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.,	)	Case Nos. 1:07-cv-188-jgm & 1:07-220-jgm (consolidated)
Plaintiffs,	)	
vs.	)	
WILLIAM H. SORRELL, as Attorney General of the State of Vermont,	)	
Defendant.	)	

Trial Memorandum & Proposed Findings of Fact
and Conclusions of Law of IMS Health Incorporated,
Verispan, LLC, and Source Health Care Analytics, Inc.

Thomas R. Julin,
Patricia Acosta
& Michelle Milberg
Admitted Pro Hac Vice
Hunton & Williams LLP
1111 Brickell Ave. Suite 2500
Miami, FL 33131
305.810.2516 Fax 2460
tjulin, pacosta, or
mmilberg@hunton.com

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

Mark Ash
Admitted Pro Hac Vice
Smith Anderson Blount Dorsett
Mitchell & Jernigan LLP
2500 Wachovia Capitol Center
P.O. Box 2611
Raleigh, NC 27602-2611
919.821.1220 Fax 6800
mash@smithlaw.com

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

TABLE OF CONTENTS

TABLE OF AUTHORITIES iv

INTRODUCTION 1

PROPOSED FINDINGS OF FACT 3

The Publisher Plaintiffs 3

The Information at Issue: Prescriber-Identifiable Data 3

New Hampshire Enacts a Prescription Restraint Law & it is Challenged 4

Vermont Considers Numerous Reforms 7

Jan. 29 - Feb. 5, 2007: The New Hampshire Bench Trial 7

Feb. 15 - Feb. 22, 2007: The Vermont Senate Finance Committee Develops a Package of Reforms 8

Feb. 27 - Mar. 15, 2007: The Senate Health & Welfare Committee Briefly Considers the Bill 9

March 23 & 27, 2007: The Senate Finance Committee Has a Change of Heart 10

March 27 - April 30, 2007: A New-Hampshire Style Bill Races Through the House 10

April 30, 2007: The New Hampshire Prescription Restraint Law is Declared Unconstitutional 12

May 1-3, 2007: The House Committee on Health Care Quickly Amends the Bill 13

The House Floor Reaction 15

The Findings 17

The Vermont Prescription Restraint Law 18

The Law Imposed Serious Penalties 18

The Imminent Threat & Reasonable Fear of Enforcement....19

The Amendment to the Prescription Restraint Law....19

Violations of the Law, as Amended, are Punishable by Severe Penalties....24

Damage Inflicted by the Amended Law on the Plaintiffs & Others....25

The Continuing Threat of Harm & Reasonable Fear of Enforcement....25

The Lack of Research to Justify the Law....27

The State's Expert Witnesses....28

Dr. Ashley Wazana....31

Dr. Aaron Kesselheim....29

Dr. Meredith Rosenthal....29

Dr. David Grande....30

Mr. Shahram Ahari....30

The Plaintiffs' Expert Witnesses....31

Dr. Thomas Wharton....31

Dr. Andrew Cole....32

Dr. Kenneth Ciongoli....33

Dr. Michael A. Turner....34

Dr. Micky Kolassa....35

Mr. Peter Hutt....35

PROPOSED CONCLUSIONS OF LAW....36

I. The Prescription Restraint Law Violates the First Amendment....36

A. The Law Fails Intermediate Scrutiny....44

1. The Law Applies to Speech That Is Not Misleading....44

2. The Governments Interests Are Not Substantial or Important....44

a. Protecting Prescriber Privacy is Not a Substantial or Important Interest 45

b. Simply Lowering Costs by Suppressing The Publication of Truthful and Important Information is Not a Substantial or Important Interest 48

3. The Law Does Not Directly Advance a Substantial or Important Government Interest.....49

4. The Law is Broader Than Necessary to Serve a Substantial or Important Government Interest 53

B. The Law is Subject to and Cannot Survive Strict Scrutiny 55

1. Strict Scrutiny Applies Here 55

a. The Law Regulates the Content of Non-Commercial Speech.....55

b. The Law Prohibits Dissemination of Lawfully-Obtained, Truthful Information of Public Concern 58

c. The Law Imposes a Prior Restraint on Speech 58

2. The Law Cannot Survive Strict Scrutiny 59

C. The Law is Void for Vagueness & Overbreadth 61

II. The Prescription Restraint Law Violates the Commerce Clause.....65

A. The Law has an Impermissible Extraterritorial Reach 65

B. Plaintiffs are Not Asserting a Facial Commerce Clause Challenge 70

C. The Publisher Plaintiffs Have Standing.....71

CONCLUSION.....72

CERTIFICATE OF SERVICE .....

ATTACHMENTS

The Vermont Prescription Restraint Law ..... Ex. A

The New Hampshire Prescription Restraint Law ..... Ex. B

The Maine Prescription Restraint Law ..... Ex. C

Comparison of the 3 Prescription Restraint Laws Ex. D

TABLE OF AUTHORITIES

Cases

44 Liquormart, Inc. v. Rhode Island,
517 U.S. 484 (1996).....39, 42, 44, 53

Alexander v. United States,
509 U.S. 544 (1993).....58

America Booksellers Foundation v. Dean,
342 F.3d 96 (2d Cir. 2003).....65

Ashcroft v. ACLU,
542 U.S. 656 (2004).....59

Ashcroft v. Free Speech Coalition,
535 U.S. 234 (2002).....63

Bad Frog Brewery, Inc. v. N.Y. State Liquor Authority,
134 F.3d 87 (2d Cir. 1998).....49, 52, 53, 56

Baldwin v. G.A.F. Seelig, Inc.,
294 U.S. 511 (1935).....66, 67, 68

Baldwin v. G.A.F. Seelig, Inc.,
294 U.S. 511 (1935).....70

Bantam Books, Inc. v. Sullivan,
372 U.S. 58 (1963).....59

Bartnicki v. Vopper,
532 U.S. 514 (2001).....40, 58

Bates v. State Bar of Ariz.,
433 U.S. 350 (1977).....40, 49

Board of Trustees of State University of New York v. Fox,
492 U.S. 469 (1989).....55

Brown-Forman Distillers Corp. v. N.Y. State Liquor Authority,
476 U.S. 573 (1986).....65

CBC Distributing & Marketing v. Major League Baseball Advanced Media, L.P.,
505 F.3d 818 (8th Cir. 2007) 37

Carey v. Brown,
447 U.S. 455 (1980).....45

Central Hudson Gas & Electric Corp. v. Public Service Commission,
447 U.S. 557 (1980).....40, 44, 49, 50, 51, 52, 53, 55

Chaplinsky v. New Hampshire,
315 U.S. at 568 (1942).....59

City of Cincinnati v. Discovery Network, Inc.,
507 U.S. 410 (1993).....55

City of Littleton v. Z.J. Gifts D-4, L.L.C.,
541 U.S. 774 (2004).....59

Cohen v. California,
403 U.S. 15 (1971).....48

Consumers' Checkbook v. United States Dep't of Health & Human Servs.,
502 F. Supp. 2d 79 (D.D.C. 2007).....45

Crawford v. Marion County Election Board,
128 S. Ct. 1610 (2008).....63, 64

Edenfield v. Fane,
507 U.S. 761 (1993).....38, 45, 46, 47, 49

El Dia, Inc. v. P.R. Department of Consumer Affairs,
413 F.3d 110 (1st Cir. 2005).....12, 13, 55

Fla. Bar v. Went For It, Inc.,
515 U.S. 618 (1995).....45

Florida Star v. B.J.F.,
491 U.S. 524 (1989).....58

Frost & Frost Trucking Co. v. Railroad Commission of Cal.,
271 U.S. 583, 46 S. Ct. 605, 70 L. Ed. 1101 (1926).....39

Gentile v. State Bar of Nev.,
501 U.S. 1030 (1991).....61

Gonzalez v. O Centro Espirita Beneficente Uniao do Vegetal,
126 S. Ct. 1211 (2006).....59

Gonzalez v. O Centro Espirita Beneficente Uniao do Vegetal,
126 S. Ct. 1211 (2006).....60

Government Suppliers Consolidating Services, Inc. v. Bayh,
975 F.2d 1267 (7th Cir. 1992).....72

Grayned v. City of Rockford,
408 U.S. 104 (1972).....61

Greater New Orleans Broadcast Association, Inc. v. United States,
527 U.S. 173 (1999).....51

Healy v. Beer Institute,
491 U.S. 324 (1989).....65, 66

IMS Health Inc. v. Ayotte,
490 F. Supp. 2d 163 (D.N.H. Apr. 30, 2007), *appeal docketed*,
No. 07-1945 (1st Cir. June 20, 2007)..... *passim*

IMS Health, Inc. v. Ayotte,
No. 06-280-Civ-PB (D.N.H. 2006).....5, 38, 51, 55, 65

IMS Health Incorporated v. Rowe,
532 F. Supp. 2d 153 (D. Me. 2008), *appeal docketed*,
No. 08-1248 (1st Cir. Mar. 4, 2008)..... *passim*

Landmark Comm'ns, Inc. v. Virginia,
435 U.S. 829 (1978).....58

Landmark Communications Inc., v. Virginia,
435 U.S. 829 (1978).....42

Lorillard Tobacco Co. v. Reilly,
533 U.S. 525 (2001).....53

Los Angeles Police Department v. United Reporting Publishing Corp,
528 U.S. 32 (1999).....40

Mainstream Marketing Services, Inc. v. FTC,
358 F.3d 1228 (10th Cir. 2004).....39, 45

Miller v. California,
413 U.S. 15 (1973).....59

Montgomery v. David,
915 A.2d 270 (Vt. 2006).....62

N.Y. Association of Realtors, Inc. v. Shaffer,
27 F.3d 834 (2d Cir. 1994).....53, 56

National Electrical Manufacturers Association v. Sorrell,
272 F.3d 104 (2d Cir. 2001).....70, 71

Ohralik v. Ohio State Bar Association,
436 U.S. 447 (1978).....37, 38, 46, 47

Ohralik v. Ohio State Bar Association,
436 U.S. 447 (1978).....46

Perry v. Sindermann,
408 U.S. 593, 92 S. Ct. 2694, 33 L. Ed. 2d 570 (1972).....39

Pharmacy Care Management Association v. Rowe,
429 F.3d 294 (1st Cir. 2005).....55

Pharmaceutical Research & Manufacturers of America v. District of Columbia,
406 F. Supp. 2d 56 (D.D.C. 2005), *aff'd sub nom on other grounds, Biotech. Indus. Org. v. Dist. of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007).....65, 66, 67, 68, 70

R.A.V. v. St. Paul,
505 U.S. 377 (1992).....59

Reno v. ACLU,
521 U.S. 844 (1997).....61, 64

Reno v. America Civil Liberties Union,
521 U.S. 844 (1997).....40, 59

Reno v. Condon,
528 U.S. 141 (2000).....40

Rubin v. Coors Brewing Co.,
514 U.S. 476 (1995).....42, 44, 49, 51, 53

SPGGC, LLC v. Blumenthal,
505 F.3d 183 (2d Cir. 2007).....70, 71

Sable Communications of California., Inc. v. FCC,
492 U.S. 115 (1989).....42, 59

Sherbert v. Verner,
374 U.S. 398 (1963).....60

Smith v. Butterworth,
494 U.S. 624 (1990).....58

Smith v. Daily Mail Publishing Co.,
443 U.S. 97 (1979).....58

Tennessee Secondary Schools Athletic Association v. Brentwood Academy,
127 S. Ct. 2489 (2007).....46

Thomas v. Collins,
323 U.S. 516 (1945).....60

Thompson v. W. States Medical Ctr.,
535 U.S. 357 (2002).....38, 44, 53

Trans Union Corp. v. FTC,
267 F.3d 1138 (D.C. Cir. 2001).....39

Trans Union Corp. v. FTC,
295 F.3d 42 (D.C. Cir. 2002).....39

Turner Broadcast System, Inc. v. FCC,
512 U.S. 622 (1994).....42, 43, 57

United States v. Hilton,
167 F.3d 61 (1st Cir.1999).....61

United States v. Playboy Entertainment Group, Inc.,
529 U.S. 803 (2000).....48, 59

United States v. Williams,
128 S. Ct. 1830 (2008).....62

Universal City Studios, Inc. v. Corley,
273 F.3d 429 (2d Cir. 2001).....37

Virginia Board of Pharmacy v. Virginia Consumer Council,
425 U.S. 748 (1976).....37, 40, 49

Virginia v. America Booksellers Association,
484 U.S. 383 (1988).....64

Ward v. Rock Against Racism,
491 U.S. 781 (1989).....57

Washington State Grange v. Washington State Republican Party,
128 S. Ct. 1184 (2008).....63, 64

U.S. West, Inc. v. FCC,
182 F.3d 1224 (10th Cir. 1999).....38, 39

Whitney v. California,
274 U.S. 357 (1927).....54

Constitutional Provisions, Statutes & Laws

U.S. Const., amend. I ..... *passim*

U.S. Const., art. I, sec. 8, cl. 3..... 1, 65-72

22 Me. Rev. Stat. Ann. § 1711-E (2007) 1, 2, 5, 6

22 Me. Rev. Stat. Ann. § 8704 (2007).....2

22 Me. Rev. Stat. Ann. § 8713 (2007).....2

2007 Me. Laws ch. 460.....2

N.H. Rev. Stat. Ann. § 318:47-f (2006).....1, 5

N.H. Rev. Stat. Ann. § 318:47-g (2006) 5

N.H. Rev. Stat. Ann. § 318-B:12 (IV) (2006).....5

2006 N.H. Laws § 328 .....1, 5

18 V.S.A. § 4631 .....1, 17, 19, 21, 24, 73

18 V.S.A. § 4631(b)(5) 62, 69

18 V.S.A. § 4631(c) 1

18 V.S.A. § 4631(d) 1, 61, 68

18 V.S.A. § 4631(e)(1) 62

2007 Vt. Acts No. 80 § 1 .....17, 19

2007 Vt. Acts No. 80 § 17 1

2008 Vt. Acts No. 89 .....1, 41

INTRODUCTION

This memorandum provides a guide for the Court regarding the evidence that is expected to be introduced by the parties on the publisher plaintiffs' claims against the Attorney General, including brief descriptions of the witnesses and their testimony. It also provides a summary of the legal arguments expected to be advanced. It is structured in the form of proposed findings of fact and proposed conclusions of law.

The challenged Vermont law[1] (Exhibit A) is similar to the New Hampshire law (Exhibit B) and the Maine law (Exhibit C) that already have been invalidated in *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163 (D.N.H. Apr. 30, 2007) (final judgment), *appeal docketed*, No. 07-1945 (1st Cir. June 20, 2007), and *IMS Health Incorporated v. Rowe*, 532 F. Supp. 2d 153 (D. Me. 2008) (preliminary injunction), *appeal docketed*, No. 08-1248 (1st Cir. Mar. 4, 2008).[2] Accordingly, much of the relevant law already has been fully developed in these opinions.

The Court previously has asked how the Vermont law differs from the laws at issue in these prior cases.[3] The Vermont law is not very different from the New Hampshire law at all. The Vermont law includes an opt-in feature[4] not found in the New Hampshire law.[5] The feature

---

[1] The challenged law is 2007 Vt. Act 80 § 17, as amened by 2008 Vt. Act 89, codified as 18 V.S.A. § 4631. It is referred to herein as "the Prescription Restraint Law." Exhibit A attached to this memorandum is the full text of the law, including the 2008 amendment.

[2] The appeal from the New Hampshire decision was argued in the First Circuit on January 9, 2008. No decision had been rendered as of the date of this memorandum. The appeal from the Maine decision has been stayed by the agreement of the parties until the appeal from the New Hampshire case is decided.

[3] Exhibit D to this memorandum is the chart previously submitted to the Court that compares the features of the three laws.

[4] *See* 18 V.S.A. § 4631(c) & (d).

[5] *See* 2006 N.H. Laws § 328, codified as N.H. Rev. Stat. Ann. §§ 318:47-f, 318:47-g, 318-B:12(IV) (2006).

allows doctors who want information about their prescribing to be used for marketing to volunteer to allow such use. But that feature of the Vermont law does not have much, if any, impact on the operation of the law because few, if any, Vermont prescribers would make this election. The Vermont law also is accompanied by legislative findings of the facts that the legislature believed to justify the law. The New Hampshire legislature made no such findings. As will be discussed, this distinction also is unimportant because the Court cannot surrender its duty to determine the constitutionality of the law by deferring to legislative fact-finding; the process that led to the fact-finding, is, in any event, not the type of process that warrants deference; and, the process otherwise was flawed in several respects.

Notably, the Maine law was accompanied by similar legislative findings,[6] but the Maine district court found such findings could not foreclose its inquiry into the constitutionality of that law. The Maine Law also had an "opt-out" feature rather than an opt-in feature. It provided that a prescriber's information could be used for marketing purposes unless a doctor elected to prohibit its use for such purposes. This aspect of the Maine law lessened its impact on speech, but even this could not save it from invalidation. In both of the prior cases, the laws fell because the state could not show that prescribers have a privacy interest in the information at issue, the law would directly and materially advance their interests in reducing unnecessary prescription costs, or that there are not abundant alternative means of achieving their objectives without restricting speech.

This following proposed findings of fact and conclusions of law show that the Vermont law should be invalidated for the same reasons that the New Hampshire and Maine laws were invalidated. It also sets forth additional reasons for invalidating the Vermont law.

[6] 2007 Me. Laws ch. 460, which amends 22 Me. Rev. Stat. Ann. §§ 1711-E, 8704, 8713 (2007).

PROPOSED FINDINGS OF FACT

The following facts are a summary of the pertinent legislative record, declarations, and other materials previously filed with the Court. The publisher plaintiffs anticipate that the trial record will contain evidence consistent with the proofs filed with their preliminary injunction motion. This statement also draws on evidence adduced by both the plaintiffs and the defendant during the discovery period, which also is expected to be offered at trial. Citations are to declarations and depositions which contain testimony expected to be offered through live witnesses or depositions and to documents expected to be offered in evidence.[7]

The Publisher Plaintiffs

IMS Health Incorporated ("IMS Health"), Verispan LLC ("Verispan"), and Source Healthcare Analytics, Inc. ("Source Healthcare") (referred to collectively as the "publisher plaintiffs") are the world's leading providers of information, research, and analysis to the pharmaceutical and health care industries. (Sadek ¶ 2, Fisher ¶¶ 4-5, Livingston ¶¶ 3-5).

