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The Moral from Sorrell: Educate, Don't Legislate

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THE MORAL FROM *SORRELL*: EDUCATE, DON'T LEGISLATE

George R. Gooch,[†] *J. James Rohack*^{††}
& *Marisa Finley*^{†††}

ABSTRACT

This Article argues that in response to the United States Supreme Court's 2011 decision in *Sorrell v. IMS Health Inc.*, state legislators should refrain from enacting prescription confidentiality laws and instead implement policies supporting academic detailing, a form of continuing medical education in which trained health professionals such as physicians, registered nurses, advanced practice nurses, and pharmacists provide evidence-based information about prescription drugs to prescribers.

According to *Sorrell*, pharmaceutical companies may freely use physicians' prescribing data to better promote, or "detail," products to physicians without government interference. While pharmaceutical companies may profit from detailing drugs to physicians, detailing increases health care costs for patients and negatively affects patient health outcomes. These problems motivated Maine, New Hampshire, and Vermont to enact prescription confidentiality laws that banned the use of information about the prescribing habits of physicians to help market drugs to physicians.

Recent state attempts to stop drug detailing to physicians have been found to violate the First Amendment. This Article provides a history and background on the pharmaceutical-detailing process and analyzes recent legal decisions relating to prescription confidentiality. It concludes that academic detailing is a viable solution to the negative effects of pharmaceutical detailing and is consistent with the First Amendment.

CONTENTS

INTRODUCTION.....	238
I. HISTORY AND BACKGROUND	243

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A. <i>The History of Drug Detailing</i>	243
B. <i>Physician Resistance to Pharmaceutical Detailing and the American Medical Association's Response</i>	244
C. <i>Pharmaceutical Detailing Today</i>	246
II. IMS HEALTH INC. LITIGATION IN THE FIRST CIRCUIT.....	248
A. <i>Some Clarification on Parties to the IMS Health Inc. Cases</i>	248
B. <i>New Hampshire's Prescription Confidentiality Law</i>	249
C. <i>Maine's Prescription Confidentiality Law</i>	250
D. <i>The First Circuit's Decision in the IMS Health Cases</i>	251
III. VERMONT'S PRESCRIPTION CONFIDENTIALITY LAW AND THE SUPREME COURT'S DECISION IN <i>SORRELL V. IMS HEALTH INC.</i>	252
A. <i>How Vermont's Prescription Confidentiality Law Differs from Maine and New Hampshire's Laws</i>	252
B. <i>Vermont's Prescription Confidentiality Law in the Lower Courts</i>	254
C. <i>The Supreme Court's Decision</i>	255
D. <i>"Heightened" Judicial Scrutiny and the First Amendment</i>	256
E. <i>Protecting Physician Privacy under Heightened Scrutiny</i>	256
F. <i>Containing Prescription Drug Costs under Heightened Scrutiny</i>	257
G. <i>Promoting Public Health under Heightened Scrutiny</i>	258
H. <i>The Majority Provides Some Guidance</i>	258
IV. GOVERNMENT RESPONSES TO PHARMACEUTICAL DETAILING.....	259
A. <i>Enacting Legislation Banning the Use of Prescriber-Identifying Data Will Likely Fail Under the First Amendment</i>	259
B. <i>Giving Physicians More Privacy Options Is Irrelevant to the Courts</i>	261
C. <i>Telling Physicians to Close Their Doors Will Not Solve Anything</i>	262
V. ACADEMIC DETAILING IS THE BEST RESPONSE TO <i>SORRELL</i>	263
A. <i>What Is Academic Detailing?</i>	263
B. <i>Federal Initiatives for Academic Detailing Programs</i>	266
C. <i>Legal Advantages of Academic Detailing</i>	266
D. <i>Protecting Physician Privacy with Academic Detailing and the PDRP</i>	267
E. <i>Reducing Prescription Drug Costs with Academic Detailing</i>	268
F. <i>Academic Detailing Programs' Costs Weighed against Profits</i>	270
G. <i>Promoting Public Health with Academic Detailing</i>	274
H. <i>Prescriber-Identifying Data Can Improve Academic Detailing</i>	276
CONCLUSION.....	277

INTRODUCTION

Physicians often work upwards of eighty hours each week.¹ Between seeing patients, filling out paperwork, and managing a practice, physicians have little time to research the drugs they prescribe. Although

1. Shirley S. Wang, *New Rx for Young Doctors: Shorter Work Day*, WALL ST. J. (June 24, 2010), <http://online.wsj.com/article/SB10001424052748703900004575325130511028968.html>.

physicians can seek drug information from any number of sources—including colleagues, journal articles and advertisements, direct mail, commercial sources, Medicare updates, conferences, and continuing medical education activities²—they rely on information from pharmaceutical sales representatives (drug reps).³ Drugs reps are mindful of physicians' limited time and offer them succinct drug information.⁴ This direct-to-physician marketing is hugely successful; indeed, it is a highly profitable form of advertising for drug companies.⁵ While research shows that physicians understand the conflict of interest between marketing and patient care, they nevertheless frequently communicate with drug reps.⁶ In 2005, the average primary care physician interacted with twenty-eight drug reps each week; the average specialist interacted with fourteen.⁷

Drug reps promote their products to physicians in offices and hospitals through a process called detailing. Detailing is a marketing technique used to educate physicians about a pharmaceutical company's products in hopes that physicians will prescribe them more.⁸ Drug reps, also known as detailers, bring physicians drug samples and medical studies explaining the advantages of their company's products.⁹

Detailers can market a particular drug more effectively when they have information about doctors' unique prescribing practices, or "prescriber-identifying data." Using prescriber-identifying data, detailers can target physicians who adopt new drugs quickly, regularly prescribe competitors' drugs, or prescribe large quantities of drugs for particular

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2. Puneet Manchanda & Elisabeth Honka, *The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review*, 5 YALE J. HEALTH POL'Y L. & ETHICS 785, 797 (2005).
 3. See Pew Prescription Project & Community Catalyst, *Academic Detailing: Evidence-Based Prescribing Information*, COMMUNITY CATALYST 1 (Apr. 2, 2009), http://www.communitycatalyst.org/doc_store/publications/Academic_Detailing_Fact_Sheet.pdf [hereinafter Prescription Project] (describing the amount of resources the pharmaceutical industry expends on soliciting).
 4. See Jerry Avorn, *Academic Detailing: An Introduction*, NAT'L RES. CTR. FOR ACAD. DETAILING 9 (2011), <http://www.narcad.org/wp-content/uploads/2011/01/Avorn-AD-talk-for-web-1-15-2011.pdf>.
 5. J. A. Greene, *Pharmaceutical Marketing Research and the Prescribing Physician*, 10 ANNALS INTERNAL MED. 742, 744 (2007) (describing the history of data mining from its origins in the mid-twentieth century).
 6. Prescription Project, *supra* note 3, at 1.
 7. Rayna Herman & Ashley Mahoney, *2005 Access Report: The Current State of Pharma Sales*, PHARMACEUTICAL REPRESENTATIVE, July 1, 2005, at 16.
 8. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2659 (2011).
 9. *Id.*

conditions.¹⁰ Because detailing is an expensive process, pharmaceutical companies typically use it to promote expensive brand-name, patent-protected drugs.¹¹ Once a brand-name drug's patent expires, cheaper, generic alternatives are manufactured and sold.¹² Because of their lower profit margins, generic drugs are not marketed by drug reps.¹³

Pursuant to federal law, pharmacies receive prescriber-identifying data when processing prescriptions.¹⁴ Several pharmacies sell this information to data miners, also known as health information organizations (HIOs) or prescription drug intermediaries (PDIs). HIOs and PDIs are firms that analyze prescriber-identifying data to create reports on prescriber behavior.¹⁵ The Health Insurance Portability and Accountability Act (HIPAA) mandates that this prescriber-identifying data contain no patient identifiers such as names, addresses, and social security numbers.¹⁶ Some integrated health care organizations such as Kaiser Permanente restrict use of prescription data because they object to influencing prescribing patterns to promote more costly, brand-name drugs when cheaper generics are often equally effective.¹⁷ Only a small fraction of pharmacies, however, restrict the use of prescriber data.¹⁸

HIOs combine the prescription information from pharmacies with physicians' demographic, practice, and contact information from the American Medical Association's (AMA) Masterfile to create reports on physician prescribing patterns.¹⁹ HIOs lease these reports, subject to nondisclosure agreements, to pharmaceutical manufacturers, medical researchers, and government agencies.²⁰ "Detailers, who represent drug

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10. *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 47 (1st Cir. 2008), *abrogated by Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011).
 11. *Sorrell*, 131 S. Ct. at 2660.
 12. *Id.*
 13. *Id.* at 2662.
 14. 21 U.S.C. § 353(b)(2) (2006).
 15. *Sorrell*, 131 S. Ct. at 2660.
 16. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified as amended in scattered sections of 18, 26, 29, and 42 U.S.C.).
 17. Robert Steinbrook, *For Sale: Physicians' Prescribing Data*, 354 NEW ENG. J. MED. 2745, 2747 (2006).
 18. *Id.*
 19. Michelle M. Mello & Noah A. Messing, *Restrictions on the Use of Prescribing Data for Drug Promotion*, 365 NEW ENG. J. MED. 1248, 1248 (2011).
 20. Robert A. Musacchio & Robert J. Hunkler, *More Than a Game of Keep Away*, PHARMACEUTICAL EXECUTIVE (May 1, 2006), <http://pharmexec.findpharma.com/pharmexec/article/articleDetail.jsp?id=323311>.

manufacturers, then use these reports to refine their marketing tactics and increase [pharmaceutical] sales.”²¹

Some physicians welcome detailers, claiming that detailers provide them with studies relevant to their practices, useful free drug samples, and targeted data about the prescribing patterns of other physicians.²² Generally, these physicians claim they are immune to detailers’ influence and see no conflicts of interest.²³ Other physicians, however, object that detailing intrudes into their prescribing decisions.²⁴ These physicians insist that detailers should be restricted from using their prescribing patterns for direct-to-physician marketing purposes.²⁵

Studies show that detailing influences requests to add brand-name medications to hospitals’ formularies, thus increasing prescribing costs that add to the burgeoning cost of health care in the United States.²⁶ In 2010, health-care expenditures in the United States surpassed \$2.5 trillion, more than three times the \$724 billion spent in 1990 and eight times the \$255 billion spent in 1980.²⁷ Prescription drugs account for about ten percent of these increasing costs.²⁸ Between 2002 and 2005, the pharmaceutical industry spent \$7 billion annually detailing brand-name drugs to physicians.²⁹ Aggressive marketing campaigns by large drug companies and the billions spent in direct-to-consumer drug

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21. Sorrell v. IMS Health Inc., 131 S. Ct. 2653, 2660 (2011).
 22. For those physicians who do not welcome detailers, the AMA offers physicians the ability to withhold prescribing data from drug representatives while still making it available for medical research. *AMA Program Offers Physicians a Choice When It Comes to Prescribing Data: Q&A with Jeremy Lazarus*, AMA, <http://www.ama-assn.org/resources/doc/dbl-public/pdrp-qa-final.pdf> (last visited Jan. 6, 2013) [hereinafter *AMA Program*].
 23. *Id.*
 24. *Id.*
 25. *Id.*
 26. Fadi M. Alkhateeb & William R. Doucette, *Electronic Detailing (E-detailing) of Pharmaceuticals to Physicians: A Review*, 2 INT’L J. PHARMACEUTICAL & HEALTHCARE MARKETING 235, 236 (2008).
 27. OFFICE OF THE ACTUARY, CTRS. FOR MEDICARE & MEDICAID SERVS., TABLE 1: NATIONAL HEALTH EXPENDITURES; AGGREGATE AND PER CAPITA AMOUNTS, ANNUAL PERCENT CHANGE AND PERCENT DISTRIBUTION: SELECTED CALENDAR YEARS 1960-2011 (2011), available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/tables.pdf>.
 28. *Id.* at TABLE 4.
 29. Julie M. Donohue et al., *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 NEW ENG. J. MED. 673, 676 (2007).

advertising lead to increased drug costs that are passed along to patients.³⁰

Detailing can also adversely affect health outcomes. Although the Food and Drug Administration (FDA) requires pharmaceutical companies to engage in extensive drug testing to ensure that drugs are both safe and effective,³¹ a drug's long-term effects are sometimes unknown until the drug has been on the market for several years.³² When detailers market to "early adopters," i.e., physicians who prescribe new drugs earlier than other physicians,³³ the number of patients taking a drug with potentially unknown side effects increases.³⁴

In response to these concerns, some states have enacted legislation banning the use of prescriber-identifying data for marketing purposes,³⁵ and at least twenty-five other states have considered similar legislation.³⁶ Implementation of these statutes has been unsuccessful, however, with the most recent blow coming from a 6–3 Supreme Court decision, *Sorrell v. IMS Health Inc.*, ruling that a Vermont law banning the use of prescriber-identifying data for marketing purposes violated the Free Speech Clause of the First Amendment.³⁷

Rather than banning the use of prescriber-identifying data, other states have incorporated detailing programs of their own to balance the information physicians receive from the pharmaceutical industry.³⁸ This practice is known as academic detailing, "a form of continuing medical education in which a trained health professional such as a physician or pharmacist visits physicians in their offices to provide evidence-based information."³⁹

30. See Prescription Project, *supra* note 3.

31. 21 U.S.C. §§ 355(b)(1), (d) (2006).

