHEN HYDROCHLOROTHIAZIDE OR A LESS EXPENSIVE BLOOD PRESSURE LOWERING PRODUCT MIGHT HAVE BEEN PRESCRIBED LED TO, YOU KNOW, BILLIONS OF DOLLARS IN EXCESS COSTS FOR UM, GOVERNMENT PROGRAMS.

[1101] Q. AND THEN OTHER EXAMPLES THAT YOU'VE ALREADY DISCUSSED, THE NEXIUM AND LIPITOR, THOSE ARE JUST OTHER EXAMPLES THAT WOULD ALSO REPRESENT

INCREASED FINANCIAL BURDEN TO THE SYSTEM?

A. YEAH. THEY ARE, YOU KNOW, AGAIN, OTHER, ANOTHER, ANOTHER CASE EXAMPLE IS NEXIUM WHICH, YOU KNOW, I DID A STUDY ON LOOKING AT THE PRESCRIPTIONS OF NEXIUM AND PRILOSEC IN MEDICAID AND FOUND THAT IF A LOW COST GENERIC PRILOSEC WAS AVAILABLE WHEN IT SHOULD HAVE BEEN, AND WAS PRESCRIBED IN THE PLACE OF THE BRAND NAME PRILOSEC AND THE BRAND NAME NEXIUM, THE MEDICAID PROGRAMS, YOU KNOW, FROM 2001 TO 2005 COULD HAVE SAVED HUNDREDS OF MILLIONS, \$800 MILLION IN COSTS THAT, YOU KNOW, OVER THE, OVER THE 50 STATES THAT THOSE MEDICAID PROGRAMS COULD HAVE USED TO HELP MEET THEIR BUDGETS AND PROVIDE OTHER SERVICES

\* \* \*

[1103] Q. IS YOUR RESEARCH RELIANT ON THE USE OF PRESCRIBER LEVEL DATA?

A. WELL, I MEAN THERE IS RESEARCH – YES, YOU CAN DO RESEARCH USING PRESCRIBER LEVEL DATA THAT HELPS, THAT CAN HELP IDENTIFY TRENDS IN PHYSICIAN PRESCRIBER AND PHYSICIAN PRESCRIPTION PRACTICES. AND THERE ARE STUDIES THAT OUR GROUP HAS DONE THAT LINK PHYSICIANS TO THE PRESCRIPTIONS THAT THEY

PROVIDE TO PATIENTS. AND WE USE THAT INFORMATION FOR RESEARCH AND EDUCATIONAL RESEARCH PURPOSES THAT, YOU KNOW, HELP INFORM, YOU KNOW, THE MEDICAL COMMUNITY ABOUT WHAT, YOU KNOW, TRENDS IN PHYSICIAN PRESCRIBING PRACTICES ARE.

SO WE DO – WE HAVE USED PRESCRIBER LEVEL DATA FOR RESEARCH PURPOSES.

[1104] Q. AND ARE YOU AWARE THAT THE VERMONT LAW PERMITS THE USE OF PRESCRIBER LEVEL DATA FOR RESEARCH PURPOSES?

A. YES. IT SPECIFICALLY PERMITS THAT.

Q. NOW, THERE'S SOME SUGGESTION THAT IF THEY CAN'T SELL IT FOR MARKETING PURPOSES THESE POOLS OF PRESCRIBER LEVEL DATA WILL DRY UP AND THEY WOULD NOT BE AVAILABLE FOR RESEARCH PURPOSES. ARE THERE OTHER RESOURCES THAT YOU USE?

A. YEAH. WE USE STATE LEVEL INFORMATION AND OTHER, AND OTHER DATABASES TO LINK THE DATA. WE DON'T USE THE, THE IMS OR OTHER SORT OF THE COMPANIES BECAUSE THE COSTS ARE FAR TOO EXPENSIVE FOR US.

\* \* \*

[1108] Q. AND YOU'VE NEVER DONE A STUDY OF PRESCRIBER-IDENTIFIABLE DATA; IS THAT RIGHT?

A. NO.

Q. AND YOU ARE NOT AWARE OF ANY STUDIES BY ANYONE ELSE CONCERNING PRESCRIBER-IDENTIFIABLE DATA?

A. NO.

Q. AND YOU DON'T KNOW OF ANY STUDIES ON PRESCRIBER-IDENTIFIABLE DATA THAT ARE NOT YET COMPLETED; RIGHT?

A. THAT'S RIGHT.

Q. AND THERE'S NOTHING IN THIS LITERATURE THAT IS ASSESSED IN AN EMPIRICAL WAY WHERE THE LIMITS ON PRESCRIBER DATA WILL RESULT IN INCREASES OR DECREASES IN HEALTH COSTS?

[1109] A. THAT'S RIGHT.

\* \* \*

[1115] Q. SO, DOCTOR, A SALES REPRESENTATIVE USING PRESCRIBER DATA COULD PROVIDE AN ACCURATE DESCRIPTION OF THE DRUG; RIGHT?

A. I'M SORRY?

Q. A SALES REPRESENTATIVE USING PRESCRIBER DATA COULD PROVIDE AN ACCURATE DESCRIPTION OF THE DRUG?

A. SURE.

Q. AND AS YOU UNDERSTAND ACT 80 IT APPLIES, IT RESTRICTS THE MARKETING IN THAT SITUATION?

A. I THINK IT TAKES, YOU KNOW, A PHARMACEUTICAL SALES REPRESENTATIVE COULD GO IN THERE AND TALK ABOUT THE BENEFITS AND STUDIES OF A DRUG UM, AND DOESN'T NEED THE PRESCRIBER-IDENTIFIABLE DATA TO DO THAT.

Q. AND A SALES REPRESENTATIVE NOT USING PRESCRIBER DATA COULD STILL OVERSTATE THE BENEFITS OF THE DRUG; RIGHT?

A. YES.

Q. NOW, SOME NEW DRUGS ARE WIDELY USED BECAUSE OF THEIR CLINICAL ADVANCEMENTS; RIGHT?

A. YES.

Q. AND ACT 80 APPLIES TO THE MARKETING OF THOSE DRUGS?

A. UM, YEAH. IT APPLIES TO ALL DRUGS.

[1116] Q. AND SOME NEW DRUGS ARE WIDELY USED BECAUSE PATIENTS ARE MORE

LIKELY TO TAKE THEM AS PRESCRIBED;  
RIGHT?

A. I MEAN, YOU KNOW, A DRUG IS –  
SHOULD BE APPROPRIATELY USED AS THE  
INDICATIONS SAY. AND IF THE STUDIES SHOW  
THAT A DRUG, THAT ONE DRUG IS MORE LIKE-  
LY TO BE USED THAN ANOTHER THEN THAT  
DRUG – AND ITS APPROPRIATE TO PRESCRIBE  
IN THAT CASE THEN YOU SHOULD PRESCRIBE  
THAT DRUG.

