09-1913-cv(L)
09-2056-cv(CON)

IN THE

United States Court of Appeals

FOR THE SECOND CIRCUIT

IMS HEALTH INCORPORATED, VERISPAN, LLC, SOURCE HEALTHCARE ANALYTICS, INC., a subsidiary of Wolters Kluwer Health, Inc., and PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiffs-Appellants,

—against—

WILLIAM H. SORRELL, as Attorney General of the State of Vermont, JIM DOUGLAS, in his official Capacity as Governor of the State of Vermont, and ROBERT HOFMANN, in his capacity as Secretary of the Agency of Human Services of the State of Vermont,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT (BRATTLEBORO)

BRIEF FOR PLAINTIFFS-APPELLANTS IMS HEALTH INCORPORATED, VERISPAN LLC AND SOURCE HEALTHCARE ANALYTICS, INC.

THOMAS R. JULIN
JAMIE Z. ISANI
PATRICIA ACOSTA
HUNTON & WILLIAMS LLP
1111 Brickell Avenue, Suite 2500
Miami, Florida 33131
(305) 810-2516

ROBERT B. HEMLEY
MATTHEW B. BYRNE
GRAVEL & SHEA, P.A.
P.O. Box 369
Burlington, Vermont 05402
(802) 658-0220

THOMAS C. GOLDSTEIN
AKIN GUMP STRAUSS HAUER & FELD LLP
Robert S. Strauss Building
1333 New Hampshire Avenue, N.W.
Washington, D.C. 20036-1564
(202) 887-4060

MARK A. ASH
SMITH, ANDERSON, BLOUNT, DORSETT, MITCHELL & JERNIGAN, LLP
2500 Wachovia Capitol Center
P.O. Box 2611
Raleigh, North Carolina 27602-2611
(919) 821-1220

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

CORPORATE DISCLOSURE STATEMENT

IMS Health Incorporated has no parent corporation. Verispan LLC is wholly owned by SDI Health LLC. Source Healthcare Analytics, Inc. is wholly owned by Wolters Kluwer Health, Inc. which is wholly owned by Wolters Kluwer N.V. No publicly held company owns 10 percent or more of any party's stock.

/s/ Thomas R. Julin
Thomas R. Julin

TABLE OF CONTENTS

CERTIFICATE OF INTERESTED PARTIES AND CORPORATE DISCLOSURE STATEMENT C1

TABLE OF CONTENTS i

TABLE OF AUTHORITIES iii

STATEMENT REGARDING ORAL ARGUMENT viii

EXPLANATION OF REFERENCES viii

PRELIMINARY STATEMENT 1

JURISDICTIONAL STATEMENT 1

ISSUES PRESENTED FOR REVIEW 1

STATEMENT OF THE CASE 2

STATEMENT OF THE FACTS 3

The Plaintiffs' Publications 3

The Vermont Prescription Restraint Law 7

Proceedings Before the District Court 11

STANDARD OF REVIEW 18

SUMMARY OF THE ARGUMENT 19

ARGUMENT 22

I. The Prescription Restraint Law Violates The First Amendment 22

A. The Law Should Have Been Subjected to Strict Scrutiny 22

B. The District Court Misapplied the Central Hudson Test. 30

1. The Prescription Restraint Law Rests on an Impermissible Purpose of Limiting the Persuasive Effect of Truthful, Non-Misleading Information.....31

2. The District Court Avoided Deciding Whether the Law Directly Advances Substantial or Important Interests.....34

3. The District Court Failed to Apply Central Hudson's Fourth Prong.....45

II. The Law Violates the Dormant Commerce Clause by Prohibiting Commerce Wholly Outside of Vermont.....57

CONCLUSION.....61

CERTIFICATE OF COMPLIANCE.....62

CERTIFICATE OF SERVICE.....63

TABLE OF AUTHORITIES

Cases

44 Liquormart, Inc. v. Rhode Island,
517 U.S. 484 (1996).....25, 35, 48

Alexander v. United States,
509 U.S. 544 (1993).....29

America Booksellers Foundation v. Dean,
342 F.3d 96 (2d Cir. 2003) 58, 59

Anderson v. Treadwell,
294 F.3d 453 (2002).....15, 30

Bad Frog Brewery, Inc. v. New York State Liquor Authority,
134 F.3d 87 (2d Cir. 1998) 27, 36, 48

Baldwin v. G.A.F. Seelig, Inc.,
294 U.S. 511 (1935).....58

Bantam Books, Inc. v. Sullivan,
372 U.S. 58 (1963).....29

Bartnicki v. Vopper,
532 U.S. 514 (2001).....28

Bates v. State Bar of Arizona,
433 U.S. 350 (1977).....36

Board of Trustees of State University of New York v. Fox,
492 U.S. 469 (1989).....22, 25, 26

Bolger v. Youngs Drug Products Corp.,
463 U.S. 60 (1983).....24

Bose Corp. v. Consumers Union of United States, Inc.,
466 U.S. 485 (1984).....18, 19

Brown-Forman Distillers Corp. v. New York State Liquor Authority,
476 U.S. 573 (1986).....57

CFTC v. Vartuli,
228 F.3d 94 (2d Cir. 2000) 23, 27, 29

Cal-Almond, Inc. v. USDA,
14 F.3d 429 (9th Cir. 1993) 38, 40, 41, 44, 46

Central Hudson Gas & Electric Corp. v. Public Service Commission,
447 U.S. 557 (1980).....14, 30, 36

Pagan v. Fruchey,
492 F.3d 766 (6th Cir. 2007) 38

City of Cincinnati v. Discovery Network, Inc.,
507 U.S. 410 (1993).....23, 29, 35, 49

City of Littleton v. Z.J. Gifts D-4, L.L.C.,
541 U.S. 774 (2004).....29

Florida Bar v. Went For It,
515 U.S. 618 (1995).....25

Greater New Orleans Broadcast Association, Inc. v. United States,
527 U.S. 173 (1999).....23, 35, 48, 55, 56

Healy v. Beer Institute,
491 U.S. 324 (1989).....57, 58

IMS Health Inc. v. Ayotte,
490 F. Supp. 2d 163 (D.N.H. 2007), *rev'd*, 550 F.3d 42 (1st Cir. 2008).....8, iv

IMS Health Inc. v. Ayotte,
550 F.3d 42 (1st Cir. 2008),
cert. denied, 77 U.S.L.W. 3562 (U.S. June 29, 2009).....iv

IMS Health Inc. v. Rowe,
532 F. Supp. 2d 153 (D. Me. 2007),
appeal docketed, No. 08-1208 (1st Cir. Mar. 4, 2008).....27, iv

IMS Health Inc. v. Sorrell, 01:07-CV 2009 WL 1098474 (D. Vt. Apr. 23, 2009) 1

Landmark Communications Inc., v. Virginia, 435 U.S. 829 (1978).....35

Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001).....23, 50, 52

New York Association of Realtors, Inc. v. Shaffer, 27 F.3d 834 (2d Cir. 1994) 23, 36, 48

New York State Restaurant Association v. N.Y. City Board of Health, 556 F.3d 114 (2d Cir. 2009) 23

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) 58, 59

R.A.V. v. St. Paul, 505 U.S. 377 (1992).....24, 28

Reno v. ACLU, 521 U.S. 844 (1997).....53

Reynolds v. Giuliani, 506 F.3d 183 (2d Cir. 2007) 18

Rose v. AmSouth Bank of Fla., 391 F.3d 63 (2d Cir. 2004) 18

Rubin v. Coors Brewing Co., 514 U.S. 476 .....35, 48, 55

SPGGC, LLC v. Blumenthal, 505 F.3d 183 (2d Cir. 2007) 59

Sable Communications of California, Inc. v. FCC,
492 U.S. 115 (1989).....35

Smith v. Butterworth,
494 U.S. 624 (1990).....28

Thompson v. Western States Medical Ctr.,
535 U.S. 357 (2002).....passim

Turner Broadcast System v. FCC,
512 U.S. 622 (1994).....passim

United States v. Playboy Entertainment Group,
529 U.S. 803 (2000).....30

United States v. Williams,
128 S. Ct. 1830 (2008).....54

Universal City Studios, Inc. v. Corley,
273 F.3d 429 (2d Cir. 2001) 14

Virginia State Board of Pharmacy v.
Virginia Citizens Consumer Council, Inc.,
425 U.S. 748 (1976).....23, 26, 36, 47

Virginia v. Hicks,
539 U.S. 113 (2003).....52

Statutes

21 U.S.C. § 352(a) 6

28 U.S.C. § 1291.....1

28 U.S.C. § 1331.....1

42 U.S.C. § 1983.....1, 2

9 Vt. Stat. Ann. § 2458(a).....10

9 Vt. Stat. Ann. § 2451(a) 10

9 Vt. Stat. Ann. § 2461 54

18 Vt. Stat. Ann. § 4605 48

18 Vt. Stat. Ann. § 4631 .....passim

Rules

Fed. R. App. P. 32(a)(7)(B) 62

Fed. R. Evid. 201(f) 54

STATEMENT REGARDING ORAL ARGUMENT

The district court rejected plaintiffs' constitutional challenge to a Vermont statute that limits the distribution and use of information regarding pharmaceutical prescribing practices for the purpose of marketing drugs. The seriousness and complexity of this appeal are illustrated by the fact that the ruling below upholds a state law similar to a state law upheld by the First Circuit in *IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008), *cert. denied*, 77 U.S.L.W. 3562 (U.S. June 29, 2009), but disagrees with the majority's main holding, and conflicts with two considered district court decisions holding such laws violate the First Amendment. *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163 (D.N.H. 2007), *rev'd*, 550 F.3d 42 (1st Cir. 2008); *IMS Health Inc. v. Rowe*, 532 F. Supp. 2d 153 (D. Me. 2007), *appeal docketed*, No. 08-1208 (1st Cir. Mar. 4, 2008). Oral argument would materially assist this Court's disposition of this important case.

EXPLANATION OF REFERENCES

Citations follow the following form: docket entry (DE __); appendix (A __); special appendix (SPA ___).