32. See Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, 14 J. AM. BD. FAM. PRAC. 362, 366 (2001).

33. *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 47 (1st Cir. 2008), *abrogated by Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011).

34. See *id.* at 85.

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

36. Brief for Illinois et al. as Amici Curiae Supporting Petitioners at 8, *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011) (No. 10-779), 2011 WL 771332.

37. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2672 (2011).

38. Telephone Interview with Michael Fischer, Program Dir., Nat'l Res. Ctr. for Acad. Detailing (Sept. 23, 2011).

39. Michael Allen et al., *Family Physicians' Perceptions of Academic Detailing: A Quantitative and Qualitative Study*, 7 BMC MED. EDUC., Oct. 12, 2007, at 2, available at <http://www.biomedcentral.com/content/pdf/1472-6920-7-36.pdf>.

In the wake of *Sorrell*, with patients' health and wallets hanging in the balance, what is the right solution to this problem? Should states continue attempts to enact legislation carved around *Sorrell* that ban the use of prescriber-identifying data? Should states go so far as to regulate the practice of detailing itself? Or should states counterbalance commercial detailing with academic-detailing programs?

This Article argues that state legislators should implement policies supporting academic-detailing programs. Part I of this Article provides a history and background of the pharmaceutical-detailing process. Part II analyzes the First Circuit's holding regarding prescription confidentiality laws in Maine and New Hampshire. Part III examines the holdings in the Second Circuit and the Supreme Court in *Sorrell*. Part IV analyzes responses to pharmaceutical detailing. Part V examines the use of academic detailing to respond to the negative effects of pharmaceutical detailing and concludes that state legislators should implement policies that support academic-detailing programs.

I. HISTORY AND BACKGROUND

Pharmaceutical drug detailing has evolved with the use of health information technology over the last several decades. Data gathering, physician resistance, and legislation have changed the landscape for pharmaceutical companies that promote their drugs to physicians. This section provides a history and background of how drug detailing started, how physicians responded, and the status of drug detailing today.

A. *The History of Drug Detailing*

The practice of selling prescriber-identifying data in direct-to-physician marketing has existed for decades. Detailers began gathering data from doctors and pharmacists in the 1940s; some successful drug reps maintained prescription data sources for years and sometimes even decades.⁴⁰ The federal government did not require prescriptions for drug sales until the mid-1950s.⁴¹ Before then, the pharmaceutical industry's primary goal was to persuade pharmacies to stock their drugs, as opposed to persuading doctors to prescribe them.⁴² In the 1950s, pharmacist Raymond Gosselin formed a company that marketed a database that could segment the prescription drug market by region and supply information on the performance of specific drugs.⁴³ In 1970, the company was sold to IMS Health Inc., a recurring plaintiff in several cases dealing with the sale of prescriber-identifying data today.⁴⁴

40. Musacchio & Hunkler, *supra* note 20.

41. Greene, *supra* note 5, at 742.

42. *Id.*

43. *Id.* at 743.

44. *Id.*

As database technology has become more sophisticated and affordable, HIOs have created systematic, nationwide directories similar to the one created by Gosselin. These directories, available for license since 1993, depict physicians' prescribing habits categorized by product and volume of prescriptions.⁴⁵

In the seminal 1983 *New England Journal of Medicine* article that defined academic detailing, Dr. Jerry Avorn and Stephen Soumerai described a randomized, controlled trial of clinical pharmacists visiting physicians' offices to reduce the excessive use of specific drugs.⁴⁶ The trial resulted in a 14 percent decrease in prescribing the drugs.⁴⁷ The authors concluded that "academically-based 'detailing' may represent a useful and cost-effective way to improve the quality of drug-therapy decisions and reduce unnecessary expenditures."⁴⁸

B. Physician Resistance to Pharmaceutical Detailing and the American Medical Association's Response

Within the last decade, physicians have responded to the effects commercializing prescriber-identifying data has had on prescribing decisions. In 2004, the AMA conducted a physician survey regarding the use of prescriber-identifying data by pharmaceutical companies.⁴⁹ The survey showed that the majority of physicians felt that the ability to withhold their prescribing data from pharmaceutical sales representatives would alleviate their concerns of drug reps intruding upon the doctor-patient relationship.⁵⁰ In response to these findings, the AMA created the Prescription Data Restriction Program (PDRP). Launched in 2006, the PDRP allows physicians to restrict drug reps' access to prescriber-identifying data.⁵¹

In practice, the PDRP is simple for physicians to use: they visit a web site to opt out of sharing their prescriber-identifying data with pharmaceutical representatives.⁵² Pharmaceutical companies are then

45. Musacchio & Hunkler, *supra* note 20.

46. Jerry Avorn & Stephen B. Soumerai, *Improving Drug-Therapy Decisions Through Educational Outreach: A Randomized Controlled Trial of Academically Based "Detailing"*, 308 *NEW ENG. J. MED.* 1457, 1457 (1983); see Biography of Dr. Jerry Avorn, *NAT'L RES. CTR. FOR ACAD. DETAILING*, <http://www.narcad.org/experience/avorn/> (last visited Feb. 28, 2013) (explaining that Dr. Avorn invented the concept of academic detailing and is recognized as a leading expert on the topic).

47. Avorn & Soumerai, *supra* note 46, at 1457.

48. *Id.*

49. *AMA Program*, *supra* note 22.

50. *Id.*

51. *Id.*

52. *Id.*

required to check the opt-out list a minimum of four times a year and have ninety days to comply with any opt-out requests.⁵³ The program also ensures that physicians know how to report inappropriate pharmaceutical-employee behavior, that HIOs help physicians understand how prescribing data is used, and that reports are created for physicians from the data to enhance their clinical practices.⁵⁴

The AMA does not collect, sell, or have access to prescribing data, but HIOs do match information from the AMA's Physician Masterfile to prescribing data from other sources, such as pharmacies.⁵⁵ The Masterfile contains all physicians' current and historical data.⁵⁶ HIOs create reports by combining prescribing and Masterfile data and license these reports to pharmaceutical companies.⁵⁷

Nevertheless, the PDRP has had little impact on restricting prescriber-identifying data. As of June 2011, only 28,000 of roughly 650,000 practicing physicians in the country have opted out through the PDRP.⁵⁸ The AMA claims that it has distributed information about the PDRP to over 500,000 physicians in the last three years.⁵⁹ Other sources claim, however, that only 25 percent of physicians are aware that the PDRP even exists.⁶⁰

The PDRP helps address many concerns, but it does not protect all prescribers and does not restrict all pharmaceutical employees from accessing prescribers' identifying data. Only medical doctors can opt out through the PDRP, while other prescribers (for example, osteopathic physicians or nurse practitioners) are ineligible to opt out.⁶¹ While physicians account for the largest portion of prescribers, this gap allows drug reps to target other prescribers potentially against their wishes. This loophole may create a problem for states where advanced practice

53. *See id.*

54. *Id.*

55. *AMA Physician Masterfile*, AMA, <http://www.ama-assn.org/ama/pub/about-ama/physician-data-resources/physician-masterfile.page> (last visited Jan. 10, 2013).

56. *Id.*

57. *AMA Program*, *supra* note 22.

58. *Physicians Discuss Use of Prescribing Data*, AMA, http://www.ama-assn.org/resources/doc/dbl-public/pdrp_two_sides.pdf (last visited Jan. 8, 2013); David Orentlicher, *Prescription Data Mining and the Protection of Patients' Interests*, 38 J.L. MED. & ETHICS 74, 78 (2010).

59. *AMA Program*, *supra* note 22.

60. Greene, *supra* note 5, at 746.

61. *IMS Health Inc. v. Mills*, 616 F.3d 7, 23 n.17 (1st Cir. 2010), *cert. granted*, *judgment vacated by IMS Health Inc. v. Schneider*, 131 S. Ct. 3091 (2011).

nurses or other medical professionals have independent authority to prescribe medications to patients.⁶²

Furthermore, the PDRP restricts only drug reps and their direct supervisors from accessing prescriber-identifying data.⁶³ Other officials at pharmaceutical companies are still allowed access to the information.⁶⁴ Other than the pharmaceutical industry's own code of ethics,⁶⁵ nothing prevents an executive in a pharmaceutical company from "reminding" a sales representative about a particular physician's prescribing history regardless of whether the physician has opted out.⁶⁶ To address this issue, the AMA created mechanisms to allow physicians to report inappropriate conduct by pharmaceutical representatives or companies.⁶⁷ Allowing physicians to monitor pharmaceutical companies acts as safety net for when the companies fail to police themselves.⁶⁸

Finally, the primary concerns at issue are safety and cost of prescription drugs for *patients*. Should physicians be the only ones making the decisions regarding sales reps' roles in the physician-patient relationship? This has led some states to enact legislation banning the use of prescriber-identifying information with varying degrees of physician privacy options, which will be discussed in further detail in Section III.⁶⁹

C. *Pharmaceutical Detailing Today*

While establishing the PDRP was a seemingly reasonable compromise between physicians and the pharmaceutical industry, some claim that the program does not restrict enough, while others argue that the program is too limiting. Those claiming that the PDRP is not restrictive enough argue that a drug rep's job is to increase sales—not to offer unbiased, evidence-based information to physicians. Hence, allowing the pharmaceutical industry to influence the prescribing patterns of physicians by offering them potentially biased information runs counter

62. See, e.g., Lauren E. Gattanglia, *Supervision and Collaboration Requirement: The Vulnerability of Nurse Practitioners and Its Implications for Retail Health*, 87 WASH. U. L. REV. 1127, 1137 n.55 (2010) (observing that in 2008 about twenty percent of states allowed nurse practitioners independent prescriptive authority).

63. *AMA Program*, *supra* note 22.

64. Steinbrook, *supra* note 17, at 2745.

65. PHARMACEUTICAL RESEARCH & MFRS. OF AM., CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS 13 (2009).

66. Allison Torres Burtka, *Drug Reps and the Art of Manipulation*, 46 TRIAL 28, 34 (2010).

67. *AMA Program*, *supra* note 22.