Q. AND COMPLIANCE IS IMPORTANT IN  
THE PRESCRIPTION OF DRUGS; RIGHT?

A. YES.

Q. AND SO SOME DRUGS HAVE AN IM-  
PROVED RECORD OF COMPLIANCE?

A. YES.

Q. AND ACT 80 WOULD APPLY TO THE  
MARKETING OF THOSE DRUGS?

A. YES.

Q. AND THE USE OF SOME NEW DRUGS  
MIGHT ACTUALLY DECREASE HEALTHCARE  
COSTS COULDN'T THEY?

A. UM, I MEAN, YOU KNOW, IF A NEW  
DRUG IS PROVIDED THAT, YOU KNOW, PRE-  
VENTS A PATIENT FROM NEEDING SURGERY  
UM, THEN PRESCRIPTION OF THAT DRUG

WOULD BE A, YOU KNOW, COST EFFECTIVE OVER THE SURGICAL OPTION.

Q. AND ACT 80 APPLIES TO THE MARKET-ING OF THOSE DRUGS?

A. YEAH.

Q. AND, IN FACT, AS YOU'VE INDICATED ACT 80 DOES NOT DISCRIMINATE BETWEEN DIFFERENT TYPES OF DRUGS; RIGHT?

[1117] A. RIGHT

Q. IT APPLIES EQUALLY TO THOSE DRUGS THAT ARE VERY BENEFICIAL TO PATIENTS AND THOSE THAT MIGHT NOT BE?

A. RIGHT.

\* \* \*

[1121] Q. IN FACT, YOU CANT PREDICT HOW PHARMACEUTICAL COMPANIES WOULD REACT TO ACT 80?

A. NO.

Q. AND, FOR EXAMPLE, THEY COULD INCREASE THE RESOURCES FOR DETAILING?

A. UM, THEY COULD.

Q. THEY COULD VISIT WITH MORE DOC-TORS?

A. THEY COULD.

Q. YOU JUST DON'T KNOW HOW, WHAT THE PHARMACEUTICAL COMPANIES WILL DO IF THIS ACT PASSES?

A. YES.

Q. OR IS EFFECTIVE?

A. RIGHT. BUT I THINK WE SHOULD GIVE IT A SHOT THOUGH.

\* \* \*

[1130] Q. DO YOU RECALL TESTIFYING THAT PRESCRIBER-IDENTIFIABLE DATA WAS USED TO TARGET A COUNTER DETAILING MESSAGE TO PARTICULAR PHYSICIANS?

A. WELL, WE USE THE DATA GIVEN TO US BY THE STATE OF PENNSYLVANIA TO IDENTIFY WHICH PHYSICIANS PRESCRIBE MEDICATIONS TO THEIR UM, TO THE CORPORATE – TO THE PEOPLE WHO ARE CARED FOR BY THE, BY THE PENNSYLVANIA STATE AUTHORITIES. SO, YOU KNOW, THAT, THAT WAY WE USE THE [1131] MESSAGE TO FIGURE OUT WHICH PHYSICIANS TO TALK TO.

\* \* \*

---

VERMONT MEDICAL SOCIETY  
RESOLUTION

*Adopted on October 14, 2006*

**Ensuring the Privacy of  
Prescription Information**

Whereas, prescription drugs are the fastest growing component of health care spending in Vermont,

Whereas, spending on pharmaceutical marketing to doctors in the United States increased by over 200 percent between 1996 and 2004,<sup>1</sup>

Whereas, the most recent report by the Vermont Attorney General shows that marketing to physicians by pharmaceutical manufactures in Vermont for July 1, 2004 – June 30, 2005 totaled \$2.17 million, an 11% increase from the previous year,<sup>2</sup>

Whereas, the doctor-patient relationship requires confidentiality and privacy to work effectively,

Whereas, according to a story in the New York Times, two-thirds of physicians oppose access to physician prescribing information for pharmaceutical company sales representatives,<sup>3</sup>

---

<sup>1</sup> Kaiser Family Foundation, "Trends and Indicators in the Changing Health Care Marketplace," 2005. <http://www.kff.org/insurance/7031/print-sec1.cfm>.

<sup>2</sup> "2006 Pharmaceutical Marketing Disclosures Report", Vermont Attorney General. [http://www.atg.state.vt.us/upload/1150802902\\_2006\\_Pharmaceutical\\_Marketing\\_Disclosures\\_Report.pdf](http://www.atg.state.vt.us/upload/1150802902_2006_Pharmaceutical_Marketing_Disclosures_Report.pdf).

<sup>3</sup> Stephanie Saul, Doctors Object to Gathering of Drug Data, NY Times, Business Section, May 4, 2006.

Whereas, sales representatives create physician prescribing profiles that allow for tailored sale pitches in order to convince physicians to prescribe their brand name drug, rather than a competitor's or generic drug,

Whereas, the combination of detailed marketing profiles and the provision of marketing incentives for physicians by pharmaceutical representatives raises the possibility that representatives could exert too much influence on prescription patterns,

Whereas, the information obtained by the pharmaceutical companies is used only for marketing to individual physicians, and restriction of that information would not impact federal or state reporting requirements regarding care management, clinical intervention, or research, and information could still be collected in aggregate form,

Whereas, restricting pharmaceutical companies' access to information used for marketing to individual physicians would not impact federal or state reporting requirements regarding care management, clinical intervention, or research, and would not impact health insurer or practitioner access to information for purposes of treatment, payment, utilization review, quality review or other similar activities.

Whereas, while patient information is de-identified, in small communities identifying a drug prescription can equal the release of an individual's diagnosis,

Whereas, the use of physician prescription information by sales representatives is an intrusion into the way physicians practice medicine; therefore, be it

**RESOLVED, that the Vermont Medical Society work with appropriate consumer organizations and the Vermont Attorney General to enact legislation, similar to legislation recently enacted in New Hampshire that would prohibit the disclosure of physician's prescribing information for any commercial purpose while permitting legitimate uses such as reporting requirements and research.**<sup>4</sup>

---

<sup>4</sup> New Hampshire HB 1346. <http://www.gencourt.state.nh.us/legislation/2006/HB1346.html>.

---

*The New York Times*

---

November 16, 2000

**High-Tech Stealth Being Used To Sway Doctor Prescriptions**

**By SHERYL GAY STOLBERG AND JEFF GERTH**

\* \* \*

Doctors who do not want their names sent to marketers can ask the association to remove them from the file, Dr. Reardon said. But in interviews, several prominent doctors said they were unaware that their biographies were being sold.