The Information at Issue: Prescriber-Identifiable Data

Retail pharmacies acquire prescription data during the regular course of business. For each prescription filled, a record is kept that includes the patient's name; the prescriber's name and address; the name, dosage and quantity of the drug; and the date the prescription is filled. (Sadek ¶ 6). Retail pharmacies or third parties remove patient information and sell the remaining prescription data to the plaintiffs. (Rite Aid - Wolfe ¶ 5-11) (CVS - Tierney ¶¶ 5-11). Plaintiffs, in turn, analyze and sell the acquired information to make a profit and to improve public health

[7] The publisher plaintiffs' trial exhibits are cited herein as "PX-page," and PhRMA's trial exhibits are cited as "PhX-page." The page numbers are designated in the trial exhibits either as the "LR" or "LC" documents stipulated between the parties or to Bates numbers. Depositions are cited as "(Deponent Dep. at [page]"). Declarations are referenced as (Declarant ¶ __)."

and welfare. (Sadek ¶ 13, Fisher ¶ 15, Livingston ¶ 14). Most of the plaintiffs' subscribers and other customers use the information for advertising, marketing, and promotional purposes. (Sadek ¶¶ 14-17, Fisher ¶¶ 16-19, Livingston ¶¶ 15-18).

The publisher plaintiffs obtain information about prescribers doing business in Vermont and writing descriptions dispensed in Vermont, from computers that are located outside of Vermont. Plaintiffs then license the information from these reports and services to third parties, including pharmaceutical and biotechnology clients, that are located outside of Vermont. Those companies then use the information in conjunction with their marketing activities inside Vermont (Sadek ¶ 11, Fisher ¶ 12 , Livingston ¶ 12).

Prescriber information is particularly useful to pharmaceutical companies in identifying those prescribers, so-called "early adopters," who are willing to adopt innovative drugs when the drugs first become available in the market. Early adoption of new and innovative drugs is critical to patient well-being and containing health care costs by keeping people out of hospitals, emergency rooms, and nursing homes. (Frankel ¶ 25).

Many doctors find it useful that pharmaceutical sales representatives can access data regarding their individual prescribing practices because this allows sales representatives to (1) deliver only relevant information, and (2) alert doctors who are prescribing products that are not as useful to patient health or as economical or as consistent with the practice guidelines. Doctors do not generally expect that information about their prescribing practices will be kept private. (Wharton ¶ 17).

New Hampshire Enacts a Prescription Restraint Law & it is Challenged

During its 2006 legislative session, the New Hampshire legislature began consideration of a bill introduced by freshman legislator Cindy Rosenwald. The bill would prohibit

pharmacies and similar entities from selling prescriber-identifiable information from prescription records for commercial purposes. Rep. Rosenwald believed that the proposed law would protect the privacy of doctors such as her husband and also might reduce the costs of New Hampshire's Medicare and Medicaid programs by making it more difficult for drug manufacturers to market their expensive patent-protected drugs. Neither Rep. Rosenwald, the New Hampshire Legislature, nor any administrative or scientific bodies made any study of whether the law would be effective to achieve its objectives, but the bill drew support in light of the possibility that it might work.

Vermont Medical Society President Peter Dale learned of the proposed New Hampshire law in the spring of 2006 at a New England Medical Society meeting. On July 1, 2006, New Hampshire Legislature enacted the law. *See* 2006 N.H. Laws § 328, codified at N.H. Rev. Stat. Ann. §§ 318:47-f, 318:47-g, 318-B:12 (IV) (2006). The Legislature made no findings setting forth its objective, that the law would meet its objectives, or that it had no alternative means of accomplishing its objectives that would be less restrictive of speech.

With the New Hampshire law now on the books, Dale felt that Vermont should consider passing its own law. He therefore presented it one Saturday morning in July 2006 to about 30 members of the Vermont Medical Society who were planning the society's annual meeting in October 2006. (Harrington Dep. at 203). The Society, like the New Hampshire Legislature, had done no study of whether the law would be effective, but it was agreed that the law was something that should be pursued, and the group drafted a resolution which it then e-mailed to its body Council of about 50 doctors.

On July 28, 2006, IMS Health and Verispan filed suit seeking to declare unconstitutional and enjoin the statute. *IMS Health, Inc. v. Ayotte*, No. 06-280-Civ-PB (D.N.H. 2006). Plaintiffs

claimed the law violated the First and Fourteenth Amendments and the Commerce Clause. The trial judge, the Hon. Paul Barbadoro, consolidated the plaintiffs' motion for a preliminary injunction with a trial on the merits for the last week in January, 2007.

The Vermont Medical Society Council held a teleconference in September, 2006, and, notwithstanding the challenge to the New Hampshire law, recommended submission of the resolution to the general membership at its annual meeting at the Basin Harbor Yacht Club in October, 2006. (Harrington Dep. at 204). Approximately 60 to 80 of the 1500 members of Society ultimately attended the annual meeting. Before voting on the resolution, they heard a panel discussion that included New Hampshire Society President Mark Sadowski, New Hampshire Rep. Rosenwald, and Vermont Attorney General William Sorrell. No representatives of pharmaceutical manufacturers or those opposing the law were invited to express opposing views. The 60 to 80 Society members then approved the resolution. (Harrington Dep. at 59).

With the resolution in hand, Attorney General Sorrell established a team of lawyers in his office to consider the proposal -- Julie Brill, Wendy Morgan, Bridget Asay, and Janet Murnane. (Brill Dep. at 168-9). The Attorney General had not previously evaluated such legislation (Brill Dep. at 168-69), but all that was done was to talk about it. (Brill Dep. at 169) ("[W]e talked about it, we talked about it, we -- I mean that's pretty much it, you know. Little bit of research was done I think probably, but you know, . . . There weren't specific steps other than what we usually do when we're thinking about bills, which is we think about them"). No effort was made to survey legislation in other states. (Brill Dep. at 171). Brill has no recollection of trying to evaluate how the law would influence the prescribing practices of doctors or the hundreds of millions of dollars spent through Medicare and Medicaid. (Brill Dep. at 172-73, 177-78) ("I'm not remembering with any particularity . . . There wasn't a formal process"). The Attorney

General did not consult with the Joint Fiscal Office, an administrative agency that assesses the fiscal impact of proposed laws. (Brill Dep. at 180) (Kappel Dep. at 74). Instead, the group simply started to draft a bill so that it would be ready for the legislative session that would begin in January, 2007. (Brill Dep. at 172, 175).

Vermont Considers Numerous Reforms

While the Attorney General was working up a draft bill like the New Hampshire Law, the Vermont Legislature was working on a "a major drug prescription package" (PX81-LC1001) that included other reforms. On January 10, 2007, a legislative aide, Rachel Levin, asked Maine State Rep. Sharon Treat, a leading advocate for legislation to reduce the cost of prescription drugs,[8] if she could provide "a list of options for Vermont for continuing to lower the price of prescription drugs." (PX-81-LC1001). Rep. Treat sent model bills reflecting a dozen reforms for Vermont to consider. (PX-81-LC001 & PX13-LC994-998). From this, Robin Lunge, a lawyer working for the Vermont Legislative Council, prepared a 22-section bill, S.115. (PX81-LC381-417) (Lunge Dep. at 39) ("I was the primary legislative drafter"). Section 13 of the draft bill proposed creation of a law to mirror precisely the New Hampshire law in litigation. (PX12-LC381-417). Ms. Lunge first presented the bill to the Vermont Senate Health & Welfare Committee on January 17, 2007, 12 days prior to the start of the New Hampshire trial. (PX92-5173; PhX248).

Jan. 29 - Feb. 5, 2007:
The New Hampshire Bench Trial

The New Hampshire case proceeded to trial on January 29, 2007. The parties presented live witnesses and videotaped deposition testimony over the course of four days. Dr. Jerry

[8] Treat serves as executive director of the National Legislative Association on Prescription Drug Prices, an organization of state legislators. (PX81-LC1001).

Avorn served as the state's primary expert regarding the likely impact that the law would have on the decisions of prescribers. The Court observed that Dr. Avorn "hasn't studied the specific problem that we're dealing with here" and that the use of prescriber-identifiable data "hasn't yet been studied empirically and there really isn't any scientific data." (PX99 - 2/5/2007 at 17-18). The bench trial concluded on February 5, 2007.

Feb. 15 - Feb. 22, 2007:
The Vermont Senate Finance Committee Develops a Package of Reforms

With no immediate decision from New Hampshire, the Vermont Finance Committee proceeded to hear from a small group of witnesses over the course of one week. (PX92-5175-5180). Most were state employees involved in drafting the legislation or representing agencies that pay for health care costs, and they testified in favor of any reforms that had a possibility of reducing prescription costs. (PX92-5175-80; PX11; PX93). They also explained that many factors – wholly unrelated to the use of prescriber-identifiable data – such as an increasing and aging population, the development of improved drugs, and better utilization of existing drugs, drive up the annual cost for prescription drugs. (PX13-LC1085-1108)

One of the witnesses, Madeleine Mongan, vice president for the Vermont Medical Society, presented the resolution of the Vermont Medical Society that had been adopted on Oct. 14, 2006. (PX89-LR232). It claimed that "the combination of detailed marketing profiles and the provision of marketing incentives for physicians by pharmaceutical representatives raises the possibility that [sales] representatives could exert too much influence on prescription patterns" and called for "legislation, similar to legislation recently enacted in New Hampshire" on the basis of this speculation. (PX89-LR232) (emphasis added). The resolution did not indicate that any Vermont doctors actually had been improperly influenced by any sales representatives through the use of prescriber data.

None of the Committee's witnesses presented any evidence showing a likelihood that the prescription restraint aspect of S.115 would reduce costs or, if it did, that it would not harm public health by decreasing the efficiency of marketing drugs that are cost-effective in improving public health. Seven of the witnesses from various industries, including two witnesses from IMS Health, testified against the bill, pointing to the lack of evidence that the bill would achieve its intended purpose and the likelihood that the bill would have pernicious effects.

Notwithstanding this testimony, on February 23, 2007, the Committee introduced S.115 in the Vermont Senate, with section 13's flat ban on the use of prescriber-identifiable data for marketing. (PX81-LC2976-3021). The Senate passed it on first reading, then referred the bill to its Health & Welfare Committee. (PX81-LC969).

Feb. 27 - Mar. 15, 2007:
The Senate Health & Welfare Committee Briefly Considers the Bill

The Senate Health & Welfare Committee held hearings on two days at the end of February and three days in mid-March. This Committee also heard from government employees about the need to reduce state spending on prescription drugs through the Medicaid and Medicare programs. (PX92-5181-5186; PX11-Tabs G,H). The witnesses from the private sector, including IMS Health, again cautioned the legislators that there was *no* evidence that imposition of a restraint on publication of prescriber-identifiable data would achieve any of the state's objectives in protecting the privacy of prescribers or reducing prescription drug costs without harming public health. They also warned that the law would make marketing of improved, cost-effective drugs more difficult and would thereby increase health costs and harm public health. Notwithstanding the testimony, this Committee also sent the bill back to the Senate with certain amendments. (PX81-LC2106-2112).

March 23 & 27, 2007:
The Senate Finance Committee Has a Change of Heart

The Senate returned the bill to the Senate Finance Committee for two additional days of hearing, March 23 and 27, 2007.[9] (PX92-5169-70). Again, no witness offered evidence that the prescription restraint aspect of the bill would directly advance the state's interests in cost reduction or that it would not harm marketing efficiencies and patient health. The Committee now backed off of its original proposal to restrain the publication of prescriber-identifiable data and recommended an amendment that only would require marketers to disclose the prescriber-identifiable data they were using to prescribers who requested such disclosure. (PX81-LC2073). On April 3, 2007, however, the Committee withdrew the amendment and the Senate passed a New Hampshire-style ban. (PX81-LC2060, LC2074).

March 27 - April 30, 2007:
A New-Hampshire Style Bill Races Through the House

The House Healthcare Committee commenced its review of the bill on March 27, 28, and 29, 2007. (PX11-Tabs M,N). Maine State Rep. Sharon Treat appeared to advocate for the comprehensive package of reforms. (PX11-Tab N). The Committee heard testimony on April 10, 11, and 12, and April 17, 18, 19, and 20, 2007. (PX11-Tab 0). Again, government employees testified about the increasing costs experienced in the Medicaid and Medicare programs and the need to hold costs down, and representatives of the private sector made presentations arguing there was no evidence to suggest that a restraint on speech would lower those costs. (PX92-5221). Much of the testimony related to other aspects of the bill. The Committee heard from few practicing prescribers who had actual experience with sales

[9] The Committee heard again from Robin Lunge (legislative counsel), Julie Brill (AG), Madeleine Mongan (VMS), Steve Kimbell (IMS), Susan Gretowski (PhRMA), and Paul Harrington, the VMS president. (PX11-Tab L).

representatives.[10]

Drs. Avorn and Kesselheim submitted a letter on April 3, 2007, claiming that "numerous studies have shown how promotion of drug products to physicians by pharmaceutical manufactures can have important negative effects on public health." (PX89-LR168). The letter further claimed "we feel that commercial sale of physician-identified prescription data greatly supports the harmful aspects of pharmaceutical promotion at the expense of its possible educational value." (PX89-LR168). It did not address whether pharmaceutical marketing also has beneficial effects on public health or whether the commercial sale of physician-identified prescription data supports beneficial effects.

In 47 minutes of oral testimony, Dr. Avorn complimented the Committee for its focus on expanding academic detailing. He said that his research, including active participation in a large-scale program in Pennsylvania, had shown that for every one dollar invested, the state would reduce its prescription drug expenses by two dollars. (PX11-Tab O).

The Committee voted on April 24, 2007, to approve the New Hampshire-style bill. The House scheduled its vote on the bill for May 3, 2007. (PX81-LC969).

---

[10] Dr. Frank Landry testified by telephone for 37 minutes. He estimated 2 in 100 physicians would elect to allow marketers to use their information, if given the choice. He acknowledged that manufacturers used the data to "hone in" on certain prescribers and that prescribers liked to see the representatives to "get some sources of information and they like the free samples." He advocated adoption of a generic drug sampling program, education of doctors regarding marketing, and "academic detailing" to balance the presentation of marketers. He also criticized direct-to-consumer advertising. (PhX398). Dr. Carol Boerner, an ophthalmologist in rural New Hampshire, testified for 20 minutes. She said that a good sales representative "is absolutely invaluable" especially to doctors "in the hinterlands" and provided examples of how they helped doctors, but that she did not like sales representatives telling her how she should prescribe. (PX11-Tab O). Dr. Elliot Fisher, a Dartmouth University professor of medicine, wrote to the Committee that "Having information about what is prescribed . . . can provide important information on trends in use (and abuse). I think we should be cautious about the potential adverse impact of legislation that would block all commercial uses of the data." (PX92-1483). None of these doctors testified that they had been misled by sales representatives or that they had mis-prescribed due to communications from sales representatives.

April 30, 2007:
The New Hampshire Law is Declared Unconstitutional

Late in the afternoon, on Monday, April 30, 2007, however, the United States District Court for the District of New Hampshire issued a 53-page memorandum opinion permanently enjoining the New Hampshire law for violating the First Amendment. *Ayotte*, 490 F. Supp. 2d 163. The opinion held the law should be analyzed as a regulation of "commercial speech" which could be upheld "only if it '(1) is in support of a substantial government interest, (2) "directly advances the government interest asserted," and (3) "is not more extensive than is necessary to serve that interest."'" *Id.* at 177 (quoting *El Dia, Inc. v. P.R. Dep't of Consumer Affairs*, 413 F.3d 110, 113 (1st Cir. 2005)). It observed that the state had the burden of proof and the court could not simply defer to the Legislature's predictive judgments regarding how the statute would operate because the Legislature acted quickly after the bill was introduced, received testimony from witnesses who had yet to review proposed amendments, made no express findings either on the record or incorporated into the statute, failed to discuss alternative measures that would not restrict speech, and cited no evidence as to how effective the restriction might prove to be. *Id.* at 177 n.12.

The opinion held that protecting prescriber privacy was not a substantial state goal. *Id.* at 179. It then concluded that the evidence failed to show that the law either directly advanced the state's interests in promoting public health or reducing costs, or that the law was not more extensive than was necessary to serve the state's interests. *Id.* at 180-82. It observed that the New Hampshire law "does not discriminate between beneficial detailing and harmful detailing. Instead, it imposes a sweeping ban on the use of prescriber-identifiable information to enhance the effectiveness and efficiency of all detailing." *Id.* at 182. It noted that even the state's primary witness, Dr. Avorn, was "quick to acknowledge that [detailing] has beneficial uses and should

not be banned." *Id.* at 181 n.16.

May 1-3, 2007:
The House Committee on Health Care Quickly Amends the Bill

The New Hampshire decision jolted the Vermont House. The author of the original legislation, Robin Lunge of the Legislative Council, immediately set to work to try to avoid its impact. She prepared a sweeping amendment and presented it to the House Health Care Committee on Wednesday, May 2, 2007. (PX92-5206; PhX463). The 10:14 a.m. draft asked the Committee to endorse 20 factual findings. (PhX453-LC2825-2829). The draft inserted new language regarding the intent of the Legislature in adopting a restraint on speech. (PhX453-LC2830). It added new definitions of "marketing" and "promotion," neither of which had been debated previously. (PX453-LC2831). It also added a new subsection which would allow each prescriber to authorize use of information about their prescribing practices, even though the Committee had concluded days earlier that prescribers should not have this option. (PhX453-LC2831-2832).

The 10:14 a.m. draft also provided that a prescriber's consent to the use of his or her prescribing information would not be enough to lift the imposed ban. In addition, the new draft specified that "the entity using the regulated records" would also have to comply with a brand new disclosure requirement prepared the night before. (PhX453-LC2832, 2834).

Some Committee members reacted with alarm. One commented: "I almost feel that this is flaunting free speech." (PhX463 at 31). Another asked: "Is there any rhyme or reason to which these findings are placed?" (PhX463). Marjorie Powell, counsel for the pharmaceutical manufacturers' trade association, commented by phone that she had not had time to read the amendments carefully but expressed concern that the new disclosure requirements would conflict with FDA regulations. (PhX482 at 27). Vermont Medical Society President Paul Harrington

attended this meeting to express his support for the revision. He noted that the provision allowing doctors to allow use of their data would have little impact because only "a very small percentage" would make that election. (PhX482 at 17-18).

After the morning session, Ms. Lunge returned with another 2:33 p.m. draft. The 20 findings now mushroomed to 27, and these varied substantially from the original 20. (PX81-LC2582-2600). The Committee adjourned and agreed to return to work on the proposed amendment further in the morning, as a 2 p.m. full House vote loomed on the bill that would impose a New Hampshire-style ban. When the Committee returned the next day, Thursday, May 3, 2007. Ms. Lunge produced yet another draft at 9:40 a.m., now with 31 proposed findings, all of which had been rewritten, and substantial revisions to other sections of the bill. (PX12-LC2550-2559). The Speaker of the House now agreed to allow the Committee to keep working beyond the 2 p.m. deadline, and further drafts were produced at 1:20 p.m. (PX12-LC2533-2559) and 3 p.m. (PX12-LC2516-2532), each containing new and complex changes.

