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SHRINKING DRUG COSTS WITHOUT SILENCING PHARMACEUTICAL DETAILERS: MARYLAND'S OPTIONS AFTER *SORRELL V. IMS HEALTH*

KRISTINA L. MILLER*

In *Sorrell v. IMS Health*, the Supreme Court settled a circuit split regarding the concern that state laws prohibiting data mining for brand-name prescription drug marketing purposes violated the First Amendment right to free speech.¹ The Court held that Vermont's version of such a law, the Vermont Prescription Confidentiality Law,² violated the Petitioners' right to free speech because Vermont unjustifiably burdened pharmaceutical marketing, a protected form of expression.³

In reaching this conclusion, the Court analyzed the Vermont Prescription Confidentiality Law, hereinafter the Vermont Act, to determine whether the prohibition against prescription drug data mining infringed upon the Petitioners' First Amendment freedom of speech.⁴ After finding that heightened judicial scrutiny applied because the statute involved protected speech and targeted certain content and speakers, the Court then analyzed whether the government advanced an important public policy goal.⁵ Although the Court recognized that Vermont's goals to lower health care costs and protect medical record privacy were proper, the Court ultimately found that the Vermont Act burdened commercial speech in

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1. 131 S. Ct. 2653, 2662 (2011).

2. VT. STAT. ANN. tit. 18, § 4631 (2012), *partially invalidated by Sorrell*, 131 S. Ct. 2653.

3. *Sorrell*, 131 S. Ct. at 2671–72. Justice Kennedy, writing for the majority, explained, “[t]he State has burdened a form of protected expression that it found too persuasive. At the same time, the State has left unburdened those speakers whose messages are in accord with its own views. This the State cannot do.” *Id.* at 2672.

4. *Id.* at 2662–63.

5. *Id.* at 2666, 2670. A State may burden protected expression to directly advance a substantial government interest as long as the legislature's means are narrowly tailored and do not suppress disfavored messages. *Id.* at 2667–68.

violation of the First Amendment by exclusively restricting a disfavored speaker and message.⁶

Maryland is among the states that attempted to burden pharmaceutical marketing by statute.⁷ In light of *Sorrell*, any attempt to revitalize the Maryland Prescription Privacy Act would be futile.⁸ There are alternative measures, however, that Maryland can take to reduce state spending on brand-name pharmaceutical drugs. Continuing to encourage pharmacies to dispense generic drugs when possible, continuing to battle prescription drug abuse, and educating physicians about the benefits of generic drugs are viable measures Maryland can employ.⁹

I. THE CASE

A. *Although a Highly Effective Marketing Technique, Pharmaceutical Detailing May Jeopardize Public Health and Medical Privacy*

A physician's prescribing practices are called "prescriber-identifying information."¹⁰ This data includes the prescriber's name, the dosage and quantity of a named prescribed drug, and when and where the prescription was filled.¹¹ The patient's age and sex are also included in the prescriber-identifying information, although the patient's name is encrypted.¹² Pharmacies receive this information as a matter of business routine and federal law when processing prescriptions.¹³ Many pharmacies then sell prescription-identifying information to "data miners," firms that analyze the information and report on prescriber behavior.¹⁴ Data miners obtain

6. *Id.* at 2670–72. The Court noted, "[t]he State may not burden the speech of others in order to tilt public debate in a preferred direction." *Id.* at 2671.

7. Maryland Prescription Privacy Act, S.B. 266, 423d Gen. Assemb., Reg. Sess. (Md. 2007) (prohibiting the transfer of patient-identifying prescription information unless no payment is received and the recipient is one of the listed parties, which does not include parties involved in pharmaceutical marketing).

8. *Id.* The Maryland Act is similar to the Vermont Act in that it essentially only burdens pharmaceutical marketing speech, and *Sorrell v. IMS Health* held this measure to be an unconstitutional burden on disfavored speech. 131 S. Ct. at 2671.

9. *See infra* Part IV.B.

10. *Sorrell*, 131 S. Ct. at 2659.

11. *See* Marcia M. Boumil et al., *Prescription Data Mining, Medical Privacy and the First Amendment: The U.S. Supreme Court in Sorrell V. IMS Health Inc.*, 21 ANNALS HEALTH L. 447, 450 (2012).