68. *Id.*

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

to the AMA's mission of promoting the science of medicine and the betterment of public health.⁷⁰ Conversely, others argue that restricting pharmaceutical companies from accessing the data would likely increase sales calls, decrease targeted educational information, and decrease drug samples for physicians.⁷¹ Furthermore, if pharmaceutical manufacturers are overly restricted from purchasing prescriber-identifying data, then HIOs may no longer have a financial incentive to maintain valuable data on physicians' prescribing habits.⁷²

Pharmaceutical manufacturers are not the only entities that purchase prescriber-identifying data from HIOs. Several other parties purchase HIO-collected data for medical research, law enforcement, public health studies, drug recalls, studies on drug interactions, and even bioterrorism response.⁷³ For example, the FDA, the Center for Disease Control, and the Federal Drug Enforcement Agency all use prescriber-identifying data to monitor use of controlled substances and to identify prescribers who need time-sensitive safety information.⁷⁴ Insurance companies and pharmacy benefit managers also use prescriber-identifying data to process claims and manage formulary compliance.⁷⁵ These other parties, however, spend far less on this data than the pharmaceutical industry.⁷⁶ If too many physicians opt out through the PDRP or if legislation bans the use of prescriber-identifying data, then HIOs may stop maintaining their billion-dollar databases or divert those resources to areas that do not benefit the healthcare industry.⁷⁷

Increased drug costs, patient safety issues, and complaints about the PDRP eventually led three states—Maine, Vermont, and New Hampshire—to enact legislation banning the use of prescriber-identifying data for marketing purposes.⁷⁸ However, suppressing the free flow of information to pharmaceutical companies was not an effective solution to these states' concerns.

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70. See Laurie Barclay, *AMA Discloses Masterfile Physician Data to Pharmaceutical Companies*, MEDSCAPE MED. NEWS (July 12, 2007), <http://www.medscape.com/viewarticle/559704>.
71. *AMA Program*, *supra* note 22.
72. Steinbrook, *supra* note 17, at 2747.
73. Greene, *supra* note 5, at 747.
74. Brief of Respondents IMS Health Inc. et al. at 37-38, *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011) (No. 10-779).
75. *Id.* at 2-3.
76. Steinbrook, *supra* note 17, at 2747.
77. Brief for American Business Media et al. as Amici Curiae Supporting Respondent at 11, *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011) (No. 10-779).
78. ME. REV. STAT. ANN. tit. 22, § 1711-E-2-A (2008); N.H. REV. STAT. ANN. § 318:47-f (2006); VT. STAT. ANN. tit. 18, § 4631(d) (2009), *invalidated by Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011).

II. IMS HEALTH INC. LITIGATION IN THE FIRST CIRCUIT

Before the Supreme Court of the United States decided *Sorrell v. IMS Health Inc.*, several states were concerned with the impact of prescriber-identifying data on drug detailing, the patient-physician relationship, and higher drug costs borne by patients. These concerns led New Hampshire, Maine, and Vermont to enact statutes banning the use of prescriber-identifying data for marketing purposes.⁷⁹ This section provides a synopsis of the legal battles that Maine and New Hampshire faced in district court and the Court of Appeals for the First Circuit after enacting these statutes.

A. *Some Clarification on Parties to the IMS Health Inc. Cases*

Confusion exists over exactly who the parties are to these lawsuits. The defendant in each case is the attorney general of the state implementing its prescription confidentiality law.⁸⁰ The plaintiffs are not only pharmaceutical companies but also several organizations variously identified as “data miners,” “health information publishers,” and “prescription drug information intermediaries.” Judge John Woodcock, writing the majority opinion in *IMS Health Inc. v. Rowe* for the United States District Court for the District of Maine, explained the reasoning behind the many names assigned to the plaintiffs in these cases:

The Plaintiffs refer to themselves as “health information publishers,” a name that evokes an image consistent with their First Amendment argument; the Attorney General refers to them as “data miners,” a term that evokes an image consistent with his regulatory contentions. The Court appreciates the cleverness and power of characterization, but avoids value-laden terms [T]o describe the Plaintiffs, the Court uses the term the law uses, ‘prescription drug information intermediary.’⁸¹

These “value-laden terms” mislead readers because all the above-listed names refer to a single type of organization—firms that analyze prescriber-identifying data to create reports on prescriber behavior. Judge Woodcock referred to them as “prescription drug information intermediaries” because that is the legal term used in Maine.⁸² This

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

80. *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163 (D.N.H. 2007), *rev'd and vacated by IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008); *IMS Health Corp. v. Rowe*, 532 F. Supp. 2d 153 (D. Me. 2007), *rev'd by IMS Health Inc. v. Mills*, 616 F.3d 7 (1st Cir. 2010).

81. *Rowe*, 532 F. Supp. 2d at 158 n.3.

82. ME. REV. STAT. ANN. tit. 22, § 1711-E-1-I (2008).

Article refers to this group of plaintiffs as health information organizations.

B. New Hampshire's Prescription Confidentiality Law

In 2006, New Hampshire enacted its prescription confidentiality law to contain prescription drug costs and protect both prescriber and patient privacy.⁸³ The law banned the sale, license, transfer, or use of prescriber-identifying data for any commercial purpose, although it recognized several enumerated exceptions like pharmacy reimbursement, medical research, and insurance functions.⁸⁴ Several HIOs, including IMS Health Inc., filed suit against New Hampshire's Attorney General, challenging the constitutionality of the law under the First Amendment.⁸⁵ The threshold question was whether the law regulated *speech* or *conduct*, with conduct being entitled to substantially less First Amendment protection.⁸⁶ The United States District Court for the District of New Hampshire found that the statute restricted speech because, although it did not hinder transmission of prescription records directly, the statute prevented pharmaceutical companies from using prescriber-identifiable data both to identify a specific audience for their marketing efforts and to refine their marketing messages.⁸⁷

After finding that the statute regulated speech instead of conduct, the court determined that the speech in question was "commercial speech" and applied the US Supreme Court's test from *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*.⁸⁸ Under *Central Hudson*, so long as the speech is a non-misleading, lawful activity, government regulation is constitutionally permissible only if the statute (1) serves a substantial governmental interest, (2) directly advances that interest, and (3) restricts speech only as necessary to further that interest.⁸⁹ The district court found that New Hampshire's interests in containing health care costs and protecting physician confidentiality were insufficient to justify restriction under *Central Hudson*.⁹⁰ First, New Hampshire failed to provide enough evidence to

83. N.H. REV. STAT. ANN. § 318 (2006).

84. *Id.* at § 318:47-f.

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

86. *Id.* at 174.

87. *Id.* at 183.

88. *Central Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 566 (1980).

89. *Id.*

90. *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163, 183 (D.N.H. 2007), *rev'd and vacated by IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008).

prove it had a substantial interest in protecting prescriber privacy.⁹¹ Second, although the court agreed that reducing health care costs was a substantial state interest, the statute did not directly advance that interest, as there were several ways in which the state could address the law's underlying concerns without restricting protected speech.⁹² The court also found that the statute was overly restrictive because many other regulatory options—such as gift bans, continuing medical education, and Medicaid revisions—existed to restrict detailing without restricting speech.⁹³ The court rendered New Hampshire's prescription confidentiality law unconstitutional and issued an injunction preventing the law's enforcement.⁹⁴ New Hampshire's Attorney General appealed to the United States Court of Appeals for the First Circuit.

C. Maine's Prescription Confidentiality Law

Following in the footsteps of New Hampshire, Maine enacted its prescription confidentiality law the next year.⁹⁵ Like New Hampshire, Maine passed its statute to contain prescription drug costs and protect prescriber and patient privacy.⁹⁶ However, Maine also added “improv[ing] public health” to its list of policy concerns.⁹⁷

Unlike New Hampshire, Maine allows the use of prescriber-identifying data in detailing drugs to physicians unless a physician affirmatively opts out of sharing her data.⁹⁸ Thus, Maine's law is narrower than New Hampshire's by banning the sale, license, transfer, exchange for value, or marketing use of prescriber-identifying data of only those physicians who petition the state for confidentiality protection.⁹⁹

Several HIOs, including IMS Health Inc., filed suit against Maine's Attorney General, claiming that Maine's prescription privacy law was unconstitutional under the First and Fourteenth Amendments and the Dormant Commerce Clause.¹⁰⁰ With guidance from the New Hampshire district court's decision earlier that year, the District Court for the

91. *Id.* at 179.

92. *Id.* at 182-83.

93. *Id.* at 182.

94. *Id.* at 183.

95. ME. REV. STAT. ANN. tit. 22, § 1711-E-2-A (2008).

96. *Id.*

97. § 1711-E-1-B.

98. *Compare* N.H. REV. STAT. ANN. § 318:47-f (2006) (allowing physician to “opt in” to the prescription confidentiality program), *with* ME. REV. STAT. tit. 22, § 1711-E-2-A (2008) (allowing physicians to “opt out” of the prescription confidentiality program).

99. ME. REV. STAT. ANN. tit. 22, § 1711-E-2-A (2008).

100. *IMS Health Corp. v. Rowe*, 532 F. Supp. 2d 153, 153 (D. Me. 2007), *rev'd by* *IMS Health Inc. v. Mills*, 616 F. 3d 7 (1st Cir. 2010).

District of Maine concluded that the state's prescription confidentiality law restricted commercial speech and was subject to intermediate scrutiny under *Central Hudson*.¹⁰¹ Maine tried to distinguish its law from New Hampshire's by arguing that it restricted less speech due to the opt-out provision,¹⁰² but the court ultimately held Maine's statute unconstitutional under the First Amendment.¹⁰³

The district court prohibited enforcement of the law but lifted the injunction as to certain non-enforcement provisions, such as allowing prescribers to register with the state's opt-out program to gather data until the appellate process finalized the court's decision.¹⁰⁴ The plaintiffs appealed to the First Circuit.

D. The First Circuit's Decision in the IMS Health Cases

In two different decisions, *IMS Health v. Ayotte* in 2008 and *IMS Health v. Mills* in 2010, the First Circuit Court of Appeals held that both Maine's and New Hampshire's prescription confidentiality laws did not violate the First Amendment.¹⁰⁵ In reversing the lower courts' decisions, the First Circuit found that both statutes regulated conduct rather than speech.¹⁰⁶ The court characterized prescriber-identifying information as a "commodity" with no greater right to protection under the First Amendment than "beef jerky."¹⁰⁷ Regulation of conduct under the First Amendment requires only that the law be rationally related to a legitimate government purpose.¹⁰⁸ In both cases, the First Circuit held that the statute satisfied this low burden.¹⁰⁹

The First Circuit reasoned that even if the statutes regulated speech, as opposed to mere conduct, they both still withstood intermediate scrutiny.¹¹⁰ Applying the factors from *Central Hudson*, the First Circuit held that the statute directly advanced at least one substantial government interest and that there were no other less-restrictive means of accomplishing those interests.¹¹¹

101. *Id.* at 169.

102. *Id.* at 168-69.

103. *Id.* at 183.

104. *Id.*

105. *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 47 (1st Cir. 2008), *abrogated by* *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011); *IMS Health Inc. v. Mills*, 616 F.3d 7, 18 (1st Cir. 2010), *cert. granted, judgment vacated by* *IMS Health Inc. v. Schneider*, 131 S. Ct. 3091 (2011).

106. *Mills*, 616 F.3d at 19.

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

108. *Regan v. Taxation with Representation of Wash.*, 461 U.S. 540, 547 (1983).

109. *Ayotte*, 550 F.3d at 47; *Mills*, 616 F.3d at 13.

110. *Ayotte*, 550 F.3d at 47; *Mills*, 616 F.3d at 13.

111. *Ayotte*, 550 F.3d at 47; *Mills*, 616 F.3d at 19.

The only distinguishing factor the First Circuit found between the Maine and New Hampshire laws concerned physician privacy options. While Maine allowed physicians to opt out of sharing their prescriber-identifying information, New Hampshire imposed a total ban on the data with some enumerated exceptions.¹¹² The court found that Maine's law differed from New Hampshire's "only in ways that weaken[ed] the plaintiffs' First Amendment challenges,"¹¹³ and the distinction did not change the First Circuit's holding.¹¹⁴

After the First Circuit's decisions, it appeared as if states were finally able to the efforts of pharmaceutical detailers. However, the holding of one appellate court was far from the final say in the matter. As discussed below, the Second Circuit and the Supreme Court were not as lenient in their interpretation of a similar prescription confidentiality law in Vermont.

