

Winter 2012

Prescription Data Mining, Medical Privacy and the First Amendment: The U.S. Supreme Court in *Sorrell v. IMS Health Inc.*

Marcia M. Boumil
Tufts University School of Medicine

Kaitlyn Dunn
Northeastern University School of Law and Tufts School of Medicine

Nancy Ryan
Northeastern University School of Law and Tufts School of Medicine

Katrina Clearwater
Northeastern University School of Law and Tufts School of Medicine

Follow this and additional works at: <http://lawcommons.luc.edu/annals>

 Part of the [Health Law and Policy Commons](#)

Recommended Citation

Marcia M. Boumil, Kaitlyn Dunn, Nancy Ryan & Katrina Clearwater *Prescription Data Mining, Medical Privacy and the First Amendment: The U.S. Supreme Court in Sorrell v. IMS Health Inc.*, 21 *Annals Health L.* 447 (2012).
Available at: <http://lawcommons.luc.edu/annals/vol21/iss2/7>

This Article is brought to you for free and open access by LAW eCommons. It has been accepted for inclusion in *Annals of Health Law* by an authorized administrator of LAW eCommons. For more information, please contact law-library@luc.edu.

Prescription Data Mining, Medical Privacy and the First Amendment: The U.S. Supreme Court in *Sorrell v. IMS Health Inc.*

Marcia M. Boumil^{*}, Kaitlyn Dunn^{**}, Nancy Ryan,^{***} and Katrina Clearwater^{****}

INTRODUCTION

The 2011 United States Supreme Court decision in *Sorrell v. IMS Health Inc.* is an important statement on how the current Court analyzes laws that restrict commercial speech, even in the name of protecting patients' medical privacy. At issue in *Sorrell* was a Vermont law that would have limited the ability of pharmaceutical companies to purchase certain physician-identifiable prescription data (PI data) without the affirmative consent of the prescriber.¹ Data mining companies, such as IMS Health Inc., collect this information about physician prescribing habits and sell it to pharmaceutical companies, which, in turn, use it to tailor their marketing solicitations to physicians to promote their brand-name products.²

Vermont's Prescription Confidentiality Law³, enacted in 2007, would have substantially restricted the purchase and sale of PI data without the express permission of the prescriber. The law's stated purpose was

^{*} Marcia M. Boumil, M.A., M.S., J.D., LL.M, Associate Professor of Public Health and Community Medicine and Assistant Dean for Conflicts of Interest Administration at Tufts University School of Medicine.

^{**} Kaitlyn Dunn, J.D./M.P.H. Candidate, 2013, Northeastern University School of Law and Tufts University School of Medicine.

^{***} Nancy Ryan, J.D./M.P.H. 2012, Northeastern University School of Law and Tufts University School of Medicine.

^{****} Katrina Clearwater, J.D./M.P.H. 2012, Northeastern University School of Law and Tufts University School of Medicine.

1. VT. STAT. ANN. tit.18, § 4631(d) (2009), *invalidated by Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011).

2. David Orentlicher, *Prescription Data Mining and the Protection of Patients' Interests*, 38 J.L. MED. & ETHICS 74, 75 (2010). Pharmaceutical companies routinely send "detailers" to physicians' offices to provide information concerning the company's new drug products. *Id.* While most physicians recognize that detailers are primarily engaged to promote a company's product, many also rely upon them to learn about new pharmaceuticals on the market. *Id.* at 75-76.

3. VT. STAT. ANN. tit.18, § 4631(d) (2009).

threefold: to protect the privacy of medical information; to promote public health by ensuring that prescription decisions are based on scientific evidence, rather than one-sided marketing pitches; and to help contain health care costs by encouraging prescription of cheaper, generic drugs.⁴ The issue before the Supreme Court was whether the Vermont law represented a legitimate, common-sense program intended to regulate PI data or a brazen attempt to suppress commercial speech when the message was disfavored by the state.⁵ The decision ultimately hinged on what level of First Amendment scrutiny the Supreme Court would apply to the Vermont law.

Imagine you are a pharmaceutical representative (“detailer”) seeking to market your company’s new, brand-name antidepressant to an individual community psychiatrist targeted by your sales force.⁶ There are eleven competing products on the market, including a number of less expensive, generic labels. To assist your sales effort, your company has purchased proprietary data telling you that this psychiatrist has prescribed your company’s product eight percent of the time over the past twelve months and a particular competitor’s product (brand-name or generic) twenty-three percent of the time. For this particular sales call, you assemble data, which is usually company-generated sales data, not peer-reviewed professional literature (unless it happens to support your marketing goals) that favorably compares your company’s product to the product that was this physician’s choice twenty-three percent of the time. Is such a marketing scheme ethical? Is it a violation of patient privacy? Should the purchase of such information be protected as commercial speech? These were the questions that confronted the *Sorrell* Court in 2011.

The Prescription Confidentiality Law limited, but did not prohibit, the purchase and sale of PI data used to promote the marketing of prescription drugs.⁷ If the prescriber consented to the sale or use of the PI data (the so-called “opt-in” feature), the restriction would not apply.⁸ Further, the law contained a number of other exceptions to the restriction, including use for scientific research, compliance issues, pharmacy reimbursement, and other purposes provided by law.⁹

Part I of this paper explains the practice of data mining in the

4. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2661 (2011) (discussing Vermont’s legislative findings).

5. *Id.*

6. The hypothetical describes a process known as “detailing” due to the fact that the pharmaceutical representatives provide “details” on the various prescriptions they are selling. See *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 71 (1st Cir. 2008).

7. VT. STAT. ANN. tit.18, § 4631(d) (2009).

8. *Id.*

9. *Id.* § 4631(e).

pharmaceutical context and examines the role of PI data in direct-to-physician marketing, or detailing, of pharmaceutical products. Part II examines the state laws designed to curb access to PI data that would eventually divide the First and Second Circuit Courts of Appeals, leading to review by the United States Supreme Court. Parts III and IV review the lower courts' opinions, including the split in the federal circuits, the Supreme Court's grant of certiorari, and the oral arguments considering the constitutionality of the Vermont law. Part V examines the Supreme Court's opinion striking down the Vermont law primarily on the basis that it amounts to an unconstitutional infringement of protected commercial speech. Part VI examines the implications of the Supreme Court's decision and provides suggestions for revising state laws to make them consistent with the Court's ruling.

I. BACKGROUND: HOW DOES DATA MINING WORK?

Every year, physicians in the U.S. write nearly four billion prescriptions, which is an average of twelve scripts for every American.¹⁰ According to IMS Health 2009 figures, pharmaceutical manufacturers devoted approximately \$6.3 billion to marketing prescription drugs to physicians,¹¹ which is nearly twice as much as the pharmaceutical industry spent on research and development.¹² The industry employs more than 90,000 drug representatives¹³ and spends upwards of \$20,000 per physician per year to pitch its products.¹⁴ Reportedly, there is "one drug representative for every four to five physicians in the [U.S.]."¹⁵ One attractive tool that drug companies currently have in their arsenal is access to pre-packaged information, PI data that indicates which physicians may be suitable candidates for the marketing of a particular brand-name drug based upon their prescribing patterns and/or certain characteristics of the patients they

10. Janet Lundy, *Prescription Drug Trends*, HENRY J. KAISER FAMILY FOUND. 1, 3 (May 2010), <http://www.kff.org/rxdrugs/upload/3057-08.pdf>.

11. Natasha Singer, *A Fight Over How Drugs Are Pitched*, N.Y. TIMES, Apr. 25, 2011, at B1, available at <http://www.nytimes.com/2011/04/25/business/25privacy.html?PageWanted=all>.

12. *Big Pharma Spends More On Advertising Than Research And Development, Study Finds*, SCIENCE DAILY (Jan. 7, 2008), <http://www.sciencedaily.com/releases/2008/01/080105140107.htm>.

13. *Fact Sheet: Prescription Data Mining*, THE PRESCRIPTION PROJECT, 1 (Nov. 19, 2008), http://www.prescriptionproject.org/tools/initiatives_factsheets/files/0004.pdf [hereinafter PRESCRIPTION PROJECT].

14. This figure includes perks such as gifts, meals, and travel, as well as consultancy fees and continuing medical education (CME) programs. Joshua Weiss, Note, *Medical Marketing in the United States: A Prescription for Reform*, 79 GEO. WASH. L. REV. 260, 261 (2010).

15. *IMS Health Corp. v. Rowe*, 532 F. Supp. 2d 153, 159 (D. Me. 2007).

serve, such as gender and age.¹⁶

The data mining process begins with so-called health information organizations (data mining companies or data vendors) that purchase information collected by pharmacies, including the prescriber's name; the name, dosage, and quantity of the drug prescribed; the date and place the prescription was filled; and the patient's age and sex.¹⁷ Although patient names are encrypted, each patient is assigned a unique identifier, thereby allowing data mining companies to link prescriptions and physicians to individual patients and thus track prescribing patterns over time.¹⁸ The American Medical Association (AMA) also plays a key role in the data mining process by selling lists of physicians from its "Physician Masterfile" to these data vendors.¹⁹ Data mining companies then match up the bundled information from pharmacy records with the identities on the AMA's physician lists to create individual prescriber profiles.²⁰

After aggregating this information, data mining companies such as IMS Health then license the PI data to pharmaceutical companies, whose representatives use it to develop, monitor, and/or adapt their targeted marketing strategies to boost drug sales.²¹ In fact, data vendors tout the availability of PI data as a way for pharmaceutical companies to "gain a level of insight that allows them to predict and influence physician-prescribing behavior like never before."²² Pharmaceutical companies have taken advantage of this new insight, exponentially increasing their spending on direct-to-physician marketing since the advent of PI data in this form.²³

Notwithstanding pharmaceutical companies' claims that data mining is necessary to ensure that physicians learn about the latest, most effective drugs for their patients, the practice has been heavily criticized for what it is: strategic marketing.²⁴ Furthermore, critics have cited a connection

16. *Id.* at 158-59.

17. Gregory D. Curfman, et al., *Prescriptions, Privacy, and the First Amendment*, 364 *NEW ENG. J. MED.* 2053, 2053 (2011).

18. *Id.*

19. *PRESCRIPTION PROJECT*, *supra* note 13, at 3 (stating that the sale of Masterfile information to data vendors provides a significant stream of revenue for the AMA – "\$44.5 million in 2005" alone). *See also* Jennifer L. Klocke, *Prescription Records for Sale: Privacy and Free Speech Issues Arising from the Sale of De-identified Medical Data*, 44 *IDAHO L. REV.* 511, 514 (2008) (stating "the AMA earns \$40 million per year selling [PI-data] about the nation's doctors").

20. *PRESCRIPTION PROJECT*, *supra* note 13, at 2.

21. Brief for Petitioners at 8-9, *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011) (No. 10-779).

22. Defendant's Memorandum of Law in Support of its Objection to Plaintiff's Motion for Preliminary Injunction at 13, *IMS Health Inc. v. Ayotte*, 490 F.Supp.2d 163 (D.N.H. 2007) (No. 06-CV-280-PB).

23. *IMS Health Inc. v. Sorrell*, 631 F.Supp.2d 434, 442 (D. Vt. 2009).

24. *See* Brief of AARP & The Nat'l Legislative Ass'n on Prescription Drug Prices as

between the collection and sale of PI data and both a detrimental impact on public health and a rise in prescription drug costs.²⁵ Data mining and the sales-focused marketing tactics it fosters have been linked to over-prescription of newer, costlier drugs with little-known side effects that, in fact, may have no demonstrable benefit over existing brand-name or generic choices.²⁶ Ample evidence of inaccurate, incomplete, or misleading statements made in the course of pharmaceutical marketing only heightens the concern that data mining may lead to irrational over-prescription of new and expensive medications that carry increased risks of patient harm.²⁷

Research reveals that the quality of prescribing decisions decreases as more physicians rely upon information from pharmaceutical sales representatives.²⁸ For example, a seminal study in the mid-1990s concluded that eleven percent of observed statements made by drug company salespeople to doctors were clearly false, despite the fact that only twenty-six percent of physicians detected such erroneous messages.²⁹ Another significant study found that after interactions with sales representatives, physicians, while claiming to have changed their prescribing behavior based on scientific data, actually wrote more prescriptions consistent with the promotional claims of the sales representatives.³⁰

The marketing leverage that data mining affords pharmaceutical companies vis-à-vis physicians also drives up health care costs as physicians shift to prescribing these more expensive drugs for their patients. Physicians' reliance on false or misleading representations about the safety and effectiveness of particular drugs may also lead them to prescribe new products for inappropriate, off-label uses, saddling public programs, private health plans, and consumers with the associated costs.³¹ Finally, given that low-income individuals and/or seniors are often forced to make decisions about whether to adhere to a medication regimen based upon cost, higher prescription drug prices may drive up overall health care spending through increased hospitalizations and complications that eventually result from the

Amici Curiae in Support of Petitioners at 8, *Sorrell*, 131 S. Ct. 2653 (No. 10-779) [hereinafter Brief of AARP & NLARxAss'n].

25. See Brief of AARP & NLARxAss'n, *supra* note 24, at 24-25.

26. Brief of AARP & NLARxAss'n, *supra* note 24, at 24-25.

27. Brief of AARP & NLARxAss'n, *supra* note 24, at 24-25.

28. David Orentlicher, *Prescription Data Mining and the Protection of Patients' Interests*, 38 J.L. MED. & ETHICS 74, 76 (2010).

29. Michael G. Ziegler et al., *The Accuracy of Drug Information from Pharmaceutical Sales Representatives*, 273 JAMA 1296, 1296 (1995).

30. Orentlicher, *supra* note 28, at 76.

31. Brief of Amici Curiae AFSCME District Council 37, Health Care for All, and Community Catalyst in Support of Petitioners at 20, *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011) (No. 10-779).

patients' inability to afford necessary medications.³²

Notwithstanding its facilitation of targeted detailing, the AMA reached an agreement with the data mining companies in 2006 whereby physicians could "opt out" of having their prescription data shared with pharmaceutical industry representatives.³³ However, the effectiveness of this offered solution depends upon physicians knowing that their prescribing habits are monitored and used as a marketing tool by the pharmaceutical companies. In 2002, approximately one-third of physicians studied were unaware that drug industry representatives receive information about their prescribing histories³⁴ and many reportedly were "shocked" upon learning that pharmacies sell such information to data vendors without their consent.³⁵ Thus, the issue of allowing one's prescribing data to be available only if the physician "opts in" (instead of unavailable only if he "opts out") is an essential point, since most physicians do not respond to notices at all.