A Committee member asked Assistant Attorney General Julie Brill whether the Committee needed evidence to support its findings and fretted that the lack of evidence might be the Achilles' Heel in any challenge. Ms. Brill told the Committee not to be concerned: "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." (PhX483 at 111).

Ultimately, the Committee chair called for a final vote. Some of the Committee members now expressed their frustration with the disorderly process. Rep. Bill Keough stated: "We need more time to address some of the issues that we are trying to address here. And we just haven't got the time -- devoted the time to do that." (PhX485 at 189). Another Committee member commented: "I felt as if I was trying to write legislation to get around a decision that was made

by a judge as opposed to writing legislation to solve the problem." (PhX485 at 190). Representative Pat O'Donnell[11] had had enough. She told the Committee:

> I think it comes as no surprise that I am 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 is telling me that we don't know that we are going to win in court. We don't know that we are not passing a law that is unconstitutional.
>
> And I think that one of the most important things for me was that we were sworn in for office, we take an oath to uphold the Constitution of the 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 are waiting to deal with out on the floor, and I don't feel like I even know what's in this bill now.
>
> It's being pushed past us way too fast. 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 it's fair to the people we represent.
>
> It doesn't have anything to do with the drug companies. It has to do with the fact that we have a legal responsibility to follow the law, and one judge is a very serious judge. It's a federal judge and our case will go in front of a federal court.
>
> And when you start getting into these lawsuits, you can easily spend millions of dollars. So what we may save on one end, if we even save anything, we're going to spend on the other in a lawsuit and that's not fair to the people we represent.

(PhX485 at 195-96). Still, the Committee voted 7 to 4 for the Amendment. (PX81-LC969)

The House Floor Reaction

The amendment ultimately reached the House on Thursday, May 3, 2007. (PX81-LC969). Rep. Steve Adams stated: "Madam Speaker: In light of the U.S. District Court ruling on New Hampshire's Prescription Data Ban, I vote 'no' simply because this bill, S.115, should be deferred until final disposition of the 'IMS Health' decision to avoid a similar fate here in

[11] Rep. O'Donnell is misidentified in the transcript as Rep. Chen.

Vermont, especially since this body continues to refuse to have our committee on Judiciary review this bill." (PX81-LC1967). Rep. Peg Flory criticized the Vermont Legislature's failure to conduct a proper constitutional analysis: "[T]his 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." (PX92-4911).

Another representative commented: "This bill is so full of legal holes as to represent another 'full employment act' for lawyers. It represents another effort to use someone else's resources for an ideology that fails to deliver for the needs of human beings it dains [sic] to benefit. It's transparent . . . Just as transparent as the emperor's new clothes. What an awful picture." (PX81-LC1967).

Other legislators expressly recognized that allowing prescribers to consent to the use of their information did not cure the constitutional infirmities in the New Hampshire law. Rep. Francis McFaun stated: "[W]e have a decision, on the NH case, given by a U.S. District Court judge - That decision as far as I understand, was based on the 1st Amendment dealing with freedom of speech - the Judges specifically stated the NH law restricts constitutionally protected speech. I wish we could have had the Judiciary committee take a look at this bill and take testimony on this point. I don't see how the doctor being able to opt in or out is any different than the state of NH trying to restrict the use of this prescribing information." (PX81-LC1968).

Still, the House voted to pass the bill as amended by its Health Care Committee. The Senate accepted the House version of the bill and the Governor signed the bill into law with an effective date of January 1, 2008.

The Findings

Subsection 1 is entitled "Legislative Findings" and states that "The general assembly makes the following findings. . . ." Vt. Acts No. 80 § 1 (2007). The general thrust of the findings is that pharmaceutical marketing is at odds with the State's goal of containing health care costs because pharmaceutical companies tend to promote the most expensive name brand drugs. They cite Dr. Avorn for the proposition that detailing increases the cost of prescription drugs. (PX81-LC82-83). The findings make no attempt to link a rise in health care costs to the use of prescriber-identifiable data in marketing. Moreover, the long list of findings does not make any finding regarding the benefits that the use of prescriber-identifiable data for commercial purposes has on the cost of health care or on public health generally; whether the benefits of commercial use of the data outweigh the supposed harm caused by the commercial use of the data; or whether there are legislative alternatives which would achieve the State's objectives but restrict less speech.

The Vermont Prescription Restraint Law

Section 17 of Senate Bill No. 115 has now been codified as Vt. Stat. Ann. tit. 18, § 4631 (2007), and section 4631 states, in pertinent part that

> (d) A health insurer, a self insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity may use regulated records[12] 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

[12] The term "regulated records" is defined by the statute as "information or documentation from a prescription written by a prescriber doing business in Vermont or a prescription dispensed in Vermont." (PX81-LC115).

> (2) the entity meets one of the exceptions provided in subsection (e) of this section.[13]

(PX81-LC116).

Subsection (f) imposes disclosure requirements on pharmaceutical marketers, as follows:

> 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.

(PX81-LC117-118).

The Law Imposed Serious Penalties

Section 4631 (g) provides that the attorney general may enforce the law and shall have the same remedies for violations as those in the Vermont consumer fraud act, chapter 63 of Title 9. (PX81-LC118). Chapter 63 authorizes injunctive relief and the imposition of a civil penalty of not more than $10,000.00 for each violation of its general provisions; imprisonment of up to 18 months or fines not more than $10,000 or both for making prohibited telephone solicitations; and imprisonment of up to 1 year or fines not more than $1,000 or both for violations of

[13] The exceptions to which subsection (d) does not apply include health care research; care management educational communications *provided to a patient* about adherence to a prescribed course of therapy, recall or patient safety notices, or clinical trials; and 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. (PX81-LC116-117).

children's product safety provisions. The new law leaves unclear whether all of these civil and criminal remedies are available to punish a violation of the Prescription Restraint Law.

The Imminent Threat & Reasonable Fear of Enforcement

Prior to filing suit, IMS Health contacted the Vermont Attorney General's office to attempt to determine how the law would be interpreted and enforced if IMS Health were to continue its existing business practices after January 1, 2008. The Attorney General provided no assurance that the plaintiffs, their sources, or their subscribers would not be subjected, at a minimum, to $10,000 fines for each acquisition of prescriber data, use of it to create reports for manufacturers to use, and sale of the reports to manufacturers. (Sadek ¶ 24).

Plaintiffs commenced this action before the law went into effect so that the parties and the Court would have sufficient time to adjudicate the claims before an emergency need for relief arises.

The Amendment to the Prescription Restraint Law

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). In doing so, it did not revisit the findings made in support of Act 80 to ascertain whether they could support Act 80 as amended by Act 89 and it did not make any new findings in support of Act 89. Section 3 of Act 89 provided:

> 18 V.S.A. § 4631 is amended to read:
>
> § 4631. CONFIDENTIALITY OF PRESCRIPTION INFORMATION
>
> * * *
>
> (b) As used in this section:
>
> * * *
>
> (9) "Regulated records" means information or documentation from a

prescription dispensed in Vermont and 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~~ shall not sell, license, or exchange for value regulated records containing prescriber-identifiable ~~data~~ information, nor permit the use of regulated records containing prescriber-identifiable information 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~~, unless the prescriber consents as provided in subsection (c) of this section. Pharmaceutical manufacturers and pharmaceutical marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents as provided in subsection (c) of this section.

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

(1) the sale, license, ~~transfer,~~ exchange for value, or 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;

* * *

(7) the ~~collection, use, transfer, or~~ 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.

(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.

118. Section 7 of Act 89 also postponed the effective date of the Prescription Restraint Law until July 1, 2009.

119. The Prescription Restraint Law, as amended, by Act 89, now 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

Section 5 of Act 89 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.

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

The Prescription Restraint Law, as amended, imposes the same 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.

If the publisher plaintiffs cannot use the information other than for purposes identified as permissible in the Prescription Restraint Law, as amended, 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.

It remains 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. (PhX482 at 17-18). The law therefore will operate to freeze all or virtually all communication of prescriber identifiable information from the regulated records.

The Continuing Threat of Harm & Reasonable Fear of Enforcement

Since the amendment to the law, the publisher plaintiffs have been able to resume 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. Sadek Dep. at 112-17.

Plaintiffs today have the same reasonable fear that they had when the Prescription Restraint Law was first enacted that an action for injunctive relief and damages will be brought by the Attorney General if they execute those concrete plan on those on or after July 1, 2009.

If the law is not enjoined before July 1, 2009, plaintiffs will have no alternative but to halt gathering, analysis and publication of any information from prescriptions about prescribers doing business in Vermont or whose prescriptions are dispensed in Vermont for marketing or promotion purposes if they wish to avoid placing themselves, their sources, and their subscribers and other customers at serious risk of being subjected to massive fines and perhaps even criminal sanctions. (Sadek ¶¶ 19-26; Fisher ¶¶ 21-26; Livingston ¶¶ 20-25). The plaintiffs will be injured each day that the Prescription Restraint Law remains in force. As important, all those who benefit from their publishing activities including manufacturers, prescribers, patients, researchers, and others will lose the value of the information.

Significantly, although the law will stop the use of prescriber-identifiable data, it will not stop marketing. Manufacturers will continue marketing, but will be unable to focus those efforts on the prescribers whose practices and patients will benefit most from their drugs. Unfocused marketing results in waste of resources such as free samples. (Frankel ¶ 24). The law also will not eliminate prescribing of branded drugs when a generic is available because generics are not required by the FDA to be an exact bioequivalent of the branded drug. For this reason, doctors must continue to specify in some circumstances that patients take a branded drug. (Cole ¶¶ 13-22) (describing reason epileptics must be prescribed branded drugs).

The Lack of Research to Justify the Law

Prior to enactment of the law, its supporters did not research whether it would be effective to achieve the state's objectives. Dr. David Johnson, former president of the Vermont Medical Society, testified, for example, that his belief that the law would reduce costs is based on "either a presumption or as speculation." Johnson Dep. at 13. "We supported it because we thought, and you can, I'll use the legal term, it was a speculation." Johnson Dep. at 31. As to whether the law would achieve its objective, he candidly explained: "I will admit that it was a hope, a speculation, that if controlling this information . . . , that we felt that if this information was made unavailable to drug mining companies, that in fact this might limit costs, pharmaceutical costs." Johnson Dep. at 90.

Paul Harrington confirmed that he also had done no studies and knew of no stdies that linked the use of prescriber-identifiable data with an increase in health care costs. Harrington Dep. at 113.

Dr. Carol Boerner confirmed that she had not conducted any studies of the impact that the law would have and was not aware of any such studies. Boerner Dep. at 27.

Several witnesses who had conducted academic detailing through a state-funded program at the University of Vermont testified that while they have made an effort to evaluate whether their program has been effective to combat messages disseminated by manufacturer sales representatives, no study has been completed as yet. Kennedy Dep. at 170-71 (data may be reviewed in the early summer of 2008); Pinkney Dep. at 151-52 (it is too soon to tell whether academic detailing has been effective).

Steve Kappel, an analyst with the Legislature's Joint Fiscal Office during the 2007 legislative session, testified that the Legislature never asked him to evaluate the fiscal impact that

Act 80 would have. Kappel Dep. at 21 ("Q. Were you asked to conduct any analysis of the effect of restricting the use of prescriber-identifiable information? A. No. Q. Did you ever conduct any sort of analysis on the effect of restricting prescriber-identifiable information? A. No.").

Josh Slen, the director of Office of Vermont Health Access, testified that his agency had not conducted any investigation into the practices of pharmaceutical representatives and their sales practices before deciding to support Act 80 and that it had not studied the use of prescriber-identifiable data. Slen Dep. at 129-30

Sharon Moffat, acting commissioner of the Vermont Department of Health, testified that she was unaware of any study that evaluated whether information provided by sales representatives was biased, whether prescribers were over-prescribing patented drugs, or whether Act 80 would have any impact on health care costs or prescriber privacy interests. Moffat Dep. at 69-81.

The State's Expert Witnesses

After this legislation was filed, Vermont attempted to create a *post hoc* justification for its legislation, retaining five witnesses who together the state hoped could provide the evidentiary support that it lacked at the time that the Prescription Restraint Law was enacted -- Dr. Ashley Wazana, a child psychiatrist; Dr. Aaron Kesselheim, an internist and patent lawyer; Dr. Meredith Rosenthal; Dr. David Grande, an internist; and Shahram Ahari, a former Eli Lilly sales representative.

Dr. Wazana has reviewed literature which he concludes show that the giving of gifts to prescribers by sales representatives can induce prescribers to prescribe the drugs that the sales representatives are selling. He did not, in any of his research, reach any conclusions about the effects of using prescriber identifiable data in pharmaceutical marketing. Wazana Dep. at 39-40

Dr. Wazana had not even read the Prescription Restraint Law and could not testify about whether it would advance the state's interests. Wazana Dep. at 46.

Dr. Kesselheim testified that he is not aware of any research or studies of the use of prescriber-identifiable information by manufacturers of pharmaceutical products. Kesselheim Dep. at 26-27. He conceded that he and his colleague, Dr. Jerry Avorn, had supported the legislation in New Hampshire and Vermont on their "belief" that the laws "would be helpful in promoting and improving prescribing practices and promoting fairness in communication of -- between pharmaceutical representatives and physicians." Kesselheim Dep. at 28. He said he formed his belief on the basis of his review of literature, but had not "found anything through the date of [his] deposition in the literature that is a study of an impact that a law like the Vermont law would have on the prescribing practices of prescribers." Kesselheim Dep. at 31-32. Asked how to determine the impact that the Prescription Restraint Law might have, Dr. Kesselheim testified that the state would have to evaluate its impact *after* it goes into effect. Kesselheim Dep. at 28-29. Dr. Kesselheim did not base his opinions on personal experience with sales representatives. Indeed, he testified that he does not now see sales representatives and has not since he started his residency six years ago in 2002. Kesselheim Dep. at 22-23. Dr. Kesselheim's experience as a doctor and lawyer was limited. He received his J.D. and M.D. in 2002 at age 25. He then went on to obtain a masters degree in public health in 2007 at age 32. Kesselheim Dep. at 336.

Dr. Rosenthal testified that increasing the percentage of generic drugs prescribed would decrease the costs incurred by the State of Vermont's Medicaid and Medicare programs, but that she could not opine whether the Prescription Restraint Law would have any impact on the percentage of generic drugs prescribed. Rosenthal Dep. at 90-92, 161.

Dr. Grande, a 34-year-old-medical doctor, was retained by the Attorney General to provide opinions concerning the impact that the use of prescriber identifiable data has prescribing practices. Grande ¶ 6; Grande Dep. at 11-12. Grande graduated from medical school in 1999, and has not interacted with sales representatives since 2003. *Id.* at 108, 122. Grande has not personally conducted any studies regarding issues affecting the pharmaceutical industry; he has only read published literature and bases his expertise on such review of the literature. *Id*. at 126; 318. Grande testified that he is not aware of any research or studies of the use of prescriber-identifiable information by manufacturers of pharmaceutical products, nor has he ever outlined or undertaken to perform such a study. He admitted that he has not performed nor designed an empiric study of the Vermont law or a similar law that imposes restrictions on the communication of prescriber-identifiable information. Grande Dep. at 138-39. In his view, the effects of the Vermont law could only be measured after the restrictions imposed by the law have been in effect for at least ten months. Grande Dep. at 143-145). But he could not know one way or another what the net impact of banning prescriber identifiable data would be when one weighs the benefits against the negatives of such a prohibition. *Id*. at 138-39, 191, 319). He therefore could not determine whether the limits that the Vermont law imposes on the use of prescriber identifiable data will protect (or harm) the health of Vermonters. *Id*. at 318.

Finally, Shahram Ahari is a witness who had worked for a year and a half as a sales representative for Eli Lilly in 1999 and 2000 after receiving a B.S. degree in 1998. Ahari Dep. at 36, 42-43. He currently is unemployed and owes student loans of approximately $80,000. Ahari Dep. at 19, 34. At the time that he resigned from Eli Lilly, he had incurred more than $8,000 of charges on a credit card issued to him by Eli Lilly that Eli Lilly contended were not for its benefit. Ahari Dep. at 228-71 & PhX65. Eli Lilly's insurer then sued Ahari to recover that sum,

Ahari agreed to pay the charges, but then defaulted on the settlement agreement. PX65. Ahari contended that Eli Lilly's accusation that the charges on his card were not for his benefit were false and that he was angry at his manager "for putting me on the spot" about the expenses. Ahari Dep. at 256. Although Ahari is offered as a witness to try to portray sales representatives as pushing prescribers to make bad prescribing decisions, it is far from clear that his experience is typical within the industry and he does appear to have certain biases.

The Plaintiffs' Expert Witnesses

None of the defendants' experts have significant experience dealing with sales representatives of manufacturers. By contracts, plaintiffs' expert witnesses have extensive experience with this.

Dr. Thomas P. Wharton, a practicing cardiologist for 31 years, currently serves as chief of the Section of Cardiology and Director of the Cardiac Catheterization Laboratory at Exter Hospital in New Hampshire. After graduating from Yale in 1967, Dr. Wharton received his M.D. from Washington University School of Medicine in 1971.

Dr. Wharton testified regarding how pharmaceutical sales representatives provide "excellent information about the products they are selling, including specific testing information that I might not otherwise learn about, recent reports of scientific studies in peer-reviewed medical journals that I may have missed, and recent updates of national Guidelines." (Wharton ¶ 4). Additionally, Dr. Wharton described his experiences interacting with sales representatives. "Neither I nor my four partners have found any of the myriad interactions that we have had with pharmaceutical sales representatives to be aggressive, let alone coercive or harassing." (Wharton ¶ 5).

Dr. Wharton drew upon his 31 years of experience as a cardiologist to testify why a

doctor relying on evidence-based medicine may choose to switch patients from a generic drug to a newer, patent-protected one. "It is also an established fact that the cheapest medication in the short term may not be the least expensive in the long term, if it leads to increased morbidity and increased hospitalization because it is less efficacious or has increased side effects or unfavorable interactions compared to a more expensive drug with greater efficacy and fewer negative effects." (Wharton ¶ 5) (Wharton Dep. at 31:1-23).