Among them is Dr. Christine K. Cassel, a former president of the American College of Physicians and chairman of the department of geriatrics at Mount Sinai School of Medicine in Manhattan. In Dr. Cassel's view, information about doctors' prescribing habits may appropriately be used by their health plans to improve quality of care. She called the commercial use of the data outrageous, saying, "This is not about quality. It's about sales."

\* \* \*

---

Dear Senators and Representatives of the State of Maine,

I am writing in SUPPORT of your important move to enact LD 838: An Act Protecting the Confidentiality of Prescription Information.

Everyday I receive glossy mailings encouraging me to prescribe this or that brand or formulation of medicine.

I don't get my information from these vehicles of propaganda any more than I would trust information on new medications from watching TV commercials. I work hard to stay unbiased about how to practice medicine and what medications and treatments are objectively best. I subscribe to journals and websites to obtain recommendations untainted by a drug company's desire to make a buck at my expense and that of my patients health and pocketbook.

Like the majority of physicians, I don't want my prescribing habits monitored so that organizations and corporations can profit by selling or using that information with the goal of trying to then subvert what I do.

I strongly support the enactment of LD 838: An Act Protecting the Confidentiality of Prescription Information.

Sincerely,  
Richard Entel MD

Medical Director  
Islands Community Medical Services  
Vinalhaven, Maine

---

Benjamin Schaefer, MD  
Northeast Cardiology Associates  
One Northeast Drive  
Bangor, ME 04401  
(207) 949 4816

I am writing this to give testimony in support of LDL 838 (“Act Protecting the Confidentiality of Prescription Information”). I am a practicing cardiologist in Bangor, taking care of patients from Waterville all the way to Fort Kent. I am also the chair of a task force of the National Physicians Alliance (NPA) that is promoting the ban of the sale of prescriber data nationwide.

The objective of the bill is clear: to ban the license, use, sale, transfer or exchange of physician prescriber information for any **commercial** purpose.

### **What goes on?**

The cost of drugs is one of the fastest growing expenditures in health care (1) and in recent years, aggressive pharmaceutical marketing has contributed to inappropriate prescribing of expensive brand name drugs. Currently, data on prescriptions written by individual physicians is sold by pharmacies to “Health Information Organizations”. Personal profiles on each physician are constructed by linking this pharmacy data with personal information sold by the American Medical Association (AMA). These profiles are then sold to pharmaceutical companies, which uses the information to target specific providers with tailored

marketing strategies designed to influence their prescribing behavior (2). Unfortunately we know from multiple studies that although physicians may deny being influenced by industry provided incentives such as free lunch, it is quite effective. Prescribing data has been called the “greatest tool in planning (an) approach to manipulating doctors.” (3) Three quarters of physicians in the U.S. disapprove of the sale of their prescribing data to drug companies, as shown in a study by the Kaiser Family Foundation (4). The AMA claims to have addressed this and it has instituted a little-advertised “opt out” policy, which is limited to three years at a time. It also only restricts access to the data by sales representatives that come in direct contact with the physician (5). The data would still be sold. The AMA makes over \$44 million from the sale database products, among them the sale of physicians’ individual data (6).

### **Why should the sale be stopped?**

In my view, this sale leads to the following:

- Physicians are targeted to prescribe ‘new’ medicines, which are often not more effective than older, generic drugs; have less of a safety record; and are generally more expensive. Furthermore, studies have shown that sales representatives gear their presentation towards the beneficial effects of the new drugs and minimize the risks (7-9). The Vioxx® story can serve as a prime example here. The effects are readily

apparent: higher healthcare cost, and potentially less safety.

- Although now strictly regulated, there is ample evidence that off label use of new medications has been actively promoted by the industry. An exemplary case is the promotion of Neurotin® by Lambert-Warner (now Pfizer), which led to a \$430 million dollar fine. Availability of prescribing data facilitates this practice.

- Last but not least, the privacy and trust of the physician-patient relationship is disturbed.

\* \* \*

---

## POLICY FORUM

**Following the Script: How Drug Reps Make Friends and Influence Doctors****Adriane Fugh-Berman\***, Shahram Ahari

**Citation:** Fugh-Berman A, Ahari S (2007) Following the Script: How Drug Reps Make Friends and Influence Doctors. *PLoS Med* 4(4): e150. doi:10.1371/journal.pmed.0040150

**Published:** April 24, 2007

**Copyright:** © 2007 Fugh-Berman and Ahari. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

**Funding:** This work was supported by a grant from the Attorney General Prescriber and Consumer Education Grant Program, created as part of a 2004 settlement between Warner-Lambert, a division of Pfizer, and the Attorneys General of 50 States and the District of Columbia, to settle allegations that Warner-Lambert conducted an unlawful marketing campaign for the drug Neurontin (gabapentin) that violated state consumer protection laws.

**Competing interests:** Shahram Ahari is a former pharmaceutical sales representative for Eli Lilly, and the primary findings of this paper summarize points he made in testimony as a paid expert witness on the defendant's side in litigation against a New Hampshire law prohibiting

the sale of prescription data. Adriane Fugh-Berman has accepted payment as an expert witness on the plaintiff's side in litigation regarding menopausal hormone therapy.

**Abbreviations:** AMA, American Medical Association

\*To whom correspondence should be addressed.  
E-mail:ajf29@georgetown.edu

Adriane Fugh-Berman is an Associate Professor in the Department of Physiology and Biophysics, Georgetown University Medical Center, Washington, District of Columbia, United States of America. Shahram Ahari is with the School of Pharmacy, University of California San Francisco, San Francisco, California, United States of America.

---

*It's my job to figure out what a physician's price is. For some it's dinner at the finest restaurants, for others it's enough convincing data to let them prescribe confidently and for others it's my attention and friendship . . . but at the most basic level, everything is for sale and everything is an exchange.*

– Shahram Ahari

*You are absolutely buying love.*

– James Reidy [1]

In 2000, pharmaceutical companies spent more than 15.7 billion dollars on promoting prescription drugs in the United States [2]. More than 4.8 billion dollars was spent on detailing, the one-on-one promotion of

drugs to doctors by pharmaceutical sales representatives, commonly called drug reps. The average sales force expenditure for pharmaceutical companies is \$875 million annually [3].

Unlike the door-to-door vendors of cosmetics and vacuum cleaners, drug reps do not sell their product directly to buyers. Consumers pay for prescription drugs, but physicians control access. Drug reps increase drug sales by influencing physicians, and they do so with finely titrated doses of friendship. This article, which grew out of conversations between a former drug rep (SA) and a physician who researches pharmaceutical marketing (AFB), reveals the strategies used by reps to manipulate physician prescribing.