III. VERMONT'S PRESCRIPTION CONFIDENTIALITY LAW AND THE SUPREME COURT'S DECISION IN *SORRELL V. IMS HEALTH INC.*

With favorable decisions from the First Circuit, Vermont was likely confident in successfully enacting its own prescription confidentiality law. However, unlike those in Maine and New Hampshire, Vermont's law reached Supreme Court. This section analyzes the decisions of the United States District Court for the District of Vermont, the Second Circuit Court of Appeals, and the Supreme Court in *Sorrell v. IMS Health Inc.*

A. *How Vermont's Prescription Confidentiality Law Differs from Maine and New Hampshire's Laws*

Vermont's prescription confidentiality law, also known as Act 80, had several components aimed at hindering pharmaceutical detailing. The law's most controversial provision was Section 4631(d):

A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity shall not sell, license, or exchange for value regulated records con-

112. *Mills*, 616 F.3d at 19.

113. *See id.* (noting that "[u]nlike New Hampshire's law, the Maine law only prohibits plaintiffs from licensing, using, selling, transferring or exchanging data identifying prescribers licensed in Maine who have opted-in for confidentiality protection;" and "[u]nlike New Hampshire's legislature, the Maine legislature included specific findings that limiting detailers' use of Maine prescribers' identifying data would reduce health care costs, ensure Maine prescribers' decisions were based on unbiased medical and scientific evidence, and protect Maine prescribers from unwanted detailing visits.").

114. *Id.*

taining prescriber-identifiable information, nor permit the use of regulated records containing prescriber-identifiable information for marketing or promoting a prescription drug, unless the prescriber consents Pharmaceutical manufacturers and pharmaceutical marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents¹¹⁵

Section 4631(d) comprises three prohibitions: (1) pharmacies, health insurers, and similar entities may not sell prescriber-identifying information; (2) those entities may not use prescriber-identifying information for marketing; and (3) pharmaceutical manufacturers and pharmaceutical marketers may not use prescriber-identifying information for marketing purposes.¹¹⁶ The prohibitions do not apply, however, if an individual prescriber “opts in” to sharing his information with HIOs and pharmaceutical representatives.¹¹⁷

The prescriber’s privacy options in Vermont fall somewhere between Maine’s opt-out provision and New Hampshire’s blanket ban.¹¹⁸ While a seemingly important issue, physician privacy options have proven to be of little importance in court decisions. The lower courts extensively discussed the differences in how each of these privacy options burdened speech, but the issue never changed their decisions.

Each state’s prescription confidentiality law also asserted different state interests. Maine and New Hampshire listed patient privacy as a state interest but Vermont did not. The only court to reach the patient-privacy issue was the District Court of Maine, which found that the interest did not survive intermediate scrutiny under *Central Hudson*.¹¹⁹ Courts likely do not find that patient privacy is an issue in prescription confidentiality laws because healthcare providers must de-identify patients’ medical records (i.e., they must remove personal information like names, addresses, and social security numbers) pursuant to HIPAA.¹²⁰ Many privacy advocates argue that although the prescriptions have been de-identified,

115. VT. STAT. ANN. tit. 18, § 4631(d) (2010), *invalidated by* Sorrell v. IMS Health Inc., 131 S. Ct. 2653 (2011).

116. Sorrell v. IMS Health Inc., 131 S. Ct. 2653, 2660 (2011).

117. VT. STAT. ANN. tit. 18, § 4631(d) (2010), *invalidated by* Sorrell v. IMS Health Inc., 131 S. Ct. 2653 (2011).

118. *Compare* VT. STAT. ANN. tit. 18, § 4631(d) (2010), *invalidated by* Sorrell v. IMS Health Inc., 131 S. Ct. 2653 (2011) (allowing physicians to opt in to sharing prescriber information), *and* N.H. REV. STAT. ANN. § 318:47-f (2006) (placing a ban on prescriber information with several listed exceptions), *with* ME. REV. STAT. ANN. tit. 22, § 1711-E (allowing physicians to opt out of sharing prescriber information).

119. IMS Health Inc. v. Mills, 616 F.3d 7, 19 (1st Cir. 2010), *cert. granted, judgment vacated by* IMS Health Inc. v. Schneider, 131 S. Ct. 3091 (2011).

120. 45 C.F.R. §§ 164.502(d)(2), 164.514(a)-(b) (2011).

they can be re-identified using outside sources of data.¹²¹ For example, in 2006, America Online accidentally released users' search query information, which others were able to combine with publicly available data to identify people's medical conditions.¹²² However, while providing prescriber-identifying data to pharmaceutical companies runs the risk of re-identification, state and federal medical privacy laws already address this issue.¹²³

B. Vermont's Prescription Confidentiality Law in the Lower Courts

In 2007, the Vermont legislature passed its prescription confidentiality law banning the sale, disclosure, and use of pharmacy records that reveal the prescribing practices of individual physicians.¹²⁴ Violators faced a \$10,000 penalty for each infraction, ensuring that pharmaceutical companies would not treat the statute as merely "the cost of doing business."¹²⁵ In 2009, Vermont HIOs, including IMS Health Inc., and several pharmaceutical manufacturing associations, filed suit to challenge the constitutionality of the law.¹²⁶

Following a bench trial, the District Court for the District of Vermont denied the plaintiffs' motions for declaratory judgment and injunctive relief.¹²⁷ The court found that Vermont's statute regulated speech and was thus subject to intermediate scrutiny under *Central Hudson*.¹²⁸ Additionally, the court found that Vermont's cost-containment and public health interests were substantial, but not its interest in prescriber privacy.¹²⁹ The court further found that the statute directly advanced both of those interests and that no less-restrictive means were available to further them.¹³⁰ The plaintiffs appealed to the

121. Brief for Electronic Privacy Information Center (EPIC) et al. as Amici Curiae supporting Petitioners at 24, *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011) (No. 10-779).

122. Carol Eisenberg, *Drugmakers Mine Data for Trial Patients*, BLOOMBERG BUSINESSWEEK (Nov. 2, 2011), <http://www.businessweek.com/magazine/drugmakers-mine-data-for-trial-patients-11032011.html>.

123. 45 C.F.R. § 164.502(d)(2) (2011); *see also* 45 C.F.R. §§ 164.514(a)-(b) (2011) (explaining the rules pertaining to de-identification of protected health information).

124. VT. STAT. ANN. tit. 18, § 4631(d) (2010), *invalidated by* *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011).

125. *Id.*

126. *See Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2661 (2011).

127. *IMS Health Inc. v. Sorrell*, 631 F. Supp. 2d 434, 464 (D. Vt. 2009).

128. *Id.* at 449.

129. *Id.* at 449-50.

130. *Id.* at 454-55.

Court of Appeals for the Second Circuit, which reversed the district court's decision and remanded the case.¹³¹

The Second Circuit found that Section 4631(d) of Vermont's prescription confidentiality law qualified as a restriction on commercial speech and was subject to intermediate scrutiny under *Central Hudson*.¹³² The court first found Vermont's physician privacy interest too speculative to qualify as a substantial state interest.¹³³ The court then found that, while Vermont's interests in public health and reducing health care costs were substantial, the statute did not advance those interests in a direct and material way.¹³⁴ Finally, the court found that the law was not narrowly tailored to serve Vermont's cost-containment and public health interests.¹³⁵ Vermont's Attorney General appealed to the Supreme Court of the United States. Recognizing the split between the First and Second Circuits, the Court granted certiorari on January 7, 2011.¹³⁶

C. The Supreme Court's Decision

On June 23, 2011, the Supreme Court affirmed the Second Circuit's decision in a 6-3 decision that ruled Vermont's law unconstitutional as a violation of the First Amendment right to free speech.¹³⁷ The majority, led by Justice Anthony Kennedy, held that Vermont's law imposed a specific, content- and speaker-based burden on protected expression, thereby warranting "heightened" judicial scrutiny to determine whether the statute violated First Amendment free-speech protections.¹³⁸ The Court further held that Vermont's asserted interests in physician confidentiality, protecting physicians from bothersome pharmaceutical sales representatives, and protecting the doctor-patient relationship did not justify restricting protected free speech.¹³⁹ Finally, the Court held that the statute did not permissibly advance Vermont's policy goals of lowering medical costs and promoting public health.¹⁴⁰

131. *IMS Health Inc. v. Sorrell*, 630 F.3d 263, 282 (2d Cir. 2010).

132. *Id.*

133. *Id.* at 276.

134. *Id.* at 279.

135. *Id.* at 282.

136. *Sorrell v. IMS Health Inc.*, 630 F.3d 263 (2nd Cir. 2010), *cert. granted*, 131 S. Ct. 857 (Jan. 7, 2011) (No. 10-779).

137. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2672 (2011).

138. *Id.* at 2667.

139. *Id.* at 2669-70.

140. *Id.* at 2670.

D. “Heightened” Judicial Scrutiny and the First Amendment

The threshold issue in *Sorrell* was which level of scrutiny applied to Vermont’s prescription confidentiality law. While Vermont argued that intermediate scrutiny was appropriate under *Central Hudson*, the plaintiffs argued not only that Vermont’s law failed under *Central Hudson*, but also that the Court should apply a different test affording commercial speech greater First Amendment protection.¹⁴¹

Ultimately, the Court applied what it termed “heightened scrutiny” after determining that Vermont’s law unconstitutionally placed content- and speaker-based restrictions on free speech.¹⁴² The strictness of “heightened scrutiny” is unclear, but based on the structure of the majority’s analysis, dissenting Justice Breyer characterized it as “an unforgiving brand of intermediate scrutiny.”¹⁴³ Vermont argued that heightened scrutiny was unwarranted because the law was attempting to regulate only commercial activity.¹⁴⁴ The Court agreed that the First Amendment does not prevent restrictions directed at commerce or conduct from imposing *incidental* burdens on speech.¹⁴⁵ The Court noted, however, that Vermont’s statute allowed prescription information to be studied and used by all but pharmaceutical companies, thereby imposing content- and speaker-based restrictions on speech.¹⁴⁶

Obviating the need to decide which level of scrutiny applied to Vermont’s prescription confidentiality law, the Court held that the statute failed under either heightened or intermediate scrutiny.¹⁴⁷ The dissent, led by Justice Breyer, argued that *Central Hudson* should have applied and that Vermont’s law was a reasonable effort to regulate commercial activity that imposed no significant burden on free speech.¹⁴⁸ Breyer opined that the majority was returning to a time in which the Court stepped into the shoes of state legislators.¹⁴⁹

E. *Protecting Physician Privacy under Heightened Scrutiny*

While the Court noted that Vermont’s physicians had an interest in maintaining the confidentiality of their prescription decisions,¹⁵⁰ it found

141. *See id.* at 2667-68.

142. *Id.* at 2664.

143. *Id.* at 2679.

144. *Id.* at 2664.

145. *Id.*

146. *Id.* at 2667.

147. *See id.* at 2668.

148. *Id.* at 2673.

149. *Id.* at 2679.