The AMA, in an effort to publicize the issue, strongly promoted the opportunity for physicians to withhold their prescribing information from data miners through its Prescription Drug Restriction Program (PDRP).³⁶ However, current statistics suggest that only about twenty-five percent of physicians report being aware that this program exists.³⁷ Furthermore, as of 2010, less than four percent of all physicians have opted out through the PDRP.³⁸ Finally, pharmaceutical companies may still access the PI data of the physicians who choose to opt out, even for marketing purposes, so long as the pharmaceutical companies do not provide the information directly to detailers.³⁹

The AMA's failure to adequately address the concerns raised by the use of data mining in direct-to-physician marketing by pharmaceutical companies was instrumental in spurring individual states to regulate this practice. The rising costs of pharmaceuticals and evidence of compromised clinical decision-making support the position that the use of PI data negatively affects the health care system. Indeed, despite the assertions of

32. Brief of AARP & NLARx as Amici Curiae in Support of Petitioners, *supra* note 24, at 31, *Sorrell*, 131 S. Ct. 2653 (No. 10-779).

33. Stephanie Saul, *Federal Court Upholds Drug Privacy Law*, N.Y. TIMES, Nov. 19, 2008, at B10, available at <http://www.nytimes.com/2008/11/19/business/19drug.html?ref=imshhealthinc>.

34. *National Survey of Physicians: Part II: Doctors and Prescription Drugs*, KAISER FAMILY FOUND., 3 (March 2002), <http://www.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=13965>.

35. Brief for Petitioner, *supra* note 21, at 13-14, *Sorrell*, 131 S. Ct. 2653 (No. 10-779).

36. Orentlicher, *supra* note 28, at 77-78.

37. Jeremy A. Greene, *Pharmaceutical Marketing Research and the Prescribing Physician*, 146 ANNALS INTERNAL MED. 742, 746 (2007).

38. Orentlicher, *supra* note 28, at 78.

39. PRESCRIPTION PROJECT, *supra* note 13, at 3.

data vendors and pharmaceutical companies that detailing is a valuable practice for physicians, the evidence simply does not support it. Furthermore, the AMA's PDRP initiative does not address the concerns of physicians who are unaware that their prescribing information is being sold and used in such a manner.

II. STATE LEGISLATIVE RESPONSES

The state legislative responses to the concerns raised by the use of PI data for pharmaceutical detailing have been deliberate and comprehensive. Between 2006 and 2010, twenty-six states proposed legislation that would limit the use of PI data for commercial/marketing purposes.⁴⁰ New Hampshire was the first to enact such legislation in June 2006, followed closely by Vermont and Maine, both in June 2007.⁴¹ The New Hampshire, Vermont, and Maine statutes all represent similar efforts to contain the negative effects of detailing using PI data, but there are important differences in the way the laws are structured. These three statutes were the ones reviewed by the First and Second Circuit Courts of Appeals, resulting in inconsistent appellate rulings and, ultimately, review by the U.S. Supreme Court.

The New Hampshire, Vermont, and Maine laws reflect three primary interests in limiting commercial use of PI data: protection of public health, maintenance of physician privacy, and containment of rising health care costs.⁴² The theory behind these statutes is that a ban on the commercial use of PI data would accomplish each of these goals by addressing the insidious nature of detailing itself.⁴³ Specifically, protection of public health would be advanced by focusing physicians' decision-making on medical and scientific knowledge and by reducing the number of new drugs without well-documented track records being prescribed with the attendant risk of potentially dangerous health effects.⁴⁴ Cost containment would be achieved

40. Petition for a Writ of Certiorari at 26-27 n.5, *Sorrell, v. IMS Health Inc.*, 131 S. Ct. 2653 (No. 10-779). See also Brief for the States of Ill., Ala., Ariz., Ark., Cal., Colo., Del., Ga., Haw., Idaho, Ind., Iowa, Ky., La., Me., Md., Minn., Miss., Mont., Nev., N.H., N.M., N.Y., N.C., N.D., Ohio, Okla., Or., R.I., S.C., S.D., Tenn., Utah, Wash., and W. Va. and D.C. as Amici Curiae in Support of Petitioners at 8-9, *Sorrell*, 131 S. Ct. 2653 (No. 10-779).10-779) [hereinafter Amicus Brief for the States].

41. Act of June 30, 2006, ch. 328:1, 2006 N.H. Laws 750, 750-51 (codified at N.H. REV. STAT. ANN. §§ 318:47-f, 318:47-g, 318-B:12(IV) (2006)); Act of June 9, 2007, No. 80, § 17, 2007 Vt. Acts & Resolves 635, 650-53, amended by Act of March 5, 2008, No. 89, § 3, 2008 Vt. Acts & Resolves 5, 5 (codified as amended at VT. STAT. ANN. tit. 18, § 4631 (2009)); ME. REV. STAT. ANN. tit. 22, § 1711-E(2-A) (2008).

42. *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 47 (1st Cir. 2008); VT. STAT. ANN. tit. 18, § 4631(a) (2009); ME. REV. STAT. ANN. tit. 22, § 1711-E(1-B) (2008).

43. See ME. REV. STAT. ANN. tit. 22, § 1711-E(1-A(D)) (2008).

44. See *id.*

through fewer brand-name drugs being prescribed under circumstances where a generic substitute – or no drug at all – would be equally effective.⁴⁵ To some extent, the goal of prescriber privacy would be advanced simply through the law’s limitation on the dissemination of individual prescribing information. However, because each statute allows the release of prescriber data for purposes other than commercial use, the statutes only moderately limit the actual dissemination of individual physicians’ information. The privacy interest advanced, therefore, is best understood as increasing prescribers’ control over the use of their own prescribing data, rather than keeping the physicians’ data “private” *per se*.⁴⁶

Each of the three laws that was reviewed contemplates a similar method of achieving these goals. None of the laws seeks to ban the practice of pharmaceutical detailing or even attempts to directly regulate the interaction between pharmaceutical representatives and physicians. Instead, the statutes would effectively restrict pharmacies, health insurers, and other similar entities from disseminating PI data for the sole purpose of advertising, marketing, or promoting prescription drugs.⁴⁷ Thus, the statutes would regulate the dissemination of PI data at its source by preventing pharmacies and other entities from engaging in specific commercial transactions without prescriber permission. Each statute expressly allows for the dissemination of PI data for other purposes, such as pharmacy reimbursement, care management or utilization review by a health insurer, or legitimate public health research.⁴⁸

The three laws vary, however, with respect to whether and how PI data may be disseminated, including for otherwise prohibited purposes. The New Hampshire law is the most far-reaching as it imposes an absolute ban on using all “records relative to prescription information containing patient-identifiable and prescriber-identifiable data” for “any commercial purpose.”⁴⁹ The New Hampshire statute defines “commercial purpose” to include “advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical

45. *See id.* §§ 1711-E(1-A(D)), 1711-E(1-A(E)).

46. *See id.* § 1711-E(1-B(A)); *IMS Health Inc. v. Sorrell*, 630 F.3d 263, 275-76 (2d Cir. 2010); Transcript of Oral Argument at 11-12, *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011) (No. 10-779).

47. VT. STAT. ANN. tit. 18, § 4631(d) (2009), *invalidated by Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011); N.H. REV. STAT ANN. § 318:47-f (2006); ME. REV. STAT. ANN. tit. 22, § 1711-E(2-A) (2008).

48. VT. STAT. ANN. tit. 18, § 4631(e) (2009), *invalidated by Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011); N.H. REV. STAT ANN. § 318:47-f (2006); ME. REV. STAT. ANN. tit. 22, § 1711-E(1)(F-1) (2008).

49. N.H. REV. STAT ANN. § 318:47-f (2006).

detailing sales force.”⁵⁰ Through the use of explicit exemptions, the New Hampshire law aims to proscribe the transfer of PI data for direct marketing to physicians while continuing to permit the use of PI data for other purposes.⁵¹ The New Hampshire statute, however, does not give health care providers the option to either opt in or opt out of the commercial use of their PI data and, in this way, is the most restrictive of the three laws as physicians have no control at all.

The Maine law does give health care providers an option and thus is the least restrictive by way of its “opt-out” mechanism. Through exemptions and definitions similar to the New Hampshire statute, the Maine statute is structured to limit the use of PI data for direct marketing to physicians and other prescribers.⁵² However, the Maine legislature chose to limit the law’s restriction to “prescription drug information that identifies a prescriber who has filed for confidentiality protection.”⁵³ The statutory scheme provides the means by which prescribers may elect to withhold their PI data from being used for “marketing purposes by carriers, pharmacies and prescription drug information intermediaries.”⁵⁴

By signing and submitting a “confidentiality protection form” or the equivalent online procedure, prescribers may elect to opt out, withholding their PI data from use in direct-to-prescriber marketing.⁵⁵ Until a prescriber affirmatively indicates a desire to protect his or her identifiable information, the law does not affect the normal course of business between entities receiving PI data, such as pharmacies, and the pharmaceutical manufacturers that purchase the data to inform marketing activities.⁵⁶ In practice, such opt-out provisions have limited utility because the “default,” which occurs when no individual action is taken, maintains the status quo. If a Maine prescriber does not act to limit the dissemination of his or her PI data, the information will continue to be sold to pharmaceutical manufacturers for use in detailing.

The Vermont law differs here. Whereas the Maine statute offers prescribers a method to obtain additional confidentiality protection, the Vermont law is structured as an “opt-in” with respect to the dissemination of confidential information. The statutory scheme provides that PI data shall not be transferred “for marketing or promoting a prescription drug, unless

50. *Id.*

51. *Id.*

52. ME. REV. STAT. ANN. tit. 22, § 1711-E(2-A) (2008). *See also id.* § 1711-E(F-1) (defining the term “marketing”).

53. *Id.* § 1711-E(2-A).

54. *Id.* § 1711-E(4(A)(1)).

55. *See id.*

56. *See id.* § 1711-E(2-A).

the prescriber consents.”⁵⁷ In other words, the Vermont statute’s default position prohibits the use of PI data for marketing purposes, only allowing the data to be used toward that end if the prescriber affirmatively so permits. The practical effect of this opt-in approach is that the breadth of the Vermont statute’s application more closely resembles New Hampshire’s total ban than it does Maine’s more limited, opt-out approach. In order for PI data to be available for pharmaceutical manufacturers to use in marketing efforts, a physician must give consent after such consent is solicited through a state-created “prescriber data-sharing program” in which the state shall “solicit the prescriber’s consent on licensing applications or renewal forms and shall provide a prescriber a method for revoking his or her consent.”⁵⁸

The Vermont statute is also unusual in its inclusion of language directly regulating the pharmaceutical manufacturers and marketers. In addition to limiting the transfer of PI data by entities such as pharmacies, Vermont’s law states that, “[p]harmaceutical manufacturers and pharmaceutical marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents.”⁵⁹ Neither New Hampshire nor Maine’s law contains a comparable provision. It is unclear exactly what practical effect this provision might have had, other than the possibility of a civil action against the pharmaceutical manufacturers,⁶⁰ because the goal of limiting dissemination of this data may be wholly achieved by regulating at the point of collection.

This provision did, however, fit squarely within the general character of the Vermont statute – one that is directly at odds with the goals of pharmaceutical manufacturers. The Vermont legislature was more explicit about the harms it believes emanate from the practice of detailing than either New Hampshire or Maine’s legislatures. Recognizing the “strong link between pharmaceutical marketing activities, health care spending, and the health of Vermonters,” the legislative findings pit the goals of those marketing programs against the goals of the state.⁶¹ The legislature found that “progress toward [the aims of marketing programs] comes at the expense of cost-containment activities and possibly the health of individual patients.”⁶² Further elaborating on this dichotomy of interests, the Vermont legislature found that the “marketplace for ideas on medicine safety and

57. VT. STAT. ANN. tit. 18, § 4631(d) (2009), *invalidated by* Sorrell v. IMS Health Inc., 131 S. Ct. 2653 (2011).

58. *Id.* § 4631(c)(1).

59. *Id.* § 4631(d).

60. *Id.* § 4631(f).

61. Act of June 9, 2007, No. 80, §§ 1(2)-(3), 2007 Vt. Acts & Resolves 635, 635 (codified as amended at VT. STAT. ANN. tit. 18, § 4631(d) (2009)).

62. *Id.* § 1(3).

effectiveness is frequently one-sided” because of the expensive investment in marketing campaigns for brand-name drugs.⁶³ Accordingly, this results in “doctors prescribing drugs based on incomplete and biased information.”⁶⁴ Not mincing words, the Vermont legislature found that “[p]ublic health is ill served by the massive imbalance in information presented to doctors and other prescribers.”⁶⁵ The language of the Vermont statute was most directly confrontational to pharmaceutical interests, reflecting the broader concerns of each of the three states whose laws were challenged on constitutional grounds.

The three statutes, each emphasizing the substantial interests of public health, cost containment, and prescriber privacy, reflect novel approaches to regulating the pharmaceutical industry’s impact on physicians’ individual prescribing decisions. The statutes are similar, yet not identical to each other. The limited scope of the Maine statute stands in contrast to the broad application of the New Hampshire statute, with the Vermont statute representing a middle ground. Additionally, Vermont’s law is the only one to directly regulate the pharmaceutical manufacturers and is based upon pointed criticisms of pharmaceutical marketing practices couched within the legislative findings.

III. LEGAL CHALLENGES

Constitutional challenges to the New Hampshire, Maine, and Vermont statutes quickly followed their enactment. Data mining and pharmaceutical industry plaintiffs brought a myriad of claims seeking to overturn the states’ restrictions on the use of PI data. As the cases progressed through the lower courts, and eventually the U.S. Supreme Court, it became apparent that the First Amendment challenge lay at the heart of determining whether the statutes would be upheld.⁶⁶ The various courts approached the First Amendment analyses in very different ways and, in doing so, paved the way for rulings that varied significantly.

IMS Health Inc., the largest data mining company, led the charge in challenging all three statutes. In 2006, when New Hampshire passed its law, IMS Health’s revenues totaled \$1.96 billion, a twelve-percent increase from the previous year.⁶⁷ Almost half of that revenue was attributed to “sales

63. *Id.* § 1(4).

64. *Id.*

65. *Id.* § 1(6).

66. The plaintiffs in *IMS Health Inc. v. Sorrell*, 631 F. Supp. 2d 434 (D. Vt. 2009), brought claims relating to different sections of the Vermont statute in addition to the First Amendment free speech claim, alleging that the statute (1) was unconstitutionally vague, (2) violated the dormant Commerce Clause, (3) compelled speech in violation of the First Amendment, (4) violated the Commerce Clause, and (5) was federally preempted.