#### BETTER THAN YOU KNOW YOURSELF

*During training, I was told, when you're out to dinner with a doctor, "The physician is eating with a friend. You are eating with a client."*

– Shahram Ahari

Reps may be genuinely friendly, but they are not genuine friends. Drug reps are selected for their presentability and outgoing natures, and are trained to be observant, personable, and helpful. They are also trained to assess physicians' personalities, practice styles, and preferences, and to relay this information back to the company. Personal information may be more important than prescribing preferences. Reps ask for and remember details about a physician's

family life, professional interests, and recreational pursuits. A photo on a desk presents an opportunity to inquire about family members and memorize whatever tidbits are offered (including names, birthdays, and interests); these are usually typed into a database after the encounter. Reps scour a doctor's office for objects – a tennis racquet, Russian novels, seventies rock music, fashion magazines, travel mementos, or cultural or religious symbols – that can be used to establish a personal connection with the doctor.

Good details are dynamic; the best reps tailor their messages constantly according to their client's reaction. A friendly physician makes the rep's job easy, because the rep can use the "friendship" to request favors, in the form of prescriptions. Physicians who view the relationship as a straightforward goods-for-prescriptions exchange are dealt with in a business-like manner. Skeptical doctors who favor evidence over charm are approached respectfully, supplied with reprints from the medical literature, and wooed as teachers. Physicians who refuse to see reps are detailed by proxy; their staff is dined and flattered in hopes that they will act as emissaries for a rep's messages. (See Table 1 for specific tactics used to manipulate physicians.)

### **Table 1. Tactics for Manipulating Physicians**

[Graphic Omitted]

Gifts create both expectation and obligation. "The importance of developing loyalty through gifting

cannot be overstated,” writes Michael Oldani, an anthropologist and former drug rep [26]. Pharmaceutical gifting, however, involves carefully calibrated generosity. Many prescribers receive pens, notepads, and coffee mugs, all items kept close at hand, ensuring that a targeted drug’s name stays uppermost in a physician’s subconscious mind. High prescribers receive higher-end presents, for example, silk ties or golf bags. As Oldani states, “The essence of pharmaceutical gifting . . . is ‘bribes that aren’t considered bribes’” [1].

Reps also recruit and audition “thought leaders” (physicians respected by their peers) to groom for the speaking circuit. Physicians invited and paid by a rep to speak to their peers may express their gratitude in increased prescriptions (see Table 1). Anything that improves the relationship between the rep and the client usually leads to improved market share.

#### SCRIPT TRACKING

---

*An official job description for a pharmaceutical sales rep would read: Provide health-care professionals with product information, answer their questions on the use of products, and deliver product samples. An unofficial, and more accurate, description would have been: Change the prescribing habits of physicians.*

– James Reidy [4]

Pharmaceutical companies monitor the return on investment of detailing – and all promotional efforts –

by prescription tracking. Information distribution companies, also called health information organizations (including IMS Health, Dendrite, Verispan, and Wolters Kluwer), purchase prescription records from pharmacies. The majority of pharmacies sell these records; IMS Health, the largest information distribution company, procures records on about 70% of prescriptions filled in community pharmacies. Patient names are not included, and physicians may be identified only by state license number, Drug Enforcement Administration number, or a pharmacy-specific identifier [5]. Data that identify physicians only by numbers are linked to physician names through licensing agreements with the American Medical Association (AMA), which maintains the Physician Masterfile, a database containing demographic information on all US. physicians (living or dead, member or non-member, licensed or non-licensed). In 2005, database product sales, including an unknown amount from licensing Masterfile information, provided more than \$44 million to the AMA [5].

Pharmaceutical companies are the primary customers for prescribing data, which are used both to identify “high-prescribers” and to track the effects of promotion. Physicians are ranked on a scale from one to ten based on how many prescriptions they write. Reps lavish high-prescribers with attention, gifts, and unrestricted “educational” grants (Table 1). Cardiologists and other specialists write relatively few prescriptions, but are targeted because specialist

prescriptions are perpetuated for years by primary care physicians, thus affecting market share.

Reps use prescribing data to see how many of a physician's patients receive specific drugs, how many prescriptions the physician writes for targeted and competing drugs, and how a physician's prescribing habits change over time. One training guide states that an "individual market share report for each physician . . . pinpoints a prescriber's current habits" and is "used to identify which products are currently in favor with the physician in order to develop a strategy to change those prescriptions into Merck prescriptions" [6].

A *Pharmaceutical Executive* article states, "A physician's prescribing value is a function of the opportunity to prescribe, plus his or her attitude toward prescribing, along with outside influences. By building these multiple dimensions into physicians' profiles, it is possible to understand the 'why' behind the 'what' and 'how' of their behavior." [7] To this end, some companies combine data sources. For example, Medical Marketing Service "enhances the AMA Masterfile with non-AMA data from a variety of sources to not only include demographic selections, but also behavioral and psychographic selections that help you to better target your perfect prospects" [8].

The goal of this demographic slicing and dicing is to identify physicians who are most susceptible to marketing efforts. One industry article suggests categorizing physicians as "hidden gems": "Initially considered

'low value' because they are low prescribers, these physicians can change their prescribing habits after targeted, effective marketing." "Growers" are "Physicians who are early adopters of a brand. Pharmaceutical companies employ retention strategies to continue to reinforce their growth behavior." Physicians are considered "low value" "due to low category share and prescribing level" [9].

In an interview with *Pharmaceutical Representative*, Fred Marshall, president of Quantum Learning, explained, ". . . One type might be called 'the spreader' who uses a little bit of everybody's product. The second type might be a 'loyalist', who's very loyal to one particular product and uses it for most patient types. Another physician might be a 'niche' physician, who reserves our product only for a very narrowly defined patient type. And the idea in physician segmentation would be to have a different messaging strategy for each of those physician segments" [10].

In *Pharmaceutical Executive*, Ron Brand of IMS Consulting writes ". . . integrated segmentation analyzes individual prescribing behaviors, demographics, and psychographics (attitudes, beliefs, and values) to fine-tune sales targets. For a particular product, for example, one segment might consist of price-sensitive physicians, another might include doctors loyal to a given manufacturers brand, and a third may include those unfriendly towards reps" [11].

In recent years, physicians have become aware of – and dismayed by – script tracking. In July 2006, the

AMA launched the Prescribing Data Restriction Program (see <http://www.ama-assn.org/ama/pub/category/12054.html>), which allows physicians the opportunity to withhold most prescribing information from reps and their supervisors (anyone above that level, however, has full access to all data). According to an article in *Pharmaceutical Executive*, “Reps and direct managers can view the physician’s prescribing volume quantiled at the therapeutic class level” and can still view aggregated or segmented data including “categories into which the prescriber falls, such as an early-adopter of drugs, for example. . . .” [12]. The pharmaceutical industry supports the Prescribing Data Restriction Program, which is seen as a less onerous alternative to, for example, state legislation passed in New Hampshire forbidding the sale of prescription data to commercial entities [13].