150. *Id.* at 2668.

that Vermont's law was not drawn to serve that interest because pharmacies could share prescriber-identifying data "with anyone for any reason" except marketing.¹⁵¹ Vermont argued that the statute's opt-in provision allows the statute to withstand scrutiny. The Court, however, found that this created only a "contrived choice" under which Vermont offered doctors two options: (1) allow everyone to use their prescribing data, or (2) forbid the use of their prescribing data by those Vermont did not support without an option to curtail use by Vermont's favored speakers.¹⁵² The Court hinted that a broader choice of options in restricting the use of the data might help—but would "not necessarily save"—the statute from failing under the First Amendment.¹⁵³

The Court never reached the argument of whether the statute *directly* advanced Vermont's interest in physician privacy.¹⁵⁴ Rather, the Court ended its inquiry immediately, finding that the statute did not advance Vermont's interest in physician privacy *at all* because the statute granted such extensive use of prescriber-identifying information to other parties, such as medical researchers and government entities.¹⁵⁵

The Court ended Vermont's physician-privacy argument by finding not only that the statute did not advance the state's interest in physician privacy, but that the interest could be achieved by "remedies other than content-based rules."¹⁵⁶ The Court noted that "physicians can, and often do, simply decline to meet with detailers, including detailers who use prescriber-identifying information."¹⁵⁷ Interestingly, the Court failed to mention the PDRP, a private-sector solution not subject to the First Amendment.

F. Containing Prescription Drug Costs under Heightened Scrutiny

The majority acknowledged that Vermont's second policy concern, containing prescription drug costs, was a proper government interest.¹⁵⁸ But the Court found yet again that Vermont's statute did not advance that interest in a constitutionally permissible way.¹⁵⁹ The Court found that the statute did not directly regulate the price of prescription drugs, but only sought to lower drug costs by *indirectly* curbing detailers' ability

151. *Id.*

152. Mello & Messing, *supra* note 19, at 1250.

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

154. *See id.*

155. *Id.*

156. *Id.*

157. *Id.*

158. *Id.* at 2670.

159. *Id.*

to influence prescribing decisions.¹⁶⁰ The Court noted that “the ‘fear that people would make bad decisions if given truthful information’ cannot justify content-based burdens on speech.”¹⁶¹ Sufficiently convinced that Vermont’s interest in cost containment of prescription drugs failed under the First Amendment, the Court did not offer any examples of less restrictive means for achieving that interest. In short, the Court suggested that drug reps are simply too good at their jobs and that Vermont could not restrict speech merely because physicians are persuaded by detailers’ messages.

G. Promoting Public Health under Heightened Scrutiny

The Court paid little attention to Vermont’s final asserted interest of promoting public health, noting that “[e]ven the United States, which appeared here in support of Vermont, took care to dispute the State’s unwarranted view that the dangers of new drugs outweigh their benefits to patients.”¹⁶² Lumping this policy interest with containing drug costs, the Court noted that promoting public health was a proper government interest. Yet again, the Court found that the statute did not advance that interest in a constitutionally permissible way by indirectly curbing drug reps’ ability to influence prescription decisions.¹⁶³

The Court failed to mention Vermont’s evidence showing that pharmaceutical drug detailing boosted the prescribing of newly approved, brand-name drugs, including Vioxx and Baycol.¹⁶⁴ This may be because Vermont and other states argued that generic alternatives were safer, not that certain brand-name drugs may be dangerous. Even though the Supreme Court did not address this issue in its opinion, *Ayotte* pointed out that no evidence was offered to prove that generic alternatives are safer than even the most dangerous brand-name drugs.¹⁶⁵

H. The Majority Provides Some Guidance

Sorrell struck a major blow to the movement against the use of prescriber-identifying data in pharmaceutical detailing. However, the Court did provide some guidance for lawmakers to craft statutes that may survive the heightened scrutiny applied by the Court in *Sorrell*.

160. *Id.*

161. *Id.* at 2670-71 (quoting *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 374 (2002)).

162. *Id.* at 2671 (quoting Brief for the United States as Amicus Curiae Supporting Petitioners at 24 n.4, *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011) (No. 10-779)).

163. *Id.* at 2670.

164. Mello & Messing, *supra* note 19, at 1251.

165. *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163, 180 (D.N.H. 2007), *rev’d and vacated by IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008).

First, the majority suggested that Vermont could have constructed “a more coherent policy,” similar to the HIPAA Privacy Rule.¹⁶⁶ The Court was likely implying that more than one party (detailers) should be excluded from using prescriber-identifying information. Second, the Court suggested that if Vermont changed its prescription confidentiality law from an opt-in to an opt-out structure like Maine’s law, then the proposed law “might burden less speech” but “would not necessarily save” the statute.¹⁶⁷ Third, the Court advised that physicians should simply close their doors to drug reps—a private-sector solution to the problem not subject to the First Amendment.¹⁶⁸

The Court never stated that following the first two suggestions would automatically harmonize a statute with the First Amendment. Any state that implements a prescription confidentiality law based on those suggestions would still be taking a risk when other, less-objectionable approaches might be equally effective. While not involving any government action, the third above-listed suggestion is equally ineffective. The next section will explain why these suggestions will not work.

IV. GOVERNMENT RESPONSES TO PHARMACEUTICAL DETAILING

Critics of increased oversight view the government’s actions as paternalistic and argued that physicians should be responsible enough to close their doors to drug reps and find time to seek out additional information on prescription drugs.¹⁶⁹ On the other hand, proponents of increasing regulation believe that the government should more actively oversee the health of its citizens and assist busy physicians who receive potentially biased information from drug reps.¹⁷⁰ However, no perfect solution exists. This section explores possible solutions to the problems raised by detailing and how they would likely fail in light of *Sorrell*.

A. *Enacting Legislation Banning the Use of Prescriber-Identifying Data Will Likely Fail Under the First Amendment*

Although Maine’s prescription confidentiality law may still be constitutional, it needs to be reconsidered in light of *Sorrell*. Because of the Supreme Court’s strict interpretation of the First Amendment in regards to these statutes, states should refrain from enacting prescription

166. *Sorrell*, 131 S. Ct. at 2668 (quoting *Greater New Orleans Broad. Ass’n, Inc. v. United States*, 527 U.S. 173, 195 (1999)).

167. *Id.* at 2669.

168. *Id.* at 2669-70.

169. *See Prescribing Data*, *supra* note 58.

170. *AMA Program*, *supra* note 22.

confidentiality laws of their own even if they learn from other states' mistakes or take the Supreme Court's advice.

While the Supreme Court did leave state legislators some leeway to create statutes banning the use of prescriber-identifying data for marketing purposes, it left them that room at the bottom of the steep hill called "heighted judicial scrutiny." Not only did the Supreme Court find that heightened judicial scrutiny applies to prescription confidentiality laws, it noted that Vermont's statute would still fail under intermediate scrutiny.¹⁷¹ Thus, state legislators may find crafting a similar prescription confidentiality law that would pass constitutional muster very difficult.

The majority in *Sorrell* suggested that other states might be more successful than Vermont by permitting the sale or disclosure of prescriber-identifying data in only a few narrow and well-justified circumstances, similar to the Privacy Rule set out in HIPAA.¹⁷² The HIPAA Privacy Rule provides federal regulations for protecting certain health information held by healthcare providers, health plans, and healthcare clearinghouses, while giving patients rights with respect to that information.¹⁷³ The Privacy Rule also permits the disclosure of protected health information needed for patient care and in narrow instances important to public health.¹⁷⁴ The HIPAA Privacy Rule does not focus on any single group when restricting access to protected health information.

The *Sorrell* Court found that, unlike the HIPAA Privacy Rule, Vermont's prescription confidentiality law made prescriber-identifying information available to "an almost limitless audience" while barring only pharmaceutical manufacturers and HIOs from accessing that information.¹⁷⁵ The majority explained that the structure of the statute allowed the information to be studied and used by all but a narrow class of disfavored speakers—the pharmaceutical industry—and did not justify the burden the statute places on protected free speech.¹⁷⁶

The dissent observed that the majority's proposed solution of likening Vermont's prescription confidentiality law to HIPAA would ironically deny access to prescriber-identifying data to *more* people, thus imposing a *greater* burden upon the dissemination of information.¹⁷⁷ As noted above, a number of parties have access to prescriber-identifying information: pharmaceutical companies; medical researchers; and

171. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2667-68 (2011).

172. *Id.* at 2668.

173. Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. § 1320d-2 (1996); 45 C.F.R. pts. 160 and 164 (2012).

174. 45 C.F.R. pts. 160 and 164 (2012).

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

176. *Id.*

177. *Id.* at 2684 (Breyer, J., dissenting).

government programs monitoring bioterrorism threats, drug recalls, and public health.¹⁷⁸ Some parties use prescriber-identifying information to help reduce prescription drug costs. For example, government healthcare programs, such as Medicare, use prescriber-identifying information to convince physicians to prescribe generic drugs.¹⁷⁹ Similarly, insurance companies contact physicians with high rates of prescribing brand-name drugs to persuade them to prescribe drugs that cost the insurance company less money.¹⁸⁰ A statute that excludes any of these additional parties from accessing this data risks countering essential state interests such as promoting public health or reducing prescription drug costs. Therefore, although the Court seemingly afforded other states an opportunity to pass similar legislation, following the majority's advice may prove counterintuitive.

Finally, statutes banning the use of prescriber-identifying data may *slow* but will not *stop* pharmaceutical companies from detailing brand-name drugs to physicians.¹⁸¹ No provisions in Maine, New Hampshire, or Vermont's statutes expressly prohibited detailers from communicating truthful information to physicians; detailers must simply convey it without the aid of prescriber-identifying information. Drug sales are far too lucrative for pharmaceutical companies to stop promoting their products to physicians. Even if prescription confidentiality laws were to stop drug reps from detailing brand-name drugs to physicians, pharmaceutical companies would likely divert more money to direct-to-consumer drug advertising, resulting in patients themselves becoming the new drug reps.¹⁸²

B. Giving Physicians More Privacy Options Is Irrelevant to the Courts

The distinguishing provision between Vermont's and Maine's prescription confidentiality laws was the prescribers' ability to opt in or opt out of sharing prescriber-identifying information with drug reps. Opting in generally prohibits the sale, license, or transfer of the prescriber-identifying data for marketing purposes *unless* an individual physician chooses to make the data available.¹⁸³ Opting out, on the other hand, prohibits the sale, license, or transfer of the data for marketing purposes *only if* an individual physician chooses to restrict third parties from

178. Greene, *supra* note 5, at 747.

179. Brief for Respondent at 6, *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011) (No. 10-779).

180. *Id.* at 8.

181. Allison Torres Burtka, *Court Strikes Down Law Protecting Doctors' Prescription Data*, 43 TRIAL 84, 84 (2007).

182. See Donohue et al., *supra* note 29, at 676 (noting the increase in spending on direct-to-consumer drug advertising).

183. See, e.g., VT. STAT. ANN. tit. 18, § 4631(d) (2010) (allowing physicians to opt in to sharing their prescriber data with pharmaceutical companies).

accessing the data, similar to the AMA's PDRP.¹⁸⁴ An unconditional ban prohibits the sale, license, or transfer of this data, leaving prescribers no choice in the matter.¹⁸⁵

As noted in the previous section, Vermont allowed physicians to opt in to sharing their prescriber-identifying information, and the Supreme Court found the statute unconstitutional.¹⁸⁶ Maine's law, on the other hand, allowed physicians to opt out of sharing their prescriber-identifying information, and its statute's constitutionality is still undecided. New Hampshire's law, which placed an unconditional ban on the release of prescriber-identifying information, is also unconstitutional, as it is even more restrictive than Vermont's law.

Most states will likely refrain from enacting prescription-confidentiality laws similar to those in Vermont or New Hampshire. However, states that wish to enact statutes similar to Maine's prescription confidentiality law should also refrain from doing so because it could still be invalidated. The majority in *Sorrell* noted that Vermont might have restricted less speech by switching to Maine's opt-out format, though that "would not necessarily save" Vermont's statute from failing under the First Amendment.¹⁸⁷

C. Telling Physicians to Close Their Doors Will Not Solve Anything

The majority in *Sorrell* suggested that physicians could simply close their doors to detailers.¹⁸⁸ According to the Court, "[d]octors who wish to forgo detailing altogether are free to give 'No Solicitation' or 'No Detailing' instructions to their office managers or to receptionists at their places of work."¹⁸⁹ In fact, several hospitals and physician offices already deny drug reps entry.¹⁹⁰ So why should it matter if drug reps access physicians' prescribing information?