Additionally, Dr. Wharton testified that 1) doctors do and should rely on numerous sources of information in order to make prescription decisions, and that pharmaceutical sales representatives represent only one of many sources; 2) doctors do and should find it useful that pharmaceutical representatives can access data regarding their individual prescribing practices as it provides another assurance that doctors receive the most up-to-date information regarding medicines used in their practices; and 3) doctors do not and should not expect that information in their prescriptions about their prescribing practices will be kept private as the public's interest in healthcare information trumps any interest in so-called professional privacy.

Dr. Andrew J. Cole, M.D., F.R.C.P. serves as the director of Epilepsy Clinic and Epilepsy Services at Massachusetts General Hospital in Boston, Massachusetts. After graduating from Dartmouth in 1979, Dr. Cole received his M.D. from Dartmouth Medical School in 1982.

Based upon his experiences with epilepsy patients he has treated, Dr. Cole testified regarding the differences between a branded drug and its so-called "generic equivalent." He explained the FDA only requires that a generic drug have bioequivalence defined by absorption parameters generally falling between 80% and 125% of those obtained with the proprietary agent. (Cole ¶ 3).

In Dr. Cole's experience, "when patients are switched from a branded drug to a generic

drug, there is a risk therefore that the patient will absorb significantly more or less of the medication than the patient was absorbing while taking the branded drug and that the new level of absorption will place the patient outside of the range necessary to control the patient's seizures." This is one reason why Dr. Cole has been reluctant in his practice to switch a patient from a branded drug to a generic drug. (Cole ¶ 3).

Dr. Cole testified regarding his concerns about how these percentages of bioequivalence can shift dramatically depending on which version of a generic medication a pharmacy dispenses. In addition to shifts in absorption rates, subtle differences in the formulation of filler, dye, and shape allowed for generic drugs can cause adverse side effects that patients may not experience with branded medications (Cole ¶ 4).

Based on his 26 years as a licensed physician, Dr. Cole testified that, "Prohibiting pharmacies and similar entities from communicating prescriber-identifiable data from prescription records will not, in my opinion, significantly, reduce the number of prescriptions being written for branded drugs that are not protected by patents or other exclusivity rights." (Cole ¶ 5).

Dr. Kenneth Ciongoli, D.O., a physician licensed in Vermont for 39 years, is a board certified neurologist. After graduating from the University of Pennsylvania in 1964, Dr. Ciongoli received a D.O. degree from the Philadelphia College of Osteopathic Medicine in 1968.

Dr. Ciongoli based his opinions regarding the Prescriber Restraint Law on nearly four decades of practicing medicine, the vast majority of which have been spent in Vermont. Dr. Ciongoli testified about the potential negative impacts that Vermont Act 80 would have on prescribers. As he strongly believes that he does not have a privacy right to his prescribing practices, Dr. Ciongoli believes that "Information is power." (Ciongoli Dep. at 15 - May 16,

2008). In denying manufactures access to the information, Dr. Ciongoli believes that the state is essentially only allowing those with an interest in cutting costs--rather than patient health--access to prescriber information. "If only payers have my prescribing information and only they can use it to influence my decisions, this would create a serious risk that I would not have the information that I need to make the optimal decision for each patient." Act 80 also concerns Dr. Ciongoli in terms of the amount of wasted time it will create for busy prescribers. "[I]f manufacturers can no longer use prescribing information for marketing, the information that they deliver to me and others will be far less focused. This threatens to waste the limited time that I and others have to see, diagnose and treat patients." (Ciongoli ¶ 6).

Dr. Michael A. Turner, who earned his Ph.D. in political economy from Columbia University, is president and senior scholar of the Political and Economic Research Council (PERC), which is a non-partisan policy institute dedicated to research, public education, and outreach on public policy matters. Prior to his graduate studies, Dr. Turner received a B.A. from Miami University in Economics (Turner ¶ 2).

Utilizing his experience examining the economic and social impact of data expansions and data contractions or restrictions in different contexts, Dr. Turner testified regarding the generally accepted methodology that economists use to make predictive judgments about the impact of laws restricting the flow of customer-identified data. Dr. Turner reviewed the legislative record regarding the Prescription Restraint Law and testified that the Legislature could not reasonably predict from the evidence considered that the law would reduce healthcare costs without harming the quality of healthcare.

Dr. Mick Kolassa is managing partner and chief executive officer of Medical Marketing Economics, a consulting firm providing advice and training to clients regarding health care

marketing and economics. Dr. Kolassa is also on the faculties of the University of the Sciences in Philadelphia and the University of Mississippi. (PhX564 at 1). Based on working in every aspect of pharmaceutical marketing during his three decade career, Dr. Kolassa testified that Vermont Act 80 will not further the legislature's stated objectives of reducing health care costs, improving public health, or protecting prescriber privacy. "However well-intentioned, the Act simply prevents pharmaceutical companies from marketing their products to Vermont prescribers efficiently. The result may be to deprive Vermont health care providers of important sources of information and sample medication." (PhX564 at . 2).

Dr. Kolassa further testified that the information collected regarding prescribers is far less detailed than other industries' collection of information regarding consumers, such as supermarkets and other retail settings. (PhX564 at 5). In addition, Dr. Kolassa noted that the Act's exemption of health care payers among others prevents any meaningful protection of so-called prescriber privacy. (PhX564 at 7). Dr. Kolassa also asserted that Vermont Act 80 contains a flawed premise -- that innovator drugs may be less valuable than older, generic drugs.

Peter Barton Hutt, senior counsel with Covington & Burling, has specialized in Food & Drug Law for more than four decades. With the exception of four years of government service as Chief Counsel for the Food and Drug Administration, Hutt spent his entire career as a Food and Drug Lawyer at Covington & Burling. Since 1994, Hutt has also taught a yearly course at Harvard on food and drug law. He co-authored the authoritative *Food and Drug Law: Cases and Materials*. Hutt testified that Act 80 will not only fail to advance Vermont's interest in lowering health care costs or improving patient safety, but will actually undermine these goals. (PhX578 at 2). His testimony described the FDA's costly drug approval process, which is risky and expensive for manufacturers as very few drugs are approved. Hutt explained that the Federal

Food and Drug Law balances the interests that manufacturers have in recouping their research and development investment and earning a fair profit against the public interest in access to drugs. If the Vermont law is successful at slowing the adoption of newly approved patented drugs as suggested by Dr. Kesselheim, manufacturers will have to raise drug prices substantially, according to Mr. Hutt's testimony, to assure recovery of their enormous investment prior to the time patents are to expire. "If manufacturers find that they cannot feasibly recoup their expenditures in the allotted time even with much higher prices, they will have no option but to decrease investment in drug development." (PhX578 at 2).

PROPOSED CONCLUSIONS OF LAW

The Prescription Restraint law violates both (I) the First and Fourteenth Amendments, and (II) the Commerce Clause of the U.S. Constitution.

I.

The Prescription Restraint Law Violates the First Amendment

The law violates the First and Fourteenth Amendments for three separate reasons: (A) the law fails the intermediate scrutiny test applicable to commercial speech, as found by Judge Barbadoro; (B) the law is subject to strict scrutiny and cannot survive such scrutiny; and (C) the law is void for vagueness and overbreadth.

As a threshold matter, however, the Attorney General contends that the Prescription Restraint Law ought not be regarded as regulating speech at all and instead urges the Court to treat the law as simply regulating commercial activities. This argument was rejected in both the New Hampshire and Maine decisions, *see Rowe*, 532 F. Supp. 2d at 167 ("the Maine statute restricts speech"); *Ayotte*, 490 F. Supp. 2d at 174-76 (the New Hampshire law is "a speech restriction"), and must equally be rejected here.

The Attorney General's argument is impossible to reconcile with the Supreme Court's ruling in *Virginia Board of Pharmacy v. Virginia Consumer Council*, 425 U.S. 748, 762 (1976) that "[p]urely factual matter of public interest," including prescription drug price information is entitled to constitutional protection, and the Second Circuit's opinion in *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 446-49 (2d Cir. 2001), that "[e]ven dry information, devoid of advocacy, political relevance, or artistic expression," such as computer code or a computer program, constitutes protected speech. Contrary to the Attorney General's attempt to characterize the information at issue as "identifying data" that has no communicative function (DE 247 at 8 n.2), important information is conveyed when a pharmacy advises the publisher plaintiffs, who in turn communicate to their subscribers, that prescribers have prescribed a certain product.[14] The information is critical to an understanding of whether a drug is being accepted in the market, whether prescribers are following prescribing practice guidelines, whether prescribers could benefit from educational information about alternative or competing drug therapies, and myriads of other purposes. If the price of a prescription drug conveyed by a pharmacist to a potential customer constitutes protected speech, *see Va. Bd. of Pharm.*, 425 U.S. at 762, then certainly the communication of information regarding the type and amount of a drug prescribed by a prescriber by a pharmacy is also protected as speech.

The Attorney General cites *Ohralik v. Ohio State Bar Association*, 436 U.S. 447 (1978), for the proposition that "several exchanges of information in the commercial marketplace" are "unprotected" by and "are freely regulated without implicating" the First Amendment. (DE 247 at 6, 8). The Supreme Court held in *Ohralik* that a restriction on in-person solicitation by a

[14] *Cf. CBC Distrib. & Mktg. v. Major League Baseball Advanced Media, L.P.*, 505 F.3d 818, 823 (8th Cir. 2007) (holding that identifying data about professional baseball players – including names, nicknames, and biographical data – is entitled to First Amendment protection).

lawyer of a client did not violate the First Amendment. The Court described solicitation as a "business transaction in which speech is an essential but subordinate component," and stated that "[w]hile this does not remove the speech from the protection of the First Amendment . . . it lowers the level of appropriate judicial scrutiny." 436 U.S. at 457. The Court in *dicta* also stated that several types of communications, including proxy statements and exchange of price information among competitors, may be regulated "without offending the First Amendment," but it never stated that those communications did not constitute speech – merely that the government's interest in regulating those communications was sufficient to withstand intermediate scrutiny. Since *Ohralik*, the Supreme Court has made clear that the government has the burden of articulating a substantial interest and demonstrating that the law directly advances that interest in a manner that is no broader than necessary, and has struck down regulations on solicitation by professionals that were not narrowly drawn to advance an important government interest. *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002) (invalidating restriction on pharmacies' advertisement of compounded drugs); *Edenfield v. Fane*, 507 U.S. 761 (1993) (invalidating ban on in-person solicitation by CPAs).

These principles were applied not only in both *Ayotte* and *Rowe*, but also in a Tenth Circuit case involving an attempt to limit use of information for marketing. In *U.S. West, Inc. v. FCC*, 182 F.3d 1224, 1228 (10th Cir. 1999), the court of appeals invalidated as an unconstitutional burden on commercial speech FCC regulations which restricted use, disclosure of, and access to customer proprietary network information ("CPNI") (including information such as when, where, and to whom a customer places calls) by telecommunications companies for marketing purposes. The government argued that the regulations "do not violate or even infringe upon petitioner's First Amendment rights because they only prohibit it from using CPNI

to target customers and do not prevent petitioner from communicating with its customers or limit anything that it might say to them," but the Tenth Circuit rejected the government's argument as "fundamentally flawed [because] [e]ffective speech has two components: a speaker and an audience." *Id.* The Attorney General simply contend that this case is wrongly decided. This Court disagrees. Where laws are imposed that restrict publication of information for marketing purposes, First Amendment interests are plainly implicated.[15]

The Attorney General next contends that pharmacies are licensed by the state and argues that the legislature may impose conditions on their licenses without violating the First Amendment.[16] The Supreme Court expressly rejected a similar argument in *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996). The Court held:

> That the State has chosen to license its liquor retailers does not change the analysis. Even though government is under no obligation to provide a person, or the public, a particular benefit, it does not follow that conferral of the benefit may be conditioned on the surrender of a constitutional right. See, e.g., Frost & Frost Trucking Co. v. Railroad Comm'n of Cal., 271 U.S. 583, 594, 46 S.Ct. 605, 607, 70 L.Ed. 1101 (1926). In Perry v. Sindermann, 408 U.S. 593, 92 S.Ct. 2694, 33 L.Ed.2d 570 (1972), relying on a host of cases applying that principle during the preceding quarter century, the Court explained that government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interests-especially his interest in freedom of speech." Id., at 597, 92 S.Ct., at 2697. That teaching clearly applies to state attempts to regulate commercial speech, as our cases striking down bans on truthful, nonmisleading speech by licensed

[15] Even in cases that have upheld restrictions placed on the use of information for marketing purposes such as *Trans Union Corp. v. FTC*, 267 F.3d 1138, 1140 (D.C. Cir. 2001), *Trans Union Corp. v. FTC*, 295 F.3d 42, 52 (D.C. Cir. 2002), and *Mainstream Marketing Services, Inc. v. FTC*, 358 F.3d 1228 (10th Cir. 2004), the courts have recognized that the laws implicate serious First Amendment concerns and could be upheld only because they survive First Amendment scrutiny. In the *Trans Union* cases, the information revealed the personal financial circumstances of individual consumers. The Do-Not-Call law at issue in *Mainstream Marketing* safeguarded the personal privacy of residential homes. The information at issue in the instant case is of a wholly different nature, as discussed *infra*.

[16] This argument could not apply to other entities regulated by the law that are not licensed such as self-insured employers, electronic transmission intermediaries, other similar entities, and pharmaceutical manufacturers.

> professionals attest. See, e.g., Bates v. State Bar of Ariz., 433 U.S., at 355, 97 S.Ct., at 2694; Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 96 S.Ct. 1817, 48 L.Ed.2d 346 (1976).

Under none of the arguments advanced by the Attorney General is there a basis to treat the Prescription Restraint Law as anything other than a restriction on speech.[17]

Plaintiffs maintain that the law is subject to strict scrutiny, but the decisions in both *Ayotte*, 490 F. Supp. 2d 163, and *Rowe*, 532 F. Supp. 2d 153, found that the laws at issue in those cases could not even survive the intermediate scrutiny applicable to commercial speech under the four-prong test set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980). Accordingly, the law first will be reviewed using the *Central Hudson* intermediate scrutiny test and, as a precautionary measure, it also will be reviewed under strict scrutiny.

Before applying either of these tests, it is important to consider the weight that this Court

---

[17] Other cases cited by the Attorney General for the proposition that the Prescription Restraint Law is not a regulation of speech are inapposite. In *Los Angeles Police Department v. United Reporting Publishing Corp*, 528 U.S. 32 (1999), the Court held that the government could, without violating the First Amendment, place conditions on the disclosure of addresses of arrestees to prevent third parties from obtaining them for certain commercial uses. The Court specifically noted that "[t]his is not a case in which the government is prohibiting a speaker from conveying information that the speaker already possesses," and that the government could decide not to give out arrestee information at all without violating the First Amendment. *Id*. at 40. By contrast, the prescriber-identifiable information at issue in this case is *not* in the hands of the State of Vermont. Rather, it is in the hands of pharmacies and similar entities that wish to communicate the information to plaintiffs. Reliance on *Reno v. Condon*, 528 U.S. 141 (2000), similarly is misplaced. In *Reno*, South Carolina challenged the Drivers' Privacy Protection Act, which prohibited state DMVs from disclosing drivers' personal information without the driver's consent, on federalism grounds. The Court addressed whether Congress was within its power under the Commerce Clause to regulate the disclosure of drivers' personal information. The Court held that "*in this context*" the drivers' information is an article of commerce and that its sale or release into the interstate stream of business is sufficient to support congressional regulation. 528 U.S. at 148 (emphasis added). The Court did not address a First Amendment challenge, and there is no basis to conclude from this decision that the First Amendment does not protect publication of lawfully obtained information by private entities. Moreover, the case involved information about a private citizen, not information about a heavily regulated prescriber.

should give to the predictive judgment of the Vermont Legislature in enacting legislation of this type and in making findings incidental to the legislation. The Attorney General contends that the Court must uphold the law if the Court concludes that the Vermont Legislature had substantial evidence from which it reasonably could conclude that the law could survive constitutional scrutiny. He contends, in essence, that the Court acts as a reviewer of the evidence before the Legislature and not as an independent finder of fact. The plaintiffs contend, to the contrary, that the Court may not defer to the judgment of the Legislature and must make a *de novo* assessment of the facts on the basis of the evidence presented to justify the statute, exercising independent judgment to ensure that the statute does not violate the federal constitution.

If the Vermont Legislature had found that the law would survive either strict or intermediate scrutiny, then it might be necessary to resolve these conflicting arguments, but it did not. Instead, the Legislature made 31 factual findings, none of which purport to predict that this law would meet the requirements of either strict or intermediate scrutiny.[18]

Even if such a finding had been made or if passage of the law itself could be treated as a predictive judgment that it would pass constitutional muster, this would not warrant judicial deference to the legislature's judgment in the manner requested. It is established that when "'Deference to a legislative finding cannot limit judicial inquiry when First Amendment rights

[18] The closest the findings come to predicting the law would meet the requirements of either test is in finding 31 which states: "This act is necessary to protect prescriber privacy by limiting marketing to prescribers who choose to receive that type of information, to save money for the state, consumers, and businesses by promoting the use of less expensive drugs, and to protect public health by requiring evidence-based disclosures and promoting drugs with longer safety records." There is no finding that protection of "prescriber privacy" or saving money is either a compelling or important government interest. There also is no finding that the law is either the least restrictive means or no broader than necessary to advance these interests. In addition, this finding incorporates a feature of the law which was repealed by Vermont Act No. 89 (2008), the requirement that less expensive drugs be promoted by requiring evidence-based disclosures.

are at stake.'" *Sable Commc'ns of Cal., Inc. v. FCC*, 492 U.S. 115, 129 (1989) (quoting *Landmark Communications Inc., v. Virginia*, 435 U.S. 829, 843 (1978)). Even where a legislature makes express factual findings, such findings do "not foreclose [the court's] independent judgment of the facts bearing on an issue of constitutional law." *Id.* This requirement applies most obviously in cases involving challenges to content restrictions on non-commercial speech, but even when a challenged law regulates solely commercial speech, the Court may not defer to a legislative judgment. *See 44 Liquormart,*. 517 U.S. at 508-12 (rejecting argument that the courts were required to defer to a legislative judgment because that because expert opinions as to the effectiveness of the price advertising ban at issue "go both ways"); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 483 n.2 (1995).