#### THE VALUE OF SAMPLES

The purpose of supplying drug samples is to gain entry into doctors’ offices, and to habituate physicians to prescribing targeted drugs. Physicians appreciate samples, which can be used to start therapy immediately, test tolerance to a new drug, or reduce the total cost of a prescription. Even physicians who refuse to see drug reps usually want samples (these docs are denigrated as “sample-grabbers”). Patients like samples too; it’s nice to get a little present from the doctor. Samples also double as unacknowledged gifts to physicians and their staff. The convenience of an

in-house pharmacy increases loyalty to both the reps and the drugs they represent.

Some physicians use samples to provide drugs to indigent patients [14,15]. Using samples for an entire course of treatment is anathema to pharmaceutical companies because this “cannibalizes” sales. Among the aims of one industry sample-tracking program are to “reallocate samples to high-opportunity prescribers most receptive to sampling as a promotional vehicle” and “identify prescribers who were over-sampled and take corrective action immediately” [16].

Studies consistently show that samples influence prescribing choices [14,15,17]. Reps provide samples only of the most promoted, usually most expensive, drugs, and patients given a sample for part of a course of treatment almost always receive a prescription for the same drug.

#### FUNDING FRIENDSHIP

*While it's the doctors' job to treat patients and not to justify their actions, it's my job to constantly sway the doctors. It's a job I'm paid and trained to do. Doctors are neither trained nor paid to negotiate. Most of the time they don't even realize that's what they're doing . . .*

– Shahram Ahari

Drug costs now account for 10.7% of health-care expenditures in the US [18]. In 2004, spending for prescription drugs was \$188.5 billion, almost five

times as much as what was spent in 1990 [19]. Between 1995 and 2005, the number of drug reps in the US increased from 38,000 to 100,000 [20], about one for every six physicians. The actual ratio is close to one drug rep per 2.5 targeted doctors [21], because not all physicians practice, and not all practicing physicians are detailed. Low-prescribers are ignored by drug reps.

Physicians view drug information provided by reps as a convenient, if not entirely reliable, educational service. An industry survey found that more than half of “high-prescribing” doctors cited drug reps as their main source of information about new drugs [22]. In another study, three quarters of 2,608 practicing physicians found information provided by reps “very useful” (15%) or “somewhat useful” (59%) [23]. However, only 9% agreed that the information was “very accurate”; 72% thought the information was “somewhat accurate”; and 14% said that it was “not very” or “not at all” accurate.

Whether or not physicians believe in the accuracy of information provided, detailing is extremely effective at changing prescribing behavior, which is why it is worth its substantial expense. The average annual income for a drug rep is \$81,700, which includes \$62,400 in base salary plus \$19,300 in bonuses. The average cost of recruiting, hiring, and training a new rep is estimated to be \$89,000 [24]. When expenses are added to income and training, pharmaceutical companies spend \$150,000 annually per primary care sales representative and \$330,000 per specialty sales

representative [25]. An industry article states, “The pharmaceutical industry averages \$31.9 million in annual sales spending per primary-care drug . . . Sales spending for specialty drugs that treat a narrowed population segment average \$25.3 million per product across the industry.” [25]

#### CONCLUSION

---

As one of us (SA) explained in testimony in the litigation over New Hampshire’s new ban on the commercial sale of prescription data, the concept that reps provide necessary services to physicians and patients is a fiction. Pharmaceutical companies spend billions of dollars annually to ensure that physicians most susceptible to marketing prescribe the most expensive, most promoted drugs to the most people possible. The foundation of this influence is a sales force of 100,000 drug reps that provides rationed doses of samples, gifts, services, and flattery to a subset of physicians. If detailing were an educational service, it would be provided to all physicians, not just those who affect market share.

Physicians are susceptible to corporate influence because they are overworked, overwhelmed with information and paperwork, and feel underappreciated. Cheerful and charming, bearing food and gifts, drug reps provide respite and sympathy; they appreciate how hard doctor’s lives are, and seem only to want to ease their burdens. But, as SA’s New Hampshire testimony reflects, every word, every courtesy, every

gift, and every piece of information provided is carefully crafted, not to assist doctors or patients, but to increase market share for targeted drugs (see Table 1). In the interests of patients, physicians must reject the false friendship provided by reps. Physicians must rely on information on drugs from unconflicted sources, and seek friends among those who are not paid to be friends.

---

**Journal of the House**

---

**THURSDAY, MAY 3, 2007**

\* \* \*

At eight o'clock and forty minutes in the evening, the Speaker called the House to order.

**Consideration Resumed; Proposal  
of Amendment Agreed to and  
Third Reading Ordered****S. 115**

Consideration resumed on Senate bill, entitled

An act relating to increasing transparency of prescription drug pricing and information;

The recurring question, Shall the House amend the recommendation of proposal of amendment offered by the committee on Health Care, as amended? as recommended by Rep. Chen of Mendon? was agreed to on a Division vote. Yeas, 79. Nays, 22.

Pending the question, Shall the House propose to the Senate to amend the bill as recommended by the committee on Health Care, as amended? **Rep. Adams of Hartland** moved to commit the bill to the committee on Judiciary.

Pending the question, Shall the House commit the bill to the committee on Judiciary? **Rep. Adams of Hartland** demanded the Yeas and Nays, which demand was sustained by the Constitutional number.

The Clerk proceeded to call the roll and the question, Shall the House commit the bill to the committee on Judiciary? was decided in the negative. Yeas, 29. Nays, 89.

\* \* \*

**Rep. Flory of Pittsford** explained her vote as follows:

“Madam Speaker:

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 and we dishonor the oath we all took to protect our Constitution.”

Thereupon, the recurring question, Shall the House propose to the Senate to amend the bill as recommended by the committee on Health Care, as amended? was agreed to and third reading ordered.

\* \* \*

---

STATE OF VERMONT  
STATE COMMITTEE ON FINANCE

Re: Senate Bill 115

Date: Friday, February 16, 2007

Type of Committee Meeting: Standard

Committee Members:

Senator Ann Cummings, Chair

Senator Claire Ayer, Vice Chair

Senator Bill Carris

Senator James Condos

Senator Mark MacDonald, Clerk

Senator Hull Maynard, Jr.