While closing the door to drug reps may protect physicians' privacy, it will do nothing to lower drug costs for patients and leaves physicians with less information on brand-name prescription drugs.¹⁹¹ Furthermore, closing the door to drug reps would heavily reduce physicians' access to

184. See ME. REV. STAT. ANN. tit. 22, § 1711-E-2-A (2008); *AMA Program*, *supra* note 22.

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

186. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2672 (2011).

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

188. *Id.* at 2670.

189. *Id.*

190. See, e.g., *Managing Visits from Pharmaceutical Sales Representatives*, INST. FOR SAFE MEDICATION PRACTICES (May 22, 2008), <http://www.ismp.org/newsletters/acutecare/articles/20080522.asp>.

191. *Sorrell*, 131 S. Ct. at 2683 (Breyer, J., dissenting).

free drug samples that physicians provide to patients at no cost.¹⁹² As noted above, physicians have limited time to research new prescription drugs without sacrificing time with patients. If physicians choose to simply turn a deaf ear, then where will they find time to research information on the drugs they are prescribing to patients?

V. ACADEMIC DETAILING IS THE BEST RESPONSE
TO *SORRELL*

According to the Supreme Court, providing physicians with *more*—not *less*—information is the answer to states’ issues with the use of prescriber-identifying data in drug detailing.¹⁹³ As one Vermont physician stated: “We have a saying in medicine, information is power. And the more you know, or anyone knows, the better decisions can be made.”¹⁹⁴ The Supreme Court agreed, announcing that “information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them.”¹⁹⁵ To avoid the legal pitfalls faced by Vermont, New Hampshire, and Maine, states should take the Supreme Court’s advice by supporting academic-detailing programs. This section explains how academic detailing can successfully protect physician privacy, contain prescription drug costs, and promote public health without legal interference.

A. *What Is Academic Detailing?*

Academic detailing, otherwise known as “educational outreach,” is a form of continuing medical education in which trained health professionals such as physicians, registered nurses, advanced practice nurses, and pharmacists visit prescribers to provide evidence-based information on prescription drugs.¹⁹⁶ Academic detailing combines the direct-to-physician marketing approach of the pharmaceutical industry with academic, evidence-based, noncommercial information.¹⁹⁷ As an initial matter, it is important to distinguish academic detailing from “counter detailing.”

Critics contend that academic and counter detailing are no different because they both attempt to limit access to newer, breakthrough drugs

192. Tara Parker-Pope, *Who Gets Free Drug Samples?* N.Y. TIMES (Jan. 7, 2008, 10:26 AM), <http://well.blogs.nytimes.com/2008/01/07/who-gets-free-drug-samples/>.

193. *See Sorrell*, 131 S. Ct. at 2671.

194. *Id.*

195. *Id.*

196. Allen et al., *supra* note 39, at 2.

197. *Id.*

in the interest of saving money.¹⁹⁸ The goals of each program, however, differ greatly. Counter detailing involves dissuading physicians from prescribing a particular drug and perhaps prescribing a different drug in its place.¹⁹⁹ Pharmaceutical companies often engage in counter detailing against each other.²⁰⁰ Some states, such as Vermont, have been accused of engaging in counter detailing merely to persuade physicians to prescribe generics over brand-name drugs solely in the name of cost savings.²⁰¹

On the other hand, academic detailing, as described by its inventor Jerry Avorn, “is not about promoting the cheapest drugs or generic drugs per se; it is about prescribing the most appropriate drugs based on safety and efficacy data, and when all else is equal, prescribing cost-effective therapeutic options. The primary focus is on the evidence.”²⁰² Presenting evidence-based information improves patient health outcomes and lowers prescription drug costs, thus aligning the interests of patients, physicians, and payers.²⁰³

Pharmaceutical companies argue that academic detailers hold an unfair competitive advantage in communicating with prescribers because academic detailers do not hold themselves to the same ethical standards as pharmaceutical detailers, who voluntarily refrain from providing gifts and meals to physicians.²⁰⁴ While the government does not regulate academic detailers in the same way as pharmaceutical detailers, comparing the two is inapposite. Academic detailers have some form of higher education with a clinical background, whereas many pharmaceutical detailers have no clinical background beyond a few weeks of on-the-job training.²⁰⁵

198. THE HILLTOP INSTITUTE, ACADEMIC DETAILING: A REVIEW OF THE LITERATURE AND STATES’ APPROACHES 1 (2009), *available at* <http://www.hilltopinstitute.org/publications/AcademicDetailing-ReviewOfTheLiteratureAndStates'Approaches-December2009.pdf> [hereinafter HILLTOP INSTITUTE].

199. *Academic Detailing at a Glance*, MAINE MED. ASSOC., <http://www.mainemed.com/academic/glance.php> (last visited Jan. 6, 2013).

200. Prescription Project, *supra* note 3, at 1.

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

202. JENNIFER RECK, PRESCRIPTION POLICY CHOICES, A TEMPLATE FOR ESTABLISHING AND ADMINISTERING PRESCRIBER SUPPORT AND EDUCATION PROGRAMS 5 (2008), *available at* <http://www.policychoices.org/documents/ADPITemplate91708.pdf>.

203. *Id.*

204. *See* PHARMACEUTICAL RESEARCH, *supra* note 65, at 13.

205. Ann Woloson & Jennifer Reck, *Cheerleaders vs. Clinicians: Where do You Want Your Doctor Getting Information on Prescription Drugs?*,

Academic detailers are more analogous to “medical science liaisons” (MSLs), therapeutic specialists within pharmaceutical, biotechnology, and medical device companies who have advanced scientific training and pharmaceutical degrees in the life sciences.²⁰⁶

The exact number of states utilizing academic detailing programs is difficult to ascertain because states choose many different levels of implementation, ranging from fully-funded government programs to smaller, private programs with little to no government involvement.²⁰⁷ Thus far, eighteen states and Washington, D.C. have academic detailing programs in some form.²⁰⁸

While the United States began implementing academic detailing just recently, several other countries have utilized it successfully for years.²⁰⁹ Five Canadian provinces currently have academic detailing programs employing a total of thirty detailers.²¹⁰ The programs collaborate through an umbrella program known as the Canadian Academic Detailing Collaboration that is facilitated by monthly conference calls.²¹¹ Many other countries, including the United Kingdom, France, and the Netherlands, also have academic detailing programs currently in place.²¹² Since 1991, Australia has utilized academic detailing through the Drug and Therapeutics Information Service and the National Prescribing Service, which conduct more than 9,000 academic detailing visits annually, demonstrating academic detailing’s ability to operate in large countries.²¹³

PRESCRIPTION POLICY CHOICES (Feb. 6, 2008),
<http://www.progressivestates.org/files/PressRelease-PrescriptionPolicy-Choices-AcademicDetailing2-6-08.pdf>.

206. Samuel Dyer, *What is a Medical Science Liaison?*, MSL WORLD (June 30, 2011), <http://www.mslworld.com/news/29/What-is-a-Medical-Science-Liaison-.html>.
207. Telephone Interview with Michael Fischer, Program Dir., Nat’l Res. Ctr. for Acad. Detailing (Sept. 23, 2011).
208. These states are Alabama, California, Connecticut, Georgia, Idaho, Illinois, Kansas, Louisiana, Maine, Massachusetts, Mississippi, New York, North Dakota, Oklahoma, Oregon, Pennsylvania, South Carolina, and Vermont. *Id.*
209. RECK, *supra* note 202, at 7; HILLTOP INSTITUTE, *supra* note 198, at 11.
210. HILLTOP INSTITUTE, *supra* note 198, at 12; Rosemary Bacovsky et al., *Canadian Academic Detailing Collaboration: Evaluating Processes and Outcomes of Academic Detailing*, 139 CAN. PHARMACIST J. 54 (2006).
211. RECK, *supra* note 202, at 7.
212. *Id.*
213. *Id.*

B. Federal Initiatives for Academic Detailing Programs

Although academic detailing has been around since 1983,²¹⁴ the federal government took an interest in the idea only recently. In 2009, the American Recovery and Reinvestment Act (ARRA) allocated \$1.1 billion to the Department of Health and Human Services to conduct comparative effectiveness research analyzing different healthcare interventions.²¹⁵ Of these funds, \$300 million was directed to lay the groundwork for a broader federal academic detailing program.²¹⁶ One year later, the Patient Protection and Affordable Care Act further solidified government-funded comparative effectiveness research by creating the Patient Centered Outcomes and Research Institute (PCORI), an independent program intended to provide patients with a better understanding of the best prevention, treatment, and care options available as well as the scientific information supporting those options.²¹⁷

In April 2010, the Agency for Healthcare Research and Quality (AHRQ), a government-run program under the Department of Health and Human Services, solicited contractors to support an academic-detailing initiative to integrate the agency's comparative-effectiveness tools through on-site visits with clinicians, nurses, health plan formularies, and professionals.²¹⁸ AHRQ awarded a contract to create a publicity center and regional dissemination centers and to evaluate the impact of the other contracts."²¹⁹

C. Legal Advantages of Academic Detailing

As shown in *Sorrell*, Vermont's attempt to suppress the free flow of prescriber-identifying data to pharmaceutical detailers was impermissible under the First Amendment.²²⁰ Academic detailing, on the other hand, can sufficiently achieve many of the same policy goals, such as containing prescription drug costs and promoting public health, with no legal interference. Academic detailing does not stifle or necessarily even

214. See Avorn & Soumerai, *supra* note 46.

215. American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115 (2009).

216. Mike Mitka, *New Physician Education Initiatives Seek to Remove the Devil from the Detailing*, 306 JAMA 1187 (2011) ("The DHHS in turn is spending \$300 million through its Agency for Healthcare Quality and Research (AHRQ), in part to conduct an Academic Detailing Initiative.").

217. Patient Protection and Affordable Care Act, Pub L No. 111-148, 124 Stat 727, § 6301 (2010).

218. *Academic Detailing*, FEDBIZOPPS.GOV, <https://www.fbo.gov/spg/HHS/AHRQ/DCM/AHRQ-10-10011A/listing.html> (last visited Jan. 8, 2013).

219. *Id.*

220. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2672 (2011).

contradict the speech of pharmaceutical detailers; it simply provides physicians with more information on prescription drugs.²²¹ It offers physicians greater prescribing autonomy by supplying scientific information.²²² As the Court noted in *Sorrell*, “private decision-making can avoid governmental partiality and thus insulate privacy measures from First Amendment challenge.”²²³ Because courts will not monitor an academic detailing program under the high-power judicial microscope of “heightened scrutiny,” any legal action brought against a program will likely not face such judicial challenges.

D. Protecting Physician Privacy with Academic Detailing and the PDRP

Protecting physician privacy was the only policy goal that the prescription confidentiality laws in Vermont, Maine, and New Hampshire all had in common.²²⁴ The Court did not recognize physician privacy as a substantial government interest and further noted that banning the use of prescriber-identifying data would not solve the issue.²²⁵ Outside of banning drug reps from physicians’ offices altogether, nothing will stop drug reps from promoting their products to physicians. There is simply too much money at stake.

The larger concern of courts, legislatures, and society is not to protect physicians; rather, it is to protect patients, whether that involves their personal health information, health outcomes, or money spent on health care.²²⁶ HIPAA and other state medical privacy laws already protect patients’ privacy by restricting disclosure of patients’ protected

221. RECK, *supra* note 202, at 5.

222. See *Sorrell*, 131 S. Ct. at 2669 (June 23, 2011) (describing the “contrived choice” Vermont gave to physicians to protect their prescriber-identifying data: “[e]ither consent, which will allow the doctor’s prescriber-identifying information to be disseminated and used without constraint; or, withhold consent, which will allow the information to be used by those speakers whose message the State supports.”).

223. *Id.*

224. Compare N.H. REV. STAT. ANN. § 318:47-f (2006) and VT. STAT. ANN. tit. 18, § 4631(d) (2010) with ME. REV. STAT. ANN. tit. 22, § 1711-E-1-B.