12. *Id.* Patient names are encrypted; however, patients are each assigned an unique identifier allowing data mining companies to link and track patient prescriptions and their prescribing physicians. *Id.*

13. *See* 21 U.S.C. § 353(b) (2011); *Sorrell*, 131 S. Ct. at 2660; *see also* Initial Brief: Appellant-Petitioner at *1, *Sorrell*, 131 S. Ct. 2653 (No. 10-779). Patients' names are encrypted, but information about doctors and extensive details about prescribing practices are identified. *Id.*

14. *Sorrell*, 131 S. Ct. at 2660. One such data mining firm, IMS Health, Inc., states on its website that it is "committed to protecting a patient's right to privacy" and uses de-identified patient information. *Privacy Commitment*, IMS, <http://www.imshealth.com/portal/site/ims/> (follow "About IMS" hyperlink; then follow "Privacy Commitment" hyperlink) (last visited Apr. 15, 2013).

more information about the prescribers themselves from the American Medical Association (AMA), which sells lists of physicians to data miners.¹⁵ Combining records from pharmacies with prescriber identities from the lists, data miners create individual profiles of the prescribers.¹⁶

Data mining is an efficient¹⁷ means of analyzing profuse amounts of data to detect complex patterns.¹⁸ Data mining is used to comb through data in a variety of contexts and businesses, such as the tracking of fraudulent transactions by credit card companies.¹⁹ In the pharmaceutical context, data mining can be used to determine and predict physician prescribing practices.²⁰

IMS Health, Inc. is a data mining firm that collects health care intelligence.²¹ IMS Health tracks over eighty percent of global pharmaceutical sales activity and processes over thirty-nine billion transactions annually.²² IMS Health provides services to “optimize commercial effectiveness,”²³ and it creates reports that incorporate prescriber and patient behavior to reveal commercial opportunities for pharmaceutical companies.²⁴ Pharmaceutical companies are interested in prescriber behavior and obtain these reports, which are subject to nondisclosure agreements, from data mining companies like IMS Health.²⁵

Pharmaceutical manufacturers use detailers to represent them and promote their drugs to doctors by “detailing.”²⁶ Detailing is a sophisticated and expensive

15. See Boumil et al., *supra* note 11, at 450.

16. See *id.*

17. See generally David Orentlicher, *Prescription Data Mining and the Protection of Patients' Interests*, 38 J.L. MED. & ETHICS 74, 74–75 (2010). To temper the high costs of detailing, pharmaceutical companies increase efficiency by targeting prescribers who favor existing similar drugs, adopt new drugs quickly, and are already prescribing drugs from that pharmaceutical company. *Id.*

18. See Hian Chye Koh & Gerald Tan, *Data Mining Applications in Healthcare*, 19 J. HEALTHCARE INFO. MGMT. 64, 65 (2005) (describing data mining in the health care field as “essential” in light of recent pressure for health care entities to base decisions off clinical and financial data).

19. See Michael Heesters, *An Assault on the Business of Pharmaceutical Data Mining*, 11 U. PA. J. BUS. L. 789, 793 (2009). The Richmond police department was able to decrease the number of robberies at payday check cashing stores after data mining was used to analyze 911 calls, police reports, demographics, weather, traffic, and sporting event times. *Id.* (citing Steve Lohr, *Reaping Results: Data-Mining Goes Mainstream*, N.Y. TIMES, May 20, 2007, at BU3 (indicating that a twenty percent drop in crime in Richmond coincided with the implementation of data mining techniques)).

20. *Id.* at 795 (explaining that predicting prescribing patterns allows pharmaceutical companies to dispatch detailers to market to prescribers who write the most prescriptions).

21. *Overview*, IMS, <http://www.imshealth.com/portal/site/ims/> (follow “Overview” hyperlink) (last visited Apr. 15, 2013).

22. *Id.* IMS Health’s revenue in 2006 was \$1.96 billion. Heesters, *supra* note 19, at 792–93.

23. *Overview*, IMS, *supra* note 21.

24. See, e.g., IMS LIFELINK, CASE STUDY: TARGETING HIGH VALUE V. HIGH WRITING PRESCRIBERS (2012), available at http://www.imshealth.com/deployedfiles/ims/Global/North%20America/United%20States/LifeLink/Targeting_High_Value_Prescribers.pdf.

25. *Sorrell v. IMS Health*, 131 S. Ct. 2653, 2659–60 (2011). See also *Privacy Commitment*, IMS, *supra* note 14 (explaining that IMS uses de-identified patient information and will only use identifying patient information with patient consent and for limited purposes).