Senator Richard McCormack

\* \* \*

[14] MS. MONGAN: Good afternoon. I'm Madeleine Mongan from the Vermont Medical Society, and I'm here to express support for (inaudible) medical society on two sections of the Bill and there may be others that we, you know, have (inaudible) later

\* \* \*

[16] The other Section that I want to speak about is Section 12, the prescription drug data confidentiality section. And I'll start out by giving you a little background. We – the medical society first heard about this issue through the – the New England medical societies, that all the New England states get together and meet twice a year. And New Hampshire was presenting about the law that had just passed in New Hampshire. And what it regulates is the ability of

pharmacies to sell prescription information to data mining companies which – and – and – so that's one piece of it.

\* \* \*

[17] So what we think is that the – these practices may lead to increased prescribing of more expensive drugs; may – you know, more expensive brand drugs when equally effective generics are available.

\* \* \*

[26] MS. MONGAN: And, I mean, we don't have any problem with the insurance companies having that information. It's that when it goes to the data mining companies, to the manufacturing companies and gets into the whole marketing and commercial use, we don't think that's real good.

\* \* \*

---

STATE OF VERMONT  
SENATE CHAMBER  
STATE COMMITTEE ON FINANCE

RE: SENATE BILL 115.

DATE: WEDNESDAY, FEBRUARY 21, 2007

TYPE OF COMMITTEE MEETING: PRESCRIPTION

DRUGS: MARK UP. CD 55/ T1 & T2

COMMITTEE MEMBERS: ROBIN LUNGE,  
LEGISLATIVE COUNSEL

JULIE BRILL, ASSISTANT ATTORNEY GENERAL,  
ATTORNEY GENERAL'S OFFICE

ED MILLER, LOBBYIST, VERMONT POLICE  
ASSOCIATION

STEVE TRUMBELL, LOBBYIST, IMS HEALTH  
MADELEINE MONGAN, VERMONT MEDICAL  
SOCIETY

PAULETTE THABAULT, COMMISSIONER,  
DEPARTMENT OF BANKING, INSURANCE,  
SECURITIES AND HEALTH CARE ADMIN-  
ISTRATION

HERB OLSON, COUNSEL, DEPARTMENT OF  
BANKING, INSURANCE, SECURITIES AND  
HEALTH CARE ADMINISTRATION

CHARLES STORROW, LOBBYIST, EXPRESS  
SCRIPTS

\* \* \*

[47] SENATOR CUMMINGS: Okay. Any  
questions for the Medical Society?

UNIDENTIFIED SPEAKER: Yes. You're  
representing the Vermont doctors?

MS. MONGAN: That's right, yes

UNIDENTIFIED SPEAKER: And yet the American Medical Association is just 180 degrees, and the opt out rate is less than a percent. I'm just –

MS. MONGAN: Yeah. Well, I think that might have something to do with the fact of how busy physicians are. You know, and Steve Kimbell the other day said they're sophisticated. And they are sophisticated about science and about medicine and about treating patients, but they're not really business people and they don't necessarily pay [48] attention to our newsletters that urge them to opt out of the program. So –

MS. BRILL: I can vouch for that.

MS. MONGAN: Yes, and so can we by the things that we send out.

So they are sophisticated, but they're not in business. They didn't know about this. I mean, we heard that our doctors heard about this from the doctors in New Hampshire at a meeting of the New England doctors. And they were – You know, to a doctor that has heard about it they don't think it should be going on, because they think it undermines evidence based prescribing, you know, which is our focus, is on the evidence based prescribing that you're putting in there, transferring from over to the Department of Health. So we think that that's important.

Now, the Medical Society in the AMA. Some members of the Medical Society, I think about five

percent of the docs in Vermont, one of the smallest rates in the country, are members of the American Medical Association which is the national organization for doctors. We're a state membership organization for doctors. We're completely separate.

\* \* \*

---

STATE OF VERMONT  
 S.115 – Prescription Drugs, regulation  
 April 10, 2007

COMMITTEE MEMBERS:

REP. STEVEN MAIER, Chair  
 REP. HARRY CHEN, Vice-Chair  
 REP. SARAH COPELAND-HANZAS  
 REP. FRANCIS McFAUN  
 REP. WILLIAM KEOGH  
 REP. LUCY LERICHE, Clerk  
 REP. VIRGINIA MILKEY  
 REP. PAT O'DONNELL  
 REP. HILDE OJIBWAY  
 REP. SCOTT WHEELER  
 REP. JOHN ZENIE

\* \* \*

[23] UNIDENTIFIED ATTENDEE 2: (inaudible) I'm just going to make, just a comment (inaudible) I actually was never aware of this (inaudible) had I been aware (inaudible) without me knowing [24] it and all after sudden they know every drug I prescribe. This person comes knowing every drug I prescribe, how many I did this month, how many I did last month. I think that's outrageous. And I think that an opt out, I've already opted out but an opt-out clause is obviously a very weak (inaudible).

\* \* \*

[23] MR. KIMBELL: Great. Thank you. The [24] chairman's is Steve Kimbell, and I'm an attorney and lobbyist from Montpelier.

\* \* \*

[29] I can sympathize with Representative Chen's outrage, but I think there's two different issues.

\* \* \*

---

STATE OF VERMONT  
HOUSE COMMITTEE ON HEALTH CARE

Re: Senate Bill 115

Date: Friday, April 13, 2007

Type of Committee Meeting: Standard

Committee Members:

Rep. Steven Maier,      Rep. Harry Chen, Vice-Chair  
Chair

Rep. Francis McFaun    Rep. Sarah Copeland-Hanzas

Rep. William Keogh    Rep. Lucy Leriche, Clerk

Rep. Virginia Milkey   Rep. Pat O'Donnell

Rep. Hilde Ojibway    Rep. Scott Wheeler

Rep. John Zenie

\*           \*           \*

[55] DR. BOERNER: Okay. I am that dreaded thing, I'm a flatlander. I practiced in Boston for 20 years and then moved six years ago to my weekend Vermont house in Reading, Vermont, and took a job with Lane and Nice (phonetic) Associates in Springfield.

Dr. Lane expanded his practice into New Hampshire and he put a satellite in Claremont and I'm the doctor in Claremont. So although I feel like a Vermonter, I practice mostly in New Hampshire unless I'm covering the E.R. near [56] Springfield Hospital. So that's my story, that's who I am.

\*           \*           \*

[69] REPRESENTATIVE CHEN: Doctor, we've heard that – that some of the prescriber identified information is used to – by drug companies to notify people of problems related to drugs. Do you feel that your ability –

DR. BOERNER: No, that's done by the pharmacist – the pharmacies and the health plans.

REPRESENTATIVE CHEN: So you don't think [70] that that's a problem.

DR. BOERNER: The pharmacy – the pharmacy catches that. You get – the pharmacy will call you and say, your lady, she's already on X, you can't do Y. And I go thank you.

Did she tell you she's allergic to this?