The Attorney General contends that the Supreme Court's decisions in *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622 (1994), is authority that the Court should defer to the judgment of the Legislature. Deference was paid to a judgment of Congress in *Turner*, however, only because of a confluence of factors that are not present here: (1) the regulation at issue, a requirement that cable operators carry local broadcast signals, was content neutral and had only an incidental burden on speech, (2) the regulation sought to address the relationship between two technical, rapidly changing and closely interdependent industries, broadcast and cable television, (3) Congress had acquired considerable experience in broadcast and cable regulation over decades, and (4) Congress had developed over a three-year period tens of thousands of pages of evidence including not only anecdotal testimony, but extensive studies, upon which it based the findings expressed in the statute. In those limited circumstances, Justice Kennedy, writing for the majority on this issue, concluded that deference to the predictive judgments of Congress as to future events and the likely impact of these events was appropriate. *Id.* at 665-66.

Deference in this case is inappropriate under *Turner* because the Prescription Restraint Law is not a content-neutral statute. The law expressly targets for regulation the content of prescription records which show prescriber-identifiable information. It applies not at all to other information used for marketing by pharmaceutical manufacturers and it applies not at all to other information used by other industries for marketing. The burden imposed on speech by this law is thus not incidental to a regulation of commercial activity, but a direct regulation of the content of speech itself. In addition, deference is not appropriate here because the Vermont Legislature does not have the same type of institutional expertise in regulating pharmaceutical marketing as the FCC and Congress had in regulating the cable and broadcast industry, and the Vermont Legislature did not study the subject matter for a lengthy period of time. The legislative record reflects that the Legislature first considered the matter in January, 2007; that it intended to enact a law similar to the New Hampshire Prescription Restraint Law; after just four months the Legislature was prepared to pass such a law without making any findings that it was necessary to achieve important or compelling objectives; that after the New Hampshire law was invalidated on April 30, 2007, the Vermont Legislature made material changes to its law and, in a matter of days, created findings on the basis of evidence that had been offered in support of a prior version of the law. These circumstances are then exacerbated by the fact that the law was amended *after* the findings were adopted to eliminate an important feature of the law, but no new findings were made and the old findings were not reaffirmed as valid in light of the amendment. Under these particular circumstances, deference is not warranted. The district courts in New Hampshire and Maine reached the same conclusions for similar reasons. *See Ayotte,* 490 F. Supp. 2d at 177 n.12 ("Deference under *Turner* is not warranted"); *Rowe,* 532 F. Supp. 2d at 178-79 (a court's deference to legislative findings "does not 'foreclose . . . independent judgment of the facts

bearing on an issue of constitutional law . . . "') (citations omitted).

With these preliminary issues resolved, the law may now be examined for validity.

A. The Law Fails Intermediate Scrutiny

In *Central Hudson*, the Supreme Court held that commercial speech is entitled to First Amendment protection when (1) the speech concerns lawful activity and is not misleading, (2) the regulation does not support a substantial or important government interest, (3) the regulation does not "directly advance[] the governmental interest asserted," and (4) the regulation is "more extensive than is necessary" to the purpose for which it was enacted. 447 U.S. at 566. The State, as the party seeking to uphold a restriction on commercial speech, bears the burden of proof with respect to all four elements. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002). Deference to legislative findings is inappropriate when holding the government to its burden under *Central Hudson*. *See 44 Liquormart, Inc.*, 517 U.S. at 508-12; *Rubin*, 514 U.S. at 482-483 n. 2.

1. The Law Applies to Speech That is Not Misleading

It is beyond dispute that the speech that is the subject of the Vermont law – the information that pharmacies convey to third parties regarding the prescribing practices of individual prescribers – involves a lawful activity, and it cannot be argued that any of the information is misleading. It simply shows the historical record regarding which drugs which prescribers have prescribed.

2. The Government Interests are Not Substantial or Important

The second prong of the *Central Hudson* test requires that the regulation serve an important or substantial interest. The Legislature stated that the law was intended to achieve a number of objectives which can be grouped as follows: (1) protection of the privacy of

prescribers by preventing drug manufacturers from scrutinizing their prescribing decisions; and (2) reducing costs of prescription drugs that are attributable to manufacturers' use of prescriber-identifiable data. Neither interest is important or substantial.

a. Protecting Prescriber Privacy Is Not a Substantial or Important Interest

The notion that protecting *prescriber* privacy is a substantial government interest previously has been rejected. *Ayotte*, 490 F. Supp. 2d at 179-80. Although a state has a substantial and perhaps even compelling interest in regulating speech that (1) intrudes upon "the well being, tranquility, and privacy of the home," *Carey v. Brown*, 447 U.S. 455, 471 (1980); (2) is "pressed with such frequency or vehemence so as to intimidate, vex, or harass the recipient," *Edenfield*, 507 U.S. at 769; or (3) involves "willful or knowing affront to the invasion of the tranquility of the bereaved or injured individuals," *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 630 (1995), publication of information about their prescribing practices does not intrude upon the home, subject prescribers to harassment, or intrude upon the tranquility of vulnerable individuals. *Ayotte*, 490 F. Supp. 2d at 179-80; *see also Rowe*, 532 F. Supp. 2d at 170 ("Prescribers' prescribing patterns are . . . dissimilar to the traditional areas of privacy and, by contrast, are a matter of public concern"). Plainly, there is in this case no issue regarding the sanctity of a home, nor the invasion of the tranquility of the bereaved or injured individuals.[19] Even more recently, the federal district court in the District of Columbia rejected arguments that the federal government's disclosure of prescriber-identifiable data in its Medicare records would constitute an unwarranted invasion of the prescribers' privacy. *Consumers' Checkbook v. United*

[19] Only when a law protects a legitimate interest in privacy, such as the interest of the resident of a private home in not receiving commercial telephone call, can it be upheld on privacy grounds against a First Amendment attack. *See, e.g., Mainstream Marketing Services, Inc. v. FTC*, 358 F.3d 1228 (10th Cir. 2004).

States Dep't of Health & Human Servs., 502 F. Supp. 2d 79 (D.D.C. 2007) (interpreting Exemption 6 of the Freedom of Information Act).

The Attorney General claims that the information is used to intimidate or harass a prescriber. There is no evidence to support such a contention or even that marketing generally is so harassing of prescribers that the state has no choice other than to step in to save the prescribers and their patients from the consequence of bad decisions caused by marketing or evidence that such bad decisions outweigh the good decisions that may fairly be attributable to marketing. But even if there were such evidence, it would not be sufficient to save this law, because the law does not target marketing itself; rather, it bans the publication of truthful speech by pharmacies and others about prescribing practices that ultimately may be used in marketing. Thus, it reaches far beyond speech that is intimidating or harassing and prohibits publication of information that simply may be used for marketing purposes. The "intimidate, vex, or harass" language cited in *Ayotte*, 490 F. Supp. 2d at 179, from *Edenfield* originates with *Ohralik v. Ohio State Bar Association*, 436 U.S. 447, 462 (1978). In *Ohralik*, the Court upheld a ban on lawyers' in-person solicitation of clients because it viewed solicitation as inconsistent with the profession's ideal of the attorney-client relationship and as posing a significant potential for harm to the prospective client. 436 U.S. at 454-57. The Court has repeatedly emphasized that *Ohralik*'s holding is narrow and depended upon certain 'unique features of in-person solicitation by lawyers' that were present in the circumstances of that case."[20] *Edenfield*, 507 U.S. at 774 (citations omitted).

[20] The Supreme Court recently held in *Tennessee Secondary Schools Athletic Association v. Brentwood Academy*, 127 S. Ct. 2489 (2007), that a rule prohibiting high school coaches from recruiting middle school athletes could not survive First Amendment scrutiny on the theory that it would protected young recruits from harassment in the same way that bar rules protect accident victims from lawyers. Justice Kennedy, for the majority, noted that *Ohralik* never had been applied outside the context of lawyer regulation, *id.* at 2498 (Kennedy, J.) and Justice Thomas commented that any attempt to use *Ohralik* to justify speech restrictions on the

In *Edenfield*, the Court invalidated a ban on in-person solicitation by CPAs because it concluded that solicitation by a CPA, whose training emphasizes independence and objectivity, does not involve the same risk of overreaching and misconduct as that by a lawyer, who is a trained advocate reaching out to an unsophisticated, injured, or distressed lay person. *Id.* at 775. Thus, even though solicitation by a CPA involves speech proposing a commercial transaction, such a ban on speech violates the First Amendment. Similarly, the Vermont law restricts the publication of lawfully obtained information, and it does not even directly target the commercial transaction that the State claims is the underlying ill (detailing by pharmaceutical representatives). Prescribers are not unsophisticated, injured, or distressed, like the clients protected in *Ohralik*. Rather, they are "highly trained professionals who are committed to working in the public interest." *Ayotte*, 490 F. Supp. 2d at 181. This situation is much closer to *Edenfield*, where the Court held that "[i]nvasion of privacy is not a significant concern," 507 U.S. at 776, for potential clients of CPAs, who are expected to deliberate over the decision to hire a CPA and can simply reject the CPA's overtures. Prescribers are not asked by detailers to write prescriptions on the spot; rather, the detailer provides the prescriber information which the prescriber is then free to utilize (or not), balanced against medical journals and other sources of information that a prescriber is not only expected, but ethically required, to consult before making a prescribing decision for a particular patient. A prescriber is free to ask a detailer to leave, or to ban all detailers from the prescriber's office. "[T]he State simply does not have a substantial interest in shielding [prescribers] from sales techniques that enhance the effectiveness of truthful and non-misleading marketing information." 490 F. Supp. 2d at 181. Where a law

---

theory that they would protect targets of speech from harassment was "outright wrong" *Id.* at 2499 (Thomas, J.). Similarly, Vermont's reliance on *Ohralik* as allowing it to protect prescribers from the speech of manufacturers is outright wrong.

strives "to shield the sensibilities of listeners, the general rule is that the right of expression prevails, even where no less restrictive alternative exists. We are expected to protect our own sensibilities 'simply by averting [our] eyes.'"[21]

b. Simply Lowering Costs by Suppressing the Publication of Truthful and Important Information is Not a Substantial or Important Interest

No authority supports the proposition that a state has even a legitimate interest in adopting a law simply to lower its cost or the public's cost of prescription drugs. A law designed with such a narrow objective could have a highly detrimental effect on public health. For example, some less expensive drugs are not as effective as higher cost drugs in preventing heart attacks. An increase in heart attacks increases overall healthcare costs by increasing costs associated with emergency care and hospitalization. An increased in heart attacks also decreases patient welfare and life expectancy. The obvious point is that cheaper is not always better.

In the New Hampshire litigation, the Court recognized this proposition, commenting: "The Attorney General appears to assume that any health care cost savings that will result from a ban on the use of prescriber-identifiable data can be achieved without compromising patient care. However, this proposition is far from self-evident. " *Ayotte*, 490 F. Supp. 2d at 180. A state may have a substantial or important interest in preventing prescribing practices that are wasteful or unnecessary. If, however, that is the state's interest, then it has a heavy burden to show that the measure it has adopted will directly advance that interest, that the measure does not cause as much waste and unnecessary prescribing as it prevents, and that it does not have alternative means of achieving its objective that are less restrictive of speech.

[21] *United States v. Playboy Entm't Group, Inc.*, 529 U.S. 803, 813 (2000) (quoting *Cohen v. California*, 403 U.S. 15, 21 (1971)). This major First Amendment tenet undermines the Vermont legislature's motives and prescribers' arguments regarding abusive marketing practices by pharmaceutical representatives.

3. The Law Does Not Directly Advance a Substantial or Important Government Interest

Under the third prong of the test, "[t]he limitation on expression must be designed carefully to achieve the State's goal." *Central Hudson*, 447 U.S. at 564. Toward this end, "the restriction must directly advance the state interest involved; the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose." *Id.* A "governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restrictions will *in fact* alleviate them to a material degree." *Edenfield*, 507 U.S. at 771 (emphasis added). "[M]ere speculation or conjecture" is insufficient to fulfill these requirements. *Id*. at 770. This requirement "is critical; otherwise, 'a State could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression.'" *Rubin*, 514 U.S. at 487 (quoting *Edenfield*, 507 U.S. at 771).

The Supreme Court has repeatedly invalidated restrictions on commercial speech that "only indirectly advance the state interest involved." *Central Hudson*, 447 U.S. at 564; *see also Va. Bd. of Pharm,,* 425 U.S. at 766-68 (ban on advertising of drug prices would not directly advance the state's goals of maintaining professionalism among licensed pharmacists and protecting patient health); *Bates v. State Bar of Ariz.*, 433 U.S. 350, 368, 377 (1977) (rejecting claim that advertising ban would protect quality of attorneys' work and result in higher legal fees). To satisfy its burden, the State must not merely make assumptions. Rather, it must marshal "empirical evidence to support those assumptions." *Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87, 100 (2d Cir. 1998).

Here, the State has not imposed a direct restriction on marketing that is false or misleading or that is designed to persuade prescribers to prescribe drugs that are unnecessarily

expensive. Neither does the law impose a restriction on marketing generally. Rather, it simply prohibits pharmacies and similar entities from selling prescription information for marketing purposes. This prevents companies such as the publisher plaintiffs from obtaining and analyzing the information. It prevents those companies from selling the information to pharmaceutical manufacturers. Ultimately, it prevents the manufacturers from obtaining and using the information in their marketing efforts and irrespective of whether those marketing efforts are designed to persuade prescribers to make good or bad decisions for their patients. This is hardly a *direct* effort to stop marketing practices that are harmful or to improve the prescribing practices of prescribers. For this reason, the law fails the third prong of the *Central Hudson* test.

The law also fails this prong of the test because the Attorney General has not pointed to *any* empirical evidence that restricting the flow of prescriber- information will result in lower drug costs, anecdotal evidence that the law would achieve this objective, or even a logical argument that the law would work in this fashion. If manufacturers cannot acquire information about their prescribing practices, they undoubtedly will continue to market their products, but will do so in a far more unfocused and expensive fashion. Such marketing is not prohibited by the law. On the contrary, it will be encouraged and it seems logical that this will drive up the cost of pharmaceutical drugs by making the marketing of them less efficient.

Vermont has not, of course, imposed a wholesale ban as did New Hampshire. It abandoned that plan as soon as the New Hampshire law was declared unconstitutional. Instead, it adopted a scheme that will allow each prescriber to decide whether information about his or her prescribing practices may be published for marketing purposes. The rationale behind the law, however, is that preventing manufacturers from obtaining prescriber-identifiable data will

reduce drug costs. By creating an exemption to the law for any prescribers who consent, the Legislature arguably has undermined the cost-saving rationale for the law.[22] A law that is "pierced by exemptions and inconsistencies," typically fails the third *Central Hudson* prong because it does not directly and materially advance the government's objectives.[23]

In *Ayotte,* 490 F. Supp. 2d at 181-82, the court concluded that New Hampshire did not meet its burden of showing that its law would directly advance its cost saving objectives and the same is true here.

The State's alternative theory for upholding the law is that it directly advances the privacy interests of prescribers. In *Ayotte*, the Court saw the state's the privacy argument as indistinguishable from its cost-saving argument since protection of prescriber privacy was regarded by the State as beneficial to ensure that prescribers would not be persuaded to prescribe unnecessarily expensive drugs.[24] *Ayotte*, 490 F. Supp. 2d. at 179-80. For this reason, the court

---

[22] Whether prescribers actually would consent to use of information about them for marketing purposes remains to be seen. But if the purpose of the law is to keep prescriber information away from manufacturers, then why have an exemption at all? It logically may induce manufacturers or others to pay prescribers to release their information, driving healthcare costs up. In addition, prescribers who wish to shield their prescribing practices from scrutiny almost certainly would not elect to lift the restriction whether paid or not, so manufacturers would lose information which would help them direct information to prescribers who need it most to improve their prescribing practices. *See IMS Health Incorporated v. Rowe*, 532 F. Supp. 2d 153, 180 n.40 (D. Me. 2008), *appeal docketed*, No. 08-1248 (1st Cir. Mar. 4, 2008), observing that "physicians who prescribe high amounts of Oxycontin or Methadone, would have an added incentive" to shield their prescribing patterns from scrutiny.

[23] *See, e.g.*, *Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173, 190 (1999) (invalidating restrictions on advertising private casinos where advertisements for tribal casinos were allowed); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 488 (1995) (invalidating ban on disclosure of alcohol content in beer labels and advertising unless required under state law, purportedly to prevent "strength wars," where several states require disclosure and the federal government requires disclosure of alcohol content on wine and spirits).

[24] The *Ayotte* Court also found it unsurprising that no broader privacy rationale was advocated in light of the fact that privacy principles historically have been available only to "protect the privacy of personal information" rather than information regarding the activities of a

rejected the argument "that the law can be justified on the distinct basis that it promotes prescriber privacy." *Id.* at 180. In *Rowe*, the State advanced a distinct privacy argument, but the court found it to be "extremely narrow," in that it "only indirectly impacts one-on-one marketing" to prescribers, *Rowe*, 532 F. Supp. 2d at 171, and, ultimately, that the law only "marginally" advanced the objective of protecting prescribers against use of the information in such communications because it "does not affect the ability of government agencies, academics, insurers, and others from obtaining and analyzing the data. It does not even prevent the sale and transfer of opt-out prescribers' data to pharmaceutical companies for purposes other than marketing." *Id*. at 173.

This Court also has rejected protection of prescriber privacy as an important interest at all, but even if it could be so classified, the law would not survive the third prong of *Central Hudson* for the same reasons that the New Hampshire and Maine laws did not. The law allows disclosure of their information for a whole host of purposes, commercial and non-commercial, including pharmacy reimbursement, formulary compliance, patient care management, utilization review by a health care professional, the patient's health insurer, or the agent of either, health care research, the dispensing of prescription medications to a patient or the patient's authorized representative, certain pharmacy file transfers, and a whole host of other purposes. In addition, nothing in the statute prevents patients or health care researchers from transferring the information for any purposes whatsoever. Thus, prescriber privacy is not actually protected. The statute is not "part of a substantial effort to advance a valid interest"; rather, the most it accomplishes is "the removal of a few grains of [non-private] sand from a beach of" unfettered disclosure of prescriber-specific information. *Bad Frog*, 134 F.3d at 100.

---

regulated professional. 490 F. Supp. 2d 163, 179 n.13 (D.N.H. Apr. 30, 2007), *appeal docketed*, No. 07-1945 (1st Cir. June 20, 2007).

4. The Law is Broader Than Necessary to Serve a Substantial or Important Government Interest

The fourth step of *Central Hudson* requires the State to demonstrate a reasonable fit between the legislature's ends and the means chosen to accomplish those ends, a means narrowly tailored to achieve the desired objective. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 528 (2001); *Bad Frog*, 134 F.3d at 101. In applying this prong, the Supreme Court has made clear that if the Government can achieve its interests in a manner that restricts less speech, it must do so.[25] "If the First Amendment means anything, it means that regulating speech must be the last – not first – resort." *Thompson*, 535 U.S. at 373. The State must demonstrate empirically that less speech-restrictive measures would not provide an alternative means of accomplishing its legislative objectives. *See N.Y. Ass'n of Realtors, Inc. v. Shaffer*, 27 F.3d 834, 843 (2d Cir. 1994).