PRELIMINARY STATEMENT

Plaintiffs appeal from the final judgment of the U.S. District Court for the District of Vermont upholding Vt. Acts No. 80, § 17 (2007), codified as Vt. Stat. Ann. tit. 18, § 4631 (2007), as amended by Vt. Acts No. 89 (2008) (Prescription Restraint Law). *IMS Health Inc. v. Sorrell*, 01:07-CV-188, 2009 WL 1098474 (D. Vt. Apr. 23, 2009) (Murtha, J.). The district court's ruling errs in rejecting plaintiffs' claims that the statute violates the First Amendment and Commerce Clause of the U.S. Constitution.

JURISDICTIONAL STATEMENT

Plaintiffs filed suit pursuant to 42 U.S.C. § 1983. The district court had jurisdiction pursuant to 28 U.S.C. § 1331. The district court entered a final judgment on April 23, 2009. (DE 431). Plaintiffs timely filed their notice of appeal on May 4, 2009. (DE 432). This Court has jurisdiction pursuant to 28 U.S.C. § 1291.

ISSUES PRESENTED FOR REVIEW

I. Whether the Prescription Restraint Law violates the First Amendment.

II. Whether the Prescription Restraint Law violates the Commerce Clause.

STATEMENT OF THE CASE

On June 9, 2007, Vermont enacted the Prescription Restraint Law. The statute prohibits the transfer of information relating to prescriptions issued in Vermont for the purpose of pharmaceutical marketing, absent the physician's consent. See Vt. Acts No. 80, § 17 (2007), codified as Vt. Stat. Ann. tit. 18, § 4631 (2007), as amended by Vt. Acts No. 89 (2008) (SPA 67-69). As amended, the statute goes into effect on July 1, 2009.

On August 29, 2007, plaintiffs-appellants IMS Health Incorporated, Verispan LLC, and Source Healthcare Analytics (the "publisher plaintiffs" or the "publishers") filed suit in the U.S. District Court for the District of Vermont under 42 U.S.C. § 1983, alleging that the statute violates the First Amendment and the Commerce Clause. (DE 1). A further claim that the statute is preempted by federal law was later dropped in response to a statutory amendment. (DE 220). Plaintiffs moved for a preliminary injunction. (DE 6).

On October 23, 2007, the Pharmaceutical Research and Manufacturers of American (PhRMA) filed its own complaint in the same court challenging the Prescription Restraint Law under, *inter alia*, the First Amendment. The district court consolidated the cases. (DE 60).

The district court combined plaintiffs' preliminary injunction request with a trial on the merits, which was held from July 28, 2008 through August 1, 2008.

The parties then submitted proposed findings of fact and conclusions of law. (DE 410, 412-14).

On April 23, 2009, the district court ruled for the State on the merits and denied the plaintiffs' request for an injunction. (DE 430; SPA 1-61).

This appeal followed.

STATEMENT OF THE FACTS

Plaintiffs analyze and publish information regarding the prescribing history of physicians around the nation, including in Vermont. The information that plaintiffs publish is truthful and not misleading. It is used for a variety of purposes, including public health research, drug development, and targeted pharmaceutical marketing to individual physicians. (A 78-79). Vermont's Prescription Restraint Law, however, prohibits plaintiffs' publication of that information for marketing and promotion, absent the consent of the prescribing physician. The district court rejected plaintiffs' First Amendment and Commerce Clause challenges to the statute, finding sufficient proof that it is narrowly tailored to further the State's interests in reducing health care costs and improving public health.

The Plaintiffs' Publications

Plaintiffs-appellants IMS Health Incorporated, Verispan LLC and Source Healthcare Analytics aggregate, analyze, and publish information related to health

care. Among the publisher plaintiffs' publications are reports on the prescribing histories of physicians. Collectively, plaintiffs acquire billions of prescription records annually, always with the patient information removed to protect individual privacy. (A 78, 80, 97-98, 111).

Plaintiffs do not acquire or publish information in the State of Vermont. When a resident in that state fills a prescription, the pharmacy transfers that information in the regular course of business to an out-of-state data center, where it is then edited, stripped of patient-identifiable information, merged with other data and sent electronically to the publishers outside of Vermont. (A 78, 80-81, 98-99, 11, 221).

The publishers analyze and edit this data extensively to confirm its accuracy. (A 80, 99). Plaintiffs then produce a variety of news reports on a daily, weekly, and monthly basis. The reports contain truthful information showing physicians' prescribing histories and patterns. (A 101).

Plaintiffs' audiences for their publications are varied. Journalists, academics, governments, and public health organizations make extensive use of the information. (A 78, 99). Researchers, for example, develop programs to combat drug overuse. (A 79). Government officials track inappropriate uses of controlled substances and identify prescribers who should receive time-sensitive

health alerts. (A 79-80, 103-04, 178, 283). The media uses the data for news reporting. (A 88).

Plaintiffs' publications also have significant commercial applications, which subsidize the many other non-commercial uses of the information. Research-based pharmaceutical and biotechnology companies use the data in both developing and marketing drugs. (A 78-80, 177). The reports help to determine the need for new drugs by identifying patterns in the treatment of diseases with existing drugs. During the clinical trial stage of drug development, plaintiffs' publications can be used to identify physicians with significant pools of patients with a potential need for the medication. (A 79).

The Prescription Restraint Law targets a further use of plaintiffs' publications. After a drug has been tested, approved as safe and effective, and launched into the marketplace, plaintiffs' reports are useful in making decisions regarding outreach to physicians. *Id.* The publishers' information allows drug companies to identify the doctors who are the most likely to be interested in their medications. The information also allows companies to select the most relevant information to convey to these prescribers during brief, but informed, face-to-face interactions. (A 211-12). The publisher's information, for example, reveals how drugs are prescribed in combination, whether patients are complying with doctors' instructions, when doctors switch patients from one drug to another, and how

patients pay for their medications. (A 99-101).

Pharmaceutical companies meet directly with physicians through the practice known as "detailing." During these meetings pharmaceutical representatives provide physicians with approved, FDA-regulated information about their own products. (A 172-73, 197). All information provided by drug representatives must be "fair and balanced" and cannot be "false or misleading in any particular" under federal law. 21 U.S.C. § 352(a); (A 138-39).

Many prescribers want to receive information from pharmaceutical representatives because informed discussions between drug companies and doctors produce useful exchanges of information. For example, the companies learn about side-effects of medications. For their part, prescribers are informed about best practices in treatment. (A 125, 195). Prescribers who do not find the interactions useful can simply decline to meet with drug company representatives. (A 197).

The publishers do not themselves sell, market or promote pharmaceutical drugs to prescribers. Nor do they develop messages that the pharmaceutical companies can use to discuss their drugs with prescribers. (A 99, 101). The publishers sell information to all companies, small or large, regardless of the product sold. (A 78, 99). The availability of the information helps drug manufacturers compete with each other in the marketplace, making it possible for

small, limited-funded biotechnology companies to reduce marketing costs. (A 285).

The collection of prescription-history information is also commonplace among governments and organizations that seek to *reduce* brand-name drug use. Insurance companies and state governments (including Vermont) collect and analyze such data to, *inter alia*, encourage doctors to prescribe less-expensive generic drugs. (A 123, 188, 283, 286-87, 298-99). But the prescription databases owned by insurers and government agencies are not as complete and robust as those maintained by the publishers because they only contain data regarding prescriptions filled by patients covered by their respective programs. In contrast, the databases maintained by the publishers house unbiased information about all prescriptions, regardless of payer or geographic location. (A 81).

To preserve the value of their services and efforts, the publishers, like most media outlets, restrict the manner in which subscribers may re-publish the information to third parties to whom the data has not been licensed. (A 79, 105).

The Vermont Prescription Restraint Law

On January 17, 2007, a Vermont senate committee began considering an omnibus bill containing numerous health care reforms, including a flat ban on the transfer and use of prescriber identifiable data. (A 405-425, 4583-4633). The ban on prescriber identifiable data was intended to rectify what the Legislature

perceived as the "one-sided nature" of the "marketplace of ideas." Vt. Act 80, § 1(4) (2009) (A 4040). The ban was modeled after a New Hampshire law that was then being challenged by the plaintiffs as a violation of the First Amendment and the Dormant Commerce clause.

On the eve of a final vote on the bill, the federal district court in New Hampshire ruled on plaintiffs' challenge and invalidated the similar law, concluding that the statute was fatally flawed for, among other things, failing to make any supported legislative findings. *IMS Health Inc. v. Ayotte,* 490 F. Supp. 2d 163 (D.N.H. Apr. 30, 2007), *rev'd,* 550 F.3d 42 (1st Cir. 2008). In response, the sponsor of the Vermont bill introduced an array of new rapidly shifting amendments and purported "findings." (A 1672-1686) (May 2 10:14 a.m. draft) (20 proposed findings); (A 1687-1717) (May 2 2:33 p.m. draft) (27 proposed findings); (A 1718-1726)) (May 3 9:40 a.m. draft) (31 new proposed findings). 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. (A 1672-1686).

Members of the House committee with jurisdiction reacted with alarm. One commented: "I almost feel that this is flaunting free speech." (A 1424). Another asked: "Is there any rhyme or reason to which these findings are placed?" (A 1400). 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." (A 1479). 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." (A 1480). Representative Pat O'Donnell had had enough. In her opinion, supporting the statute in light of the rushed changes to the bill and its findings would be contrary to the legislature's "oath to uphold the Constitution": "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." (A 1481) (misidentifying Rep. O'Donnell as Rep. Chen)).

The committee and both legislative houses nonetheless approved the statute, although not without significant controversy. Rep. Peg Flory pointed to the House'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." (A 4581).

The Governor signed the legislation, which became Vermont Act 80 (2007).

As finally enacted, the Prescription Restraint Law provides in relevant part:

> 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 use prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents . . . .

18 Vt. Stat. Ann. § 4631(d); (SPA 68). Under subsection (c), in turn, prescribers may indicate whether they consent on licensing applications and renewal forms. *Id.* at § 4631(c)(1); (SPA 68). Violations of the statute trigger liability under the Vermont Consumer Fraud Act, which provides for injunctive relief as well as civil penalties of up to $10,000 per violation. *Id*. at § 4631(f); 9 Vt. Stat. Ann. §§ 2458(a), 2451(a).