I go, no.

REPRESENTATIVE McFAUN: But what about things that are you know, like FDA notices or things like that of drugs that are – you know, that maybe indications have changed –

DR. BOERNER: Well, that comes out to me, I get those all the time. They're mailed to me by the companies even for drugs I don't particularly use. I get that. The government – FDA is real good about sending letters out.

\* \* \*

[71] DR. BOERNER: Please, please, it's a wonderful, wonderful, wonderful idea to not be spying

on doctors and having the reps come back and make us feel guilty for not doing what they want us to do.

Thank you for your attention. Thank you for taking this up. I really appreciate it.

\* \* \*



STATE OF VERMONT  
HOUSE COMMITTEE ON HEALTH CARE

Re: Senate Bill 115

Date: Friday, April 20, 2007

Type of Committee Meeting: Standard

Committee Members:

Rep. Steven Maier,      Rep. Harry Chen, Vice-Chair  
Chair

Rep. Francis McFaun    Rep. Sarah Copeland-Hanzas

Rep. William Keogh    Rep. Lucy Leriche, Clerk

Rep. Virginia Milkey   Rep. Pat O'Donnell

Rep. Hilde Ojibway    Rep. Scott Wheeler

Rep. John Zenie

\*           \*           \*

[2] DR. LANDRY: All right. I can give you my background so you can know in terms of – I really have a great interest in the pharmaceutical industry dating back to about 15 years where I actually did research on – just given to physicians and public opinion regarding that, as well as I served on many hospital regularization committees here at Fletcher Allen. I did that for a period of years and the covering on that one, but [3] military both at Walter Reed and Madigan Medical Center.

I've served on regularization committees for the government and also now in Vermont I think I've been on the Drug Utilization Regularization committee for, oh, for the last three to four years. So I bring that experience.

The other part of my experience is I have a large private practice, mainly geriatric practice so I prescribe a lot of medications.

\* \* \*

DR. LANDRY: Yeah. A couple of my thoughts about this bill, is I think – again, I think, you know, everyone is really thinking good things about these issues and I’m actually proud to read this bill and support it.

The way I look at that is I see no public good whatsoever for the pharmaceutical industry to have information on my prescribing habits.

An example, a couple years ago I was really unaware of this, probably five or six [4] years ago, when a detailing pharmaceutical representative came into my office and asked me specifically why I was not prescribing a new pharmaceutical, and I said, how do you know that I don’t prescribe this drug?

And he says, we have data that says you’ve never prescribed this drug so I need to tell you about it.

And I was very interested by that in that – in that manner.

I can’t understand why AMA and organizations like that would sell – sell information regarding physicians and to allow them to have, you know – anybody to have this data about what I prescribe to my patients. I just, you know, see really no public good on that.

And I know you heard a lot of background about detailing and marketing of drugs and what it does to pharmaceutical prices, what it does for physician prescribing practices. And we know that that pharmaceutical representative in the office talking to doctors, you know, makes doctors prescribe certain drugs, more expensive drugs than generic drugs than all the rest and [5] that's, you know, well founded in medical research.

\* \* \*

[13] DR. LANDRY: Yeah. Well, I always think this that – you know, I can only speak for myself and my thought is that if you asked 100 doctors whether they would want their personal prescribing information sold to the pharmaceutical industry, boy, if you found two physicians that said yes to that, I would be surprised.

\* \* \*

[16] REPRESENTATIVE ZENIE: Dr. Landry, this is John Zenie. Okay. If – if they're doing such a bad job even before this data and – or after this data relative to being helpful to the physicians, why do physicians even bother seeing them?

DR. LANDRY: Well, you know, physicians – physicians see them because they feel that they – they need to get some sources of information and they like the free samples, and it's another – it's unfortunately it's kind of a tragedy of our health-care system that [17] physicians take samples. And the reason they really take them is there are patients – we have

many patients that have no health insurance. I have patients in my office that have coronary artery disease that had a heart attack, they don't have health care and their cholesterol is 220, their LDL level is 220 and I know if I can give them a statin drug that they can't afford \$30 a month for a generic single statin and I know if I can give them, you know, Lipitor from a pharmaceutical rep's free sample, you know, you feel that you're helping them because they won't be on the drugs otherwise. Or a diabetic that doesn't have health insurance.

\* \* \*

[22] My point on this bill is I still don't understand why they should have information on what I write for my specific patient and why I should have a drug rep come in to me and say, you know, Dr. Landry 90 percent of your prescriptions are for Lipitor, why aren't you using this Crestor, this new drug? We don't understand. We want to show you proof of why you should be using this drug. You know, why should they do that?

Now, I can tell you I really don't meet [23] with pharmaceutical representatives other than the fact they contact me sometimes regarding the Drug Utilization Review and – and the state will try to give me some information on drugs. But I just don't understand why they should have my specific information. I feel as though they have my bank account number. They're selling something. They're gathering data for no purpose. I don't see that why they should

have that information. It would be as though, you know, they were selling – you know, I guess people do that. They can – they can figure out what you buy in the supermarket now and all these things.

But I think when the patient is the intermediary regarding drugs, they're not buying the drugs typically. I determine the drug for them and gear them in that manner and I – I just don't see how this benefits the consumer by – by having that information available and the doctor specific prescribing. I guess it's helpful to the industry, that's for sure, but I – I don't understand how it helps the patient.

\* \* \*

[36] You know, I don't mind the state in terms of, you know, we're trying to work and improve health-care. I think that's an important thing. I just do not believe that the pharmaceutical industry has any intention of – of really wanting to use this data for this means. And if we're going to do that, you know, in terms of pay for performance, let everyone move people in better prescribing and better practicing. There are other mechanisms to do that that are again, one, fair; two, objective; and three, we want to make sure we do focus on the fact that there's – there should be some confidentiality in what we do.

The fact that – I would hate to think that the pharmaceutical industry is linking my [37] prescribing to specific patients. They have absolutely no right

to that data. You know, that really frightens me to think that they could do that.

\* \* \*

---

STATE OF VERMONT  
HOUSE COMMITTEE ON HEALTH CARE

Re: Senate Bill 115

Date: 5/2/07

Committee Members: Rep. Steven Maier, Chair  
Rep. Harry Chen, Vice-Chair  
Rep. Sarah Copeland-Hanzas  
Rep. Lucy Leriche, Clerk  
Rep. Francis McFaun  
Rep. William Keogh  
Rep. Virginia Milkey  
Rep. Hilde Ojibway  
Rep. John Zenie  
Rep. Pat O'Donnell  
Rep. Scott Wheeler

\* \* \*

[2] ATTENDEE 1: Hi, Josh.

ATTENDEE 2: Hello.