In *Central Hudson*, the Court invalidated a ban on promotional advertising of electricity because as important as the government's interests were, they did not "justify suppressing information about electric devices or services that would cause no net increase in total energy use." 447 U.S. at 570. The Vermont law similarly "does not discriminate between beneficial

[25] *See Rubin*, 514 U.S. 476, 490-491 (invalidating law prohibiting beer labels from displaying alcohol content in view of available alternatives "such as directly limiting the alcohol content of beers, prohibiting marketing efforts emphasizing high alcohol strength ..., or limiting the labeling ban only to malt liquors."); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 507 (1996) (plurality opinion) (invalidating ban on advertising the price of alcoholic beverages in part because alternatives that would not restrict speech, such as increased taxation, limits on purchases, and education campaigns, would be more likely to achieve the State's goal of promoting temperance); *Bad Frog*, 134 F.3d at 101 (enjoining rejection of application for beer label depicting a frog extending its finger, because label prohibition was broader than necessary to serve state's goal of shielding minors from vulgarity; alternatives included restrictions on placement of beer advertisements in places where children were likely to see them); *N.Y. Ass'n of Realtors, Inc. v. Shaffer*, 27 F.3d 834, 844 (2d Cir. 1994) (enjoining regulation against solicitation of real estate listings, intended to prevent practice of "blockbusting," where Secretary failed to show that issuance and enforcement of cease and desist orders on an individualized basis would be inadequate).

detailing and harmful detailing. Instead, it imposes a sweeping ban on the use of prescriber-identifiable information to enhance the effectiveness and efficiency of all detailing." *Ayotte,* 490 F. Supp. 2d at 182. It cannot be disputed that detailing has beneficial uses. Of course, the Vermont law does not prohibit detailing, and the State cannot show that the law will even reduce it any way. Instead, pharmaceutical companies will continue to send their sales forces into doctor's offices, but, uninformed as to which doctors are most likely to prescribe their products, they will be inefficient and the marketing will be more costly.

Here, there are obvious alternatives that the Vermont Legislature itself recognized as available and untested. In the very same bill that contains the Prescription Restraint Law, the Legislature voted to fund an academic detailing program that it created years ago. The program must be implemented and tested before the State can claim that it is not a reasonable alternative to restricting protected speech.[26]

The bill also established a program to distribute vouchers for samples of generic drugs equivalent to frequently prescribed prescription drugs that are used to treat common health conditions. The House Ways and Means Committee estimated that spending $270,000 on generic vouchers could save the State more than $27 million annually. (PhX415-LR593).

The State also can require prescribers to receive training about marketing, license and train sales representatives, require marketers to comply with ethical codes, ban gifts to prescribers, strengthen gift disclosure requirements, and impose penalties for bribing of prescribers. Such alternatives would not require any prohibitions on speech, and it is far more likely that they would be an effective, *direct* means of ensuring prescribers are prescribing the

[26] As Court observed in the New Hampshire case: "If the State is concerned that truthful detailing is causing health care providers to make inadvisable prescribing decisions, 'the remedy to be applied is more speech, not enforced silence.' *Whitney v. California,* 274 U.S. 357, 377 (1927) (Brandeis, J. concurring)." *Ayotte,* 490 F. Supp. 2d at 181.

appropriate medications for their patients. Because the State cannot show that it lacks alternatives to achieve its interests in a manner that does not restrict speech, or that restricts less speech, Vermont's restrictions on prescriber-identifiable data must be stricken.

B. The Law is Subject to and Cannot Survive Strict Scrutiny

Because the law cannot survive intermediate scrutiny, it is not essential to determine whether the law should be subjected to strict scrutiny. The parties have fully briefed this issue and therefore the Court will address it as well.

1. Strict Scrutiny Applies Here

Strict scrutiny applies here for three reasons: (a) the law regulates the content of noncommercial speech, (b) the law prohibits dissemination of lawfully obtained, truthful, non-commercial information of public concern, and (c) the law imposes a prior restraint on speech.

a. The Law Regulates the Content of Non-Commercial Speech

In *Board of Trustees of State University of New York v. Fox*, 492 U.S. 469, 482 (1989), the Supreme Court held that "the test for identifying commercial speech" is whether the speech "proposes a commercial transaction." Commonly, speech proposing a commercial transaction is referred to as advertising. Speech which does not propose a commercial transaction is "non-commercial speech." The Supreme Court reiterated this test in *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 423 (1993).[27] The Second Circuit also has applied this test. *See*

[27] Prior to these decisions, the Supreme Court had held that "commercial speech" also encompassed "expression related solely to the economic interests of the speaker and its audience," *Ayotte*, 490 F. Supp. 2d at 176 (citing *Central Hudson*, 447 U.S. at 561). Both *Fox* and *Discovery Network* repudiated this broader test. Nevertheless, the First Circuit has used the broader *Central Hudson* definition in *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 309 (1st Cir. 2005), and *El Dia, Inc. v. Puerto Rico Dep't of Consumer Affairs*, 413 F.3d 110, 115 (1st Cir. 2005), without discussing *Fox* or *Discovery Network*. In *El Dia*, the parties "agreed" that the broader *Central Hudson* definition applied. In *Rowe*, the court simply relied on *El Dia* and again did not consider *Fox* or *Discovery Network*. As a consequence, the Court in *Ayotte* felt

Bad Frog Brewery, 134 F.3d at 97; *N.Y. Ass'n of Realtors, Inc. v. Shaffer*, 27 F.3d 834, 840 (2d Cir. 1994). The Attorney General concedes this is the correct test. (DE 247 at 6).

Applying this test, the speech restricted by the Prescription Restraint Law cannot be classified as "commercial" because it does not "propose a commercial transaction." When pharmacies or the plaintiffs publish prescriber data, they are not proposing a commercial transaction at all. They are simply communicating information which ultimately may be used by manufacturers to decide whether, how, when, and where to market their products. No Supreme Court decision ever has suggested that a communication that might ultimately be used for marketing is itself "commercial speech."

Moreover, neither pharmacies nor plaintiffs publish prescriber information solely for their economic interests. They publish this information because they believe it substantially improves public health by allowing for the detection of prescription practices that are not in the best interest of patients and the efficient distribution of information to prescribers concerning best prescription practices. Indeed, plaintiffs perform the same historic function as newspapers. They search out information of great public importance. They analyze and edit the information. They periodically publish the information in a form that will attract subscribers. The published information shows professional errors of judgment that can and do cause death, shows trends that tell the subscribers much about the health and lifestyles of the public at large, and suggests ways that the subscribers can better serve the public with new or different products. It also allows the identification of physicians whose judgments may not rise to malpractice, but who, due to a lack

---

compelled to apply the broader *Central Hudson* test in making his determination of whether the speech regulated by the New Hampshire law was commercial or non-commercial. On the basis of this broader test he found the law regulated solely commercial speech. *Ayotte*, 490 F. Supp. 2d at 176. This Court, of course, is bound to follow the Second Circuit decisions cited above, which recognize that commercial speech is that which proposes a commercial transaction.

of knowledge or curiosity, are underutilizing highly effective medications that are currently available.[28] Subscribers read the plaintiffs' publications and use the information in much the same way that a newspaper reader uses the news of the day to make decisions about the conduct of his or her life and business. Merely because readers may use information in newspapers for marketing purposes does not, however, transform the entire contents of the newspaper into commercial speech or advertising. The speech in newspapers is plainly non-commercial and the speech regulated by the Vermont law is plainly non-commercial.

"As a general rule, laws that by their terms distinguish favored speech from disfavored speech on the basis of the ideas or views expressed are content based."[29] Here, the Legislature treated prescriber-identifiable prescription data as disfavored speech because it opposes the idea or viewpoint that manufacturers should be able to target prescribers for solicitation. Plaintiffs have a different viewpoint entirely. They believe that prescribing practices can be *improved* through aggregation, analysis, and dissemination of the information.

In determining whether a regulation is content based or content neutral, courts look to the purpose behind the regulation; typically, "[g]overnment regulation of expressive activity is content neutral if it is 'justified without reference to the content of the regulated speech.'" *Ward v. Rock Against Racism*, 491 U.S. 781, 791 (1989). Here, the findings in the law itself attempt to justify the law by direct reference to the content of the speech that it prohibits.

b. The Law Prohibits Dissemination of Lawfully-Obtained, Truthful Information of Public Concern

A second, independent reason that the law must be subjected to strict scrutiny is that it

[28] *See, e.g.,* Alex Berenson, *Market Forces Cited in Lymphoma Drugs' Disuse*, N.Y. Times, July 14, 2007 (doctors tend to prescribe lengthy regime of older drugs for lymphoma even though two newer federally-approved drugs are usually effective after one dose).

[29] *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 643 (1994) ("*Turner I*") (plurality).

authorizes prescribers to impose a prior restraint against the dissemination of lawfully-obtained, truthful information of public concern.[30]

In *Bartnicki v. Vopper*, 532 U.S. 514 (2001), the Supreme Court held that a federal statute prohibiting the interception or dissemination of cell phone communications could not be applied constitutionally against a reporter who broadcast the content of a cell phone conversation that had been unlawfully intercepted by an unknown third party and delivered to the reporter. *Id.* at 520. Although the Court found the law was content-neutral and that the Government had an interest in protecting the privacy of cell phone communications, it held that "privacy concerns give way when balanced against the interest in publishing matters of public importance." *Id.* *Bartnicki* and the cases cited therein demonstrate that even if the Vermont law were considered content neutral, it must be subjected to strict scrutiny because it prohibits the dissemination of lawfully-obtained truthful information of public concern.[31]

c. The Law Imposes a Prior Restraint on Speech

In addition, state action "forbidding certain communications . . . in advance of the time that such communications are to occur" is a prior restraint. *Alexander v. United States*, 509 U.S. 544, 550 (1993). "Any system of prior restraints of expression ... bear[s] a heavy presumption against its constitutional validity." *Bantam Books, Inc. v. Sullivan*, 372 U.S. 58, 70 (1963). A

[30] *See Rowe*, 532 F. Supp. 2d at 167 n. 14 ("the information -- the prescription history of prescribers -- is . . . a matter of public concern").

[31] The Court has repeatedly held that where one "lawfully obtains truthful information about a matter of public significance then state officials may not constitutionally punish publication of the information, absent a need . . . of the highest order." *Smith v. Daily Mail Publ'g Co.*, 443 U.S. 97, 102 (1979); *see also Smith v. Butterworth*, 494 U.S. 624 (1990) (invalidating state statute that prohibited grand jury witness from disclosing his own testimony after grand jury term ended); *Florida Star v. B.J.F.*, 491 U.S. 524 (1989) (invalidating state statute that prohibited publication of the name of a victim of a sexual offense); *Landmark Comm'ns, Inc. v. Virginia*, 435 U.S. 829 (1978) (invalidating state statute prohibiting publication of confidential proceedings of state judicial disciplinary panel)

regulation that conditions in advance the exercise of protected First Amendment activity must contain narrow, objective, and definite standards to guide the prescriber's decision to censor speech, and procedural safeguards such as time limitations for acting on a request to publish also are required to prevent a licensing scheme from being used for improper censorial purposes.[32]

2. The Law Cannot Survive Strict Scrutiny

When a law is subject to strict scrutiny, it must be narrowly tailored to promote a compelling government interest, and if a less restrictive alternative would serve the government's purpose, the legislature must use that alternative.[33] As is true of challenges to laws regulating commercial speech, the Government also bears the burden of proof in challenges to laws regulating non-commercial speech.[34]

The Vermont Legislature purportedly enacted the Prescription Restraint Law because (a) it might reduce the cost of prescription drugs, and (b) it would protect prescribers' "privacy" rights. Neither of these interests is compelling, and the statute certainly cannot be regarded as achieving either goal in a manner that is the least restrictive of speech. Notably, only a few "narrowly limited classes of speech" – such as fighting words,[35] obscenity,[36] and some defamation – have been characterized as sufficiently compelling to justify prior restraints on

---

[32] *See generally City of Littleton v. Z.J. Gifts D-4, L.L.C.*, 541 U.S. 774, 779-80 (2004) (describing the safeguards required for speech licensing).

[33] *Playboy*, 529 U.S. at 804; *see also Reno v. Am. Civil Liberties Union*, 521 U.S. 844, 874 (1997); *Sable* Comm'ns of Cal., Inc. v. FCC, 492 U.S. 115 (1989).

[34] *Playboy*, 529 U.S. at 817; *R.A.V. v. St. Paul*, 505 U.S. 377, 382 (1992); *see also Gonzalez v. O Centro Espirita Beneficente Uniao do Vegetal*, 126 S.Ct. 1211, 1219 (2006) (affirming preliminary injunction against enforcement of statute; government failed to carry its burden on first prong of strict scrutiny test); *Ashcroft v. ACLU*, 542 U.S. 656, 666 (2004).

[35] *Chaplinsky v. New Hampshire*, 315 U. S. at 568 (1942).

[36] *Miller v. California*, 413 U.S. 15 (1973).

speech. None of the interests advanced by the Vermont Legislature fall within any of these recognized categories, and therefore the Court should be especially cautious about accepting the justifications offered by the Vermont legislature as compelling.[37] As discussed above, the state's articulated reasons for passing the law – protection of prescriber privacy and lowering of prescription costs – do not even rise to the level of substantial or important. No court ever has recognized either interest as so compelling that it could be used to justify a content-based restriction on speech.

The Court also cannot conclude that this statute is the least restrictive means of achieving the objective of lowering prices or protecting prescribers from scrutiny. As discussed above, the state has a variety of alternative means of achieving its objectives, none of which restrict speech.

The Vermont law also lacks the procedural safeguards that are required to uphold a law that creates a system of prior restraint.[38] Prescribers are empowered to prohibit private parties in *advance* of publication of publishing lawfully-obtained, truthful, and important information about their prescribing practices. In essence, the State has designated each prescriber as the licensor of a 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.

---

[37] "It is basic that no showing merely of a rational relationship to some colorable state interest" suffices as a compelling interest. *Sherbert v. Verner*, 374 U.S. 398, 406 (1963). "Only the gravest abuses, endangering paramount interests," *Thomas v. Collins*, 323 U.S. 516, 530 (1945), are compelling. The Court "must searchingly examine the interests that the State seeks to promote . . . and the impediment to those objectives that would flow if its statute is not enforced." *Gonzalez v. O Centro Espirita Beneficente Uniao do Vegetal*, 126 S.Ct. 1211, 1220 (2006).

[38] *See* note 32 *supra*.

c. The Prescription Restraint Law is Void for Vagueness & Overbreadth

Laws are unconstitutionally vague where they fail to provide the requisite notice and undermine public confidence that the laws are equally enforced. *Grayned v. City of Rockford*, 408 U.S. 104, 108-09 (1972); *United States v. Hilton*, 167 F.3d 61, 74-75 (1st Cir.1999). A statute must define the prohibited conduct with sufficient definiteness that ordinary people can understand what conduct is prohibited and in a manner that does not encourage arbitrary or discriminatory enforcement. *Grayned*, 408 U.S. at 108; *Hilton*, 167 F.3d at 75. The vagueness of a content-based regulation of speech "raises special First Amendment concerns because of its obvious chilling effect on free speech," *Reno v. ACLU*, 521 U.S. 844, 871-72 (1997), in part due to the risk of discriminatory enforcement when either the speaker or the message is critical of those who enforce the law. *Gentile v. State Bar of Nev.*, 501 U.S. 1030, 1050 (1991).

The Vermont law provides that covered entities may not sell regulated records for "marketing or promoting a prescription drug." 18 V.S.A. § 4631(d). When covered entities sell information about prescriber practices, how are they to determine whether this publication is for a proscribed marketing purpose? When an entity sells the information, it may not itself be marketing *any* product or service, but it cannot know whether the information ultimately will be used by the buyer or by third parties for marketing or any other purposes. They and their sources therefore have no choice but to refrain from publishing *any* information if they wish to avoid the risk of being subjected to severe fines. The publisher plaintiffs themselves cannot and will not engage in any sale of prescriber-identifiable information for any purpose while this law remains in place due to the direct threat that it poses for them even if, as the Attorney General recently has argued, the law does not apply directly to them and even though some uses of the

information are exempted from the prohibition.[39] If, for example, IMS Health were to buy regulated records from Rite-Aid and sell them to Pfizer for healthcare research, IMS Health could have little confidence that the Attorney General or others would not contend that the records actually were used for prohibited marketing purposes. Nothing would prevent the Attorney General from charging IMS with aiding and abetting others in the commission of a civil wrong[40] or from claiming that IMS should be liable for the massive $10,000 per violation fines in the statute. Although the law expressly excludes "health care research," 18 V.S.A. § 4631(e)(1), such research often can be used to "influence sales or the market share of a prescription drug," and this activity is defined under the law as "marketing." 18 V.S.A. § 4631(b)(5). Notably, the law also contains no scienter requirement, a requirement that sometimes is capable of narrowing the application of a vague law.[41]

The law suffers not only from vagueness, but also from overbreadth. While, the law may be intended to prevent large pharmaceutical manufacturers from engaging in unprotected speech such as false and misleading speech, the law is not so limited. Instead, it prohibits entirely lawful speech concerning prescribing practices for marketing purposes. First Amendment doctrine is clear that "The Government may not suppress lawful speech as the means to suppress unlawful speech. . . . '[T]he possible harm to society in permitting some unprotected speech to

---

[39] Until the Attorney General moved for summary judgment against the First Amendment claims, he had not asserted whether the law could be interpreted as applying directly to the publisher plaintiffs. He now asserts that they should not be regarded as entities similar to pharmacies and insurers who are involved in the filling and paying for prescriptions. But what sense does that interpretation of the law make? If the publisher plaintiffs obtain the regulated records why should the law contain a hole which allow them to use the information for marketing purposes while both their sources and subscribers are prohibited from doing so?

[40] *See generally Montgomery v. David*, 915 A.2d 270 (Vt. 2006) (setting forth the elements of aiding and abetting another).

[41] *See United States v. Williams*, 128 S.Ct. 1830, 1839 (2008).

go unpunished is outweighed by the possibility that protected speech of others may be muted … .' Broadrick v. Oklahoma, 413 U.S. [601], at 612 [(1973]. The overbreadth doctrine prohibits the Government from banning unprotected speech if a substantial amount of protected speech is prohibited or chilled in the process." *Ashcroft v. Free Speech Coalition*, 535 U.S. 234, 255 (2002). Here, protected speech is both chilled and prohibited altogether.