26. *Sorrell*, 131 S. Ct. at 2659–60.

marketing technique in which detailers, the pharmaceutical marketing representatives, schedule visits to a doctor's office, bring samples and medical studies,²⁷ and explain the details and advantages of the drug.²⁸ Detailers are effective marketers because they know the background and prescribing history of the doctors and are thus able to specifically cater a marketing pitch to each individual doctor.²⁹ Although detailing is expensive and time consuming, pharmaceutical manufacturers use detailing to promote high-profit brand-name drugs protected by patent to earn a profit before the patent expires, which is when less expensive bioequivalent generic alternatives can be manufactured.³⁰

The pharmaceutical industry spends more money on marketing than any other business in the United States.³¹ In 2004, drug manufacturers spent \$27 billion on marketing and directed over eighty-five percent of marketing efforts at doctors.³² In 2011, U.S. pharmaceutical companies spent approximately \$6.5 billion on detailing alone.³³ The increase in data miners and detailers³⁴ correlated with an increase in spending on brand-name drugs, reflecting the impressive effectiveness of detailing.³⁵ The Vermont legislature found that spending on drugs and nondurable medical supplies increased from \$280 to \$524 million between 2000 and 2005 in Vermont alone.³⁶

27. Detailers also often bring food "to help their sales pitches go down easier." Nathan Thornburgh, *The States Take on the Drug Pitchmen*, TIME, Aug. 12, 2008, <http://www.time.com/time/nation/article/0,8599,1831405,00.html>; see also Marcia M. Boumil, *Pharmaceutical Gift Laws and Commercial Speech Under the First Amendment in the Wake of Sorrell v. IMS Health, Inc.*, 8 J. HEALTH & BIOMED. L. 133, 137 (2012) (finding that gifts and giveaways influence prescribing patterns); Ray Moynihan, *Who Pays for the Pizza? Redefining the Relationships Between Doctors and Drug Companies*, 326 BRIT. MED. J. 1193, 1193, 1195 (2003) (describing the need to disentangle American medical schools and medical centers from pharmaceutical companies to reach the goal of unbiased health care information).

28. *Sorrell*, 131 S. Ct. at 2659.

29. *Id.* at 2659–60.

30. *Id.* at 2660.

31. Brief for Michael A. Scodro et al., as Amici Curiae Supporting Petitioners at *3, *Sorrell*, 131 S. Ct. 2653 (No. 10-779). The Vermont legislature found that pharmaceutical manufacturers "spent more than any other sector in the United States on its sales force and media advertising." 2007 Vt. Acts & Resolves 80.

32. 2007 Vt. Acts & Resolves 80. Capturing only one extra prescription per week from each prescriber has resulted in a \$52 million increase in sales annually. *Fact Sheet: Prescription Data Mining*, PRESCRIPTION PROJECT (Nov. 19, 2008), http://www.communitycatalyst.org/doc_store/publications/prescription_data_mining.pdf.

33. *Total US Promotional Spend by Type, 2011*, IMS, http://www.imshealth.com/deployedfiles/ims/Global/Content/Corporate/Press%20Room/Top-Line%20Market%20Data%20&%20Trends/2011%20Top-line%20Market%20Data/Promo_Spend_By_Type.pdf (last visited Apr. 15, 2013). U.S. pharmaceutical companies also spent \$3.9 billion on direct-to-consumer marketing, which includes advertisements on television and in magazines. *Id.*

34. 2007 Vt. Acts & Resolves 80. The Vermont legislature estimated that there was one pharmaceutical sales representative for every five office-based physicians. *Id.*

35. *Id.*

36. *Id.* This increase was the highest increase in spending in any health care category. *Id.*

The Vermont legislature also found that public health is impacted by pharmaceutical detailing because patients taking newer drugs on the market may be exposed to unknown side effects from a drug that does not provide additional benefits over an older, generic drug.³⁷ For example, brand-name drug Vioxx was removed from the market due to potentially lethal side-effects related to cardiovascular problems that were not initially disclosed.³⁸ The U.S. Food and Drug Administration (FDA) approved Vioxx in May 1999 after studies required for approval did not show any significant risk of heart disease.³⁹ After approval, Merck & Co., the pharmaceutical company that created Vioxx, conducted an eighteen-month study on whether Vioxx could prevent colon polyps.⁴⁰ This study was longer than most studies required by the FDA for drug approval⁴¹ and revealed the heart problems that led Merck & Co. to voluntarily withdraw Vioxx from the market.⁴² Generic drugs, on the other hand, are not plagued by unknown side effects because such drugs are only created after a brand-name drug's patent is expired.⁴³