MR. SLEN: Hi. I'm Josh with Slen. Everyone knows me here, I think. I'm the director of the Office of Vermont Health Access from Vermont's Medicaid office.

\* \* \*

[5] And so the – the new thing that would have to happen is that under the way we read the – I read the language is we'd have to send a written letter to each beneficiary whenever any of those changes happen and were not set up to do that right now, and so that would require us probably to send several thousand

letters a month out to people and that seems – it seems like a burden

\* \* \*

[15] The doctor can require the original prescription to be filled again, but that's a patient –

ATTENDEE 24: I hate to interrupt, because the house has just recessed and people are headed over to the governor's ceremonial office for those of you – that's all of us that wants to be there for that proclamation related to the – what is it related to?

\* \* \*

[31] ATTENDEE 35:

\* \* \*

a month overlap where two drugs is kept the – you know, preferred. And, you know, I'm just throwing that out as a possibility and that type, meaning a potential solution to this and then the second question asking your – your – my comment about – well, maybe – you're actually right, I think we all should be doing it the same way, all different – and then maybe – I hate to say

\* \* \*

---

STATE OF VERMONT  
HOUSE COMMITTEE ON HEALTH CARE

Re: Senate Bill 115

Date: 5/2/07

Committee Members: Rep. Steven Maier, Chair  
Rep. Harry Chen, Vice-Chair  
Rep. Sarah Copeland-Hanzas  
Rep. Lucy Leriche, Clerk  
Rep. Francis McFaun  
Rep. William Keogh  
Rep. Virginia Milkey  
Rep. Hilde Ojibway  
Rep. John Zenie  
Rep. Pat O'Donnell  
Rep. Scott Wheeler

\* \* \*

[2] ATTENDEE 1: We'll have it in another five or ten minutes we hope. Robin was going to – we're handing it out where – quickly before going through it with the committee. She's going to give an overview of the court case in New Hampshire.

\* \* \*

[3] MS. ROBIN:

\* \* \*

[5] So one of the things that the court indicated is that they were not going to give great difference to the New Hampshire's legislature's predictive judgments on what would be accomplished by the law because the legislature didn't – didn't have findings in the

statute and didn't illustrate that they had established a quality record.

\* \* \*

[14] ATTENDEE 25:

\* \* \*

[15] So one of the things we've tried to do, for example, is – is go back to our testimony and to – to the doc – some of the documents that were presented to us to create a stronger written record of what our findings were regarding, you know, the issues with detailing, and with data mining and so you'll see there's several pages worth of findings

\* \* \*

[31] ATTENDEE 45: I'm just curious, is there a rhyme and reason for the – of ordering which these findings are placed?

MS. ROBIN: No. I tried to make them in somewhat of a rationale order, but I didn't, to be honest, go through and really think through the order after I – I put them in there, so they certainly could be reordered.

\* \* \*

---

STATE OF VERMONT  
HOUSE COMMITTEE ON HEALTH CARE

RE: SENATE BILL 115

DATE: May 3, 2007

TYPE OF COMMITTEE MEETING: STANDARD

COMMITTEE MEMBERS:

REP. STEVEN MAIER, CHAIR

REP. FRANCIS McFAUN

REP. WILLIAM KEOGH

REP. VIRGINIA MILKEY

REP. HILDE OJIBWAY

REP. JOHN ZENIE

REP. HARRY CHEN, VICE-CHAIR

REP. SARAH COPELAN-HANZAS

REP. LUCY LERICHE, CLERK

REP. PAT O'DONNELL

REP. SCOTT WHEELER

\* \* \*

[2] MR. HARRINGTON: Good morning. I'm Paul Harrington, the executive vice president for the Vermont Medical Society. I'm here to present the Vermont Medical Society's testimony regarding Representative Chen's amendments to the Bill S115 as amended by the Committee on Healthcare and Appropriations.

\* \* \*

[3] We've done that for three reasons. Physicians in Vermont feel that the marketers having the prescription information particularly to that physician, many of whom have no idea that the marketer has

that information, is an invasion of [4] the physician's privacy.

Secondly, the Medical Society over many sessions of the general assembly has worked with committees such as this and others to try to control the cost of pharmaceutical products, and we have – I could remember when I first joined the Medical Society back in 2002, we joined in the press conference to support the development of a preferred drug list for the Medicaid program. And notwithstanding the additional administrative burden imposed upon physicians in complying with Medicaid's preferred drug list, it has certainly saved a lot of money for the state and we supported that goal.

And then finally most importantly probably for physicians who, you know, have many skill sets, but as I've come to learn, they in part view themselves appropriately as scientists. They want any information they get particularly around the treatment of modalities for their patients to be accurate and evidence-based.

So those three themes of privacy, controlling drug costs here in Vermont and ensure that any information they're receiving is evidence-based. So really the three pillars of the Medical [5] Society's advocacy.

\* \* \*

[9] UNIDENTIFIED FEMALE SPEAKER:  
With all the education you've done, you said and it's come up before that many doctors have no idea that

the data is available to the drug company. I mean by now don't most of them know, or is it still – no? Still a lot of people aren't aware of this whole thing.

MR. HARRINGTON: Well, we certainly publicized it through our newsletters. My sense is we have kind of a curious process of how we became such strong advocates for this provision. The six New England state medical societies get together once a year. We were in Portsmouth, New Hampshire a year ago last spring, and our president, then president Dr. Peter Dale, who is an internist here in central Vermont, was talking to his counterpart, a psychiatrist in New Hampshire, and he was telling [10] Dr. Dale about what New Hampshire was doing or seeking to do at that time. And you know, he had no idea. And that's been a constant comment from the physicians that they don't know that the marketers have this information. And almost all of them, and I say almost all of them, I have not heard anyone say that they want the marketers to have that information. So they are unaware of it. When they become aware of it, they don't want the marketing to have that information.

\* \* \*

[58] MS BRILL:

\* \* \*

[60] Now, I'm not saying [61] that we are removing all the First Amendment concerns. There will undoubtedly be litigation if this were to pass. And in the event that we were to lose, there is always the threat that we have to pay the other side's attorneys' fees,

because – I won't go into why, but that's something that could happen.

\* \* \*

[111] You don't have to have so much evidence that it would satisfy a jury or satisfy a judge for the ultimate conclusions. I just wanted to make that clear.

\* \* \*

[195] REPRESENTATIVE O'DONNELL: 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 were not passing a law that is unconstitutional. And I think one of the most important things for me is 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 nine years, I've never sat with a committee, sit here and pass a bill at a committee that they're waiting to deal with out on the floor, and I don't feel I even know what's in this bill. It's being pushed past us way too fast. There's 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 ten minutes is something I've never seen before, and I don't think [196] 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,

\* \* \*