67. Klocke, *supra* note 19, at 514.

force effectiveness,” which includes PI data programs.⁶⁸ IMS Health’s biggest clients are pharmaceutical companies, whose use of PI data would have been curtailed to varying degrees under each statute.⁶⁹ In fact, sales to the pharmaceutical industry accounted for “substantially all” of IMS’s revenue from 2003-2005.⁷⁰ Verispan, LLC, a smaller but similarly situated data vendor, joined IMS Health in contesting the New Hampshire law.⁷¹ A separate suit challenging the Vermont statute brought by the Pharmaceutical Research and Manufacturers of America (PhRMA) was consolidated with the similar IMS Health action.⁷² Collectively, the plaintiffs risked lost revenue and a change in business practices with the implementation of these three laws.⁷³ For these reasons, the plaintiffs also shared a vested interest in preventing the implementation of the twenty-six statutes proposed throughout the U.S.⁷⁴ The two U.S. Circuit Courts of Appeals that would eventually review these practices reached very different conclusions. The First Circuit was first to rule in 2008 and 2010, affirming the validity of the New Hampshire and Maine statutes, respectively, restricting certain transfers of physicians’ prescription histories for use by pharmaceutical manufacturers to inform their detailing activities.⁷⁵

A. *IMS Health Inc. v. Ayotte*

In *IMS Health Inc. v. Ayotte*, the U.S. Court of Appeals for the First Circuit held in the first instance that New Hampshire’s Prescription Information Law⁷⁶ represented a permissible regulation of conduct, not speech.⁷⁷ Further, to the extent that the New Hampshire statute amounted to a restriction on commercial speech, the court held that the state “ha[d] acted with as much forethought and precision as the circumstances permit[ted] and the Constitution demands” in trying to combat a “novel threat to the

68. *Id.*

69. *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163, 166 (D.N.H. 2007).

70. *Id.* (quoting IMS’s 2005 Annual Report).

71. *Id.* at 165; see *IMS Health Inc. v. Mills*, 616 F.3d 7 (1st Cir. 2010).

72. *IMS Health Inc. v. Sorrell*, 631 F. Supp. 2d 434, 444 (D. Vt. 2009).

73. See *Ayotte*, 490 F. Supp. 2d at 173-74 (describing the “substantially altered” business practices of IMS and Verispan to comply with the restrictions imposed by the New Hampshire statute); Michael Heesters, *An Assault on the Business of Pharmaceutical Data Mining*, 11 U. PA. J. BUS. L. 789, 816 (2009).

74. See Brief for Respondent Pharm. Research & Mfrs. of Am. at 25-26, *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011) (No. 10-779); Brief of Respondents *IMS Health Inc., Verispan, LLC, & Source Healthcare Analytics, Inc.* at 31-32, *Sorrell*, 131 S. Ct. 2653 (No. 10-779) [hereinafter Brief of Respondents].

75. *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 45 (1st Cir. 2008); *IMS Health, Inc. v. Mills*, 616 F.3d 7, 12-13 (1st Cir. 2010).

76. N.H. REV. STAT. ANN. § 318:47-f (2006).

77. *Ayotte*, 550 F.3d at 45.

cost-effective delivery of health care.”⁷⁸

Ayotte began when two data mining companies sued New Hampshire alleging that its Prescription Information Law: (1) violated the Free Speech Clause of the First Amendment to the U.S. Constitution, (2) was void for vagueness, and (3) offended the dormant Commerce Clause.⁷⁹ Initially, the U.S. District Court for the District of New Hampshire found in favor of plaintiffs IMS Health and Verispan, declaring the law unconstitutional and enjoining its enforcement.⁸⁰ Principally, the district court concluded that the Prescription Information Law regulated “commercial speech” and did not satisfy the elements of a “permissible commercial speech restriction” established by the Court in 1980 in the seminal *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*.⁸¹ With respect to New Hampshire’s asserted interest in cost containment, the district court emphasized the state’s failure to prove that, on balance, non-bioequivalent generic drugs would be less harmful to the public health than brand-name drugs or that reduced health care costs could be achieved without undermining care for the subset of patients who would fare better with the branded medication.⁸² Finally, the district court found New Hampshire’s statute was not narrowly tailored to achieve its stated goals. Specifically, the state had other non-speech-related options to curtail detailing without restricting protected speech, such as gift bans, counter-detailing, continuing medical education programs, and alterations to the state’s Medicaid program.⁸³

A majority of the First Circuit overturned that decision, concluding that the data miners’ aggregation, manipulation, and transfer of PI data⁸⁴ for the express purpose of facilitating pharmaceutical detailing constituted *conduct*,

78. *Id.*

79. *Id.* at 47-48.

80. *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163, 183 (D.N.H. 2007).

81. *Id.* at 176-78. Under this tripartite test, “truthful commercial speech that does not promote unlawful activity can be limited under *Central Hudson* only if it: (1) is in support of a substantial government interest, (2) directly advances the government interest asserted, and (3) is not more extensive than is necessary to serve that interest.” *Id.* at 177 (internal citation omitted) (quoting *Cent. Hudson Gas & Electric Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 566 (1980)).

82. *Id.* at 180-81.

83. *Id.* at 182-83.

84. *Ayotte*, 550 F.3d at 52. The First Circuit took pains to delineate which of three interwoven transactions involving PI data should be the subject of its analysis. *Id.* at 48-50. Specifically, the court distinguished data miners’ acquisition of information from pharmacies and subsequent sale of processed data to drug companies (i.e., upstream transactions) from the pharmaceutical detailers’ use of that information to advertise particular products to physicians (i.e., downstream use). *Id.* at 48-49. Because New Hampshire’s statute sought to regulate the upstream uses – and because the data-miner plaintiffs did not have standing to assert the interests of pharmaceutical companies, detailers, or physicians – the court resolved the conduct/speech question with an eye toward the data miners’ activities. *Id.* at 50.

as opposed to *expression*.⁸⁵ To the extent that New Hampshire's statute infringed upon speech at all, the court found such speech to be of "nugatory informational value" insofar as it only aimed to increase detailers' bargaining power vis-à-vis physicians.⁸⁶ PI data had simply become a commodity in an economic transaction that New Hampshire had every right to regulate.⁸⁷

As the court colorfully noted, "The plaintiffs . . . ask us in essence to rule that because their product is information instead of, say, beef jerky, any regulation constitutes a restriction of speech. We think that such an interpretation stretches the fabric of the First Amendment beyond any rational measure."⁸⁸ Despite IMS Health and Verispan's efforts to portray themselves as "publishers" collecting and disseminating information of public concern within the marketplace of ideas, the court recognized that New Hampshire's law still left data mining companies free to transfer the aggregated information to any entity for non-detailing purposes.⁸⁹ The fact that the statute rendered it less profitable for the plaintiffs to compile PI data had no significance for purposes of First Amendment protection.⁹⁰

As an alternative basis for upholding the Prescription Information Law, the court found that the statute survived intermediate scrutiny as a regulation of commercial speech.⁹¹ While New Hampshire had articulated three state interests served by the law – preserving patient and prescriber privacy, protecting public health, and containing health care costs – the court confined its analysis to the latter.⁹² Cost containment easily qualified as a substantial state interest, although it was less clear that the statute promised to directly advance that goal.⁹³ Ultimately, the court believed New

85. *Id.* at 51 (quoting *Rumsfeld v. Forum for Acad. & Inst. Rights, Inc.*, 547 U.S. 47, 62 (2006)) ("[I]t has never been deemed an abridgement of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed.").

86. *Id.* at 52, 54.

87. *Id.* at 54.

88. *Id.* at 53.

89. *Id.*

90. *Id.* (quoting *Wine & Spirits Retailers, Inc. v. Rhode Island*, 418 F.3d 36, 48 (1st Cir. 2005)) ("The *First Amendment's* core concern is with the free transmission of a message or idea from speaker to listener, not with the speaker's ability to turn a profit.").

91. *Id.* at 54. The data-miner plaintiffs argued that transactions involving PI data should be construed as fully protected speech, since such activities do not "propos[e] a commercial transaction." *Id.* (quoting *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 473-74 (1989)). However, the majority rejected that interpretation and proceeded to treat the transactions as commercial speech because "they at most embody 'expression related solely to the economic interest of the speaker and its audience.'" *Id.* (quoting *Cent. Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 561 (1980)).

92. *Id.* at 55.

93. *Id.* at 55-57.

Hampshire did meet its evidentiary burden for each of the inferences in the causal chain, specifically that: (1) “detailing increases the prescription of brand-name drugs, . . . [which] tend to be more expensive”; (2) access to physicians’ prescribing histories heightens the pernicious effect of detailing; and (3) notwithstanding the increased cost, “many aggressively detailed drugs provide no [enhanced] benefit” to patients as compared to their generic counterparts and may even cause medical harm.⁹⁴

Turning to the third *Central Hudson* prong (i.e., whether the regulation is “in reasonable proportion to the interest served”),⁹⁵ the court concluded that the Prescription Information Law offered a precisely defined response to a pervasive problem that had been resistant to previous regulatory efforts.⁹⁶ New Hampshire was entitled to reject the three alternatives embraced by the district court, since none of them represented effective options.⁹⁷ For example, a blanket ban on gifts between detailers and physicians would have carried the unintended consequence of cutting off the flow of free samples that doctors often dispense to indigent patients otherwise unable to afford their medications.⁹⁸ The proposed counter-detailing program “fail[ed] as a matter of simple economics” given the exorbitant amount of state resources that would have been required to compete on a level playing field with the promotional activities of the pharmaceutical companies.⁹⁹

Having decided that New Hampshire’s statute comported fully with the First Amendment’s free speech requirements, the court summarily disposed of the plaintiffs’ void-for-vagueness argument. While acknowledging that the Prescription Information Law was “not a model of legislative craftsmanship,” the court insisted the state had clearly and deliberately crafted its statute so as to prohibit commercial uses related only to detailing.¹⁰⁰ The state’s Attorney General had confirmed that nothing would bar a pharmaceutical company from using PI data for other purposes (e.g., research or recruitment of doctors to take part in clinical trials), so long as the company refrained from marketing directly to New Hampshire-based physicians participating in that research or trial.¹⁰¹ Moreover, the court dismissed the idea of a chilling effect on the transfer of PI data for permissible uses, noting that pharmacies, health plans, and other sources of such data could protect themselves from liability simply by imposing conditions in their sales or license agreements requiring purchasers to

94. *Id.* at 57-58.

95. *Id.* at 59 (quoting *Edenfield v. Fane*, 507 U.S. 761, 767 (1993)).

96. *Id.*

97. *Id.*

98. *Id.*

99. *Id.* at 60.

100. *Id.* at 61.

101. *Id.* at 61-62.

comply with the New Hampshire statute.¹⁰²

As for IMS Health and Verispan's dormant Commerce Clause challenge, the court found the plaintiffs' contention that New Hampshire had sought to regulate conduct occurring wholly outside the state equally unconvincing.¹⁰³ Although the Prescription Information Law did not contain an explicit geographic limitation, the court relied on two principles of statutory construction to resolve the issue: the doctrine of constitutional avoidance¹⁰⁴ and the presumption that state laws have no extraterritorial effect.¹⁰⁵ New Hampshire's Attorney General had encouraged the First Circuit to interpret the Prescription Information Law as governing only activity that took place within the state's borders, and the court found it reasonable to follow that narrowed reading – particularly since “the upshot of doing [otherwise] would be to annul the statute.”¹⁰⁶

B. *IMS Health Inc. v. Mills*

Nearly two years later in *IMS Health Inc. v. Mills*, a majority of the First Circuit upheld Maine's law barring so-called prescription drug information intermediaries (PDIIs)¹⁰⁷ from “licensing, using, selling, transferring, or exchanging” PI data for marketing purposes.¹⁰⁸ As noted, unlike New Hampshire's statute, Maine's amendment to its Prescription Privacy Law contained an opt-out mechanism¹⁰⁹ allowing physicians to maintain the confidentiality of their prescribing histories, and permitting pharmaceutical companies to use such information for detailing unless a physician had

102. *Id.* at 62.

103. *Id.* at 62-63 (quoting *Alliance of Auto. Mfrs. v. Gwadosky*, 430 F.3d 30, 35 (1st Cir. 2005)) (noting that a statute which attempts to regulate conduct transpiring entirely outside the enacting state “outstrips the limits of the enacting state's constitutional authority and, therefore, is per se invalid.”).

104. *Id.* at 63 (citing *Arizonans for Official English v. Arizona*, 520 U.S. 43, 78 (1997); *United States v. Nascimento*, 491 F.3d 25, 38 (1st Cir. 2007)).

105. *Id.* (citing *K-S Pharms., Inc. v. Am. Home Prods. Corp.*, 962 F.2d 728, 730 (7th Cir. 1992)).

106. *Id.* at 63-64.

107. The statute defines a “prescription drug information intermediary” as “a person or entity that communicates, facilitates or participates in the exchange of prescription drug information regarding an individual or a prescriber.” The term “includes, but is not limited to, a pharmacy benefits manager, a health plan, an administrator and an electronic transmission intermediary and any person or entity employed by or contracted to provide services to that entity.” ME. REV. STAT. ANN. tit. 22, § 1711-E(1)(I) (2008).

108. *Mills*, 616 F.3d at 12-13; *see also* § 1711-E(2-A).

109. The majority mischaracterized § 1711-E(4) as an “opt-in” provision that allowed prescribers to choose confidentiality protection, rather than an “opt-out” provision making it possible for them to safeguard their identifiable information from marketing uses. *Mills*, 616 F.3d at 19. This is inconsistent with the terms used by the parties and the district court in *IMS Health Corp. v. Rowe*, 532 F. Supp. 2d 153, 179-80 (D. Me. 2007).

chosen to designate his or her information as protected.¹¹⁰ Bound by its holding in *Ayotte*, the First Circuit concluded that the challenged portion of Maine’s law (§ 1711-E(2-A)) regulated conduct and that, to the extent § 1711-E(2-A) restricted commercial speech,¹¹¹ the statute met the *Central Hudson* test.¹¹² Moreover, the statute’s distinct opt-out provision directly advanced Maine’s “substantial purpose of protecting . . . prescribers from having their identifying data used in unwanted solicitations by detailers, and thus Maine’s interests in lowering health care costs.”¹¹³

Mills reached the First Circuit in a unique posture. In August 2007, IMS Health and Verispan – now joined by Source Healthcare Analytics, Inc. – sued Maine’s Attorney General under 42 U.S.C. § 1983.¹¹⁴ The data miners asserted that the state’s prescription data mining law imposed an unconstitutional burden on protected speech pursuant to the First Amendment; that the restrictions were void for being vague and overbroad; and that the law sought to regulate out-of-state transactions in violation of the dormant Commerce Clause.¹¹⁵ The U.S. District Court for the District of Maine agreed that § 1711-E(2-A) did not materially advance the state’s purported interest in patient and prescriber confidentiality, nor was it narrowly tailored toward that end, thus entitling the plaintiffs to a preliminary injunction.¹¹⁶ Shortly thereafter, however, the First Circuit rejected the substantially similar First Amendment claims that the plaintiffs had made in *Ayotte*.¹¹⁷

In affirming the constitutionality of § 1711-E(2-A), the First Circuit emphasized that the differences between the New Hampshire and Maine statutes only weakened the data miner plaintiffs’ challenge to the latter.¹¹⁸ For instance, Maine had incorporated several findings in its legislation indicating that curtailing the use of PI data would reduce the influence of detailing, promote prescription decisions rooted in medical and scientific knowledge, and ultimately drive down health care costs.¹¹⁹ Separate and

110. *Mills*, 616 F.3d at 12-13.