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

226. Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82462 (Dec. 28, 2000) (codified as amended at 45 C.F.R. pts. 160, 164) (“This rule includes standards to protect the privacy of individually identifiable health information. The rules below . . . present standards with respect to the rights of *individuals who are the subjects of this information*” (emphasis added)).

health information.²²⁷ There are very few, if any, existing laws addressing the privacy rights of physicians.

However, if physicians are concerned about protecting the privacy of their prescribing habits, there is an existing solution that academic detailers can remind physicians of during office visits—the AMA’s Physician Data Restriction Program.²²⁸ Through the PDRP, physicians may restrict pharmaceutical detailers from accessing the AMA’s Masterfile to obtain their contact information, which prevents them from assembling prescriber-identifying data reports.²²⁹ As discussed above, this is a private-sector solution to a problem that Vermont, New Hampshire, and Maine unsuccessfully tried to solve through government regulation.²³⁰ While academic detailing itself may not protect physicians’ privacy rights, academic detailers can at least provide physicians with the right information to do so.

E. Reducing Prescription Drug Costs with Academic Detailing

As shown in *Sorrell*, laws banning the use of prescriber-identifying information do not directly advance the goal of containing prescription-drug costs.²³¹ Academic detailing, however, has already proven to contain prescription drug costs in several ways.²³² Studies on the cost of academic detailing indicate that potential savings exist through utilizing cheaper or fewer high-cost prescription drugs.²³³ According to a Harvard Medical School study, for every dollar spent on an academic detailing program, a state saves at least two dollars in reduced drug costs.²³⁴ This study directly compared physicians who were receptive to academic detailer visits with those who were not in Medicaid programs in Arkansas, New Hampshire, Vermont, and Washington, D.C.²³⁵ The study found that academic detailing significantly reduced prescriptions

227. Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. § 1320d-2; 45 C.F.R. pt. 164.

228. See *AMA Program*, *supra* note 22.

229. See *id.*

230. See *Sorrell*, 131 S. Ct. at 2662.

231. *Id.* at 2670.

232. PEW PRESCRIPTION PROJECT, COST-EFFECTIVENESS OF PRESCRIBER EDUCATION (“ACADEMIC DETAILING”) PROGRAMS 5-6 (2008), available at http://www.communitycatalyst.org/doc_store/publications/cost-effectiveness_of_prescriber_education_programs.pdf.

233. RECK, *supra* note 202, at 5.

234. Stephen B. Soumerai & Jerry Avorn, *Economic and Policy Analysis of University-based Drug “Detailing”*, 24 MED. CARE, 313, 313-31 (1986).

235. Avorn & Soumerai, *supra* note 46, at 1459.

for three often overused drugs: Cephalexin, Propoxyphene, and Papaverine.²³⁶

In addition to decreasing utilization of over-prescribed drugs, academic detailing can save states money by persuading physicians to switch from prescribing expensive, brand-name drugs to generics when equally effective and medically appropriate.²³⁷ According to one study, increased use of generic drugs would result in a cost savings of \$8.8 billion dollars per year nationwide.²³⁸ For example, evidence shows that the first choice for treating patients with high blood pressure should be an inexpensive thiazide diuretic rather than any one of several new, more expensive, brand-name drugs that pharmaceutical detailers promote to physicians.²³⁹

Academic detailing can also reduce costs outside of prescription drugs by preventing disease. While the *IMS Health* litigation generally focused on cost savings associated with prescription drugs, states can also utilize academic detailing to expand cost savings into other medical arenas, such as techniques and tools that address office-based barriers to cancer screening.²⁴⁰ In one study assessing the effects of academic detailing on increasing breast cancer screening in two medically-underserved communities, researchers found a statistically-significant intervention effect on mammography and clinical breast examination by female patients age forty and over.²⁴¹ Physicians choosing to receive educational information from academic detailers on breast cancer screenings correctly identified significantly more risk factors for breast cancer than physicians not participating in the study.²⁴²

Academic detailing can save states money in several ways that prescription confidentiality laws cannot: by curbing overprescribing of expensive drugs, increasing prescribing of generic drugs when medically appropriate, and potentially reducing future medical expenses by preventing disease.

236. *Id.* at 1461.

237. Jennifer S. Haas et al., *Potential Savings from Substituting Generic Drugs for Brand-Name Drugs: Medical Expenditure Panel Survey, 1997-2000*, 142 ANNALS INTERNAL MED. 891, 896 (2005).

238. *Id.* at 894.

239. *Academic Detailing in Practice: A Tale of Four States*, AARP RX WATCHDOG REPORT, Dec. 2009, at 5, available at http://assets.aarp.org/www.aarp.org/_cs/health/206907rxwatchdog_dec_09.pdf.

240. Sherri Sheinfeld Gorin et al., *Effectiveness of Academic Detailing on Breast Cancer Screening Among Primary Care Physicians in an Underserved Community*, 19 J. AM. BOARD FAM. MED. 110, 111 (2006).

241. *Id.* at 111, 116.

242. *Id.* at 117

F. *Academic Detailing Programs' Costs Weighed against Profits*

The high cost of starting effective academic detailing programs raises doubts about their cost-effectiveness. Annual funding for large academic detailing programs can range from \$1-2 million.²⁴³ A portion of this budget derives from annual salaries paid to medical professionals. In 2008, the Bureau of Labor Statistics reported that the average annual wage for academic detailers ranged from \$74,370 to \$137,290.²⁴⁴

A 2001 article in the *Journal of the American Medical Association* recommends that state policymakers use a formula to decide whether implementing an academic detailing program is cost-effective.²⁴⁵ The article explores the cost-effectiveness of academic detailing on the use of ACE inhibitors and antidepressants.²⁴⁶ Although treating heart-failure patients with ACE inhibitors instead of selective serotonin reuptake inhibitors (SSRIs) yielded better health outcomes and a cost savings of \$75 per patient,²⁴⁷ under the cost-benefit formula, implementing an academic detailing program to promote ACE inhibitors over SSRIs would not save enough money to justify the program's start-up costs.²⁴⁸

These results are misleading. According to clarifications set out in the study itself, the estimated costs for an academic detailing program to deliver information on one drug assumes divisibility of each detailer's time and no scale effects.²⁴⁹ In other words, the cost-saving totals should be seen as *indicative* rather than *definitive* when deciding whether to implement an academic detailing program.²⁵⁰ For example, the formula assumed that policymakers would implement an academic detailing program to conduct educational outreach for one purpose—to utilize ACE inhibitors over SSRIs. The example failed to account for states utilizing academic detailing to change prescriber behavior for more than one drug.²⁵¹ A different study showed that Pennsylvania's academic detailing program reduced drug costs by \$120 per doctor each month for a single class of drugs.²⁵² Over the course of a year, cost savings could

243. HILLTOP INSTITUTE, *supra* note 198, at 7, 9 (noting \$1 million program cost in Pennsylvania and \$1.9 million in South Carolina).

244. *Id.* at 17.

245. James Mason et al., *When is it Cost-Effective to Change the Behavior of Health Professionals?*, 286 JAMA 2988, 2989 (2001).

246. *Id.*

247. *Id.* at 2990.

248. *Id.* at 2991.

249. *Id.* at 2990.

250. *Id.*

251. *Id.*

potentially reach \$572,000, or more than half of the original \$1 million start-up cost.²⁵³ Pennsylvania's program may not be cost-effective according to the above formula, but if the state found one more equally cost-effective drug to focus their detailing efforts on, the program's net savings would surpass start-up costs in the first year.

If state policymakers are concerned with academic detailing program start-up costs, states might consider a number of financing sources, including fees charged to manufacturers and labelers in the prescription drug industry, settlements from prescription-drug lawsuits, lottery funds, and federal grants.²⁵⁴ Maine, for example, obtains approximately \$300,000 from manufacturers' fees, funds from drug settlements, and a grant from AHRQ for the dissemination of comparative effectiveness research.²⁵⁵

Private grants may also offset program costs. For example, the Idaho Medicaid Pharmacy Unit obtained a \$50,000 grant in 2009 from The Prescription Project to support an academic detailing pilot program targeting prescribers of mental-health medications.²⁵⁶ There are several private organizations dedicated to providing nonbiased information on prescription drugs, including The Independent Drug Information Service, the Alosa Foundation, the Drug Effectiveness and Review Project, and the Pew Prescription Project.²⁵⁷

Some jurisdictions have gone so far as to regulate the practice of detailing itself to establish initial funding for academic detailing programs. For example, Washington, D.C. recently enacted legislation to regulate the practice of pharmaceutical detailing.²⁵⁸ Detailers operating in Washington, D.C. must obtain a detailing license or face a fine of up to

252. PEW PRESCRIPTION PROJECT, COST-EFFECTIVENESS OF PRESCRIBER EDUCATION ("ACADEMIC DETAILING") PROGRAMS 2 (2008), *available at* http://www.communitycatalyst.org/doc_store/publications/cost-effectiveness_of_prescriber_education_programs.pdf.

253. *Id.*

254. HILLTOP INSTITUTE, *supra* note 198, at 5.

255. *Id.* at 11.

256. *Academic Detailing*, IDAHO DEP'T OF HEALTH & WELFARE, <http://www.healthandwelfare.idaho.gov/Medical/PrescriptionDrugs/AcademicDetailing/tabid/208/Default.aspx> (last updated Dec. 31, 2010).

257. *See, e.g.*, THE INDEPENDENT DRUG INFORMATION SERVICE HOME PAGE, <http://www.rxfacts.org> (last visited Jan. 8, 2013); THE ALOSA FOUNDATION, <http://02ce0e8.netsolhost.com/blog1/> (last visited Jan. 8, 2013); OREGON HEALTH & SCIENCE UNIVERSITY, DRUG EFFECTIVENESS REVIEW PROJECT (DERP), <http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/derp/index.cfm/> (last visited Jan. 11, 2013); *Pew Prescription Project*, THE PEW CHARITABLE TRUSTS, <http://www.pewhealth.org/projects/pew-prescription-project-85899367092> (last visited Jan. 8, 2013).

258. D.C. MUN. REGS. tit. 17, § 8300 *et seq.* (2009).

\$10,000 or other sanctions.²⁵⁹ Additionally, they must obtain a biannual license, sign an affidavit swearing to a code of ethics, graduate from an institute of higher education, and pay application and licensure fees.²⁶⁰ License renewal requires a minimum of fifteen hours of continuing education every two years.²⁶¹ Detailers must also maintain a record of their communications with licensed health professionals or their representatives for five years, including the name of the business; the date, time, and location of the contact; the products discussed; whether samples were provided; and the type of materials provided.²⁶² Such regulations are not only another option for generating revenue for an academic detailing program but also more closely monitor the communications between detailers and prescribers.

Georgia received federal assistance to establish an academic detailing program through ARRA grant funding.²⁶³ In September 2010, AHRQ awarded a three-year, \$11.7 million contract to Total Therapeutic Management, a physician- and patient-education company in Georgia, to integrate the AHRQ's comparative effectiveness tools through on-site visits with clinicians, nurses, health plan formularies, and other professionals.²⁶⁴ Georgia, however, is an outlier, as the federal government has not initiated academic detailing programs in any other state.

States can also reduce program costs by learning from drug reps' use of information technology in promoting drugs to physicians. As noted above, in 2005, the average primary care physician met with twenty-eight drug reps each week for roughly two hours and fifteen minutes total.²⁶⁵ Because of the dramatic increase in the ratio of detailers to physicians, the cost of face-to-face detailing per physician rose more than 31 percent between 2000 and 2004.²⁶⁶ According to one study, this was not due to a lack of drug reps employed by pharmaceutical companies, but rather a growing trend of physicians participating in electronic detailing ("e-detailing"), the promotion of pharmaceutical products using

259. Kevin B. O'Reily, *New Plan Would Require D.C. Drug Detailers to Become Licensed*, AM. MED. NEWS (Feb. 11, 2008), <http://www.ama-assn.org/amednews/2008/02/11/prsb0211.htm>.