The Vermont law thus restricts the use of prescription history information in two respects, both of which are separate and distinct from the act of a drug company representative attempting to market a product to a prescriber. It forbids plaintiffs from acquiring, aggregating, interpreting, and distributing prescription-history information to drug companies, because those companies will subsequently "use" the data "for marketing or promoting" drugs. The law also bars the pharmaceutical companies themselves from analyzing plaintiffs' reports to identify prescribers to whom they should direct their marketing efforts.

Proceedings Before the District Court

On August 29, 2007, the publisher plaintiffs filed this suit alleging that the Prescription Restraint Law violates both the First Amendment and (because it applies to plaintiffs' wholly extraterritorial conduct) the Commerce Clause. (DE 1). Plaintiffs moved for a preliminary injunction. (DE 6). On October 23, 2007, the Pharmaceutical Research and Manufacturers of American (PhRMA) filed a complaint in the same court also challenging the Prescription Restraint Law under, *inter alia*, the First Amendment and requesting a preliminary injunction. (DE 61) The district court consolidated the cases and combined the request for a preliminary injunction (and the parties' cross-motions for summary judgment) with a trial on the merits. Before the trial, the Vermont Legislature amended the law and repealed the disclosure requirement without an affirmation that the legislative findings still applied in light of the amendment, or even any indication that the Legislature had considered that issue.

The case proceeded to trial on July 25, 2008. The publishers offered experts with extensive experience and knowledge in the pharmaceutical industry, including the former chief counsel to the FDA with 35 years of experience in drug development, approval, and regulation (A 134-152), the director of the Epilepsy Department at Massachusetts General Hospital (A 119-130), the head of the cardiology department at Exeter Hospital in New Hampshire, (A 191-209), a

prominent, highly-experienced Vermont neurologist (A 384), a former employee of a pharmacy benefits manager with decades of industry experience (A 260-288), and a political economist with extensive experience analyzing the impact of laws that restrict information flow in commercial markets (A 225-235). Collectively, as described in further detail in Point I.B. *infra*, they testified that detailers provide valuable, fair, and balanced information; the information allows detailers to identify the doctors who most likely could benefit from information about new drugs; that suppression of prescribing histories would do nothing to affect marketing other than to make it far more expensive and inefficient, the law would harm public health and drive up costs, and that the State had not followed a reliable methodology in order to assess the likelihood that the law would advance the objectives of reducing costs and protecting public health.

The State put on no fact witnesses. Instead, it offered five experts. None was aware, though, of any instance in which any Vermont prescriber made inappropriate prescribing decisions as a result of interactions with the pharmaceutical industry. Like the witnesses who testified before the Legislature, none of the State's witnesses had conducted any studies of the likely effects of restricting the use of prescriber-identifiable information for marketing, nor were any of them aware of any such studies. (A 257, 294, 351). Two of them did not even know what the law was or had read it before forming their opinion. (A 257,

313).

After trial, the district court issued an opinion ruling for the State on the merits. (DE 430; SPA 1). The district court deemed the evidence provided by the plaintiffs irrelevant as a matter of law because it concluded that its role was merely to:

> assure that [the] legislature has drawn reasonable inferences based on substantial evidence in formulating its judgments; not reweigh the evidence de novo or replace the legislature's factual predictions with its own. The Court will defer to legislative findings, predictions, and judgments to the extent they are reasonable and based on substantial evidence.

(SPA 22). In essence, the trial judge, over plaintiffs' explicit objections (A 4920-28) ("fundamentally your role is as an independent fact finder . . . rather than an appellate judge") & (A 364) ("reasonable is not enough to . . . override the First Amendment rights at stake here"), acted as a reviewing court, just as this Court would under Federal Rule of Civil Procedure 52(d), upholding findings of fact "unless clearly erroneous." The decision to proceed in this fashion meant the court decided only whether the legislature had substantial, competent evidence to support its findings, not whether the preponderance of the trial evidence satisfied the applicable evidentiary standard.

The court agreed with plaintiffs that the Vermont law restricts constitutionally protected speech. It recognized that "Supreme Court and Second Circuit precedent . . . require this Court to extend First Amendment protection to

'[e]ven dry information, devoid of advocacy, political relevance, or artistic expression.'" (SPA 13) (quoting *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 446 (2d Cir. 2001)). "A restriction on disclosure is a regulation of speech, and the 'sale' of PI data is simply disclosure for a profit"; and the statute's further "restriction on the use of PI data is likewise aptly described as a restriction on marketing." (SPA 14) "Plainly, the whole point of section 17 is to control detailers' commercial message to prescribers." (SPA 16).

The district court next concluded that the law restricts only commercial speech and therefore is subject to "intermediate scrutiny" under the standard announced in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980). In the court's view, "PI data combines commercial and non-commercial elements," because although it is "information with a degree of redeeming social importance," it is "also purely commercial information used to decide whether, how, when, and where to market products." (SPA 18) (citation omitted). The court found it sufficient to deprive plaintiffs' publications of full First Amendment protection that the statute "regulates the disclosure and use of PI data only when it is used in marketing – a decidedly commercial use," in contrast to "use of the data for non-commercial purposes such as 'health care research,' 'educational communications,' or 'safety notices.'" *Id.* (*quoting* 18 Vt. Stat. Ann. § 4631(e)).

The district court concluded that the statute survives intermediate scrutiny. The court found it uncontested that Vermont has a substantial interest in reducing health care costs and improving public health. (SPA 23). In determining whether the statute substantially furthers those interests, the court concluded that it should "defer to legislative findings, predictions, and judgments to the extent they are reasonable and based on substantial evidence," given "'the subordinate position of commercial speech in the scale of First Amendment values.'" (SPA 25) (quoting *Anderson v. Treadwell*, 294 F.3d 453, 463 (2002)); *see also* (SPA 30) (citing *Turner Broad. Sys. v. FCC*, 512 U.S. 622 (1994)).

The heart of the district court's reasoning was that detailing increases sales of brand-name drugs. The court accepted that "PI data is used as a tool to increase the success of detailing," which is employed only for "new, branded drugs." (SPA 26). The information published by plaintiffs, the court concluded, "amplifies the influence and effectiveness of detailing, but does not add to its purported educational value" because pharmaceutical companies "can provide medical literature and information regarding the drugs they are promoting without the benefit of PI data." (SPA 28).

The district court further accepted the legislature's findings that "new prescription drugs have a higher cost than older drugs but do not necessarily provide additional benefits." (SPA 27). "Detailing leads to increased prescriptions

for new drugs over generic alternatives which are often more cost-effective." (SPA 28). The court accepted as reasonable the legislature's determination that "a shift in prescribing practices from new drugs to generic would result in a significant cost savings to the State." *Id.*

For similar reasons, the court concluded that there was sufficient proof that the Prescription Restraint Law would improve public health. "Some new drugs make important contributions to health and reduce health care spending, but others may have unknown side effects and risks." (SPA 33). Though the court recognized that "[f]or patients with certain conditions, such as epilepsy, there may be medical reasons to prescribe a brand-name drug over a bioequivalent generic drug," it concluded that the statute "has no effect on doctors' ability to prescribe a brand-name drug." (SPA 34).

The district court rejected the publishers' argument that the State's asserted interest in inhibiting detailing to limit its persuasive effect on doctors through truthful and non-misleading information amounts to impermissible paternalism. The court recognized that "the Supreme Court has refused to uphold restrictions on speech predicated on paternalistic notions." (SPA 31). But it found those precedents inapposite because the statute permits prescribers to "make use of the opt-in provision, thus allowing detailers to retain the ability to use their PI data for marketing purposes." (SPA 31-32).

As to whether the law would in fact directly produce a shift in prescribing practices, the court stated that it would "not substitute its judgment for that of the Legislature," because requiring actual proof of the statute's effectiveness was as a practical matter "an unattainable burden." (SPA 30-31). The court rejected plaintiffs' contention that the statute will merely make detailing "less focused and more expensive leading to increased drug costs." (SPA 32). It reasoned that even without plaintiffs' reports, drug companies can easily "determine the specialty of a doctor or whether a prescriber would be interested in a particular drug," given that they already possess "detailed information about doctors in their territories, including office hours and specialty, staff, and personal information." *Id.*

The district court deemed "irrelevant" as a matter of law that plaintiffs had identified "alternative ways the Legislature could have advanced" its asserted interests. (SPA 34). "That other means to accomplish a goal exist does not affect whether the restriction on PI data in section 17 directly advances the State's interest. Different alternatives are not mutually exclusive." *Id.*

The court found that the Prescription Restraint Law is "narrowly tailored" to further the State's interests. "The law does not prohibit the practice of detailing. Sales representatives are free to provide medical literature and information regarding the drugs they are promoting." (SPA 37). Further, prescribers can

authorize "use of their PI data for marketing purposes." *Id.* "Perfection is not required. The law is in reasonable proportion to the State's interests." (SPA 38)

The district court finally rejected plaintiffs' argument that the Prescription Restraint Law violates the Commerce Clause by regulating conduct that occurs entirely outside of Vermont. As noted, plaintiffs acquire prescription information entirely from sources outside the state, then analyze that data and publish reports wholly outside Vermont as well. The district court found it sufficient, however, that the statute "regulates only information that originates in Vermont" as it relates to subsequent "conduct that occurs in Vermont." (SPA 46) (citation omitted). "Vermont pharmacies cannot avoid compliance simply by routing data through a parent company's server on its way to data vendors." *Id.*

STANDARD OF REVIEW

All issues presented herein are subject to *de novo* review. A district court's legal conclusions receive no deference. *Reynolds v. Giuliani*, 506 F.3d 183, 189 (2d Cir. 2007). Mixed questions of law and fact also are subject to *de novo* review. *Rose v. AmSouth Bank of Fla.*, 391 F.3d 63, 65 (2d Cir. 2004). A district court's factual findings rejecting a First Amendment challenge are considered *de novo* on appeal. *Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 485, 502 (1984). Under *Bose*, the Court "has an obligation to 'make an independent examination of the whole record' in order to make sure that 'the judgment does not constitute a

forbidden intrusion on the field of free expression.'" 466 U.S. at 499 (citations omitted).

SUMMARY OF THE ARGUMENT

I. The Vermont statute violates the First Amendment. In reaching the opposite conclusion, the district court erred both in its classification of the speech suppressed by the law as commercial and in its application of the commercial speech standards.