"Black box warnings," the withdrawal of a drug from the market voluntarily by the pharmaceutical manufacturer or initiated by the FDA due to public health concerns over life-threatening adverse drug reactions,⁴⁴ for new drugs led a team of researchers to conclude that new drugs should be avoided when older, similarly effective drugs are available.⁴⁵ Karen E. Lasser, MD, MPH, et al. found that 10.2% of new chemical entities approved between 1975 and 1999 acquired a black box warning or were withdrawn from the market, and 8.2% acquired one or more black

37. *Id.*

38. *Id.*

39. See Richard Knox, *Merck Pulls Arthritis Drug Vioxx from Market*, NAT'L PUBLIC RADIO (Sept. 30, 2004, 12:00 AM), <http://www.npr.org/templates/story/story.php?storyId=4054991>.

40. *Id.*

41. The FDA review process takes around thirteen months for standard drugs and six months for priority drugs. U.S. FOOD & DRUG ADMIN., FY 2011 INNOVATED DRUG APPROVALS 6 (2011), available at <http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/ucm278358.pdf>. The Fast Track program expedites approval for critical, groundbreaking drugs by using flexible clinical trial requirements, which allows for drugs to be approved based on a single, short-term study. *Id.* at 7. Research and development for brand-name drugs costs \$2 billion; the development and approval for generic drugs costs \$100,000–\$500,000 to develop and obtain approval of a generic drug, and generic drug manufacturers do not conduct independent research or development of new drugs. Initial Brief: Appellee-Respondent PhRMA at *3, *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011) (No. 10-779).

42. See Knox, *supra* note 39, at 3.

43. See Isabelle Bibet-Kalinyak, *A Critical Analysis of Sorrell v. IMS Health, Inc.: Pandora's Box at Best*, 67 FOOD & DRUG L. J. 191, 194–95 (2012) (noting that brand-name drug manufacturers compete more against generic drug manufacturers than against other brand-name drug companies and that they must aggressively market products while protected by patent).

44. See Karen E. Lasser, et al., *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 JAMA 2215, 2216 (2002).

45. *Id.* at 2219. The authors also noted that patients who must use a new drug should be counseled on the drug's limited safety record and should be observed for possible adverse drug reactions. *Id.*

box warnings after the drug was approved.⁴⁶ They also noted that serious adverse drug reactions are often discovered after a drug has been on the market for a number of years.⁴⁷ These findings led these researchers to recommend that “any new drug should be considered a black box.”⁴⁸

Privacy concerns are also raised by the practice of data mining and detailing, specifically that data mining could lead to disclosure of confidential patient information or personal prescriber information.⁴⁹ Prescribers and patients have a reasonable expectation that prescription information will remain private and will not be disclosed for marketing purposes.⁵⁰ Prescribers and patients do not expect that this information will be traded for purposes other than the filling and processing of the prescription.⁵¹

The unauthorized sale and disclosure of medical record information is prohibited by state and federal laws.⁵² Under federal law, providers and covered entities are prohibited from selling protected health information without the patient’s consent,⁵³ and the penalty for the intentional sale, transfer, or use of individually identifiable health information “for commercial advantage” is as much as ten years imprisonment and \$250,000 in fines.⁵⁴ States have similar restrictions on the disclosure of medical information.⁵⁵

46. *Id.* at 2216. The authors note that “[i]n Kaplan-Meier analyses, the estimated probability of a new drug acquiring black box warnings or being withdrawn from the market over 25 years was 20%.” *Id.*

47. *Id.* at 2218.

48. *Id.* at 2220. Vioxx entered the market in 1999 and was withdrawn in 2004. Knox, *supra* note 39 at 1.

49. See Boumil et al., *supra* note 11, at 485–86 (noting that privacy is implicated although the Sorrell Court did not state that there is a right of privacy in prescriber identifying information).

50. See Brief for Michael A. Scodro et al., *supra* note 31, at *1 (highlighting that states have an interest in placing reasonable limits on the unauthorized use of personal information for marketing purposes).