111. *Id.* at 13. The majority defined the “speech” subject to regulation as “data contained in databases and reports that [IMS Health, Verispan, and Source Healthcare Analytics] have designed to facilitate detailing” – a clear instance of commercial speech. *Id.* at 21. Although Maine’s law touched upon various layers of the market for PI data, it – like New Hampshire’s law – did not affect in any way the communications between pharmaceutical representatives and prescribers. *Id.* at 16.

112. *Id.* at 13, 21.

113. *Id.* at 19.

114. *Rowe*, 532 F. Supp. 2d at 166.

115. *Id.*

116. *Id.* at 176, 183.

117. *IMS Health Inc. v. Mills*, 616 F.3d 7, 13 (1st Cir. 2010).

118. *Id.* at 19.

119. *Id.*

apart from the First Circuit's rationale in *Ayotte*, the Maine statute's opt-out mechanism directly served the state's substantial interest "in vindicating Maine prescribers' rights to avoid unwanted targeting by detailers . . . on the basis of their individual prescribing histories."¹²⁰

The court likened this opt-out provision to existing "do not call" or "do not mail" registry laws, which were designed to address head-on the problem of personal identifying information being sold, licensed, transferred, exchanged, or used to bombard unwilling listeners with targeted marketing messages.¹²¹ Indeed, the court found it significant that the impetus for § 1711-E(2-A) came from Maine prescribers demanding that the legislature prevent their identifiable data from falling into the hands of, and being surreptitiously used by, detailers.¹²² Rather than enact a categorical ban on the use of PI data for marketing purposes, the legislature responded with a less restrictive measure that "provide[d] exactly the protections that Maine prescribers ha[d] requested and allow[ed] prescribers to choose whether to invoke them."¹²³ As in *Ayotte*, Maine acted well within its authority in deciding that alternatives such as restrictions on free drug samples, physician education, or formulary controls would have done little to contain health care costs and nothing to prevent the unapproved use of prescribers' identifying data for detailing.¹²⁴

With respect to the plaintiffs' void-for-vagueness argument, the court found that § 1711-E(2-A)'s terms – specifically, "for any marketing purpose" – were not "so uncertain that persons of average intelligence would have no choice but to guess at [their] meaning and modes of application."¹²⁵ Moreover, the plaintiffs could not paint themselves as "unwitting middlemen" selling PI data to pharmaceutical companies without knowledge of its ultimate application when the record made pellucid that the data mining companies intended their reports to be used in detailing.¹²⁶

Notwithstanding the reality that the plaintiffs had obtained an injunction before § 1711-E(2-A) went into effect, the court approached the dormant Commerce Clause claim in *Mills* as an as-applied, rather than a facial,

120. *Id.* at 20.

121. *Id.* at 21-22 (citing *Rowan v. U.S. Post Office Dep't*, 397 U.S. 728, 736-38 (1970) and *FTC v. Mainstream Mktg. Servs., Inc.*, 345 F.3d 850, 854-55 (10th Cir. 2003)).

122. *Id.* at 15, 22 (citing ME. REV. STAT. ANN. tit. 22, § 1711-E(1-A)(B)).

123. *Id.* at 22. Because in-state physicians themselves retained control over whether or not their information could be used for otherwise prohibited purposes, the court rejected the plaintiffs' assertions that Maine's law constituted a paternalistic attempt to shield prescribers from messages that the government found objectionable. *Id.*

124. *Id.* at 22-23.

125. *Id.* at 23 (quoting *United States v. Nieves-Castaño*, 480 F.3d 597, 603 (1st Cir. 2007) (internal citation omitted)).

126. *Id.*

challenge.¹²⁷ Unlike in *Ayotte*, Maine's Attorney General had not taken the position that the state sought only to regulate conduct within its own borders,¹²⁸ giving the court occasion to engage in a more robust dormant Commerce Clause analysis.¹²⁹ Focusing on § 1711-E(2-A)'s text, its legislative history, and Maine's canons of statutory construction, the court resolved that the law did apply to plaintiffs' out-of-state transactions involving opted-out prescribers' identifying information.¹³⁰ However, the court felt that Maine's efforts to regulate PDII's out-of-state use or sale of opted-out Maine prescribers' data posed no problem under the dormant Commerce Clause.¹³¹ As the court noted, the dormant Commerce Clause fundamentally seeks to combat economic protectionist policies that discriminate against out-of-state entities in favor of in-state competitors or impose burdensome regulatory obligations inconsistent with those found in other states.¹³² Maine's statute implicated none of these concerns; instead, the Maine legislature had acted within the scope of its police power by restricting transactions that ultimately affected the health, safety, and welfare of Maine citizens.¹³³

Finally, the majority stated that § 1711-E(2-A) easily satisfied the so-called *Pike* balancing test for gauging whether a regulation disproportionately burdens interstate commerce relative to the in-state benefits achieved.¹³⁴ The plaintiffs had failed to show that losing data about the 259 Maine prescribers who had opted out as of September 2009¹³⁵ would impact the marketability of their aggregated reports.¹³⁶ Furthermore,

127. *Id.* at 24 n.19. Given the nature of the challenge, the First Circuit left open the question of whether § 1711-E(2-A) applied to pharmacies' or pharmaceutical manufacturers' out-of-state license, use, sale, transfer, or exchange for value of opted-out Maine prescribers' data. *Id.* at 24 n.20.

128. *Id.* at 39-40 (Lipez, J., concurring) (highlighting that, "Maine distances itself from the nonsensical construction of the New Hampshire statute that was advanced by the New Hampshire Attorney General and accepted by the *Ayotte* majority, admitting that its statute inevitably reaches out of state to regulate sales of data about prescriptions written in Maine.").

129. *See id.* at 23-32.

130. *Id.* at 25-26.

131. *Id.* at 27.

132. *Id.* at 27-28.

133. *Id.* at 28. Despite the law's incidental effects on interstate commerce, the court insisted that the extraterritoriality doctrine was inapplicable to § 1711-E(2-A). *Id.* at 31. The statute only sought to protect *Maine* prescribers' identifiable information from being used to target physicians in *Maine* for pharmaceutical marketing, and to address the exclusively in-state harms flowing from those interactions. *Id.* at 29.

134. *Id.* at 32 (citing *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970)).

135. *Id.* As the court emphasized, the data mining companies still had access to information about approximately 7,250 Maine prescribers who had declined to opt out, not to mention 1.5 million prescribers nationwide. *Id.*

136. *Id.* at 32 & n.34 (pointing out that "[p]laintiffs have provided no data about [the]

the plaintiffs had not established that complying with the mandate against sale or use of these prescribers' information would be especially difficult or costly from an interstate commerce perspective.¹³⁷ On the other hand, § 1711-E(2-A) would confer clear benefits in Maine by allowing prescribers to avoid targeted detailing visits by opting out.¹³⁸

C. *IMS Health Inc. v. Sorrell*

Notwithstanding the rationale of its sister circuit, the U.S. Court of Appeals for the Second Circuit held that laws banning the sale, transmission, or use of PI data for pharmaceutical marketing purposes violate the First Amendment's Free Speech Clause.¹³⁹ In *IMS Health Inc. v. Sorrell*, a majority of the Second Circuit overturned Vermont's Prescription Confidentiality Law,¹⁴⁰ viewing it as a regulation of commercial speech that did not survive intermediate scrutiny under *Central Hudson*.¹⁴¹ So-called Act 80, § 17 did not, in the Second Circuit's eyes, directly advance Vermont's asseverated interests in safeguarding medical privacy, reining in health care costs, and promoting public health, nor was the statute narrowly tailored toward those ends.¹⁴²

As described above, § 17 contained three features that distinguished the law from those enacted in Maine and New Hampshire. First, in addition to prohibiting pharmacies, health insurers, self-insured employers, electronic transmission intermediaries, and other similar entities from selling, licensing, or exchanging for value records containing PI data, § 17 directly forbade pharmaceutical manufacturers and marketers from using such information to promote or market their products.¹⁴³ Second, § 17 included a mechanism whereby providers could affirmatively consent to having their prescribing histories used for marketing purposes, with confidentiality protection serving as the default rule.¹⁴⁴ Lastly, the Vermont legislature had incorporated thirty-one specific findings to support the statute's passage,¹⁴⁵

range of [PDII]s subject to [§] 1711-E(2-A) or the relative proportion of overall business transacted in Maine versus outside it. . . . [T]he *Pike* balancing test is about burdens on the interstate market as a whole, not about burdens on particular firms.”).

137. *Id.* at 32.

138. *Id.* Before addressing the merits of the plaintiffs' *Pike* balancing test argument, the court noted that the data miners had already waived the same by neglecting to raise that theory in the proceedings below. *Id.* (citing *Mass. Museum of Contemporary Art Found. v. Büchel*, 593 F.3d 38, 65 (1st Cir. 2010)).

139. *IMS Health Inc. v. Sorrell*, 630 F.3d 263, 267 (2d Cir. 2010).

140. VT. STAT. ANN. tit. 18, § 4631 (2009).

141. *Sorrell*, 630 F.3d at 267.

142. *Id.* at 267.

143. *Id.* at 270 (citing VT. STAT. ANN. tit. 18, § 4631(d)).

144. *Id.* at 269-70 (citing VT. STAT. ANN. tit. 18, § 4631(c)(1)).

145. *Id.* at 270 (citing Act of June 9, 2007, No. 80, § 1, 2007 Vt. Acts & Resolves 635,

several of which expressed the state's intent to amplify the volume of information about generics within the marketplace of ideas by disadvantaging information about brand-name drugs.¹⁴⁶

Sorrell moved through the courts as a consolidated case – one suit originally brought against Vermont's Attorney General by IMS Health, Verispan, and Source Healthcare Analytics, combined with another action filed by PhRMA.¹⁴⁷ The U.S. District Court for the District of Vermont refused to grant the plaintiffs' request for declaratory and injunctive relief, holding that § 17 effectuated a restriction on commercial speech that passed muster under the *Central Hudson* test and comported fully with the dormant Commerce Clause.¹⁴⁸ On appeal, however, the Second Circuit reversed the judgment on First Amendment grounds alone.¹⁴⁹

As the court saw it, § 17 could not be construed as simply the restriction of a commercial practice.¹⁵⁰ The PI data at issue represented speech, since the First Amendment protects “[e]ven dry information, devoid of advocacy, political relevance, or artistic expression,”¹⁵¹ as well as information that exists in a form distributed for profit.¹⁵² For purposes of trying to justify the rational basis review that would attend a regulation of conduct, no practical distinction could be made between the “use [of] a

635-39). Arguably, the legislative findings were crafted as part of a much broader statutory scheme to address the problem of high prescription drug costs, and the parties in *Sorrell* disagreed as to whether the findings actually corresponded to Act 80, § 17. For example, Act 80 also authorized funds for a counter-detailing initiative (i.e., an “evidence-based prescription drug education program” to give physicians and other prescribers “information and education on the therapeutic and cost-effective utilization of prescription drugs”). VT. STAT. ANN. tit. 18, § 4622(a)(1) (2010). Act 80 also included a later-repealed provision that forced detailers to provide information about alternative treatment options during their visits with prescribers. Act of March 5, 2008, No. 89, § 3(f), 2008 Vt. Acts & Resolves 4, 6 (codified as amended at VT. STAT. ANN. tit. 18, § 4631 (2009)).

146. Act of June 9, 2007, No. 80, § 1, 2007 Vt. Acts & Resolves 635, 635-39. The Second Circuit majority seemed troubled by the legislature's assertion that the goals of pharmaceutical marketing were “often in conflict with the goals of the state.” *Sorrell*, 630 F.3d at 270 (quoting No. 80, § 1(3)). Moreover, the legislature had explicitly noted its concern that “the ‘marketplace for ideas on medicine safety and effectiveness is frequently one-sided,’ leading doctors to prescribe ‘drugs based on incomplete and biased information.’” *Id.* (quoting No. 80, § 1(4)). Accordingly, the Vermont legislature had concluded that “[p]ublic health is ill served by the massive imbalance in information presented to doctors and other prescribers.” *Id.* (quoting No. 80, § 1(6)).

147. *Sorrell*, 630 F.3d at 270.

148. *Id.* at 270-71 (citing *IMS Health Inc. v. Sorrell*, 631 F. Supp. 2d 434, 455, 456-59 (D. Vt. 2009)).

149. *Id.* at 271.

150. *Id.*

151. *Id.* at 271-72 (quoting *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 446 (2d Cir. 2001)).

152. *Id.* at 272 (citing *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 761 (1976)).

particular informational asset – prescribing histories – in a particular way” that the First Circuit had described in *Ayotte* and protected speech.¹⁵³ Moreover, the court emphasized the need for judicial skepticism of legislative attempts to influence the supply of truthful information, a central First Amendment concern.¹⁵⁴

While Vermont argued that the plaintiffs had no First Amendment right to access non-public health information that pharmacies were mandated to collect under state and federal law, the court instead saw it as a matter of “prevent[ing] willing sellers and willing buyers from completing a sale of information to be used for purposes that the state disapproves.”¹⁵⁵ In support of its position, Vermont had relied upon *Los Angeles Police Department v. United Reporting Publishing Corp.*, a case in which the U.S. Supreme Court upheld limits on access to certain police department information because the policy constituted “nothing more than a governmental denial of access to information in its possession.”¹⁵⁶ However, the PI data at issue rested in the hands of private actors rather than within the government’s possession, further buttressing plaintiffs’ assertions that § 17 regulated protected speech.¹⁵⁷

Dealing first with the effect Vermont’s Prescription Confidentiality Law had on pharmaceutical manufacturers, the court declined to apply strict scrutiny to the constraints on use of PI data simply because the downstream detailing message included fully protected speech.¹⁵⁸ Although suggesting that the data miners’ aggregation and sale of physicians’ prescribing histories might come closer to fully protected speech, the court assumed without deciding that the statute regulated data mining companies’ commercial speech because § 17 could not withstand even intermediate scrutiny.¹⁵⁹

In applying the *Central Hudson* factors, the court concluded that Vermont did possess a substantial interest in containing health care costs and protecting public health, but that its proffered interest in medical privacy was too speculative to qualify.¹⁶⁰ The record contained no studies

153. *Id.* (quoting *IMS Health, Inc. v. Ayotte*, 550 F.3d 42, 54 (1st Cir. 2008)).