260. D.C. MUN. REGS. tit. 17, § 8300 *et seq.* (2009).

261. *Id.*

262. *Id.*; HILLTOP INSTITUTE, *supra* note 198, at 8-9.

263. *See Academic Detailing*, FEDBIZOPPS.GOV, <https://www.fbo.gov/spg/HHS/AHRQ/DCM/AHRQ-10-10011A/listing.html> (last visited Jan. 8, 2013).

264. *Id.*

265. Rayna Herman & Ashley Mahoney, *2005 Access Report: The Current State of Pharma Sales*, PHARMACEUTICAL REPRESENTATIVE, July 1, 2005, at 16-17.

266. *Id.*

an online channel and information technology as opposed to traditional, face-to-face detailing.²⁶⁷ Aside from increasing development of the internet, there are three reasons for the growth of e-detailing: (1) the falling effectiveness and increasing costs of employing pharmaceutical sales representatives to meet with physicians face-to-face, (2) increasingly busier physicians with less time to meet with sales representatives, and (3) increased acceptance of the internet by physicians.²⁶⁸ Another possible reason for the growth of e-detailing, and the corresponding decrease in face-to-face detailing, may be the rapid increase in direct-to-consumer pharmaceutical marketing.²⁶⁹

Over time, e-detailing has progressed far beyond using the internet to detail drugs to physicians via e-mail. Today, pharmaceutical companies utilize e-detailing generally in one of two ways: virtual e-detailing, which is a taped or interactive presentation (such as a website) conveying a message to prescribers; or video e-detailing, which is face-to-face, personal computer-based video conferencing between a prescriber and a drug rep.²⁷⁰ This latter type of e-detailing is more similar to traditional detailing and is one way for detailers to reach prescribers practicing in remote geographic areas or physicians who are not permitted to see representatives at their offices.²⁷¹

Studies on academic detailing show that face-to-face meetings with prescribers are the best approach to yield the highest cost savings.²⁷² However, face-to-face meetings may not always be feasible. For instance, detailers may find traversing the vast rural areas of Texas too time-consuming or may be stymied by snowstorms in Vermont. To overcome these obstacles, academic detailing programs can use live or virtual e-detailing when a face-to-face relationship with the prescriber has already been established.²⁷³

Efforts by the pharmaceutical industry to replace traditional detailing with e-detailing have been unsuccessful.²⁷⁴ Using e-detailing as a supplement to in-person academic detailing, however, may prove cost-

267. *Id.*

268. Andree Bates et al., *Navigating the e-Detailing Maze*, 2 INT'L J. MED. MARKETING 255, 255-56 (2002).

269. See Donohue et al., *supra* note 29, at 675 (showing that money spent on direct-to-consumer pharmaceutical advertising increased by \$29.9 billion from 1996 to 2005).

270. Alkhateeb & Doucette, *supra* note 26, at 237-38.

271. *Id.* at 239.

272. RECK, *supra* note 198, at 10.

273. Alkhateeb & Doucette, *supra* note 26, at 238-39.

274. *Id.* at 239-41.

effective and will help further implement educational outreach in remote geographic areas.²⁷⁵

In sum, as shown in several states and studies, academic detailing can decrease prescription drug costs better than prescriber confidentiality laws. With several potential funding sources to minimize start-up costs, states can utilize academic detailing to save money by reducing the amount of unnecessary, brand-name prescription drugs prescribed to patients and utilizing e-detailing to supplement face-to-face interactions with prescribers.

G. Promoting Public Health with Academic Detailing

As the Court stated in *Sorrell*, prescription confidentiality laws banning the use of prescriber-identifying information will not advance a state's interest in promoting public health.²⁷⁶ Academic detailing, however, can help prescribers pinpoint drugs that may endanger patient safety and can be substituted with alternative drugs with a proven safety history. As noted above, pharmaceutical detailers use prescriber-identifying data to locate early adopters of new prescription drugs, sometimes leading physicians to prescribe drugs without an established safety record.²⁷⁷

Vioxx began as a success story in pharmaceutical marketing but ended in tragedy. First marketed in 1999, physicians prescribed Vioxx to more than 80 million patients.²⁷⁸ Over the course of five years, the FDA estimated that Vioxx caused 88,000–139,000 heart attacks.²⁷⁹ Although pharmaceutical companies work hard to promote new drugs quickly because of a “ticking patent clock” and competition among other brand-name drugs, stories such as Vioxx suggest that a wait-and-see approach may better promote public health.²⁸⁰ Merck, the pharmaceutical company that created Vioxx, eventually withdrew the drug from the market in September 2004 due to safety issues.²⁸¹ In November 2011, Merck agreed to pay \$950 million and pled guilty to a criminal misde-

275. Bates, *supra* note 268 at 257, 260.

276. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2667 (2011).

277. *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 47 (1st Cir. 2008), *abrogated by Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011).

278. David J. Graham et al., *Risk of Acute Myocardial Infarction and Sudden Cardiac Death in Patients Treated with Cyclo-Oxygenase 2 Selective and Non-Selective Non-Steroidal Anti-Inflammatory Drugs*, 365 LANCET 475, 480 (2005).

279. *See id.* at 480.

280. *See G. Caleb Alexander et al., Enhancing Prescription Drug Innovation and Adoption*, 154 ANNALS OF INTERNAL MED. 833, 834 (2011).

281. Graham et al., *supra* note 278, at 480.

meanor charge to resolve its illegal promotion of Vioxx to physicians and consumers.²⁸²

In February 2005, Dr. David Graham produced a study comparing the risk of adverse cardiovascular events in patients taking Vioxx against patients taking Celebrex.²⁸³ According to the study, more than 27,700 heart attacks and sudden cardiac deaths occurred between 1999 and 2003 that could have been avoided.²⁸⁴ Taking 25 milligrams per day or more of Vioxx resulted in more than three times the risk of acute heart attacks or sudden cardiac death compared with patients using Celebrex.²⁸⁵ If academic detailers provided prescribers additional scientific, evidence-based information about Vioxx, some of these adverse health outcomes may have been mitigated.

In addition to focusing efforts on a particular drug, existing academic detailing programs also focus on particular ailments or diseases for which physicians can make better-informed prescribing decisions to promote public health.²⁸⁶ Focusing on a specific drug or disease allows academic detailers to better tailor messages to prescribers.²⁸⁷ For instance, in Pennsylvania's academic detailing program, detailers focus their efforts on diseases typically treated with proton pump inhibitors, antihypertensive drugs, antiplatelet therapy, lipid-lowering drugs, and COX-2 inhibitors/non-steroidal anti-inflammatory drugs.²⁸⁸ Detailers in Washington, D.C. focus on diabetes and antiplatelet therapy,²⁸⁹ South Carolina's academic detailing program focuses on mental health within the Medicaid program,²⁹⁰ and Maine focuses on diabetes and antiplatelet

282. Peter Loftus & Brent Kendall, *Merck to Pay \$950 Million in Vioxx Settlement*, WALL ST. J. (Nov. 23, 2011), http://online.wsj.com/article/SB10001424052970204531404577054472253737682.html?mod=WSJ_hp_LEFTWhatsNewsCollection.

283. Graham et al., *supra* note 278, at 475.

284. *Id.*

285. *Id.* at 478.

286. RECK, *supra* note 202, at 8.

287. *Id.*

288. *Under the Influence: Can We Provide Doctors an Alternative to Biased Drug Reviews?: Hearing Before the S. Special Comm. on Aging*, 110th Cong. 37 (2008) (statement of Nora Dowd Eisenhower, Sec'y, Penn. Dep't of Aging).

289. *The District of Columbia Academic Detailing Program Quality Improvement and Evaluation*, THE ALOSA FOUNDATION 3-4 (Aug. 2010), http://doh.dc.gov/sites/default/files/dc/sites/doh/publication/attachments/Academic_Detaling_Program_Quality_Improvement_and_Evaluation.pdf.

290. *South Carolina Offering Prescribing Excellence (SCORxE)*, SOUTH CAROLINA COLLEGE OF PHARMACY, <http://www.sccp.sc.edu/centers/SCORxE/> (last visited Jan. 8, 2013).

therapy.²⁹¹ Each of these programs found that focusing efforts on specific problem areas, as opposed to providing prescribers with an abundance of drug safety information all at once, improved the effectiveness of education outreach visits.²⁹²

Academic detailing can promote public health more effectively than the prescription confidentiality laws enacted by Maine, New Hampshire, and Vermont. By providing non-biased, evidence-based information on prescription drugs to prescribers, states will be able to increase prescriptions for appropriate drugs, decrease prescriptions for inappropriate drugs, and prevent disease and other adverse medical events.

H. Prescriber-Identifying Data Can Improve Academic Detailing

Like pharmaceutical companies, academic detailing programs can use prescriber-identifying data to locate “early adopters” and other physicians who can benefit from evidence-based information on the drugs they are prescribing. Before the Supreme Court ruled against it in *Sorrell*, Vermont’s prescription confidentiality law set aside funding for an academic detailing program that used prescriber-identifiable data to promote the use of generics in place of brand-name drugs.²⁹³ However, states could use prescriber-identifying data to aid academic detailing programs in several other ways. For example, states could use this information to locate physicians who treat certain cardiologic ailments to supply them with information on the benefits of medications designed to improve heart health.²⁹⁴ Alternatively, if a state learns about the adverse side effects of certain medications, the state’s academic detailing program could then use prescriber-identifying data to locate prescribers most in need of safety information on those problematic medications.²⁹⁵ States may view prescriber-identifying data solely as a means for pharmaceutical manufacturers to better detail brand-name drugs to prescribers. However, states should also be aware of the several ways that this information can aid academic detailers in promoting public health and decreasing prescription drug costs.

291. *Academic Detailing*, MAINE MED. ASSOC., <http://www.mainemed.com/academic/index.php> (last visited Jan. 6, 2013).

292. Mary Ann O’Brien et al., *Educational Outreach Visits: Effects on Professional Practice and Health Care Outcomes (Review)*, 3 COCHRANE LIBRARY, 7 (2008), available at <http://apps.who.int/rhl/reviews/CD000409sp.pdf>.

293. VT. STAT. ANN. tit. 18, § 4622 (2010); VT. STAT. ANN. tit. 33, § 2004 (2010).

294. Brief of Respondents IMS Health Inc. et al., at 11, 52-53, *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011) (No. 10-779).

295. *Id.* at 32.

CONCLUSION

Pharmaceutical detailing can increase prescription drug costs and worsen patients' health outcomes. Pharmaceutical companies' use of prescriber-identifying data undoubtedly magnifies these problems. However, suppressing the free flow of prescriber-identifying data to HIOs and pharmaceutical manufacturers will not solve these problems. Furthermore, crafting legislation according to the Supreme Court's guidance in *Sorrell* will result only in prescription confidentiality laws that hinder other parties, such as medical researchers, from accessing the same information. That result would run counter one of the most important reasons for enacting prescription confidentiality laws—promoting public health.

Academic detailers cannot stop pharmaceutical detailers from visiting physician offices, but they can remind physicians of their ability to opt out of sharing their prescriber-identifying data through the PDRP. Physicians will likely prescribe fewer expensive, brand-name drugs if academic detailers inform them of an equally effective, medically appropriate drug that may be cheaper for patients.

Academic detailing helps states protect physician privacy, decreases prescription drug costs, and promotes public health better than prescription confidentiality laws. Furthermore, academic detailing will not hinder medical researchers or public health programs from obtaining valuable information from HIOs. At a time when unlimited amounts of data can decrease healthcare costs and increase productivity, and in light of the Supreme Court's decision in *Sorrell*, state legislators should implement policies supporting academic detailing programs and refrain from enacting prescription confidentiality laws banning the use of prescriber-identifying data.