The Attorney General cites to two recent Supreme Court decisions, *Washington State Grange v. Washington State Republican Party*, 128 S. Ct. 1184 (2008), and *Crawford v. Marion County Election Bd.*, 128 S. Ct. 1610 (2008), rejecting facial challenges to election laws, to argue that all of the plaintiffs' claims should be rejected as premature. The problem with the facial challenges in those cases, however, was that they rested on speculation as to how the law would be implemented. In *Washington State Grange*, the Court held that the law on its face – which required the state's ballots for partisan office to designate a candidate's self-declared party preference or independent status irrespective of whether the party endorsed the candidate – did not violate political parties' First Amendment rights because the parties were free to nominate the candidate of their choice. The parties argued that even if the law did not actually choose the parties' nominees, it burdened their associational rights because voters would assume that candidates on the general election ballot are the nominees of their preferred parties. The Court rejected this argument because it depended not on any facial requirement of the law but on the *possibility* that voters would be confused as to the meaning of the party-preference designation. The Court then discussed several ways in which the ballot could be designed to avoid voter confusion and concluded that because there were a variety of ways in which the state could implement the law that would eliminate any real threat of voter confusion, the plaintiffs failed to prove their facial challenge. 128 S. Ct. at 1193-95.

Unlike the parties in *Washington Grange*, the plaintiffs' challenge does not rest on any factual assumptions, and the Attorney General has not presented any possible ways that the law could be implemented consistent with the plaintiffs' First Amendment rights. The Attorney General argues primarily that the publisher plaintiffs' vagueness challenge is premised on speculation as to how the law may be applied. To some extent, any vagueness challenge is based on speculation as to how the law will be enforced. The thrust of a vagueness challenge is that the law fails to provide the requisite notice to ensure that the law will be enforced in a non-discriminatory manner. The vagueness of a content-based regulation of speech "raises special First Amendment concerns because of its obvious chilling effect on free speech."[42] A party need not wait to see whether the law is enforced in a discriminatory manner before challenging it on vagueness grounds. Significantly, neither of the Supreme Court's recent decisions rejecting facial challenges involved a vagueness claim.[43]

The publisher plaintiffs' challenge does not rest upon speculation as to how the law will affect their business. The impact of the law is clear: immediately upon the statute becoming effective, the publisher plaintiffs' sources will no longer license to them and their pharmaceutical manufacturer subscribers will no longer license from them prescriber-identifiable information for marketing purposes. The statute undeniably has a chilling effect on speech, and the publisher plaintiffs' pre-enforcement challenge is therefore ripe. *See Virginia v. Am. Booksellers Ass'n*, 484 U.S. 383 (1988) (rejecting state's claim that First Amendment challenge to statute was premature where danger of statute was largely "one of self-censorship," a harm that can be

---

[42] *Reno v. ACLU*, 521 U.S. 844, 871-72 (1997).

[43] In *Crawford*, the Court rejected a facial challenge to Indiana's requirement that in-person voters present a government-issued photographic identification. When considering the statute's broad application to all Indiana voters, the Court found it imposed only a limited burden on voters' rights. 128 S. Ct. at 1623.

realized even without an actual prosecution").

II.

The Prescription Restraint Law Violates the Commerce Clause

The Prescription Restraint Law also violates the Commerce Clause by regulating conduct occurring wholly outside of Vermont.[44]

A. The Vermont Law Has an Impermissible Extraterritorial Reach

The dormant Commerce Clause prohibits states from enacting laws that have the practical effect of controlling "'commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the state.'" *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989) (holding that Connecticut beer-price affirmation statute violated the Commerce Clause because the law's practical effect was to regulate liquor sales in other states); *see also Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986) ("the critical consideration is the overall effect of the statute on both local and interstate activity"); *Pharm. Research & Mfrs. of Am. ("PhRMA") v. Dist. of Columbia*, 406 F. Supp. 2d 56, 67-68 (D.D.C. 2005), *aff'd sub nom on other grounds*, *Biotech. Indus. Org. v. Dist. of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) (invalidating state law that regulates commerce outside its own borders as *per se* invalid).

The intent of the legislature in enacting the legislation is irrelevant; "[t]he critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the state." *Healy*, 491 U.S. at 336; *see also Am. Booksellers Found. v. Dean*, 342 F.3d 96, 103 (2d Cir. 2003). "The practical effect of the statute must be evaluated not only by considering the consequences of the statute itself, but also by considering how the challenged statute may interact with the legitimate regulatory regimes of other States . . . . Generally speaking, the

[44] In both *Ayotte* nor *Rowe*, the plaintiffs advanced this same dormant Commerce Clause argument, but neither decision addressed the argument.

Commerce Clause protects against inconsistent legislation arising from the projection of one regulatory regime into the jurisdiction of another state." *Healy*, 491 U.S. at 336.

Even a law that on its face only prohibits sales made inside the state is invalid under the Commerce Clause if its effect is to regulate conduct occurring outside the state. In *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935), the Supreme Court affirmed that a state "regulation which uses an in-state hook to affect out-of-state conduct to be an impermissible violation of the Interstate Commerce Clause." *PhRMA*, 406 F. Supp. 2d at 69. The *Baldwin* Court held unconstitutional a similar regulation of an out-of-state transaction triggered by an in-state sale. 294 U.S. at 528. The New York Milk Control Act set minimum prices to be paid by milk dealers to producers and prohibited "the sale within the state of milk bought outside unless the price paid to the producers was one that would be lawful upon a like transaction within the state" to protect small New York farmers from manufacturers. *Id*. at 519. In *Baldwin*, a New York dealer purchased its milk from a Vermont creamery, which purchased its milk from Vermont farms. *Id.* at 518. The New York dealer purchased his milk from the Vermont creamery because the prices in Vermont were lower than the minimum payable to producers in New York. *Id.* at 520. New York refused to license the transaction unless the dealer signed an agreement to conform to the New York statute and regulations in the sale of the imported milk. *Id.*

While the only sale that the act prohibited was the sale between the dealer and its in-state buyer, the Court found that the act *effectively* regulated the out-of-state sale between Vermont producers. *Id.* at 521. The Court found that New York could not prohibit the subsequent sale of milk within its borders just because the purchaser paid less outside of New York than the purchaser would have inside New York. *Id.* The state argued that the maintenance of a regular and adequate supply of pure and wholesome milk, economic security for New York farmers, and

the promotion of a higher standard of quality and public health justified the New York law, but the Court rejected all of the interests as insufficient to justify the impediments to intrastate commerce. *Id.* at 522-524. The Court struck down the New York act pursuant to "'the established doctrine . . . that a state may not, in any form or under any guise, directly burden the prosecution of interstate business.'" *Id*. at 522 (citations omitted).

Relying on *Baldwin*, a federal court enjoined the District of Columbia's Prescription Drug Excessive Pricing Act of 2005 that made it unlawful for a drug manufacturer or its licensee to sell, supply for sale, or impose minimum resale requirements for a patented prescription drug "that results in" a drug being sold in D.C. for an excessive price because the Act had a *per se* invalid extraterritorial reach in violation of the Commerce Clause. *PhRMA*, 406 F. Supp. 2d at 69. Neither the manufacturers, the wholesalers, nor the large retail chains were headquartered or operated warehouses in D.C. *Id.* at 68. The overwhelming majority of the manufacturers' sales occurred entirely outside the District, and the act specifically exempted point of sale retail sellers from its reach. *Id.* As in *Baldwin*, an in-state sale triggered application of the Act even though the act did not explicitly reference any transaction occurring outside of D.C. *Id.* at 69. In *PhRMA*, the transaction which triggered liability under the statute was a retail sale in the District, but since all the manufacturers of patented prescription drugs and all of the wholesalers to whom they sell their products were located out-of-state, the court found it "was impossible to contend that this particular application of the D.C. Act does not effect an impermissible extraterritorial reach." *Id.* at 70. In effect, "as soon as [a] drug is sold in the District, the manufacturer's out of state sale becomes the Act's primary target." *Id.* at 69. The court noted that it was "fanciful, at best," for the government to argue that the act did not control transactions outside of D.C., especially since there were "absolutely no in-state transactions that the Act directly controls" so

the statute would be rendered inoperative. *Id.* The court rejected the protection of D.C. consumers from manufacturers and the promotion of residents' health, safety, and welfare as justifications for the act, *id.* at 70-71, and held that the D.C. Act had a *per se* invalid extraterritorial reach and therefore invalidated it as applied to transactions between manufacturers and wholesalers that occurred completely outside of D.C. *Id.* at 71.

Like the laws at issue in *Baldwin* and *PhRMA*, the Vermont law has the practical effect of regulating conduct that occurs wholly outside Vermont. It allows pharmacies located in Vermont to transfer prescriber-identifiable information from prescription records to their out-of-state headquarters but then prevents those out-of-state companies from contracting with the out-of-state publisher plaintiffs for the communication of the information that exists wholly outside of Vermont's borders.

It is irrelevant whether the publisher plaintiffs are "covered entities" under the Vermont law because the law imposes severe penalties on pharmacies and similar entities if they "permit the use" of regulated records containing prescriber-identifiable information for marketing absent prescriber consent. 18 V.S.A. § 4631(d). As the Attorney General argues in his motion for summary judgment on the First Amendment, this provision requires pharmacies and other covered entities to "place contractual limits on the nonconsensual use of the data for marketing purposes." (DE 247-2 at 22). Thus, to comply with the law, the out-of-state pharmacies must insert contractual limitations on the use of the data for marketing purposes, and they must require the out-of-state publisher plaintiffs to insert the same contractual limitations in their contracts with the out-of-state pharmaceutical manufacturers, to ensure that they do not "permit the use" of the information for marketing.[45] This projects the laws of Vermont into the contracts executed

[45] All of the pharmacies that contract with the publisher plaintiffs do so outside of

outside of Vermont and otherwise governed by the laws of other states between the pharmacies and the publisher plaintiffs and the publisher plaintiffs and the pharmaceutical manufacturers.

Significantly, the definition of "marketing" is not limited to in-person detailing of a Vermont prescriber. In fact, the definition of "marketing" includes no geographic limitation whatsoever. "Marketing" is defined broadly to include:

> [A]dvertising, promotion, or any activity that is intended to be used or is used to influence sales or the market share of a prescription drug, influence or evaluate the prescribing behavior of an individual health care professional to promote a prescription drug, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.

18 V.S.A. § 4631(b)(5). Thus, by requiring pharmacies to impose contractual limitations in their agreements with the publisher plaintiffs to prohibit the pharmaceutical manufacturers' ultimate use of the information for marketing purposes, the law effectively prohibits the out-of-state publisher plaintiffs from licensing information to out-of-state pharmaceutical manufacturers for use in any of these "marketing" purposes wholly outside the state of Vermont.

The Attorney General does not dispute that the transactions between the pharmacies and the publisher plaintiffs take place outside of Vermont, nor does he point to any in-state transactions that are regulated by the law. Rather, he merely argues that because the prescriber-identifiable information originates from a prescription dispensed in Vermont and written by a prescriber doing business in Vermont, the state has the power to restrict the communication of that information for marketing purposes irrespective of the fact that the communication takes place outside of Vermont and the marketing takes place outside of Vermont. Vermont's asserted interests in protecting Vermont prescriber privacy, reducing Vermont health care costs, and protecting Vermont public health cannot stretch so far as to prohibit the out-of-state

---

Vermont.

communication of the information and ultimate use of the information for the advertising and promotion of prescription drugs and the evaluation of pharmaceutical sales force effectiveness outside the state of Vermont. The *PhRMA* court specifically noted that "creating a public health exception to the Commerce Clause . . . would 'eat up the rule under a guise of an exception.'" *PhRMA*, 406 F. Supp. 2d at 71 (quoting *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 523 (1935)). Reliance on "police powers cannot, alone, overcome the otherwise unconstitutional reach of" a regulation. *Id.*

B. Plaintiffs Are Not Asserting a Facial Commerce Clause Challenge

Contrary to the Attorney General's assertion, the publisher plaintiffs' Commerce Clause claim is not a facial challenge to the statute. Rather than challenging the statute in all of its applications, the publisher plaintiffs ask only that the Court invalidate the Vermont law to the extent it applies to transactions occurring wholly outside the state of Vermont. The publisher plaintiffs' challenge is procedurally identical to the pre-enforcement challenge raised by PhRMA to the Washington D.C. pricing law in *PhRMA v. District of Columbia*, 406 F. Supp. 2d 56, 71 (D.D.C. 2005). There, the court held that the D.C. Act had a *per se* invalid extraterritorial reach in violation of the Commerce Clause as applied to transactions between manufacturers and wholesalers that occurred wholly outside the District. 406 F. Supp. 2d at 68.

The Second Circuit's ruling in *SPGGC, LLC v. Blumenthal*, 505 F.3d 183 (2d Cir. 2007), is distinguishable.[46] The Connecticut law at issue there applied "only to sales of gift cards

[46] The Second Circuit's rationale in *National Electrical Manufacturers Association v. Sorrell*, 272 F.3d 104 (2d Cir. 2001), also is inapposite. There, NEMA argued that Vermont's imposition of labeling requirements on mercury-containing light bulbs affected manufacturers' business in other states because as a practical matter, to continue selling in Vermont, they would have to label lamps sold in every other state. The Second Circuit rejected NEMA's extra-territoriality argument because the law did not "inescapably" require manufacturers to label all lamps wherever distributed; it was only because the manufacturers were unwilling to modify

in Connecticut." *Id.* at 194. Thus, the law did not "by its terms or its effects" directly regulate sales of gift cards in other states, nor did it prevent other states from regulating gift card sales differently within their own territories. *Id.* The Vermont law, in contrast, applies to sales of prescriber-identifiable information that occur wholly outside Vermont, and it requires national pharmacy chains that have stores in Vermont to insert in their contracts with the publisher plaintiffs, which are governed by the laws of states other than Vermont, language restricting the use of the information for marketing purposes, irrespective of where that marketing occurs. The *SPGGC* court also upheld the applicability of Connecticut's regulation as it applied to sales of gift cards to Connecticut residents via the Internet, in part because the purpose of a state consumer protection statute is to protect the consumers of that state. *Id.* at 195. Vermont cannot show that it is protecting its prescribers or consumers by regulating the out-of-state sales of prescriber-identifiable information for marketing – ranging from advertising and promotion of prescription drugs to evaluation of sales force effectiveness – that may occur anywhere outside of Vermont.

C. Plaintiffs Have Standing to Assert their Commerce Clause Claim

Finally, the Attorney General asserts that the publisher plaintiffs lack standing to pursue a Commerce Clause claim because the Vermont law does not regulate their conduct. He mistakenly asserts that the publisher plaintiffs are attempting to assert the rights of third parties. Even assuming for present purposes that the publisher plaintiffs are not "covered entities" under the statute, the Attorney General is incorrect because his argument ignores the undeniable effect

---

their production and distribution systems that they would have to label non-Vermont lamps. *Id.* at 110. Here, the Prescription Restraint Law directly imposes restrictions on the out-of-state sales of prescriber-identifiable information. The Attorney General concedes that national pharmacy chains would have to modify their out-of-state contracts with the out-of-state publisher plaintiffs to prohibit the use of the information for marketing purposes irrespective of where such marketing occurs, in order to comply with the statute.

that the Prescription Restraint Law has on the business of the publisher plaintiffs, which allows them to challenge the law in their own right.

The Seventh Circuit confronted this precise situation in a Commerce Clause challenge in *Government Suppliers Consolidating Servs, Inc. v. Bayh*, 975 F.2d 1267, 1274-75 (7th Cir. 1992). There, the plaintiffs, who were brokers of municipal solid waste and arranged for trucks to haul waste from temporary storage sites in New York, New Jersey, and Pennsylvania to landfills in Indiana, brought a pre-enforcement declaratory judgment action to an Indiana statute that restricted the practice of "backhauling" of municipal waste. The Seventh Circuit rejected an argument that the plaintiffs lacked standing because they themselves did not engage in backhauling. Since it was undisputed that the plaintiffs' "business would suffer severe adverse effects from enforcement of the backhaul ban," the court held, "[s]uch economic injury, though indirect, is sufficient to confer standing." *Id.* at 1274.

The same is true here. The Attorney General does not and cannot deny that the publisher plaintiffs' business would suffer adverse economic effects from the Prescription Restraint Law. Accordingly, the publisher plaintiffs have standing to challenge the law directly.

CONCLUSION

The Prescription Restraint Law, as amended, 18 V.S.A. § 4631, is hereby declared to violate the First and Fourteenth Amendments of the United States Constitution and the Commerce Clause of the United States Constitution. The Attorney General is permanently enjoined from enforcing the law.

Done and ordered in Brattelboro, Vermont, this ___ day of _____, 2007.

J. Garvan Murtha
United States District Judge

Copies furnished to:

Thomas R, Julin & Patricia Acosta
Robert Hemley & Matthew Byrne
Counsel for IMS Heath Inc., Verispan LLC, and
Source Healthcare Analytics

Rob Weiner & Jeffrey Handwerker
Karen McAndrew & Linda Cohen
Counsel for Pharmaceutical Researchers & Manufacturers Association

Kate Duffy, David Cassetty & Bridget Asay
Counsel for the Defendants

CERTIFICATE OF SERVICE

I, Thomas R. Julin, certify that on July ____, 2008, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system. The CM/ECF system will provide service of such filing via Notice of Electronic Filing (NEF) to the following NEF parties:

Kate G. Duffy, David Cassetty
Bridget C. Asay & Sarah London
Assistant Attorneys General
109 State Street
Montpelier, Vermont 05495

Robert N. Weiner, Jeffrey L. Handwerker &
Laura Riposo VanDruff
Arnold & Porter LLP
Attorney for PhRMA
555 Twelfth Street, N.W.
Washington, D.C. 20004-1206

Karen McAndrew & Linda Cohen
Dinse, Knapp & McAndrew, PC
Attorney for PhRMA
209 Battery Street
Burlington, VT 05402

/s/ Thomas R. Julin
Thomas R. Julin

Exhibit A

The Vermont Prescription Restraint Law

Vermont Act 80, § 17 (2007), as Amended by Act 89 (2008),
codified as 18 V.S.A. § 4631

Title 18: Health
Chapter 91: Prescription Drug Cost Containment
4631. Confidentiality of prescription information

§ 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 marketers shall not use 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.

(f) 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.

(Added 2007, No. 80, § 17, Amended 2008, No. 89)

Exhibit B

The New Hampshire Prescription Restraint Law

2006 N.H. Law ch. 328, codified as
N.H. Rev. Stat. Ann. §§ 318:47-f, 318:47-g, 318-B:12(IV) (2006)

AN ACT requiring certain persons to keep the contents of prescriptions confidential.