154. *Id.*

155. *Id.* at 273.

156. *Id.* (quoting *L.A. Police Dep’t v. United Reporting Publishing Corp.*, 528 U.S. 32, 40 (1999)).

157. *Id.*

158. *Id.* at 274 (noting that “the mere presence of non-commercial information in an otherwise commercial presentation does not transform the communication into fully protected speech.”).

159. *Id.* at 274-75.

160. *Id.* at 276. The majority parsed out Vermont’s asserted interest in medical privacy as consisting of two parts: (1) an interest in preserving “the integrity of the prescribing process itself” and (2) an interest in promoting “patients’ trust in their doctors by preventing

showing that the use of prescribing histories by pharmaceutical marketers undermined patients' confidence in their physicians, nor that specific detailing interactions had caused Vermont doctors to prescribe inappropriate and potentially harmful medications.¹⁶¹ Furthermore, § 17 did not functionally protect the privacy of individual physicians, since the statute allowed PI data to be sold, transferred, and used for any purpose other than marketing or promoting a prescription drug,¹⁶² "including widespread publication to the general public."¹⁶³

As the Second Circuit saw it, § 17 did not advance the state's interests in public health and cost containment in a direct and material way.¹⁶⁴ Rather than restricting the prescribing practices of doctors or the detailing practices of the pharmaceutical companies, Vermont had taken a circuitous approach that "restrict[ed] the information available to detailers so that their marketing practices [would] be less effective and less likely to influence the prescribing practices of physicians."¹⁶⁵ This attempt to regulate conduct (i.e., the interactions between physicians and detailers) by stifling the speech of data miners and pharmaceutical manufacturers was, according to the court, directly antithetical to First Amendment principles guarding against "regulations that seek to keep people in the dark for what the government perceives to be their own good."¹⁶⁶

With respect to the narrow tailoring prong of *Central Hudson*, the court found that § 17 also failed insofar as the statute barred the use of PI data "for the marketing of any brand-name prescription, no matter how efficacious and no matter how beneficial those drugs may be compared to generic alternatives."¹⁶⁷ Since Vermont's goal was to stem the prescription of new and expensive brand-name drugs with potentially undiscovered side

patients from believing that their physicians are inappropriately influenced by PI data-driven marketing." *Id.*

161. *Id.*

162. *Id.* at 275. Under § 17, Vermont contemplated that PI data might be used for any of the following permissible purposes: "pharmacy reimbursement; prescription drug formulary compliance; patient care management; utilization review by a health care professional, the patient's health insurer, or the agent of either; health care research; dispensing prescription medications; prescriber-to-pharmacy transmission of prescription information; "care management; educational communications provided to a patient, including treatment options, recall or safety notices, or clinical trials; and for certain law enforcement purposes or as otherwise authorized by law." *Id.* at 270 (citing VT. STAT. ANN. tit. 18, § 4631(e)(1)-(7) (2009)).

163. *Id.* at 275.

164. *Id.* at 277.

165. *Id.*

166. *Id.* at 277-78 (citing 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996)); see also *Cent. Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 n.9 (1980) ("We review with special care regulations that entirely suppress commercial speech in order to pursue a non[-]speech-related policy.").

167. *Id.* at 279-80.

effects or those brand-name medications that had generic alternatives, § 17 casted far too wide a net by prohibiting the use of PI data to market *any* brand-name drug.¹⁶⁸ The fact that Vermont prescribers could affirmatively choose to allow their data to be used for marketing purposes did not save § 17 from being considered a categorical ban in light of the statute's application to all brand-name drugs, no matter how unique and efficacious.¹⁶⁹ The court also reasoned that Vermont had more direct, less speech-restrictive methods available to advance its goals of cost containment and protecting public health, including waiting to gauge the impact of its own counter-detailing program.¹⁷⁰

D. *Analysis of Circuit Court Opinions in Mills and Sorrell*

The opposing judgments reveal fundamental differences in the First and Second Circuits' First Amendment analyses.¹⁷¹ An initial question under First Amendment analysis is whether the statutes restrict speech, as opposed to conduct.¹⁷² The First Circuit concluded its analysis with this first step, ruling that neither the New Hampshire nor the Maine statute restricted speech.¹⁷³ Rather, the First Circuit found that the New Hampshire and Maine statutes regulated commercial conduct.¹⁷⁴ The First Circuit construed the challenged provisions of the New Hampshire statute as "principally regulat[ing] conduct because those provisions serve only to restrict the ability of data miners to aggregate, compile, and transfer information destined for narrowly defined commercial ends."¹⁷⁵ Essentially, both the New Hampshire and Maine statutes sought to solve a problem "not by eliminating speech but, rather, by eliminating the detailers' ability to use a particular informational asset . . . in a particular way."¹⁷⁶ For this reason, the First Circuit held that the regulations fell outside the scope of the First Amendment, precluding a challenge under the Free Speech Clause.¹⁷⁷

The Second Circuit found its sister circuit's reasoning unpersuasive, criticizing its assumption of "freewheeling authority to declare new categories of speech outside the scope of the First Amendment."¹⁷⁸ The

168. *Id.*

169. *Id.* at 281.

170. *Id.* at 280.

171. *Id.* at 272-73; *IMS Health Inc. v. Mills*, 616 F.3d 7, 18-19 (1st Cir. 2010).

172. *Sorrell*, 630 F.3d at 271; *Mills*, 616 F.3d at 18-19; *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 50 (1st Cir. 2008).

173. *Ayotte*, 550 F.3d at 54; *Mills*, 616 F.3d at 19-20.

174. *Ayotte*, 550 F.3d at 53.

175. *Id.* at 52.

176. *Id.* at 54.

177. *Id.*

178. *IMS Health Inc. v. Sorrell*, 630 F.3d 263, 272 (2d Cir. 2010) (quoting *United States*

Second Circuit focused heavily on the findings of the Vermont legislature that bemoaned the one-sided nature of the information available to prescribers due to the high investment in PI data to inform detailing.¹⁷⁹ The Vermont statute, in the Second Circuit's view, was explicitly aimed at "influencing the supply of information, a core First Amendment concern."¹⁸⁰ Likewise, the Second Circuit dismissed the state's argument that this was "nothing more than a governmental denial of access to information in its possession," finding that the statute restricted protected speech.¹⁸¹

The finding that the regulation was within the scope of the First Amendment required the Second Circuit to analyze whether the Vermont statute violated plaintiffs' constitutional rights under the applicable precedent. Although the First Circuit held that the regulation was outside the purview of the First Amendment, it provided an alternate ground for its decision if the New Hampshire and Maine laws were to be treated as restrictions on protected speech.¹⁸² The applicable test that courts must employ depends on whether the speech is determined to be commercial in nature.¹⁸³ Although the plaintiffs in each case argued that the statutes restricted noncommercial speech, all three courts agreed that the primary purpose of detailing is "to propose a commercial transaction," and thus the speech at issue was commercial speech.¹⁸⁴

In order to be held constitutional, government restrictions on commercial speech must meet the test for intermediate scrutiny as outlined in *Central Hudson*.¹⁸⁵ The first prong was easily met in both the First and Second Circuit cases. The First Circuit reasoned that "fiscal problems have caused entire civilizations to crumble" and so, cost containment by itself satisfies the first prong of the *Central Hudson* inquiry.¹⁸⁶ The Second Circuit appellants did not dispute that protecting public health and containing health care costs were substantial government interests.¹⁸⁷ However, the

v. Stevens, 130 S. Ct 1577, 1586 (2010)) (internal quotations omitted).

179. *Id.*

180. *Id.*

181. *Id.* at 273 (quoting *L.A. Police Dep't v. United Reporting Publishing Corp.*, 528 U.S. 32, 40 (1999)).

182. *Ayotte*, 550 F.3d at 54.

183. *Id.* at 54-55; *Sorrell*, 630 F.3d at 273-74.

184. *Sorrell*, 630 F.3d at 274. See *Ayotte*, 550 F.3d at 54-55; *Mills*, 616 F.3d at 20-21.

185. *Ayotte*, 550 F.3d at 55; *Sorrell*, 630 F.3d at 275.

186. *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 55 (1st Cir. 2008). Although the First Circuit in *Ayotte* did not go on to examine either public health or prescriber privacy as substantial interests, the First Circuit did determine, in *Mills*, that the Maine statute "directly serves Maine's substantial interest in vindicating Maine prescribers' rights to avoid unwanted targeting by detailers." *IMS Health Inc. v. Mills*, 616 F.3d 7, 20 (1st Cir. 2010).

187. *IMS Health Inc. v. Sorrell*, 630 F.3d 263, 275 (2d Cir. 2010).

Second Circuit held that “the state’s asserted interest in medical privacy is too speculative” to satisfy the first prong of *Central Hudson*.¹⁸⁸ The Second Circuit reasoned that, because the statute continued to allow wide dissemination of prescriber data, the statute could not serve the purpose of protecting prescriber privacy in its traditional sense.¹⁸⁹ Although the Second Circuit clarified that it viewed medical privacy in this context as two distinct interests – an interest in “the integrity of the prescribing process itself and an interest in preserving patients’ trust in their doctors” – it held that Vermont did not have enough evidence to substantiate these privacy interests.¹⁹⁰

The second prong of *Central Hudson* is where the First and Second Circuits divided sharply in their analysis. The First Circuit found that “deference [was] in order,”¹⁹¹ given that the New Hampshire statute was the first of its kind enacted in the nation. Thus, the court did not demand “certitude” that the statute would advance the asserted interest.¹⁹² Rather, the First Circuit relied on common sense and held that the state adequately demonstrated that implementation of the law would directly advance cost containment efforts.¹⁹³ The First Circuit’s analysis with respect to Maine’s law concluded that the statute directly advanced prescriber privacy.¹⁹⁴ The court relied heavily on the fact that Maine prescribers had “identified detailers’ use of personal prescribing histories as a singularly objectionable practice. . . [and] demanded legislative action to protect their identifying data from this unwanted use.”¹⁹⁵ Therefore, the First Circuit held that the New Hampshire and Maine statutes would directly advance cost containment and prescriber privacy, respectively.¹⁹⁶

In contrast, the Second Circuit held that the Vermont statute would not advance public health and cost containment in any direct and material way.¹⁹⁷ The court held that the chain of events from the restriction on pharmacies’ sale of PI data to the eventual change in prescriber behavior was too attenuated.¹⁹⁸ The goals of cost containment and public health were not met, the court reasoned, until at least three separate steps were taken

188. *Id.* at 276.

189. *Id.* at 275-76.

190. *Id.*

191. *Ayotte*, 550 F.3d at 59.

192. *Id.* at 55.

193. *Id.*

194. *IMS Health Inc. v. Mills*, 616 F.3d 7, 22 (1st Cir. 2010).

195. *Id.*

196. *Ayotte*, 550 F.3d at 59; *Mills*, 616 F.3d at 22.

197. *IMS Health Inc. v. Sorrell*, 630 F.3d 263, 277 (2d Cir. 2010).

198. *Id.*

after the regulation went into force.¹⁹⁹ At this point, the Second Circuit elaborated upon what it saw as the real problem with the Vermont statute: its true purpose was to suppress free expression.²⁰⁰ The court characterized the state's action as putting "the state's thumb on the scales of the marketplace of ideas in order to influence conduct."²⁰¹ This arrangement failed the second prong of the *Central Hudson* inquiry. Moreover, the Second Circuit held that it was "antithetical to a long line of Supreme Court cases" and paternalistic in nature.²⁰²

Regarding the third prong of the *Central Hudson* analysis, the Second Circuit reasoned that Vermont's statute was not narrowly tailored, as it would apply to all brand-name prescription drugs – whether or not there was a generic equivalent and regardless of the clinical effectiveness of the particular drug.²⁰³ Furthermore, the court held that there were more direct and less restrictive means available to achieve the desired ends.²⁰⁴ The court suggested a government-sponsored counter-speech program, such as academic detailing, and the distribution of generic samples as methods of containing costs and protecting public health that would be less restrictive of free speech.²⁰⁵ The court also highlighted some traditional cost-containment policies, such as a generic substitution mandate, as alternatives that would be more narrowly tailored to advancing the state's interests.²⁰⁶ In contrast, the First Circuit dismissed these other means of achieving cost containment as inadequate in the face of current pharmaceutical marketing practices.²⁰⁷ The First Circuit determined that New Hampshire's statute was sufficiently narrowly tailored in that it provided the least extensive means of reducing overall health care costs and therefore met the third prong of the *Central Hudson* inquiry.²⁰⁸ With respect to Maine's statute, the First Circuit emphasized that the law's distinctive opt-out mechanism offered a targeted approach to vindicate the state's goals.²⁰⁹

Interestingly, the First Circuit consistently showed greater deference to the states' legislatures than did the Second Circuit. The First Circuit examined the legislative record with considerably less rigor. In contrast, the Second Circuit weighed the free speech interests of the data mining

199. *Id.*

200. *Id.*

201. *Id.*

202. *Id.* at 277-78.

203. *IMS Health Inc. v. Sorrell*, 630 F.3d 263, 279 (2d Cir. 2010).

204. *Id.* at 280.

205. *Id.*

206. *Id.*

207. *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 59-60 (1st Cir. 2008).

208. *Id.* at 60.

209. *IMS Health Inc. v. Mills*, 616 F.3d 7, 21-23 (1st Cir. 2010).

companies and the pharmaceutical manufacturers more heavily than the legislative agenda of Vermont, probing more deeply into the legislative reasoning behind Vermont's choice of means to realize its asseverated interests.

IV. THE U.S. SUPREME COURT'S GRANT OF *CERTIORARI* AND ORAL ARGUMENTS

In January 2011, the Supreme Court granted certiorari to review the Second Circuit's decision striking down Vermont's Prescription Confidentiality Law.²¹⁰ The Supreme Court had denied a petition for certiorari in 2009 to review the First Circuit's decision in *Ayotte*.²¹¹ However, the Second Circuit's subsequent decision in *Sorrell* highlighted a clear circuit split that contributed to making the issue ripe for review.