A. Plaintiffs publish truthful information on a matter of undeniable public importance. Although Vermont bans the publication of that information for eventual commercial uses, that does not change the character of the information or justify less rigorous constitutional protection. The government could not ban the publication of the stock reports by *The Wall Street Journal* or a book on commodities trading when that information would be used to make commercial decisions. Such publishing is often as fragile or even more fragile than political and news reporting and thus entitled to full First Amendment protection. "Commercial speech," by contrast – generally, if not exclusively, advertising – is less protected by the First Amendment because its accuracy is easily verified by the advertiser and more durable because it fuels sales of goods and services. As a regulation of noncommercial speech, the law should have been subjected to strict scrutiny and it could not have survived such scrutiny.

B. The district court committed three distinct errors in applying the *Central Hudson* test.

1. While cost containment and protection of public health are important interests, suppression of information for the purpose of preventing truthful, non-misleading information from being used to persuade prescribers to make lawful decisions with which the State disagrees is impermissibly paternalistic. The district court focused on Vermont's claimed interests in reducing health care costs and improving public health. But the court failed to appreciate that the *means* by which the statute seeks to further those interests is exclusively through suppression of truthful communication. The rationale behind the statute is that detailing persuades doctors to prescribe brand-name drugs, when the State would prefer that they not be so-persuaded and instead use generic alternatives. The First Amendment does not permit Vermont to preclude or inhibit accurate exchanges of information to pursue its goals, however legitimate.

2. In order to determine whether a law directly and materially advances an important or substantial government interest, the district court was obligated to evaluate all of the evidence presented and to make independent findings of fact. The state persuaded the district court to abandon this important role and to act merely as a reviewing tribunal, assessing whether the legislature had a reasonable basis to enact the law. *Turner Broadcasting Co. v.*

FCC does not authorize a district court to proceed in this fashion. It holds that this type of deference may be afforded a legislative body that has imposed a content-neutral restriction on speech after making extraordinarily specific and well-supported findings that the law is critical to achieve the legislative objective and that alternatives less restrictive of speech are unavailable. The law at issue here is not content neutral and it was not given the sort of careful legislative study that is a pre-condition to judicial deference. Had the district court not deferred to the legislature, it could not have found that the law directly and materially advances important or substantial government interests.

3. The district court failed to apply the fourth prong of the *Central Hudson* test which requires an assessment of whether the law is carefully tailored so that it neither suppresses speech unnecessarily or fails to curtail other causes of the perceived problem. Instead, the court erroneously held alternative means of containing costs and protecting public health which are less restrictive of speech were "irrelevant" to the constitutional equation. Such alternatives must be considered and the record established they are abundant. The law also is over- and under-inclusive in many other ways.

II. The Prescription Restraint Law is also invalid because it violates the Commerce Clause. The Constitution does not permit Vermont to regulate the communication of information entirely outside the state. Its regulatory authority

extends only to activity within its own borders.

ARGUMENT

I.

The Prescription Restraint Law Violates the First Amendment

The district court should have invalidated the law as a restriction of noncommercial speech and, in any event, misapplied the standards governing scrutiny of laws restricting commercial speech.

A. The Law Should Have Been Subjected to Strict Scrutiny

The district court erred in holding that the plaintiffs' speech is entitled to less than complete First Amendment protection, such that the Prescription Restraint Law is properly analyzed merely as a restriction on commercial speech. The statute forbids publication of truthful information on a matter of tremendous public concern. As noted, prescription-history information is central to an array of public health research and governmental decisionmaking. Drug companies also use the data to decide what drugs to research and produce, and subsequently how to market those medications. *See supra* at 3-7.

The category of "commercial speech," by contrast, is a limited subset of expression that receives lessened First Amendment protection. The Supreme Court has specified that "*the test* for identifying commercial speech" is whether the speech "proposes a commercial transaction." *Bd. of Trustees of St. Univ. of N.Y. v.*

Fox, 492 U.S. 469, 473-74 (1989) (emphasis added); *see also Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367 (2002); *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 423 (1993); *Va. State Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 776 (1976). This Court has consistently adhered to that formulation. *E.g.*, *N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 556 F.3d 114, 131 (2d Cir. 2009); *CFTC v. Vartuli*, 228 F.3d 94, 110 (2d Cir. 2000); *N.Y. Ass'n of Realtors, Inc. v. Shaffer*, 27 F.3d 834, 840 (2d Cir. 1994).

A majority of current justices have suggested that *all* laws suppressing the content of speech should be subjected to strict scrutiny, even when the speech could be classified as "commercial."[1] Justice Thomas repeatedly has called for abandonment of intermediate scrutiny "'[i]n cases such as this, in which the government's asserted interest is to keep legal users of a product or service ignorant in order to manipulate their choices in the marketplace.'" *Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173, 184 (1999) (Thomas, J., concurring in judgment) (citation omitted). Publishers agree with this reasoning and urge this Court to adopt it, but publishers' fundamental point is that the Vermont law is targeted squarely at *noncommercial* speech as the Supreme Court's and this Court's decisions use that term, and the law must be subjected to strict

[1] *See Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 554-55 (2001) (collecting opinions).

scrutiny for that reason.

The Prescription Restraint Law regulates fully protected, noncommercial speech. Plaintiffs do not publish advertisements or any other speech that could be analogized to a proposal to engage in a commercial transaction. Plaintiffs distribute information regarding the prescribing history of physicians. Their subscribers use that information to make decisions about how to operate their businesses – to direct sales representatives to focus their efforts on doctors who are prescribing a competing drug, to identify prescribers who have prescribed their drug to educate them regarding new side effects or risks of the drug, or a myriad of other decisions. In that respect, a report published by plaintiffs is no different from a stock chart in the *Wall Street Journal*. Both contain accurate information that is commercially relevant, which subscribers may use for a variety of purposes. Neither is an invitation to enter into a transaction.

For that reason, plaintiffs' publications also do not implicate the concerns underlying the government's greater authority to regulate commercial speech. There is no dispute that the prescription history information is entirely truthful and non-misleading. Nothing about that data creates a "potential for deception or confusion." *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 65 (1983). The publishers' acquisition, aggregation, and publication of prescription data neither pose a "risk of fraud" (*R.A.V. v. St. Paul*, 505 U.S. 377, 388 (1992)), nor involve

the potential for "misleading, deceptive, or aggressive sales practices" (*44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 501 (1996) (Stevens, Kennedy, & Ginsburg, J.J., concurring)) that have in the past permitted more robust regulation of commercial speech. *E.g.*, *Florida Bar v. Went For It*, 515 U.S. 618, 635 (1995) (upholding thirty-day ban on lawyer direct-mail solicitation to accident victims).

The fact that plaintiffs "sell" their reports makes no difference, and the district court did not contend otherwise. Newspapers, books, and magazines are all generally sold for a profit. They of course receive full First Amendment protection. *See Fox*, 492 U.S. at 482 ("Some of our most valued forms of fully protected speech are uttered for a profit.").

The district court nonetheless deemed the Prescription Restraint Law a restriction on "commercial speech" by looking not at the substance of plaintiffs' publications but instead at the purpose for which third parties may use them. The court reasoned that the statute "regulates the disclosure and use of PI data only when it is *used* in marketing – a decidedly commercial *use*." (SPA 18). In the court's view, the statute is not subject to rigorous First Amendment scrutiny because it forbids publication only in the instances in which pharmaceutical companies will use the information for "marketing" or "promotion."[2]

[2] In so ruling, the court ignored that the law's definitions of those terms sweep broadly to prohibit the publishers from selling and the pharmaceutical companies from using prescriber-identifiable information to communicate with

The district court's ruling conflicts with settled First Amendment precedent. The definition of commercial speech is clear: "the test" is whether the speaker proposes a commercial transaction. *Fox*, 492 U.S. at 473-74. When speech does no more than propose a commercial transaction, it partakes of a "greater objectivity and hardiness" due to its relationship with the product or service being sold by the speaker and its need to fuel those sales. *Va. State Bd. of Pharm.*, 425 U.S. at 771, n.24. The information sold by the publishers, by contrast, relates not at all to products or services they sell. It is about decisions by prescribers, it is hugely expensive to collect and verify, and easily could be lost if not fully protected.[3]

The district court's view would grant the government a free hand to regulate an array of valuable communication. Every book on "marketing" would qualify as "commercial speech" under its analysis. More broadly, there is no logical distinction between the prescriber-history information published by plaintiffs and the massive amount of information that businesses collect and analyze in the

---

prescribers about drug risks, drug safety, and disease management – non-commercial speech that is forbidden because it "publicizes" a drug. *See* 18 Vt. Stat. Ann. § 4631 (b)(5) & (7) (SPA 67).

[3] The fragility of such noncommercial speech is demonstrated by the fact that the publishers could simply withdraw prescriber-identifiable data from the market and substitute aggregated data, as is allowed. 18 Vt. Stat. Ann. § 4631(e)(7); (SPA 68). The value of prescriber-identifiable data would be lost, but their businesses would continue. By contrast, when a law suppresses advertising, the advertiser often has no choice other than to fight the law or be put out of business.

course of their operations. "Commercial speech" is not short-hand for all expression that is in some respect "related to commerce." The government may not invoke the commercial speech doctrine to forbid distribution of the stock reports of *The Wall Street Journal* to stock brokers and individual investors on the theory that the audience may use the information to guide their commercial decisions. *See Vartuli*, 228 F.3d at 109 (Sack, J.) (observing that information that "guides the user in making investments" is not commercial speech).

The district court read *Bad Frog Brewery, Inc. v. N.Y. State Liquor Authority*, 134 F.3d 87, 97 (2d Cir. 1998), as permitting regulation of speech that "combines commercial and non-commercial elements." (SPA 18). The "commercial" element in that case was *an advertisement*. The case sensibly held that an ad is not rendered fully protected speech merely through the artifice of including some discussion of a matter of public importance.

Plaintiffs do not publish advertisements for pharmaceutical products. The Vermont law instead forbids the publication of truthful information. The fact that one of the purposes the audience may subsequently use the information for is a valuable commercial purpose – identifying an audience for a commercial message – does not convert the information into "commercial speech."