Be it Enacted by the Senate and House of Representatives in General Court convened:

328:1 New Sections; Pharmacists and Pharmacies; Prescription Information to be Kept Confidential. Amend RSA 318 by inserting after section 47-e the following new sections:

318:47-f Prescription Information to be Kept Confidential. Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research; or as otherwise provided by law. Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force. Nothing in this section shall prohibit the dispensing of prescription medications to a patient or to the patient's authorized representative; the transmission of prescription information between an authorized prescriber and a licensed pharmacy; the transfer of prescription information between licensed pharmacies; the transfer of prescription records that may occur in the event a pharmacy ownership is changed or transferred; care management educational communications provided to a patient about the patient's health condition, adherence to a prescribed course of therapy or other information about the drug being dispensed, treatment options, or clinical trials. Nothing in this section shall prohibit the collection, use, transfer, or sale of patient and prescriber de-identified data by zip code, geographic region, or medical specialty for commercial purposes. In addition to other appropriate remedies under this chapter, a violation of this section is an unfair or deceptive act or practice within the meaning of RSA 358-A:2. Any right or remedy set forth in RSA 358-A may be used to enforce the provisions of this section.

318:47-g Patient Assistance Program.

I. Following the close of each calendar year, any clearinghouse that provides information to New Hampshire residents about pharmaceutical manufacturers' patient assistance programs shall, to the extent that the clearinghouse collects such information, provide aggregate information to the commissioner of the department of health and human services relative to either:

(a) The number of people in New Hampshire who may qualify for any manufacturer or government program during the calendar year; or

(b) The number of patients served during the calendar year.

II. An individual company may provide additional information about the individual company's patient assistance program; however, the commissioner shall combine all information from all sources, including individual companies and the clearinghouse, and shall report only aggregate information to the public.

328:2 New Paragraph; Controlled Drug Act; Prescription Information to be Kept Confidential. Amend RSA 318-B:12 by inserting after paragraph III the following new paragraph:

IV. Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research; or as otherwise required by law. Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force. Nothing in this paragraph shall prohibit the dispensing of prescription medications to a patient or to the patient's authorized representative; the transmission of prescription information between an authorized prescriber and a licensed pharmacy; the transfer of prescription information between licensed pharmacies; the transfer of prescription records that may occur in the event a pharmacy ownership is changed or transferred; care management educational communications provided to a patient about the patient's health condition, adherence to a prescribed course of therapy or other information about the drug being dispensed, treatment options, or clinical trials. Nothing in this section shall prohibit the collection, use, transfer, or sale of patient and prescriber de-identified data by zip code, geographic region, or medical specialty for commercial purposes. In addition to other appropriate remedies under this chapter, a violation of this paragraph is an unfair or deceptive act or practice within the meaning of RSA 358-A:2. Any right or remedy set forth in RSA 358-A may be used to enforce the provisions of this paragraph.

328:3 Effective Date. This act shall take effect upon its passage.

Approved: June 30, 2006

Effective: June 30, 2006

Exhibit C

The Maine Prescription Restraint Law

2007 Me. Laws Chapter 460,
codified at 22 Me. Rev. Stats. Ann. §§ 1711-E, 8704 & 8713

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §1711-E, as enacted by PL 2005, c. 589, §1, is amended to read:

§ 1711-E. Confidentiality of prescription drug information

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. ”Carrier” has the same meaning as in Title 24-A, section 4301-A, subsection 3.

A-1. ”Administrator” has the same meaning as in Title 24-A, section 1901, subsection 1.

A-2. ”Detailing” means one-to-one contact with a prescriber or employees or agents of a prescriber for the purpose of increasing or reinforcing the prescribing of a certain drug by the prescriber.

B. ”Electronic transmission intermediary” means an entity that provides the infrastructure that connects the computer systems or other electronic devices used by and between health care practitioners, prescribers, pharmacies, health care facilities ~~and~~, pharmacy benefit managers ~~to~~, carriers and administrators and agents and contractors of those ~~carriers and agents~~persons and entities in order to facilitate the secure transmission of an individual’s prescription drug order, refill, authorization request, claim, payment or other prescription drug information.

C. ”Health care facility” has the same meanings as in section 1711-C, subsection 1, paragraph D.

D. ”Health care practitioner” has the same meanings as in section 1711-C, subsection 1, paragraph F.

E. ”Health plan” means a health plan providing prescription drug coverage as authorized under the federal Medicare Prescription Drug, Improvement and Modernization Act of 2003, Public Law 108-173.

F. ”Individual” means a natural person who is the subject of prescription drug information.

F-1. ”Marketing” means any of the following activities undertaken or materials or products made available to prescribers or to their employees or agents related to the transfer of prescription drugs from the producer or seller to the consumer or buyer:

(1) Advertising, publicizing, promoting or selling a prescription drug;

(2) Activities undertaken for the purpose of influencing the market share of a prescription drug or the prescribing patterns of a prescriber, a detailing visit or a personal appearance;

(3) Activities undertaken to evaluate or improve the effectiveness of a professional detailing sales force; or

(4) A brochure, media advertisement or announcement, poster or free sample of a prescription drug.

"Marketing" does not include pharmacy reimbursement, formulary compliance, pharmacy file transfers in response to a patient request or as a result of the sale or purchase of a pharmacy, patient care management, utilization review by a health care provider or agent of a health care provider or the patient's health plan or an agent of the patient's health plan, and health care research.

F-2. "Pharmacy" means a mail order prescription pharmacy as defined in Title 32, section 13702, subsection 13 or a drug outlet as defined in Title 32, section 13702, subsection 10.

G. "Pharmacy benefits manager" has the same meaning as in section 2699, subsection 1, paragraph F.

G-1. "Prescriber" means a person who is licensed, registered or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice.

H. "Prescription drug information" means information concerning prescription drugs as defined in Title 32, section 13702, subsection 24 and includes prescription drug orders as defined in Title 32, section 13702, subsection 25.

I. "Prescription drug information intermediary" means a person or entity that communicates, facilitates or participates in the exchange of prescription drug information regarding an individual or a prescriber. "Prescription drug information intermediary" includes, but is not limited to, a pharmacy benefits manager, a health plan, an administrator and an electronic transmission intermediary and any person or entity employed by or contracted to provide services to that entity.

1-A. Findings. The Legislature finds that enactment of this section will assist the State to achieve the following compelling state interests: to improve the public health, to limit annual increases in the cost of health care and to protect the privacy of patients and prescribers in the health care system of this State.

A. The State has a duty to assist public and private payors and health care practitioners and consumers to maintain an effective and efficient health care system that is based on sound medical and scientific knowledge and the professional judgment of health care practitioners and that is trusted by the general public.

B. Patients and prescribers have requested that the Legislature provide a mechanism for protecting the confidentiality of identifying prescription drug information from use for marketing purposes. Joining them are payors of all types and the general public demanding from the health care system efficiency, effectiveness and increased access for all persons.

C. Across the nation data companies purchase for marketing purposes computerized prescription drug records from pharmacies and insurers that identify prescribers. These records are sold to prescription drug manufacturers that use personally identifying prescriber information to attempt to influence prescribers to prescribe higher priced drugs, thus increasing the market share and profitability of the manufacturers and driving up the cost of health care.

D. Restricting the use of prescriber identifying information will act to decrease drug detailing that targets the prescriber, thus increasing decisions to prescribe lower priced drugs and decisions made on the basis of medical and scientific knowledge and driving down the cost of health care.

E. With redirected drug detailing programs, manufacturers of prescription drugs will be able to increase their investments in new and more effective prescription drugs and savings will accrue to payors that can be used for increased access to health care and for other necessary public and private purposes.

F. The provisions of this section are narrowly and carefully tailored to address the findings listed in this subsection, to achieve the State's purposes listed in subsection 1-B and to advance the State's compelling interests.

1-B. Purposes. It is the intent of the Legislature in enacting this section to achieve the following compelling state interests: to improve public health, to limit annual increases in the cost of health care and to protect the privacy of patients and prescribers in the health care system of this State.

A. The establishment of a system to protect patient confidentiality is critical to patient trust in the integrity of the health care system of this State. It will protect prescribers' expectations of privacy, freeing them from pressure to prescribe based on comparisons among them and their peers and aiding them in making health care decisions based on the best interests of the patient and on medical and scientific evidence about prescription drugs and health care treatments. It will decrease the influence of drug representatives. This will build patient and prescriber confidence in the health care system.

B. Restrictions on the use of personally identifying information for marketing purposes will protect personal privacy rights, end the use of prescriber comparisons for purposes related to manufacturer profitability and decrease unnecessary marketing costs.

C. The provisions of this section are narrowly and carefully tailored to address the findings listed in subsection 1-A, to achieve the State's purposes listed in this subsection and in

conjunction with the following efforts to advance the State's compelling interests:

(1) Prior authorization and drug utilization review in the MaineCare program under section 3174-M;

(2) Reporting of a broad array of prescription drug marketing costs under section 2698-A and subsequent reporting by the department to the Legislature and the Attorney General;

(3) Prescription drug price disclosure under section 2698-B;

(4) Generic and therapeutically equivalent substitution of prescription drugs under Title 32, section 13781; and

(5) Protection of patient prescription drug information held by health care practitioners under section 1711-C.

2. Confidentiality of prescription drug information that identifies the individual. A carrier or prescription drug information intermediary may not license, use, sell, transfer or exchange for value, for any marketing purpose, prescription drug information that identifies directly or indirectly the individual ~~except if expressly permitted under section 1711-C, Title 24, Title 24-A or the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as amended~~.

2-A. Confidentiality of prescription drug information that identifies the prescriber. Beginning January 1, 2008, a carrier, pharmacy or prescription drug information intermediary may not license, use, sell, transfer or exchange for value, for any marketing purpose, prescription drug information that identifies a prescriber who has filed for confidentiality protection in accordance with subsection 4.

3. Enforcement. A violation of ~~this section~~subsection 2 or 2-A is a violation of the Maine Unfair Trade Practices Act.

4. Confidentiality protection procedures. The procedures in this subsection apply to the protection of prescription drug information that identifies a prescriber.

A. Beginning October 1, 2007, a board of licensure of a prescriber shall provide as part of the application process for licensure and relicensure confidentiality protection information and procedures as set forth in this paragraph.

(1) The application materials must state that prescription drug information that identifies the prescriber is used for marketing purposes by carriers, pharmacies and prescription drug information intermediaries and that, with regard to that use of information, the confidentiality of the prescriber may be protected under this section in

one of 3 ways:

(a) If the licensing procedure is done by regular mail, by signing and submitting to the Maine Health Data Organization the accompanying confidentiality protection form and addressed envelope;

(b) If the licensing procedure includes a check-off box on the application form or electronically, by completing the check-off box and submitting the form to the licensing board; or

(c) If the licensing procedure is done over the Internet and the licensing board has provided an electronic link over the Internet from the application materials, by use of the electronic link to the Maine Health Data Organization website.

(2) The licensing board shall submit to the Maine Health Data Organization on a monthly basis a list of all prescribers who have filed with the licensing board for confidentiality protection.

(3) The confidentiality protection information must inform the prescriber that filing for confidentiality protection is effective until it is revoked by the prescriber.

B. The boards of licensure may adopt rules to implement paragraph A. Rules adopted pursuant to this paragraph are routine technical rules as defined by Title 5, chapter 375, subchapter 2-A.

C. The department shall assess an annual fee payable by October 1st each year beginning in 2007 on manufacturers of prescription drugs whose drugs are dispensed to members of the MaineCare program under chapter 855 and enrollees in the elderly low-cost drug program under section 254-D. Eighty percent of the fees collected under this paragraph must be deposited in a separate account that does not lapse at the end of the fiscal year and must be used to cover the costs of the Maine Health Data Organization pursuant to paragraph A and section 8713. Twenty percent of the assessments must be retained by the department.

5. Rules. The department, after consultation with the Governor's Office of Health Policy and Finance, shall adopt rules to implement this section. Rules adopted pursuant to this subsection are routine technical rules as defined by Title 5, chapter 375, subchapter 2-A.

Sec. 2. 22 MRSA §8704, sub-§4, as amended by PL 1999, c. 127, Pt. B, §8, is further amended to read:

4. Rulemaking. The board shall adopt rules necessary for the proper administration and enforcement of the requirements of this chapter and to carry out the duties of the organization under section 1711-E, subsection 4 and section 8713. All rules must be adopted in accordance with Title 5, chapter 375 and unless otherwise provided are routine technical rules as defined in Title 5, chapter 375, subchapter ~~II-A~~2-A.

Sec. 3. 22 MRSA §8704, sub-§7, as amended by PL 2005, c. 565, §5, is further amended to

read:

7. Annual report. The board shall prepare and submit an annual report on the operation of the organization and the Maine Health Data Processing Center as authorized in Title 10, section 681, including any activity contracted for by the organization or contracted services provided by the center, with resulting net earnings, to the Governor and the joint standing committee of the Legislature having jurisdiction over health and human services matters no later than February 1st of each year. The report must include an annual accounting of all revenue received and expenditures incurred in the previous year and all revenue and expenditures planned for the next year. The report must include a list of persons or entities that requested data from the organization in the preceding year with a brief summary of the stated purpose of the request.

As part of its annual report, the organization shall report on filings for confidentiality protection under section 1711-E, subsection 4, the disclosure of the names of prescribers who filed for confidentiality protection, funding through the assessment under section 1711-E, subsection 4, paragraph C and recommendations for legislation to improve operation of section 1711-E, subsection 4.

Sec. 4. 22 MRSA §8713 is enacted to read:

§ 8713. Confidentiality protection for certain health care practitioners

The organization shall establish procedures to accept filings for confidentiality protection from health care practitioners who file with the organization under section 1711-E, subsection 4 and licensing boards that submit lists of names of practitioners who file for confidentiality protection. The procedures must provide for disclosure, upon request, of the names of practitioners who filed for confidentiality protection. The costs of the organization for performing the functions under this section must be met by funding provided under section 1711-E, subsection 4, paragraph C.

Sec. 5. Transfer to the Maine Health Data Organization. Notwithstanding any other provision of law, the State Controller after consultation with the Commissioner of Health and Human Services and the Director of the Maine Health Data Organization shall transfer funds as determined and available under section 1 of this Act in each of fiscal years 2007-08 and 2008-09 from the Bureau of Medical Services, Other Special Revenue Funds account in the Department of Health and Human Services to the Maine Health Data Organization, Other Special Revenue Funds account for costs incurred as a result of this Act.

Sec. 6. Appropriations and allocations. The following appropriations and allocations are made.

HEALTH AND HUMAN SERVICES, DEPARTMENT OF (FORMERLY DHS)

Bureau of Medical Services 0129

Initiative: Provides a base allocation for the costs of the prescription drug privacy program.

OTHER SPECIAL REVENUE FUNDS	**2007-08**	**2008-09**
All Other	$500	$500

OTHER SPECIAL REVENUE FUNDS TOTAL	$500	$500

Effective September 20, 2007

Exhibit D to Trial Memo

Publishers' Comparison of Prescription Restraint Laws

New Hampshire	Vermont	Maine
Type of Law **Flat ban** – Prohibits commercial uses of prescriber identifiable data whether prescriber elects to allow or not	**Type of Law** **Opt in** – Prohibits commercial uses of prescriber identifiable data unless prescriber opts in to such uses	**Type of Law** **Opt Out** – Prohibits commercial use of prescriber identifiable data, but only if prescriber opts out of such uses
Legislative Findings of Need No findings, but state claims in litigation that law would reduce health care costs without harming quality and would protect prescriber privacy	**Legislative Findings of Need** This act is necessary to protect prescriber privacy by limiting marketing to prescribers who choose to receive that type of information, to save money for the state, consumers, and business by promoting the use of less expensive drugs, and to protect public health by requiring evidence-based disclosures and promoting drugs with longer safety records	**Legislative Findings of Need** Enactment will assist the State to achieve compelling interests; to improve public health; to limit annual increases in the cost of health care and to protect the privacy of patients and prescribers in the health care system of this State
Records Affected Records relative to prescription information containing patient and prescriber identifiable data	**Records Affected** Records which include prescription information containing prescriber-identifiable data	**Records Affected** Prescription drug information that identifies a prescriber
Entities Targeted Pharmacy benefits manager; insurance company; electronic transmission intermediary; retail, mail order, or Internet pharmacy; **or other similar entity**	**Entities Targeted** A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, **or other similar entity,** and a pharmaceutical marketer	**Entities Targeted** Carrier, pharmacy or **prescription drug information intermediary** – which is a person or entity that communicates . . . prescription drug information regarding an individual or prescriber
Prohibited Uses Advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional detailing sales force	**Prohibited Uses** Advertising, promotion, or any activity intended to be used or used to influence sales or market share of a prescription drug, influence or evaluate prescribing behavior of an individual health care professional, to promote a prescription drug, market prescription drugs to patients, or evaluate effectiveness of a pharmaceutical detailing sales force	**Prohibited Uses** Advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional detailing sales force
Allowed Uses Pharmacy reimbursement; formulary compliance; care management; utilization review by a healthcare provider, the patient's insurance provider or the agent of either; health care research; or as otherwise provided by law; dispensing of prescription mediations to a patient or to the patient's authorized representative; transmission of prescription information between an authorized prescribed and a licensed pharmacy; transfer of prescription information between licensed pharmacies; transfer of prescription records that may occur in the event a pharmacy ownership is changed or transferred; care management educational communications provided to a patient about the patient's health condition, adherence to a prescribed course of therapy or other information about the drug being dispensed, treatment options, or clinical trials; collection, use, transfer of sale of information by zip code, geographic region, or medical specialty	**Allowed Uses** Pharmacy reimbursement; prescription drug formulary compliance; patient care management; utilization review by a healthcare professional, the patient's health insurer, or the agent of either; or health care research; the dispensing of prescription mediations to a patient or to the patient's authorized representative; 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; care management educational communications provided to a patient about a 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; the collection, use, or disclosure of prescription information ot other regulatory activity as authorized [by law]; 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 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	**Allowed Uses** Pharmacy reimbursement; formulary compliance; pharmacy file transfers in response to a patient request or as a result of the sale or purchase of a pharmacy, patient care management, utilization review by a health care provider or agent of a health care provider or the patient's health plan or an agent of the patient's health plan, and health care research

About this Chart:

This chart was prepared for IMS Health Inc., Verispan LLC, and Source Healthcare Analytics, Inc. for use in IMS Health Inc. v. Sorrell, No 1:07-cv-188 & 220 jgm, US District Court for the District of Vermont