The variant legal reasoning employed by the five courts (three district courts and two circuit courts) that considered the New Hampshire, Maine, and Vermont laws reflect doctrinal uncertainty with respect to commercial speech. In fact, statutes seeking to curtail prescription data mining have the somewhat unusual position of falling within a doctrinal analysis that is the subject of an ongoing debate among commentators and within the Supreme Court itself.²¹² The *Central Hudson* inquiry has been unevenly applied, creating uncertainty about the limits on when and how a state may impose restrictions on commercial free speech.²¹³ At the same time, while only three states have passed laws curtailing access to PI data, twenty-six other states (including the District of Columbia) have proposed such statutes in the past three years.²¹⁴ Indeed, states are searching for innovative ways to contain the ballooning costs of health care, particularly prescription drug costs, and limiting access to PI data represents one of the potential solutions in this arena.²¹⁵ However, these efforts face an uncertain fate with the possibility of being thwarted by lengthy and costly litigation.²¹⁶ The Supreme Court, by its grant of certiorari, seized the opportunity to both clarify the surrounding legal doctrine and guide pursuits in legislative policy.

The question presented before the Court was “[w]hether a law that restricts access to information in nonpublic prescription drug records and

210. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 857 (2011).

211. *IMS Health, Inc. v. Ayotte*, 129 S. Ct. 2864 (2009).

212. *Mills*, 616 F.3d at 47 (Lipez, J., concurring); *Ayotte*, 550 F.3d at 96-97.

213. *Mills*, 616 F.3d at 47; *Ayotte*, 550 F.3d at 96-97.

214. Petition for a Writ of Certiorari, *supra* note 40, at 26-27. See Amicus Brief for the States, *supra* note 40, at 8.

215. Amicus Brief for the States, *supra* note 40, at 26-27.

216. Amicus Brief for the States, *supra* note 40, at 9.

affords prescribers the right to consent before their identifying information in prescription drug records is sold or used in marketing runs afoul of the First Amendment.”²¹⁷ The parties’ briefs in response to this question mirrored the legal arguments made before the U.S. District Court for the District of Vermont and Second Circuit Court of Appeals. In addition, the parties on each side took this opportunity to refine their characterizations of the statute.

Vermont continued to depict the statute as a restriction on access to nonpublic information that bolstered physicians’ control over the distribution of their personal information.²¹⁸ By focusing on pharmacies’ dissemination of data and the allocation of greater power to prescribers, the state attempted to distance itself from any effect on the pharmaceutical representatives’ marketing messages or communications.²¹⁹ In contrast, the data mining companies and PhRMA focused precisely on the statute’s effect on the messages that pharmaceutical representatives are able to communicate to prescribers.²²⁰ The respondents sought to draw attention to what they argued was the statute’s true intention: the restraint of truthful, even socially valuable, commercial messages that the state disfavored.²²¹ The contours of the free speech doctrine would ultimately be determined based on which aspect of the transaction would persuade the Court and which party’s characterization of the statute would be adopted.

At oral arguments, the Justices seemed to focus heavily on the statute’s effective restriction of pharmaceutical representatives’ detailing communications. The Chief Justice and Justice Scalia, in particular, had little patience for the state’s characterization of the statute as one that sought to “let doctors decide whether sales representatives will have access to this inside information about what they have been prescribing to their patients.”²²² The Chief Justice saw the statute’s purpose as “prevent[ing] sales representatives from contacting particular physicians.”²²³ Likewise, Justice Scalia reiterated many times that the purpose of the statute is to “stop [pharmaceutical representatives] from using [PI data] in order to market their drugs.”²²⁴ In fact, much of the oral arguments focused on “discrimination” against a particular type of speech and a particular type of speaker – detailing and pharmaceutical representatives, respectively.²²⁵

-
217. Petition for a Writ of Certiorari, *supra* note 40, at i.
 218. Amicus Brief for the States, *supra* note 40, at 1, 4, 6.
 219. See Amicus Brief for the States, *supra* note 40, at 2.
 220. Brief of Respondents, *supra* note 74, at 16-20.
 221. Brief of Respondents, *supra* note 74, at 49-56.
 222. Transcript of Oral Argument, *supra* note 46, at 4.
 223. *Id.*
 224. *Id.* at 5.
 225. *Id.* at 54-57, 64-65.

Even the liberal-leaning justices seemed to be persuaded by IMS Health's characterization of the statute as one that aimed to limit disfavored speech.²²⁶ Justice Ginsberg, remarking on the cost-containment strategy of the law, said pointedly, "[Y]ou can't lower the decibel level of one speaker so that another speaker, in this case the generics, can be heard better. . . ."²²⁷

Further, IMS Health's position was strengthened by its strategy at oral argument of emphasizing that the case needed "to be decided somewhere in the middle" between protecting prescriber privacy and distorting the marketplace of ideas.²²⁸ Justice Sotomayor seemed particularly receptive to this compromise strategy. She asked counsel several times about the viability of an opt-out structure rather than the opt-in structure that the Vermont legislature chose to adopt, alluding to the fact that an opt-out would be less problematic under free speech doctrine.²²⁹

The middle-of-the-road approach that respondents suggested presented the Court with an opportunity to draw lines between the New Hampshire statute (which affects all prescribers) and the Maine statute (which affects only those prescribers who affirmatively indicate that they would like their PI data to be protected from use in marketing and promotion). This conservative and pragmatic approach to oral arguments benefited the respondents. In contrast, Vermont's steadfast avoidance of what the Justices believed to be the true purpose of the statute did not appear to serve the state well in making a convincing legal argument before the Court. Based upon the Justices' reaction to each party's oral arguments, media commentators predicted that the Court would find that Vermont's law violated the First Amendment's Free Speech Clause.²³⁰

V. THE U.S. SUPREME COURT: *SORRELL V. IMS HEALTH INC.*

A. *The Majority Opinion*

On June 23, 2011, the Court, by a ruling of 6-3, struck down the Prescription Confidentiality Law on grounds that the regulation imposed content- and speaker-based burdens on protected speech, thus warranting

226. *Id.* at 14.

227. *Id.*

228. *Id.* at 32-33.

229. *Id.* at 13, 46.

230. See Robert Barnes, *Supreme Court Skeptical that Prescription Data Laws Don't Violate Free Speech*, WASH. POST (Apr. 26, 2011), http://www.washingtonpost.com/politics/supreme-court-skeptical-that-prescription-data-laws-dont-violate-free-speech/2011/04/26/AFDKIzsE_story.html; Adam Liptak, *Justices' Debate Turns to Privacy for Doctors*, N.Y. TIMES (Apr. 26, 2011), <http://www.nytimes.com/2011/04/27/business/27bizcourt.html>.

“heightened” – not intermediate – scrutiny.²³¹ While recognizing the importance of Vermont’s asserted interests in protecting medical privacy, reducing health care costs, and safeguarding public health, Justice Kennedy, writing for the majority, concluded that the statute did not meet this rigorous First Amendment standard.²³²

For purposes of analysis, Justice Kennedy divided the operative provision of the statute (§ 4631(d))²³³ into three constituent parts: (1) the prohibition against pharmacies, health insurers, and other similar entities selling PI data without the physician’s consent;²³⁴ (2) the ban on pharmacies, health insurers, and other similar entities permitting the use of opted-in physicians’ identifiable information for marketing activities; and (3) the restriction directly forbidding pharmaceutical manufacturers and marketers from using PI data without consent to shape their marketing messages.²³⁵ According to the majority, the first two measures discriminated against speech on the basis of content, given that § 4631(e) contemplated several state-approved purposes for which PI data could be sold and used.²³⁶ Beyond disfavoring marketing, the statute by its terms burdened pharmaceutical companies and detailers, while leaving the door open for the information to be “purchased or acquired by other speakers with diverse . . . viewpoints” (i.e., academic organizations or other entities who might use the information for counter-detailing).²³⁷

As for the injudiciously worded legislative findings that accompanied Act 80, the majority found that the legislature’s statement that detailers’ messages often conflicted with the goals of the state evinced Vermont’s clear intent to “diminish the effectiveness of marketing by manufacturers of

231. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2659 (2011).

232. *Id.*

233. The Supreme Court used “§ 4631” as shorthand for the Prescription Confidentiality Law. This reflects the law’s official citation in the Vermont Statutes, rather than the session law citation employed by the Second Circuit.

234. *Sorrell*, 131 S. Ct. at 2660. The Court chastised Vermont for offering an interpretation of this provision at oral argument that diverged from the construction the state initially provided. *Id.* at 2662. See Transcript of Oral Argument, *supra* note 46, at 18-21. Initially, Vermont represented that the first portion of § 4631(d) barred pharmacies, health insurers, and other similar entities from selling or distributing PI data for marketing purposes only. At oral argument, Vermont represented that the sentence at issue prohibited regulated entities from selling PI data for *any* purpose, aside from the exceptions specified in § 4631(e). *Sorrell*, 131 S. Ct. at 2662. In a comment that did not bode well for Vermont’s case, the Court noted it was especially disconcerting for the state to waver on the interpretation of its own statute “in a First Amendment case, where plaintiffs have a special interest in obtaining a prompt adjudication of their rights, despite potential ambiguities of state law.” *Id.* (citing *Houston v. Hill*, 482 U.S. 451, 467-68, n.17 (1987); *Zwickler v. Koota*, 389 U.S. 241, 252 (1967)).

235. *Sorrell*, 131 S. Ct. at 2660.

236. *Id.* at 2663.

237. *Id.*

brand-name drugs.”²³⁸ The majority viewed this as a specific, content-based burden on otherwise protected speech that triggered heightened scrutiny.²³⁹ Moreover, Vermont’s argument that heightened scrutiny was inapplicable to mere commercial regulations had no merit in the majority’s view, since § 4631 exacted “more than an incidental burden on protected expression.”²⁴⁰ The ban on the sale or use of PI data imposed by § 4631 differed in material ways from, for example, a ban on race-based hiring that would in turn require employers to remove “White Applicants Only” signs²⁴¹ or a municipal ordinance prohibiting outdoor fires that might happen to forbid flag-burning.²⁴² In enacting § 4631, Vermont had explicitly regulated commercial speech based upon its content and the speakers’ dissemination of it.²⁴³

With respect to Vermont’s contention that the Prescription Confidentiality Law restricted access to information that the data-mining and pharmaceutical companies had no right to obtain, the majority found it unpersuasive that PI data was “generated in compliance with a legal mandate . . . and so could be considered a kind of governmental information.”²⁴⁴ As the Second Circuit had done, the majority distinguished *United Reporting* by pointing out that § 4631 dealt with access to records already in private hands and therefore implicated the regulated entities’ right to use or disseminate information within their possession.²⁴⁵ Also, the complainant in *United Reporting* had not suffered a personal First Amendment injury insofar as the plaintiff had neither “attempt[ed] to qualify” for access to the police records in question nor presented an as-applied challenge.²⁴⁶ By contrast, the majority believed that IMS Health,

238. *Id.*

239. *Id.* at 2664 (citing *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 418 (1993) (applying a higher level of scrutiny to “a categorical prohibition on the use of newsracks to disseminate commercial messages”); *Turner Broadcasting Sys., Inc. v. FCC*, 512 U.S. 622, 658 (1994) (emphasizing that regulations manifesting “aversion” to what “disfavored speakers” have to say should be subject to strict scrutiny)). *See also* *Ward v. Rock Against Racism*, 491 U.S. 781, 791 (1989) (noting that the First Amendment mandates strict scrutiny anytime the government promulgates “a regulation of speech because of disagreement with the message it conveys”).

240. *Sorrell*, 131 S. Ct. at 2665.

241. *Id.* (citing *Rumsfeld v. Forum for Academic & Institutional Rights, Inc.*, 547 U.S. 47, 62 (2006)).

242. *Id.* (citing *R.A.V. v. St. Paul*, 505 U.S. 377, 385 (1992)).

243. *Id.*

244. *Id.*

245. *Id.* (citing *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 32 (1984); *Bartnicki v. Vopper*, 532 U.S. 514, 527 (2001); *Florida Star v. B.J.F.*, 491 U.S. 524 (1989); *N.Y. Times Co. v. United States*, 403 U.S. 713 (1971) (per curiam)).

246. *Id.* at 2666 (quoting *L.A. Police Dept. v. United Reporting*, 528 U.S. 32, 40 (1999)).

Verispan, Source Healthcare Analytics, and PhRMA had a solid basis for asserting that § 4631 impermissibly burdened their own speech.²⁴⁷

Furthermore, the majority refused to construe § 4631 as a regulation of conduct, reasoning that the creation and distribution of information constituted protected expression within the meaning of the First Amendment.²⁴⁸ The majority noted that “[f]acts, after all, are the beginning point for much of the speech that is most essential to advance human knowledge and to conduct human affairs.”²⁴⁹ Even assuming that PI data represented a “mere commodity,” as Vermont argued, the majority found § 4631(d)’s restrictions abhorrent to the First Amendment.²⁵⁰

After finding the Prescription Confidentiality Law to be content-based on its face and viewpoint-discriminatory in practice, the majority concluded that § 4631 could not withstand even intermediate scrutiny and therefore proceeded to apply commercial-speech analysis.²⁵¹ First, the majority rejected the notion that § 4631 was drawn to serve Vermont’s asserted interest in protecting medical privacy.²⁵² Although the state’s physicians had an interest in preserving the confidentiality of their prescription decisions, § 4631 did not further that interest insofar as pharmacies retained the ability to transfer PI data to anyone for any purpose aside from marketing, and insurers, researchers, journalists, the state, and others could use that information to engage in activities expressly permitted under § 4631(e).²⁵³ The majority did intimate that Vermont could have developed

247. *Id.*

248. *Id.* at 2667 (citing *Bartnicki v. Vopper*, 532 U.S. 514, 527 (“[I]f the acts of ‘disclosing’ and ‘publishing’ information do not constitute speech, it is hard to imagine what does fall within that category, as distinct from the category of expressive conduct” (some internal quotation marks omitted)); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 481 (1995) (“information on beer labels” is speech); *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 759 (1985) (plurality opinion) (credit report is “speech”)).

249. *Id.*

250. *Id.* Notwithstanding the lower level of scrutiny traditionally applied to commercial speech, the majority displayed a markedly protectionist attitude toward such expression in this case. For example, the majority explicitly stated that, “[a] ‘consumer’s concern for the free flow of commercial speech often may be far keener than his concern for urgent political dialogue.’ That reality has great relevance in the fields of medicine and public health, where information can save lives.” *Id.* at 2664 (quoting *Bates v. State Bar of Ariz.*, 433 U.S. 350, 364 (1977)).

251. *Id.* at 2667. Since the nature of the speech bore no relevance to the outcome of the analysis, the majority also found it unnecessary to tease out whether all speech hindered by § 4631 was commercial, or whether this was an instance where “‘pure speech and commercial speech’ were inextricably intertwined, so that ‘the entirety must . . . be classified as noncommercial.’” *Id.* (quoting *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 474 (1989)).

252. *Id.* at 2668.