The law here prohibits the dissemination of lawfully-obtained, truthful information of public concern. *See IMS Health Inc. v. Rowe*, 532 F. Supp. 2d 153,

167 n. 14 (D. Me. 2007) ("the information – the prescription history of prescribers – is . . . a matter of public concern"). In *Bartnicki v. Vopper*, 532 U.S. 514 (2001), the Supreme Court held that a federal statute that prohibited the dissemination of such information must be subjected to strict scrutiny. *See also Smith v. Butterworth*, 494 U.S. 624 (1990) (invalidating state statute prohibiting grand jury witness from disclosing his own testimony after grand jury term ended).

By its very terms, the law is also invalid because it discriminates based on viewpoint by restricting pharmaceutical manufacturers from using prescriber-identifiable information to communicate with prescribers regarding their products while permitting insurers and the government itself to use the identical information to influence prescribers as they prefer. 18 Vt. Stat. Ann. § 4631(e)(1) & (5); (SPA 68). The legislature's attempt to cure the perceived "imbalance in information presented to doctors," Vt. Act 80 § 1(6); (A 4040), contradicts the basic tenet that, "[t]he point of the First Amendment is that majority preferences must be expressed in some fashion other than silencing speech on the basis of its content." *R.A.V.*, 505 U.S. at 392. The state has no authority "to license one side of a debate to fight freestyle, while requiring the other to follow Marquis of Queensberry rules." *Id.* In addition, because the distinction between permissive uses of the data for purportedly non-commercial purposes such as "health care research" and prohibited uses of the data to "promote" the sale of a drug is by no means clear,

"the responsibility for distinguishing between the two carries with it the potential for invidious discrimination of disfavored subjects." *Discovery Network*, 507 U.S. at 423 n.19.

The law also is subject to strict scrutiny as a prior restraint on speech. 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); *Vartuli*, 228 F.3d at 109. This law designates each prescriber as the licensor of a pharmacy's right to distribute prescriber-identifiable data, yet it fails to provide narrow, objective, and definite standards to guide the prescriber's decision to censor speech, or procedural safeguards such as time limitations for acting on a request to publish, as required to prevent a licensing scheme from being used for improper censorial purposes. *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).

It is obvious that the Prescription Restraint Law cannot survive the "strict scrutiny" applicable to a prohibition on fully protected speech. The district court did not suggest otherwise. The statute is constitutional only if Vermont demonstrates that it is narrowly tailored to promote a compelling governmental

interest, such that the government is required to employ any available non-speech restricting alternative. *United States v. Playboy Entm't Group*, 529 U.S. 803, 804 (2000). Here, by contrast, the district court deemed those alternatives "irrelevant" as a matter of law. (SPA 34). Strict scrutiny also triggers exacting review of whether the statute is effective, whereas the district court here instead deferred to the legislative judgment to enact the statute in light of "'the subordinate position of commercial speech in the scale of First Amendment values.'" *Id.* at 25 (quoting *Anderson*, 294 F.3d at 463).

In the sections that follow, plaintiffs demonstrate that the Prescription Restraint Law cannot survive even intermediate scrutiny.

B. The District Court Misapplied the *Central Hudson* Test

In *Central Hudson*, the Supreme Court held that a regulation of commercial speech satisfies the First Amendment when: (1) the speech concerns lawful activity and is not misleading, (2) the regulation supports a substantial or important government interest, (3) the regulation "directly advances the governmental interest asserted," and (4) the regulation is no "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. *See Thompson*, 535 U.S. at 371. The first prong of the test is not in dispute because the state advanced no argument that the speech

suppressed by the law is unlawful or misleading. (SPA 22) ("parties agree that the data vendor plaintiffs disseminate truthful, non-misleading information").

1. The Prescription Restraint Law Rests on an Impermissible Purpose of Limiting the Persuasive Effect of Truthful, Non-Misleading Information

In this case, the district court concluded that "prescriber privacy would not be a sufficient interest to justify the law," but accepted Vermont's contention that its legislature reasonably concluded that the Prescription Restraint Law furthers two significant governmental interests: "cost containment and protecting public health." (SPA 22). Both goals are legitimate state interests, just as almost all legislation has as its goal an appropriate public purpose. But that is insufficient in and of itself to justify a restriction on speech. The government could not prohibit all favorable public advocacy related to brand-name drugs or endorsement of health care systems merely because it believes they are "too expensive."

The district court specifically erred by failing to appreciate that the *manner* in which the Prescription Restraint Law pursues the State's asserted interests is impermissibly paternalistic. Vermont did not pursue its goals directly. It did not limit the brand name drugs for which it would provide reimbursement, impose price controls, or limit the prescription of brand-name medications. Nor, with respect to detailing itself, did it attempt to limit advertising of drugs that it concluded were unnecessarily expensive.

Instead, Vermont took the forbidden route of regulating truthful and accurate speech on a matter of public importance. The rationale underlying the Prescription Restraint Law is that the targeted speech is used by detailers to decide which prescribers will be the focus of their communications and the substance of the information provided in marketing, and that this significantly enhances the ability of detailers to persuade doctors with truthful, nonmisleading information to decide which drugs to prescribe their patients. The district court recited evidence that "*[d]etailing* leads to increased prescriptions for new drugs over generic alternatives which are often more cost-effective" (SPA 28) (emphasis added), and that "*[s]ome* new drugs make important contributions to health and reduce health care spending, but others may have unknown side effects and risks" (SPA 33) (emphasis added), and openly embraced the proposition that this evidence provided the legislature a reasonable basis to suppress speech. *Id.*

The avowed goal of the State is thus to make it more difficult for drug companies and prescribers to have an informed conversation and to persuade them with truthful information to prescribe a lawful product. By inhibiting detailing, Vermont hopes to make it more difficult for drug companies to identify a willing audience and thus to speak with prescribers and persuade them to use brand name-drugs.

The Prescription Restraint Law thus offends the First Amendment. The Supreme Court has specifically invalidated a statute limiting marketing of compounded drugs that was based on the "assumption that doctors would prescribe unnecessary medications," which the Court held "amounts to a fear that people would make bad decisions if given truthful information." *Thompson*, 535 U.S. at 359. Also instructive is *Shapero v. Kentucky Bar Association*, 486 U.S. 466, 473-74 (1988), which ruled that targeted marketing cannot itself be banned "merely because it is more efficient" or on the theory that focusing a message on "those whom it would most interest is somehow inherently 'objectionable,'" (quotation omitted), and *Edenfield v. Fane,* 507 U.S. 761, 766 (1993), which invalidated a ban on solicitation by certified public accountants because it "threaten[ed] societal interests in broad access to complete and accurate commercial information." The Court reasoned, "[T]he general rule is that the speaker and the audience, not the government, assess the value of the information presented." *Id.* at 767. *See*, *e.g.*, *Va. State Bd. of Pharm.*, 425 U.S. at 770; *44 Liquormart*, 517 U.S. at 503 ("The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good").

This is an *a fortiori* case under decisions such as *Thompson*, *Shapero*, and *Edenfield*. *Edenfield* also involved professionals (sophisticated accounting clients) who are capable of making thoughtful and informed decisions on the basis of

marketing information. The speech restrictions in those cases, moreover, regulated marketing – the advertisement of compounded drugs in *Western States* and direct solicitation by accountants and lawyers in *Edenfield* and *Shapero* – and thus at least implicated the government's power to regulate commercial transactions. The Prescription Restraint Law, by contrast, prohibits the publication of truthful information reflecting treatment patterns that is far more tangentially related to the sale of any product.

Notably, the district court did not doubt Vermont's goal was to insulate prescribers from truthful information. That should have been the end of the matter. Instead, the court reasoned that the statute is not paternalistic because it permits prescribers to "make use of the opt-in provision, thus allowing detailers to retain the ability to use their PI data for marketing purposes." (SPA 31-32) But the ability of the audience to request information has nothing to do with whether a speech restriction rests on an impermissibly paternalistic purpose to suppress speech that has not been requested. It was equally true in *Thompson, Shapero* and *Edenfield* that consumers could have requested and received information on compounded drugs and legal and accountant services.

2. The District Court Avoided Deciding Whether the Law Directly Advances Substantial or Important Interests

In evaluating the third prong of *Central Hudson,* the district court erroneously concluded it must "defer to legislative findings, predictions, and

judgments to the extent they are reasonable and based on substantial evidence." (SPA 22). In fact, "'[d]eference to a legislative finding cannot limit judicial inquiry when First Amendment rights are at stake.'" *Sable Commc'ns of Cal., Inc. v. FCC*, 492 U.S. 115, 129 (1989) (quoting *Landmark Commc'ns Inc., v. Virginia*, 435 U.S. 829, 843 (1978)). Even a legislature's express factual findings do "not foreclose [the court's] independent judgment of the facts bearing on an issue of constitutional law." *Id.*

Equally with respect to commercial speech, courts do not merely defer to legislative judgments. The Supreme Court consistently has held the government to its burden of showing "the harms it recites are real and that its restriction will in fact alleviate them." *Edenfield*, 507 U.S. at 762; *see, e.g., Thompson*, 535 U.S. at 373 (striking down federal law prohibiting advertisements of certain compounded drugs); *Greater New Orleans*, 527 U.S. at 183 (striking down a ban on advertisements of private casino gambling); *44 Liquormart*, 517 U.S. at 509-10 ("*Posadas* clearly erred in concluding it was 'up to the legislature' to choose suppression over a less speech-restrictive policy"); *id.* at 508-12 (rejecting argument that the courts must defer to a legislative judgment 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, 482 n.2.

The Supreme Court repeatedly has invalidated restrictions on commercial speech that "only indirectly advance the state interest involved," irrespective of contrary legislative conclusions. *Central Hudson*, 447 U.S. at 564; *see also Va. State Bd. of Pharm.*, 425 U.S. at 766-68 (ban on advertising 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) (advertising ban would not protect quality of attorneys' work but would increase legal fees). To satisfy its burden under the First Amendment, the government must marshal "empirical evidence to support [its] assumptions." *Bad Frog Brewery*, 134 F.3d at 100. This Court has recognized the need for empirical evidence even where the state's assertion may be "difficult" to prove. *Shaffer*, 27 F.3d at 843-44.