253. *Id.*

“a more coherent policy”²⁵⁴ to address physician confidentiality “by allowing the [regulated] information’s sale or disclosure in only a few narrow and well-justified circumstances.”²⁵⁵ However, by making purportedly private records “available to an almost limitless audience” – with the exception of “a narrow class of disfavored speakers” – Vermont had undermined its own medical privacy argument.²⁵⁶

As for § 4631’s opt-in provision, the majority believed this insufficient to “insulate [the Prescription Confidentiality Law] from First Amendment challenge.”²⁵⁷ The opt-in mechanism, though providing physicians a modicum of privacy, in fact presented them with a perverse choice either to consent to their information being sold and used for marketing or to withhold consent, thereby participating in the state’s objective of “burdening disfavored speech by disfavored speakers.”²⁵⁸ Given that § 4631 left numerous uses of PI data untouched, the majority concluded that replacing the statute’s opt-in language with a less-restrictive opt-out provision would not help to dispel the problematic reality that Vermont had sought to suppress a particular distasteful message.²⁵⁹

The majority seemed equally unreceptive to Vermont’s insistence that § 4631 was necessary to shield physicians from detailers’ “harassing sales behaviors.”²⁶⁰ Only “a few” physicians had apparently sought legislative relief – an insufficient basis for upholding such a sweeping content- and speaker-based speech restriction.²⁶¹ “Many are those who must endure speech they do not like, but that is a necessary cost of freedom,” offered the majority.²⁶² To the extent physicians found visits from pharmaceutical representatives bothersome or intrusive, they could easily refuse to meet with the detailers.²⁶³ The state’s argument that detailers’ manipulative use of PI data threatened the integrity of the physician-patient relationship not only lacked merit, but also ran counter to First Amendment values.²⁶⁴ As

254. *Id.* (citing *Greater New Orleans Broad. Ass’n, Inc. v. United States*, 527 U.S. 173, 195 (1999); *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 428 (1993)).

255. *Id.* (citing *Health Insurance Portability and Accountability Act of 1996*, 42 U.S.C. § 1320d-2; 45 CFR pts. 160 & 164 (2010)).

256. *Id.*

257. *Id.* at 2669.

258. *Id.*

259. *Id.*

260. *Id.* (quoting 2007 Vt. Laws No. 80, § 1(28)). The legislature had also found that “[s]ome doctors in Vermont are experiencing an undesired increase in the aggressiveness of pharmaceutical sales representatives, . . . and a few have reported that they felt coerced and harassed.” 2007 Vt. Laws No. 80, § 1(20).

261. *Sorrell*, 131 S. Ct. at 2669.

262. *Id.* (citing *Erznoznik v. Jacksonville*, 422 U.S. 205, 210-11 (1975); *Cohen v. California*, 403 U.S. 15, 21 (1971)).

263. *Id.*

264. *Id.* at 2670.

the majority opined, “If pharmaceutical marketing affects treatment decisions, it does so because doctors find it persuasive. . . . [T]he fear that speech might persuade provides no lawful basis for quieting it.”²⁶⁵

Relying largely on its rationale with respect to Vermont’s medical privacy argument, the majority decided that § 4631(d) also represented an impermissible means for the state to advance the public policy goals of reining in health care costs and protecting public health.²⁶⁶ Vermont’s approach was both indirect²⁶⁷ and premised on the paternalistic view that physicians would make inappropriate prescribing decisions if exposed to targeted detailing.²⁶⁸ The majority concluded that such an assumption was particularly noxious, where the audience (i.e., physicians and other prescribers) consisted of “‘sophisticated and experienced’ consumers.”²⁶⁹ Moreover, the record demonstrated that physicians had conflicting perspectives about the benefits of detailing; some Vermont doctors actually endorsed the use of PI data in marketing, since it allowed detailers to tailor their presentations based on the practitioner.²⁷⁰ The United States, which appeared before the Court in support of § 4631, had also challenged Vermont’s “‘unwarranted view that the dangers of [n]ew drugs outweigh their benefits to patients.’”²⁷¹

As the majority viewed it, this divergence of opinion about detailing and brand-name-drug prescriptions would be best resolved through more speech, not less.²⁷² Toward that end, Vermont remained free to pursue its own counter-detailing initiative, but the state could not “hamstring the opposition” by burdening data miners’ or pharmaceutical companies’ speech “in order to tilt public debate in a preferred direction.”²⁷³ Since Vermont in no way claimed that § 4631 sought to regulate detailing as a form of false or misleading speech, the majority insisted that the state’s purported justification for restricting the commercial expression at issue

265. *Id.* (citing *Brandenburg v. Ohio*, 395 U.S. 444, 447 (1969) (per curiam)).

266. *Id.*

267. *Id.* As the majority pointed out, Vermont itself seemed reticent to acknowledge the logistical link between prohibiting the sale and use of PI data for marketing and achieving the state’s latter two public policy goals. *Id.* At oral argument, Vermont repeatedly denied that the goal of § 4631 was to make detailing less effective and prevent such messages from influencing physicians’ prescribing decisions. Transcript of Oral Argument, *supra* note 46, at 5-6.

268. *Sorrell*, 131 S. Ct. at 2670-71 (citing *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 374 (2002); *Va. Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 769-70 (1976)).

269. *Id.* at 2671 (quoting *Edenfield v. Fane*, 507 U.S. 761, 775 (1993)).

270. *Id.*

271. *Id.* (citing Brief for the United States as Amicus Curiae Supporting Petitioners at 24 n.4, *Sorrell*, 131 S. Ct. 2653 (2011) (No. 10-779)).

272. *Id.*

273. *Id.*

“turn[ed] on nothing more than a difference of opinion.”²⁷⁴

It is important to note that, on balance, the majority appeared most sympathetic to the challenges Vermont faced in protecting physicians’ private information from unauthorized and unwanted disclosure.²⁷⁵ However, Vermont had adopted an approach ill-suited to that purpose insofar as § 4631 accorded pharmacies, insurers, and other similar entities “broad discretion and wide latitude” when it came to disclosing PI data, while simultaneously handicapping pharmaceutical companies’ ability to use the same information for marketing purposes.²⁷⁶ According to the majority, Vermont had misappropriated the privacy concept in attempts to justify its treatment of disfavored speakers and a disfavored topic.²⁷⁷

B. *The Dissenting Opinion*

Justice Breyer, joined by Justices Ginsburg and Kagan, issued the dissenting opinion. Citing the seminal 1938 case of *U.S. v. Carolene Products Co.*, the dissent noted that “regulatory legislation affecting ordinary commercial transactions is not to be pronounced unconstitutional” when it is predicated “upon some rational basis within the knowledge and experience of the legislators.”²⁷⁸ Justice Breyer suggested that the heightened scrutiny imposed by the majority was inappropriate in this case because it was applied to “legitimate commercial regulatory objectives.”²⁷⁹ According to Justice Breyer, the First Amendment properly imposes restrictions on governmental efforts to limit “core” political speech, but “looser constraints” are in order for commercial speech or speech by an entity that falls under a “traditional regulatory program.”²⁸⁰ Justice Breyer thought it crucial to maintain the Court’s longstanding distinction between the First Amendment interests in maintaining a free marketplace for “social, political, esthetic, [and] moral . . . ideas” versus for speech “proposing a commercial transaction, which occurs in an area traditionally subject to government regulation.”²⁸¹

274. *Id.* at 2672 (citing *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 69 (1983); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 376 (2002)).

275. *Id.* (stating that “The capacity of technology to find and publish personal information, including records required by the government, presents serious and unresolved issues with respect to personal privacy and the dignity it seeks to secure.”).

276. *Id.*

277. *Id.* (asserting that “Privacy is a concept too integral to the person and a right too essential to freedom to allow its manipulation to support just those ideas the government prefers.”).

278. *Id.* at 2675 (Breyer, J., dissenting) (citing *United States v. Carolene Prods. Co.*, 304 U.S. 144, 152 (1938)).

279. *Id.* at 2673.

280. *Id.* at 2674-75.

281. *Id.* at 2674 (quoting *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447, 455-56 (1978)).

Justice Breyer thus would have reviewed § 4631(d) using intermediate scrutiny – a First Amendment standard appropriate for matters involving economic regulation, but at odds with the heightened scrutiny required by the majority.²⁸² Justice Breyer pointed out that the pharmaceutical industry is already heavily regulated, including substantial regulation of the very promotional activities affected here.²⁸³ Indeed, Justice Breyer argued, the PI data restricted by the Vermont statute only existed because of government regulation.²⁸⁴ “Regulators will often find it necessary to create tailored restrictions on the use of information subject to their regulatory jurisdiction,” Justice Breyer noted.²⁸⁵ For example, a public utilities commission directing local gas distributors to collect usage information from customers might permissibly allow the distributors to give researchers the information in the interests of lowering energy costs, while prohibiting sales of the data to appliance manufacturers seeking to identify potential gas stove buyers.²⁸⁶ Justice Breyer challenged that the Supreme Court had simply “*never* found that the *First Amendment* prohibits the government from restricting the use of information gathered pursuant to a regulatory mandate – whether the information rests in government files or has remained in the hands of the private firms that gathered it.”²⁸⁷ Similarly, Justice Breyer noted that the Supreme Court had never before imposed heightened scrutiny in this type of regulatory matter.²⁸⁸

Justice Breyer also criticized the majority’s use of the “content-based” and “speaker-based” labels, arguing that such terms have no meaning in the context of commercial speech.²⁸⁹ Regulatory programs by nature draw distinctions on the basis of content,²⁹⁰ and many legislative or administrative rules affect a narrowly defined class of entities.²⁹¹ Using

(quoting *Va. Bd. of Pharmacy*, 425 U.S. at 771 n.24 (emphasis added)).

282. *Id.* at 2675.

283. *Id.* at 2676.

284. *Id.*

285. *Id.*

286. *Id.*

287. *Id.* at 2677.

288. *Id.*

289. *Id.*

290. For example, the Federal Reserve Board oversees the content of statements, advertising, loan proposals, and interest rate disclosures made by financial institutions, while the FDA exercises regulatory power over labeling, advertising, and sales proposals of drugs. *Id.* (citing 12 C.F.R. pts. 226, 230; 21 C.F.R. pts. 201-203).

291. By way of illustration, Justice Breyer pointed to regulatory provisions mandating that producers of home appliances, but not industrial equipment manufacturers, publish strategies for conserving energy. *Id.* at 2678 (citing 16 C.F.R. pt. 305). Moreover, the FDA controls what claims a pharmaceutical company can make to prospective buyers about intended uses for its products (i.e., off-label promotion), although such restrictions do not apply to researchers, providers, etc. *Id.* (citing 21 C.F.R. pt. 99).

“heightened” scrutiny as the benchmark by which to test every regulation of commercial activities would potentially “undercut the [] constitutional goal” of “facilitating the democratic creation of sound government policies without improperly hampering the ability of government to introduce an agenda, to implement its policies, and to favor them to the exclusion of contrary policies.”²⁹² In sum, Justice Breyer believed that the “unforgiving” brand of scrutiny that the Court used to assess Vermont’s statute seriously threatened the legislative/judicial balance and, if religiously applied, would constrain states’ ability to respond in a reasonable manner to problems involving commerce and industry.²⁹³

Turning to the constitutional merits of the case, Justice Breyer concluded that § 4631 withstood either intermediate scrutiny as a regulation of commercial speech or rational basis review as a mere economic regulation.²⁹⁴ Justice Breyer viewed each of Vermont’s asserted interests – preservation of medical privacy, reduction of health care costs, and protection of public health – as important purposes that were “neutral” with respect to speech.²⁹⁵ With respect to the latter two goals, Vermont’s legislature could reasonably have found that § 4631 would directly promote cost containment and public health by ensuring that detailers’ messages remained rooted in scientific research about a particular drug’s safety and effectiveness, as well as objective information about the medication’s costs.²⁹⁶ Since the legislative record for § 4631 included statements from several experts attesting to the secretive, manipulative, and harmful advantage that detailers gained through use of PI data, Justice Breyer felt that Vermont had acted appropriately in seeking to ensure a “fair balance” of information about prescription drugs.²⁹⁷ Similarly, Justice Breyer would have found that § 4631 directly advanced Vermont’s interest in maintaining the confidentiality of physicians’ prescribing patterns, a norm already embodied in Vermont’s Pharmacy Rules.²⁹⁸ The fact that the statute permitted physicians themselves to control whether their prescribing histories could be used for marketing purposes “seem[ed] sufficiently to

292. *Id.* at 2679.

293. *Id.*; see also *id.* at 2685 (stating that, “At best the Court opens a Pandora’s Box of First Amendment challenges to many ordinary regulatory practices that may only incidentally affect a commercial message. . . . At worst, it reawakens *Lochner*’s pre-New Deal threat of substituting judicial for democratic decisionmaking where ordinary economic regulation is at issue.”).

294. *Id.* at 2679.

295. *Id.* at 2681-82 (citing *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985); *Dep’t of Justice v. Reporters Comm. for Freedom of Press*, 489 U.S. 749, 762-71 (1989)).

296. *Id.* at 2682.

297. *Id.* at 2682-83.

298. *Id.* at 2683.

show that [§ 4631] serve[d] a meaningful interest in increasing the protection given to prescriber privacy.”²⁹⁹

Finally, Justice Breyer explained why Vermont’s chosen option constituted the least restrictive regulation to achieve the state’s tri-partite aim.³⁰⁰ Encouraging physicians to refuse to speak with detailers arguably would have no effect on health care costs, nor would it prevent data miners and pharmaceutical companies from infringing on prescribers’ privacy by obtaining their identifiable information.³⁰¹ Paradoxically, “[f]orcing doctors to choose between targeted detailing and no detailing at all could [] jeopardize the [s]tate’s interest in promoting public health,” since some physicians did perceive a benefit to the information delivered by pharmaceutical representatives.³⁰² As for the majority’s suggestion that Vermont could have allowed disclosure of PI data only under a limited range of circumstances, Justice Breyer maintained that the exceptions defined under § 4631(e) *were* narrow and that further restrictions would actually impose a heightened burden on speech.³⁰³

VI. PRIVACY AND PRESCRIBER-IDENTIFIABLE DATA AFTER *SORRELL*

A. Privacy

Although the *Sorrell* Court did not explicitly state that there may be a right of privacy in PI data, it did intimate that data mining practices³⁰⁴ potentially implicate privacy interests in either of two ways: (1) data mining could result in re-identification of confidential patient information³⁰⁵ or (2) data mining may compromise the privacy of providers’ personal

299. *Id.* (citing *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989) (noting that First Amendment commercial speech jurisprudence requires “a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is in proportion to the interest served” (internal quotation marks omitted); *United States v. Edge Broad. Co.*, 509 U.S. 418, 434 (1993) (stating that First Amendment does not “require that the Government make progress on every front before it can make progress on any front”).

300. *Id.* at 2683-84.

301. *Id.* at 2683.

302. *Id.*

303. *Id.* at 2684.

304. See Andis Kaulins, *Medical Prescription Data Mining Case Decided by US Supreme Court in Favor of Pharmaceutical Industry as Corporate Free Speech: Sorrell v. IMS Health*, LAW PUNDIT (June 27, 2011, 3:08 AM), <http://lawpundit.blogspot.com/2011/06/medical-prescription-data-mining-case.html> (stating that “the majority opinion did hint, briefly, at the possibility that new computer-based methods of gathering and sorting information – such as the process known as [‘]data-mining[‘] – present [‘]serious and unresolved issues with respect to personal privacy and the dignity it seeks to secure.[‘]”).

305. Latanya Sweeney, *Sorrell (Vermont) v. IMS Health Inc.*, DATA PRIVACY LAB, <http://dataprivacylab.org/people/sweeney/new.html> (June 2010).

information.³⁰⁶ While the Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides that patients have clearly defined privacy protections with respect to the collection and dissemination of confidential medical information, such as their prescription histories, there are no clear protections for physician prescribing information except pursuant to state law – the type of law that Vermont attempted to enact.

Some commentators argue that *Sorrell* is not about privacy at all.³⁰⁷ As the Court noted, while Vermont claimed that the law was intended to prevent the disclosure of private patient information, the actual language of the statute allowed the disclosure of the collected data to *anyone but* pharmaceutical companies.³⁰⁸ Thus, the only privacy safeguard afforded under the Vermont statute was protection from pharmaceutical companies – not from anyone else who requests the data.³⁰⁹ The majority accordingly left open the possibility that a statute designed to maintain the privacy of PI data by preventing disclosure under all or most circumstances might survive heightened constitutional scrutiny. Indeed, the *Sorrell* Court did not directly address whether physicians have a right of privacy in their prescribing information. Rather, it held that even if such a privacy interest exists, it would have failed as a justification for enacting § 4631(d) because the Vermont statute allowed the disclosure of the information for other purposes.³¹⁰ Had Vermont truly attempted to protect prescribing information, exempting only a few limited uses (such as for educational research), the Court intimated that law might have been upheld.³¹¹

Other commentators argue that, as a practical matter, privacy is not a legitimate concern, since it would be difficult to re-identify de-identified data.³¹² On one hand, it is speculated that it takes complex algorithms to find similarities between two data sets such that even if one took the time and effort to identify some of the patients, only a few re-identifications would ultimately prove accurate.³¹³ Yet there are those who argue that “re-

306. See Cheryl Hanna & Pamela Vesilind, *Supreme Court Doesn't Look Favorably on Vermont's David v. Goliath Style Arguments*, VT DIGGER.ORG (June 23, 2011, 11:04 PM), <http://vtdigger.org/2011/06/23/hanna-and-vesilind-supreme-court-doesn%E2%80%99t-look-favorably-on-vermont%E2%80%99s-david-v-goliath-style-arguments/>.

307. See Jim Harper, *Sorrell vs. IMS Health: Not a Privacy Case*, CATO@LIBERTY (June 24, 2011, 8:37 AM), <http://www.cato-at-liberty.org/sorrell-vs-ims-health-not-a-privacy-case/>.

308. *Sorrell*, 131 S. Ct. at 2668.

309. *See id.*

310. *Id.* at 2669.

311. *See id.* at 2668.

312. Jane Yakowitz & Daniel Barth-Jones, *The Illusory Privacy Problem in Sorrell v. IMS Health*, TECHNOLOGY POLICY INSTITUTE, 4-5 (May 2011), <http://www.techpolicyinstitute.org/files/the%20illusory%20privacy%20problem%20in%20sorrell1.pdf>.

313. *See* Yakowitz & Barth-Jones, *supra* note 312.

identifying” or “de-anonymizing” data is a relatively easy task.³¹⁴ Paul Ohm, Associate Professor at the University of Colorado Law School, suggests that if the data that pharmacies sell to the pharmaceutical companies contain enough information for mining specialists to re-identify it, the potential privacy implications of the Court’s decision in *Sorrell* could be highly concerning for any patient who fills a prescription at a pharmacy that sells its PI records to data vendors.³¹⁵

The *Sorrell* Court also hinted that a state statute allowing an “opt-out” provision for physicians might be more likely to survive heightened scrutiny, since Vermont’s “opt-in” system primarily advanced the state’s interest in discouraging a particular kind of speech.³¹⁶ That is, even if the physicians did not “opt in,” their data would still be shared with the entities permitted by the Vermont statute. Therefore, the Court held that the “opt-in” provision violated First Amendment protections enjoyed by pharmacies and pharmaceutical manufacturers as well as others.³¹⁷ The alternative “opt-out” provision would neither favor nor disfavor speech, though Justice Kennedy expressed doubt that even the opt-out provision would have saved the Vermont statute under the Court’s heightened scrutiny.

B. Speech Implications

A commentator writing for *The Incidental Economist* suggests that an unintended consequence of the *Sorrell* decision might be that it weakens the protections against promotion of off-label prescriptions because that type of commercial speech, like the speech facilitated by data mining, now enjoys strong First Amendment protection.³¹⁸ In any event, *Sorrell* supports the ability of pharmaceutical companies to utilize whatever data they can acquire for targeted marketing³¹⁹ by limiting the restrictions that states can impose on the use of that data. At the same time, however, the Court suggested that states might overcome the heightened scrutiny by enacting stronger privacy protections by means of legislation designed to protect

314. See generally Paul Ohm, *Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization*, 57 UCLA L. REV. 1701 (2010).

315. *But cf. id.* at 1723 (showing that some de-identified data is, nonetheless, uniquely identifiable).

316. See *Sorrell*, 131 S. Ct. at 2669.

317. *Id.* See also Nicole Friess, *Supreme Court Pro-Business and First Amendment - Targeted Regulations in Trouble*, INFORMATION LAW GROUP (June 28, 2011), <http://www.infolawgroup.com/2011/06/articles/lawsuit/supreme-court-probusiness-and-first-amendment-targeted-regulations-in-trouble/>.

318. See Kevin Outterson, *Sorrell v. IMS Health, 6-3 for the Companies*, THE INCIDENTAL ECONOMIST (June 23, 2011, 12:08 PM), <http://theincidentaleconomist.com/wordpress/sorrell-v-ims-health-6-3-for-the-companies/>.

319. See Hanna & Vesilind, *supra* note 302.

substantial privacy interests.³²⁰

The *Sorrell* Court determined that “the creation and dissemination of information are speech within the meaning of the First Amendment.”³²¹ Yet the information at issue neither came from the public domain nor re-enters the public domain after it is used.³²² As Professor Sean Flynn from American University Washington College of Law opines, “[t]he First Amendment’s interests in promoting a marketplace of ideas and facilitating democratic decision making through the free flow of public information are not furthered by protecting from regulation the private commercial trade of private information in medical records.”³²³ Indeed, physicians and patients do not volunteer prescription information to the public, and data vendors do not give the information they acquire to the public.³²⁴ Rather, the information is used solely for the purpose of their own economic gain.³²⁵ Indeed, it is speech intended only for the pharmaceutical companies and detailers who target physicians for promotion. Under *Sorrell*, once any data exists, however acquired, its future dissemination is protected by the First Amendment regardless of the benefit or detriment to the public interest. *Sorrell* likened the limitation on “speech” under § 4631(d) to “prohibiting trade magazines from purchasing or using ink,”³²⁶ suggesting that “speech” is so fundamental to pharmaceutical detailing that data miners’ business could not exist in its absence. Of course, detailing is not dependent upon use of PI data.³²⁷

C. Amending Vermont’s Prescription Confidentiality Law

The *Sorrell* Court offered concrete suggestions for how Vermont might address the defects of its Prescription Confidentiality Law.³²⁸ One would be to enact a provision that amounts to a state-law extension of HIPAA, making PI data another category of protected health information.³²⁹ Rather

320. See *Sorrell*, 131 S. Ct. at 2667-69.

321. *Id.* at 2667.

322. *Will Supreme Court Decision In Sorrell V. IMS Tie States’ Hands In Medical Records Privacy Efforts?*, NATIONAL LEGISLATIVE ASSOCIATION ON PRESCRIPTION DRUG PRICES (June 24, 2011), <http://www.reducedrugprices.org/read.asp?news=6207>.

323. Sean Fiil-Flynn, *PIJIP Professor Sean Flynn Responds to Supreme Court Decision in Sorrell v. IMS Health, Inc.*, PIJIP AMERICAN UNIVERSITY WASHINGTON COLLEGE OF LAW (June 23, 2011), <http://www.wcl.american.edu/pijip/go/blog-post/pijip-professor-sean-flynn-responds-to-supreme-court-decision-in-sorrell-v-ims-health-inc>.

324. Fiil-Flynn, *supra* note 323.

325. Fiil-Flynn, *supra* note 323.

326. *Sorrell*, 131 S. Ct. at 2667. See also Friess, *supra* note 317.

327. See Curfman, *supra* note 17, at 2053-54 (defining detailing as the use and sale of de-identified data).

328. *Sorrell*, 131 S. Ct. at 2668.

329. See Fiil-Flynn, *supra* note 323.

than permitting disclosure of PI data for any purpose *other than* marketing, the statute would generally prohibit disclosure and identify narrowly tailored circumstances under which disclosure would be permitted.³³⁰ For instance, the statute might prohibit all use of PI data except for uses intended for educational and medical research or medical quality assurance.³³¹ Alternatively, Vermont could impose basic standards for de-identification of the data.³³² This would differ from the patient medical data standards already established in that patient privacy laws and regulations could apply not only to the patient information, but to the de-identification of provider information as well. Yet another option would be for Vermont to prohibit data mining altogether using a contractual approach. Vermont is one of the few states with a single-payer healthcare system: Green Mountain Care. Vermont could simply require that a provision be inserted in all Green Mountain contracts with participating retail pharmacies³³³ prohibiting the sale of PI data. Thus, Vermont could impose an administrative requirement that, as a condition of doing business with Green Mountain Care, pharmacies may not sell aggregated PI data for any purpose. A variation on that theme might be that Vermont could decide that pharmacies must maintain the data as a “state-mandated record,”³³⁴ meaning the data would be protected as long as it is not already “in private hands.”³³⁵

Finally, a non-legislative alternative might be to implement educational campaigns to empower physicians and the public to assume control of their medical privacy and take measures to enforce the existing restrictions.³³⁶ For instance, Vermont could mount a public service campaign to raise awareness of the issues concerning PI data, educating the public as well as physicians about its nature and the right of physicians to refuse to meet with pharmaceutical representatives.

D. *Will the Maine and New Hampshire Statutes Survive Sorrell?*

One major difference between the Maine and Vermont statutes is that Maine’s law contains language asserting that the statute was crafted in a “narrowly and carefully tailored” manner to “advance the State’s

330. *Sorrell*, 131 S. Ct. at 2668.

331. *But cf. id.* at 2660, 2668 (suggesting that if “narrow and well-justified,” a statute permitting only limited uses may prevail).

332. Berin Szoka, *After Sorrell v. IMS Health: Reconciling Free Speech with Privacy Protections*, TECHNOLOGY LIBERATION FRONT (June 24, 2011), <http://techliberation.com/2011/06/24/after-sorrell-v-ims-health-reconciling-free-speech-with-privacy-protections/>.

333. Outterson, *supra* note 318.

334. Outterson, *supra* note 318.

335. *See Sorrell*, 131 S. Ct. at 2657.

336. Szoka, *supra* note 332.

compelling interests.”³³⁷ While incorporation of such language will not, in itself, save the statute, the fact that Maine’s law allows physicians to “opt out” rather than “opt in” to use of their PI data might suffice.³³⁸ That is, under Maine’s law, restrictions on using the information for marketing only exist after a physician has opted not to permit such use of her personal data. Whether this is enough to survive under *Sorrell* is unclear. Once the “intermediary” has the information, and the physician has not opted out of the exchange, the “intermediary” has free reign to use the information as desired.³³⁹ Thus, the restriction, while limited to “intermediaries,” does not go into effect unless the physician opts out. Additionally, there is no content-based restriction as long as the physician has not opted out. This is an example of a much more targeted law with more limited control over the dissemination of the information that the Court suggested might prevail.

As to the New Hampshire statute, the major difference between it and the Vermont law is that New Hampshire prohibits the use of PI data for “any commercial purpose,” regardless of physician permission.³⁴⁰ “Commercial purpose” includes, but is not limited to, pharmaceutical marketing and promotion.³⁴¹ This constitutes a more comprehensive ban than that imposed by Vermont’s statute. It is therefore possible that New Hampshire’s statute may survive based on another of the *Sorrell* Court’s suggestions that the prohibitions be discrete and well-defined, or that the law prohibit the selling of information altogether.³⁴² Whether New Hampshire can establish that its statute serves a substantial state interest remains to be determined. *Sorrell* supports the assumption that physicians have “an interest in keeping their prescription decisions confidential.”³⁴³ In the wake of *Sorrell*, both the New Hampshire and Maine laws could survive the required level of First Amendment scrutiny.

VII. CONCLUSION

The Court’s determination in *Sorrell* that the data vendors’ right to use acquired data for economic gain trumps Vermont’s interests in regulating the sale and use of PI data might well have been different but for the application of heightened First Amendment scrutiny. One explanation for this heightened scrutiny is that the Court sought to expand the constitutional

337. ME. REV. STAT. ANN. tit. 22, § 1711-E(1-B)(C) (2008).

338. *Id.* §1711-E (2-A).

339. *But cf. id.* (providing that the statute only proscribes “intermediary” use when the prescriber has “filed for confidentiality protection”).

340. N.H. REV. STAT. ANN. § 318:47-4 (2006); *Id.* §318-B:12 (IV).

341. N.H. REV. STAT. ANN. § 318:47-4 (2006); *Id.* §318-B:12 (IV).

342. *See Sorrell*, 131 S. Ct. at 2672.

343. *Id.* at 2668.

protections to which corporations and other businesses are entitled.³⁴⁴ However, that goal is at odds with the Court's offer of numerous suggestions to address the statutory ills. Perhaps the *Sorrell* decision was intended to send a strong message to other states that they must carefully craft their data mining statutes to protect privacy without singling out a particular industry. Similarly situated states such as Maine, New Hampshire, and others can now look to *Sorrell* to amend their laws in ways that will withstand the heightened First Amendment scrutiny applied by the Court.

344. David H. Gans, *Sorrell v. IMS Health: Corporate Commercial Speech in the Age of Citizens United*, THEUSCONSTITUTION.ORG (June 24, 2011), <http://theusconstitution.org/blog.history/?p=3035>.