Contrary to this well-established precedent, the lower court held "empirical evidence is not a requirement," (SPA 30), and instead looked only at the legislative findings to assess whether they were "reasonable" in light of the legislative record. (SPA 22). The district court recited the Supreme Court's commercial speech precedents, (SPA 19-20), but explained that it must filter them through the prism of *Turner Broadcasting System v. FCC*, 512 U.S. 622 (1994), transforming the court's role from that of independent fact-finder to that of a reviewing court, checking legislative decisions solely for clear error and not "substituting its

judgment for that of elected representatives." (SPA 20). *Turner,* however, was a completely different case. There, the Court upheld Congress's determination to enact the "must carry" regime for cable broadcasting. The Court in *Turner* deferred to Congress only because of a confluence of factors not present here: (1) the regulation at issue, a requirement that cable operators carry local broadcast signals, involved a content neutral, time place and manner restriction with an incidental impact 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 three years, tens of thousands of pages of evidence, including not only anecdotal testimony but also extensive studies, on which it based its legislative findings. In those limited circumstances, the Court 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. Justice Stevens, whose vote provided a five-judge majority, made clear that the outcome turned on the fact that the case involved "economic measures . . . that have only incidental effects on speech," which "merit greater deference than those supporting content based restrictions on speech." *Id.* at 671 n.2.

By contrast, the Vermont legislature lacks the institutional expertise in regulating pharmaceutical marketing that supported the must-carry regime. Nor did the legislature study the subject matter for years. The record demonstrates: the legislature first considered this issue in January 2007; after just four months the Legislature was prepared to adopt a law similar to the New Hampshire flat ban without any findings as to whether it would achieve important or compelling objectives; and only after the New Hampshire law was invalidated did the Vermont legislature make material changes to its law and create findings over three days, allowing only hours to review drafts that had changed dramatically between each short committee session.

Turner is entirely inconsistent with the *Central Hudson* test. *Turner* does not cite *Central Hudson*, and the Court's commercial speech decisions after *Turner* neither cite *Turner* nor mention "deference." This Court never has cited *Turner* in any of the many commercial speech cases it has decided. Two circuits have explicitly declined to defer to legislative judgment when applying *Central Hudson*. *Pagan v. Fruchey*, 492 F.3d 766, 774-75 (6th Cir. 2007); *Cal-Almond, Inc. v. USDA*, 14 F.3d 429, 437 (9th Cir. 1993).

Had the district court not afforded overriding deference to the judgment of the state legislature, it would have found that the evidentiary record demonstrated

convincingly that the Prescription Information Law will not in fact further the State's objectives.

In contrast, the publishers offered experts with extensive experience and knowledge in the pharmaceutical industry.

Peter Barton Hutt, former chief counsel to the FDA with 35 years of experience in drug development, approval, and regulation (A 134, 141), testified that the Vermont law is not likely to reduce health care costs without harming patient health. He based his opinion on his service on the boards of 20 biotechnology companies (A 134), his involvement with drafting and administration of the Hatch-Waxman Act, (A 136), and his participation in the drafting of other major food and drug legislation. In his view, the Vermont law would make marketing efforts of pharmaceutical companies less efficient and more costly. (A 148). It could also result in an increase in drug prices or a decline in innovation. (A 141, 148). He testified that if the law were to slow prescribers' acceptance of new drugs, this would undermine the goals of the Hatch-Waxman Act and companies either would have to raise prices to recoup the substantial investment into the development of drugs (approximately $2 billion per drug) or otherwise develop fewer new drugs. (A 157, 141).

Dr. Andrew Cole, director of the Epilepsy Department at Massachusetts General Hospital, explained that physicians are trained to make judgments based

on all of the available information, including published evidence, personal experience, the experiences of colleagues, journal articles, conference reports, and information from manufacturers. (A 122). Based on his 20 years of experience as a neurologist, he testified that both he and his patients would be disadvantaged if the ability to receive information from pharmaceutical companies were curtailed or altered. (A 123). In his interactions with pharmaceutical company representatives, he has found them to be informed and professional. (A 124). They often provide him with clinical studies, summaries of indications and contraindications, and other types of important information, including early warnings about any new developments. (A 125).

Dr. Thomas Wharton, head of the cardiology department at Exeter Hospital in New Hampshire, interacts with sales representatives frequently and finds those interactions a useful source of information about new drugs, in addition to what he learns from published literature, colleagues, and medical conferences. (A 195). Dr. Wharton testified that there are many sources of information for prescribers, and that prescribers are better professionals if they consider all available evidence before making decisions for their patients. *Id.* He found that sales representatives are well-trained, provide accurate information, and peer-reviewed articles. (A 197). He agreed that "a good rep is absolutely invaluable . . . you can learn from them," and "there's a lot of positives they do." (A 196-97). Dr. Wharton gave specific

examples of important information he received from sales representatives that helped him make better decisions. (A 198). Dr. Wharton explained that cheaper drugs are not always better. For example, a generic ace inhibitor may be cheaper than a brand-name one, but the newer, brand-name inhibitor may be better at preventing heart attacks. (A 200).

Dr. Kenneth Ciongoli, a prominent Vermont neurologist, testified that he met with pharmaceutical representatives weekly. (A 391). He found the representatives with whom he met to be well informed about the products they are there to discuss. (A 391). They provided information from the drug's label, as well as published papers and evidence-based study results. (A 391). Yet they always stayed within the boundaries set by the law. (A 391). Dr. Ciongoli found the information he received from sales representatives highly useful, particularly given that they are already aware of his prescribing practices and can get right to the point. *Id.*

Randy Frankel, who possesses decades of experience in the health care industry, testified regarding the various alternatives that the state has available to reduce cost without restricting speech. (A 267-68) He testified that rather than improving the public health of Vermonters, the law may create a lag in information flow that may cause harm to public health. (A 265, 284). He also testified that the way to lower costs without harming the public health is to educate physicians

about available cost-effective treatments. (A 270). He added that there are a number of situations in which newer drugs can actually result in cost savings. (A 279). He also testified that the law "will slow the dissemination of new drugs and . . . people will die" because the law does not apply selectively to new or old or good or bad drugs. "This law slows them all." (A 284). He observed that only 56 percent of adults and 46 percent of children with a chronic illness are likely to be treated consistently with best practice guidelines (A 287).

Dr. Michael Turner, a political economist, testified that there is a generally accepted methodology in the field of political economy to predict reliably the impact of laws that restrict the flow of personally identifiable information used to market good or services. He testified that the Legislature could have commissioned a study to determine the likely impact of the law, but did not do so. (A 227-29). He noted the State had not asked its Joint Fiscal Office to review the law and that the research that was done by the legislature was "not based on random selection," but rather reflected a "bias" against drug manufacturers, noting that the only drugs examined were those known to be harmful. (A 229-30). He testified that pharmaceutical manufacturers would react to the law by increasing their marketing expenditures, not decreasing them. (A 234-35).

Despite the vast discovery conducted by the state from pharmaceutical companies, it ultimately defended the constitutionality of the law at trial through

testimony of five expert witnesses and the legislative record. Like the witnesses who testified before the Legislature, however, these experts had not conducted any studies of the likely effects of restricting the use of prescriber-identifiable information for marketing, nor were any of them aware of any such studies. (A 257, 294, 351).

Dr. Meredith Rosenthal, an economist and professor of health economics, testified the state hypothetically could save money if more generic drugs were prescribed in place of brand name drugs. (A 311). Dr. Rosenthal had no opinion on whether restricting the use of prescriber-identifiable data would increase generic prescribing, nor on whether restrictions on prescriber-identifiable data could or would improve public health or protect prescriber privacy. (A 314-15).

Dr. David Grande, a Pennsylvania doctor (A 293), testified that he concluded from a literature review that use of prescriber-identifiable data by sales representatives influences doctors to prescribe the marketed drugs. He was unaware of any instance in which a Vermont prescriber prescribed inappropriately as a result of interactions with the pharmaceutical industry. (A 297-301). Grande had conducted no study, empirical or scientific, relating to prescriber-identifiable information and its effect on prescribing habits. (A 297). He claimed no expertise in economics, pharmaceutical marketing or food and drug laws. (A 4096).

Dr. Ashley Wazana, a child psychiatrist, testified that he did not even know

what Act 80 was (A 257) and could not opine on whether prohibiting use of prescriber-identifiable information for marketing would affect physician prescribing or medical outcomes. (A 256).

Dr. Aaron Kesselheim had no expertise in economics or pharmaceutical marketing, but opined that marketing with the use of prescriber-identifiable data is effective, effective marketing accelerates the uptake of new drugs, and consumption of new drugs harms patients because new drugs generally are costlier and contain unknown risks. (A 344, 348). He admitted that it sometimes is appropriate to prescribe new drugs, some new drugs are widely prescribed because of their clinical advancements, and some new drugs decrease health care costs. (A 351, 353). He could offer no evidence, only speculation, on whether the costs of accelerating the uptake of new drugs outweigh the benefits.

Dr. Kesselheim also had not conducted, nor was he aware of, empirical data documenting any contribution by prescriber-identifiable data to inappropriate prescribing. (A 357). He had no knowledge of how the pharmaceutical companies would react to the Vermont Law in terms of increasing or decreasing their marketing efforts or slowing drug development initiatives. (A 347). Kesselheim agreed that Vermont could require physicians to engage in continuing medical education to learn about appropriate prescribing. (A 353). Unlike most states, Vermont has no continuing medical education requirement for physicians. *Id.*

The state's final expert, Shahram Ahari, had been a sales representative for a major drug manufacturer briefly (less than two years), nearly a decade earlier. He portrayed detailing as a practice designed to highlight the benefits of a drug being detailed. (A 324). Ahari confirmed that prescriber-identifiable information is entirely truthful and that sales representatives are trained to follow all FDA regulations and refrain from discussions of off-label use of drugs. (A 330-31). Ahari's testimony did not link the state's asserted interests and a restriction on the use of prescriber-identifiable data.

On this record, the state failed to establish that the law directly and materially would advance its interests in cost containment and protecting public health. Indeed, it failed even to show that the legislature had a reasonable basis to conclude that it would. The findings themselves reach no such conclusion, so even deferral to them should not have been a basis to uphold the law.

3. The District Court Failed to Apply *Central Hudson's* Fourth Prong

That is not to say, of course, that the Constitution precludes Vermont from pursuing its legitimate interests in reducing unnecessary health care costs and protecting public health. To the contrary, it has an array of alternatives that do not involve offending basic First Amendment principles.

The legislature identified the influence that gifts and free samples have on prescribers as corrupting their decisions. Vt. Act. 80 § 1(16) ("pharmaceutical

companies made direct payments of almost $2.2 million to prescribers in Vermont") (A 4042) & § 1(22) (A 4043) ("drug samples may influence physicians to . . . prescribe drugs that differ from their preferred drug[s]"), yet the law imposed no restrictions on either gifts or free samples. Notably, one year after passage of the law, the Vermont Legislature did pass a restriction on gifts (but not free samples) in May, 2009, and also toughened disclosure requirements. Vt. Acts No. 59 (2009). Prior to passage of the law at issue, the state had not evaluated whether this obvious alternative to a speech restraint would itself achieve the desired cost reductions and public health protection without suppressing speech. In passing of the gift ban, that legislature specifically found "Limitations on gifts and increased transparency are expected to save money for consumers, businesses, and the state by reducing the promoting of expensive prescription drugs, biological products, and medical devices, and to protect public health by reducing sales-oriented information to prescribers." Vt. Acts No. 59 § 2(b)(11) (2009).

Vermont also has the option of pursuing "counter-speech" – *i.e.*, advocating in favor of generic alternatives. Indeed, in the very same bill that contained the Vermont Law, the Legislature voted to fund such an "academic detailing" program that it created years ago. Vt. Act 80 § 20 (A 4043). The act 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. *Id.*

at § 15a. The House Ways and Means Committee estimated that spending $270,000 on generic vouchers could save the State more than $27 million annually. (A 4351). This program is just getting underway and, if effective, may obviate entirely the need for imposing restrictions on speech. This likely will be highly effective if for no other reason than that Vermont is one of the few states in the country that imposes no continuing medical education requirements on prescribers. (A 357).

When invalidating another law suppressing the speech of pharmacies enacted to protect public health, the Supreme Court held:

> There is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful; that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them.

Va. State Bd. of Pharm., 425 U.S. at 770. A decade and a half later, when Congress sought to restrain pharmacies' speech to protect public health, the Supreme Court reiterated its earlier message and struck down that federal law. *Thompson*, 535 U.S. at 366-67.

Vermont also can decide directly when it will pay for prescribed drugs by modifying its "formulary" for Medicare and Medicaid reimbursement. (A 267). Private insurers may do the same. *Id.* If the State can demonstrate the inaccuracy of marketing materials conveyed by drug companies to prescribers (which notably

was not one of the bases on which the district court sustained the Prescription Restraint Law), it may seek to restrict such materials directly.

The Vermont legislature recently mandated a pilot program requiring "therapeutic substitution" of over-the-counter or generic drugs for certain high cholesterol and gastric acid conditions for patients receiving Medicare Part D and other state funding even when those drugs are not bioequivalent. Vt. H.B 441 § E.309.9 (2009) (veto overridden June 2, 2009). This is an extension of Vermont's law that requires substitution of a bioequivalent generic when a branded drug is prescribed. 18 Vt. Stat. Ann. § 4605. This is yet another alternative means of containing costs and protecting public health without restricting speech.

The availability of alternatives less restrictive of speech for achieving legislative objectives frequently has been dispositive of the Supreme Court's application of the fourth prong of the *Central Hudson* test.[4] Indeed, in *Thompson*,

[4] *See, e.g. Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173, 192 (1999) ("nonspeech-related forms of regulation . . . could more directly and effectively alleviate some of the social costs of casino gambling"); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 490-91 (1995) (invalidating law prohibiting beer labels from displaying alcohol content in view of available alternatives); *44 Liquormart, Inc. v. R.I.*, 517 U.S. 484, 507 (1996) (invalidating ban on advertising price of alcoholic beverages because alternatives 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 Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87, 101 (2d Cir. 1988) (label prohibition was broader than necessary to shield minors from vulgarity because state could require placement of beer advertisements in places where children would not see them); *N.Y. State Ass'n of Realtors v. Shaffer*, 27 F.3d 834, 844 (2d Cir. 1994)

535 U.S. at 373, the Court held that "If the First Amendment means anything, it means that regulating speech must be the last – not first – resort."

Here, the district court expressly refused even to consider whether the state could have achieved its objectives through means less restrictive of speech: "Plaintiffs' laundry list of alternative ways the Legislature could have advanced its substantial interest in protecting public health is irrelevant."[5] (SPA 34). Not only are these alternatives relevant, the First Amendment mandated their consideration and their availability mandated invalidation of the law. Because Vermont elected to inhibit communication on a matter of public importance with the paternalistic goal of limiting the dissemination of truthful information, the statute violates the First Amendment.

Whether a law restricting commercial speech reasonably fits its objective depends not only on whether alternatives less restrictive of speech are available, but also whether the law is over- or under-inclusive in other ways. *See Discovery*

(enjoining regulation against solicitation of real estate listings where cease and desist orders on an individualized basis would be inadequate).

[5] The district court briefly discussed why one supposed alternative could not be effective: an American Medical Association program that allows a prescriber to direct the AMA not to license directory information (such as name, address, and specialty) for use by sales representatives. (SPA 34). This was a straw man because none of the plaintiffs advocated it as an effective alternative. They stipulated it would not be. Plaintiffs argued the alternatives less restrictive of speech are those discussed in this brief. (A 67).

Network, 507 U.S. at 426-27 (invalidating underinclusive ordinance); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001) (invalidating overinclusive law). Where a law restricts a significant amount of speech that would not advance its objectives or fails to restrict a significant amount of speech that would, the contention that the law has been carefully designed fails.

Here, the district court ignored that the Prescription Restraint Law is riddled with holes and inconsistencies that demonstrate that the State is not pursuing a coherent policy and that the scheme it has enacted is doomed to fail. The district court sustained the statute on the ground detailing increases brand-name drug use. But it made no findings whatsoever regarding whether the reverse is true – *i.e.*, whether the particular statutory scheme adopted by Vermont would cause a shift to prescription of generic equivalents.

As noted, Vermont did not enact any of the measures that would have directly addressed its asserted interests in the costs and appropriateness of prescribing certain brand-name drugs. As the district court explained, the statute "has no effect on doctors' ability to prescribe a brand-name drug." (SPA 34). Nor did the State directly regulate the process of detailing.

Not only did the State fail to enact measures that would have directly targeted its objectives, it adopted a scheme that even the district court seemed to recognize bordered on incoherent. The statute freely permits pharmaceutical

companies to continue to provide the *identical* marketing information to prescribers. "The law does not prohibit the practice of detailing. Sales representatives are free to provide medical literature and information regarding the drugs they are promoting." (SPA 37). The court explained that pharmaceutical companies "can provide medical literature and information regarding the drugs they are promoting without the benefit of PI data." (SPA 28).

Nor does the law make it impossible for the companies to locate their audience. Indeed, the district court emphasized that, even without plaintiffs' reports, drug companies can "determine the specialty of a doctor or whether a prescriber would be interested in a particular drug," and they already possess "detailed information about doctors in their territories, including office hours and specialty, staff, and personal information." (SPA 32). The principal effect of the statute is thus to make detailing more expensive and less efficient, not to block it or alter the content of the message delivered. But there is every reason to believe that, given the financial stakes, pharmaceutical companies will respond by ratcheting up their marketing efforts through less-targeted approaches to doctors throughout the state. The only consequence of the statute is thus ironically to *increase* drug costs as manufacturers pass on the greater expense of their marketing.

The Prescription Restraint Law is also dramatically overbroad on its face. The district court agreed with Vermont's submission that the detailing of *some* brand name drugs unnecessarily increases costs vis-à-vis available generic equivalents and, on occasion, undermines public health. But it did not doubt that in many other instances, the marketing of brand-name drugs presents no such risks. An obvious illustration is a thoroughly tested new medication for which there is no generic alternative. Another example is the marketing of a brand-name drug that competes against a more-expensive, less-effective brand-name alternative. As applied to efforts to detail those medications, the statute only *undermines* Vermont's own asserted interests.

The vagueness of the law contributes to its overbreadth as well. The law uses a remarkably broad definition of "marketing and promotion" and such vague definitions, exclusions, and exemptions that it effectively will stop *all* communication of prescribing histories irrespective of the commercial or non-commercial nature of the communication or whether the speech has any undesired effects on prescribing practices.[6]

[6] This provides an independent basis for invalidating the law, even if it were interpreted as a valid commercial speech restriction. "The showing that a law punishes a 'substantial' amount of protected free speech, 'judged in relation to the statute's plainly legitimate sweep,' *Broadrick v. Oklahoma*, 413 U. S. 601, 615 (1973), suffices to invalidate *all* enforcement of that law, 'until and unless a limiting construction or partial invalidation so narrows it as to remove the seeming threat or deterrence to constitutionally protected expression,' *id.*, at 613." *Virginia*

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). 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) (SPA 68). "Marketing" is defined broadly to include "advertising, promotion, or any activity that is intended to be used or is used to influence sales or the market share of a prescription drug," among other things. § 4631(b)(5) (SPA 67). When covered entities provide information about prescriber practices, they are not marketing any product or service and are not able to determine whether their publication will end up being used for a proscribed marketing purpose. The phrase "intended to be used or is used" provides no indication of whose intent is relevant, and it is not elucidated by statutory definitions, narrowing context, or settled legal meanings. Further, the state never has been able to explain the dilemma created by the statute's exclusion of "health care research" from its prohibitory reach when such research often is used to "influence sales or the market share of a prescription drug" and thus prohibited.

The publishers' concern is not merely that the market for their services is "drying up." (SPA 39). The statute provides so little guidance that the publishers, in order to avoid the crushing liability imposed on violators, must stop providing

---

v. Hicks, 539 U.S. 113, 118-19 (2003).

data regarding Vermont prescribers to anyone – with or without charge – because they cannot control how the recipient will use the data or whether the recipient's "health care research" might in some way be used to increase the sales of a prescription drug. Nothing protects publishers from being charged by the Attorney General or others with aiding and abetting others in the commission of a civil wrong or from claiming that they should be liable for the massive $10,000 per violation fines. 18 Vt. Stat. Ann. § 4631(f); (SPA 68) & 9 Vt. Stat. Ann. § 2461. Notably, the law contains no scienter requirement, rendering the narrowing of its application even more difficult.[7]

The lower court's conclusion that covered entities may simply impose "contractual limits" to "protect" themselves, (SPA 40), does not solve the problem. A contractual limitation simply would pass the vagueness issues to a contracting party who, as PhRMA argues, would be in no better position to resolve them.

Equally important, the district court failed to account for the statute's opt-in mechanism, which permits prescribers to authorize use of their prescription-history data for marketing.[8] This provision illustrates that Vermont is not consistently

---

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

[8] On June 29, 2009, the State advised plaintiffs that 415 of 3180 active Vermont licensed physicians (13%) had consented. *See* http://healthvermont.gov/hc/med_board/documents/BoardofMedicalPracticePrescribers.6-29-09xls.xls. This Court can take judicial notice of these facts. *See* Fed. R. Evid. 201(f).

pursuing its objectives. If the State genuinely intends to inhibit the ability of drug companies to target marketing messages to prescribers, why does it permit such a gaping exception? Nor did the district court afford any weight to the prospect that participation in the opt-in mechanism would be broad enough to preclude the statute from accomplishing its goals.

The statute also violates the First Amendment given its basic illogic and the significant inconsistencies in its provisions. In *Rubin v. Coors Brewing Co.*, 514 U.S. at 488, the Court invalidated a federal ban on the display of alcohol content on beer labels, which was intended to suppress "strength wars" between brands. The Court not only recognized the government's objective as legitimate, it accepted as "a matter of 'common sense' . . . that a restriction on the advertising of a product characteristic will decrease the extent to which consumers select a product on the basis of that trait." *Id.* at 487. But the Court found dispositive that the statute was pierced by "exemptions and inconsistencies": strength information could be provided in advertisements; the restriction did not apply on wine labels; and strength could be indicated through the term "malt liquor." *Id.* at 488-89. It invalidated the statute in light of "the overall irrationality of the Government's regulatory scheme." *Id.* at 488.

Subsequently, *Greater New Orleans*, 527 U.S. at 179, invalidated a ban on broadcast advertising of lawful private casinos that simultaneously permitted

advertising of casinos run by the government, tribes, and nonprofits. The statute's "fundamental" flaw in the view of the Court was that "[t]he operation of [the statute] and its regulatory regime is so pierced by exemptions and inconsistencies that the Government cannot hope to exonerate it." *Id.* at 174. The scheme could not materially advance the government's stated goals because it "distinguishes among the indistinct, permitting a variety of speech that poses the same risks as the government purports to fear."" *Id.* at 195. The Court held the ban unconstitutional because, "the federal policy of discouraging gambling in general, and casino gambling in particular, is now decidedly equivocal. . . . We cannot ignore Congress's unwillingness to adopt a single national policy that consistently endorses either interest asserted by the Solicitor General." *Id.* at 187.

So too, in this case, the Prescription Restraint Law is so "equivocal" that Vermont has failed to pursue an identifiable goal in a coherent fashion in the manner required by the First Amendment. The statute's purpose is to reduce drug costs and improve health care, but it directly regulates neither. It rests on objections to pharmaceutical detailing, which it similarly leaves entirely unregulated. The state contends that it can nonetheless further its goals by inhibiting detailing by limiting the use of prescription-history information, yet it freely permits prescribers to permit the use of that very information for that precise purpose.

II.

The Law Violates the Dormant Commerce Clause
by Prohibiting Commerce Wholly Outside of Vermont

The Vermont law applies to "information or documentation from a prescription dispensed in Vermont and written by a prescriber doing business in Vermont." 18 V.S.A. § 4631(b)(9) (SPA 67). Pharmacies doing business in Vermont transfer prescription information to their out-of-state headquarters where it is merged with other data relating to inventory, merchandizing and other important business functions. The publishers, whose businesses are located in Pennsylvania and Arizona, acquire prescription information from these pharmacies and other sources entirely outside of Vermont. The publishers' subscribers, many of whom are pharmaceutical companies, are also located outside of Vermont. These companies obtain the data outside of Vermont. The Vermont law will stop all of these entirely extraterritorial activities in violation of the Commerce Clause.

State 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,'" violate the Commerce Clause. *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) (state law that regulates commerce outside its own borders as *per se* invalid). 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. *See Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935) (A state "regulation which uses an in-state hook to affect out-of-state conduct [is] an impermissible violation of the Interstate Commerce Clause").

The district court recognized that the law restricts plaintiffs' speech outside Vermont "by foreclosing their ability to sell Vermont PI data that ultimately will be used for marketing to Vermont prescribers." (SPA 45). Yet it concluded that the law did not violate the Commerce Clause because plaintiffs "remain free . . . to conduct their business in connection with all states other than Vermont," and the law "does not regulate the sale, price or use of prescription data originating in any other state." The fact that plaintiffs can publish information about prescribers in other states is entirely irrelevant. "The 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).

Under the court's logic, as long as the restricted information originates from a prescription written by a Vermont prescriber and dispensed in Vermont, the State can put a tag on the information and prevent it from being communicated for marketing purposes *outside Vermont*. In this respect the regulation is indistinguishable from the regulation in *PhRMA*, in which a court enjoined a law that prohibited drug manufacturers from selling or supplying for sale a patented prescription drug "that results in" a drug being sold in D.C. for an excessive price. *PhRMA*, 406 F. Supp. 2d at 69.

The district court's reasoning contradicts this Court's holding in *Dean*, 342 F.3d 96, a case that invalidated a state law prohibiting the transfer to minors of sexually explicit material through the Internet. The district court regarded *Dean* as distinguishable because the out-of-state publishers to which the *Dean* law applied could not prevent Vermonters from accessing their websites. As a consequence, they had to conform their content to Vermont law for all consumers, including those outside of Vermont. The district court noted that this Court had upheld a law in *SPGGC, LLC v. Blumenthal*, 505 F.3d 183 (2d Cir. 2007), that prohibited out-of-state gift card sellers from selling the cards via the Internet to consumers in Connecticut because the sellers could distinguish in-state and out-of-state targets. (SPA 47). It then asserted that "Vermont prescription records are perfectly distinguishable from other states' records." *Id.* In fact, they are not so

distinguishable, but even if they were it would not be relevant because acquisition of the regulated records and sale of the regulated records takes place entirely outside of Vermont. The *Dean* law similarly affected transactions wholly outside of the state. The *SPGGC* law only prevented sales to consumers in Connecticut. The publishers here do not make sales inside of Vermont nor do they acquire information from inside of Vermont. They acquire it from pharmacies such as CVS and Rite Aid outside of Vermont and sell it to manufacturers outside of Vermont. Yet all of these transactions are prohibited. For this reason, the law violates the dormant Commerce Clause.

CONCLUSION

The Court should reverse the district court's decision and direct entry of judgment for the plaintiffs.

Respectfully submitted,

Hunton & Williams LLP

By /s/ Thomas R. Julin

Thomas R. Julin, Jamie Z. Isani & Patricia Acosta
2d Cir. Bar Nos. 09-198412, 198411 & 198410
1111 Brickell Avenue - Suite 2500
Miami, FL 33131
305.810.2516 Fax 2460
tjulin, jisani or pacosta@hunton.com

Robert B. Hemley & Matthew B. Byrne
Gravel & Shea, P.A.
2d Cir. Bar No. 07-187166
P.O. Box 369, Burlington, VT 05402
802.658.0220 Fax 1456 rhemley@gravelshea.com

Thomas C. Goldstein
2d Cir. Bar No. 07-187661
Akin, Gump, Strauss, Hauer & Feld LLP
1333 New Hampshire Ave., NW
Washington, D.C. 20036

Attorneys for the Publisher Plaintiffs/Appellants

Mark A. Ash
2d Cir. Bar App. Pending
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

Co-Counsel for Plaintiff/Appellant Verispan LLC

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 13,833 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

/s/ Thomas R. Julin
Thomas R. Julin

CERTIFICATE OF SERVICE

09-1913-cv(L) IMS Health v. Sorrell

I hereby certify that two copies of this Brief for Plaintiffs-Appellants IMS Health Incorporated, Verispan LLC and Source Healthcare Analytics, Inc. were sent by Federal Express Next Business Day Delivery to:

William H. Sorrell
Attorney General of the State of Vermont
Bridget C. Asay
David R. Cassetty
Assistant Attorneys General
109 State Street
Montpelier, Vermont 05609
(802) 828-3171

Attorneys for Defendants-Appellees
William H. Sorrell, as Attorney General of the State of Vermont, Jim Douglas, in his official Capacity as Governor of the State of Vermont, and Robert Hofmann, in his capacity as Secretary of the Agency of Human Services of the State of Vermont

Robert N. Weiner
Jeffrey L. Handwerker
Sarah Brackney Arni
Arnold & Porter LLP
555 Twelfth Street, N.W.
Washington, D.C. 20004-1206
(202) 942-5000

Attorneys for Plaintiff-Appellant Pharmaceutical Research and Manufacturers of America

I also certify that the original brief and nine copies were also sent By Hand delivery to:

Clerk of Court
United States Court of Appeals, Second Circuit
United States Courthouse
500 Pearl Street, 3rd floor
New York, New York 10007
(212) 857-8576

on this 1st day of July 2009.

/s/ Natasha R. Monell
Natasha R. Monell
Record Press, Inc.

ANTI-VIRUS CERTIFICATION

Case Name: IMS Health v. Sorrell

Docket Number: 09-1913-cv(L)

I, Natasha R. Monell, hereby certify that the Appellant's Brief submitted in PDF form as an e-mail attachment to **civilcases@ca2.uscourts.gov** in the above referenced case, was scanned using CA Software Anti-Virus Release 8.3.02 (with updated virus definition file as of 7/1/2009) and found to be VIRUS FREE.

/s/ Natasha R. Monell

Natasha R. Monell, Esq.
Record Press, Inc.

Dated: July 1, 2009