51. 2007 Vt. Acts & Resolves 80. The Vermont legislature also found that trade of prescription information for marketing purposes occurs without consent of the patient or prescriber. *Id.*

52. See Health Insurance Portability and Accountability Act (HIPAA) of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of U.S.C.). Prescription records are considered protected health care information. 45 C.F.R. § 160.103 (2013). See Brief for Michael A. Scodro et al., *supra* note 31, at *9–*14 (noting that state and federal laws limit dissemination of personal, medical, and financial information routinely disclosed in business).

53. 42 U.S.C. § 17935(d) (2011) (restricting covered entities from disclosing protected health information and only permitting “minimum necessary” disclosures where disclosure is required).

54. 42 U.S.C. § 1320d-6 (2011).

55. See Brief for Michael A. Scodro et al., *supra* note 31, at *9–*14 (discussing numerous state and federal laws designed to protect medical record information). See, e.g., MD. CODE ANN., HEALTH-GEN. § 4-302 (Lexis Nexis 2012) (requiring health care providers to keep patient medical records confidential unless disclosure is provided by law).

Pharmaceutical data miners argue that patient privacy is not implicated by data mining because patients are not identified.⁵⁶ Pharmacies take prescriber-identifying information provided to them by prescribing physicians⁵⁷ and strip away the patient's name, an identifying factor that would compromise patient privacy,⁵⁸ before selling the data to pharmaceutical intelligence firms like IMS Health.⁵⁹ State legislatures argue that privacy can still be compromised, however, because patients are assigned a unique identifier which can be linked to prescribing physicians, allowing data miners to track individual patients.⁶⁰ The Vermont Medical Society condemned detailing as "an intrusion into the way physicians practice medicine."⁶¹

B. The Vermont Act Attempted to Curb Detailing by Limiting the Accessibility of Prescriber-Identifying Information to be Used in Detailing Campaigns

Vermont enacted the Vermont Act⁶² in 2007 to prohibit health insurers, pharmacies, and similar entities from selling prescriber-identifying information, without the prescriber's consent, to be used for marketing purposes.⁶³ The Vermont Act required doctors to decide whether their prescribing information may be sold and used for marketing purposes by the pharmaceutical industry.⁶⁴ In *Sorrell v. IMS*

56. Initial Brief: Appellee-Respondent IMS Health Inc., Verispan, LLC, & Source Healthcare Analytics, Inc. at *3, *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011) (No. 10-779) (arguing that protecting privacy is not Vermont's concern because federal and state laws already require that patient-identifying information be removed by pharmacy companies before transferring prescription information); see generally JANE YAKOWITZ & DANIEL BARTH-JONES, TECH. POLICY INST., THE ILLUSORY PRIVACY PROBLEM IN *SORRELL V. IMS HEALTH* (2011), available at <http://www.techpolicyinstitute.org/files/the%20illusory%20privacy%20problem%20in%20sorrell1.pdf> (arguing that privacy is not a practical concern because re-identifying de-identified data is difficult).

57. This practice is a matter of routine and of federal law. *Sorrell v. IMS Health*, 131 S. Ct. 2653, 2660 (2011).

58. YAKOWITZ & BARTH-JONES, *supra* note 56, at 3 (explaining that it is insufficient to only remove direct identifiers such as names and social security numbers because subjects can easily be identified through a combination of indirect identifiers).

59. Because of the requirement to de-identify information, IMS Health, Inc. argues the crux of the issue is that "states are hostile to pharmaceutical detailing." Initial Brief: Appellee-Respondent IMS Health Inc., Verispan, LLC, & Source Healthcare Analytics, Inc., *supra* note 56, at *3.

60. Initial Brief: Appellant-Petitioner, *supra* note 13, at *7-8. At trial, a Verispan LLC representative testified that its "linking codes" allow the firm to link "the five P's," the patient, product, prescriber, payer, and pharmacy. *Id.* at *8.

61. 2007 Vt. Acts & Resolves 80.

62. VT. STAT. ANN. tit. 18, § 4631 (2012), *invalidated by Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011).

63. § 4631(d). "Marketing" includes "advertising, promotion, or any activity" that is "used to influence sales or the market share of a prescription drug." § 4631(b)(5).

64. Initial Brief: Appellant-Petitioner, *supra* note 13, at *1. The Vermont Act directed the Vermont Department of Health to establish a program to solicit prescriber consent to prescriber-identifying information being used for marketing purposes on licensing applications and renewal forms. VT. STAT. ANN. tit. 18, § 4631(c)(1) (2012).

Health,⁶⁵ three data mining firms⁶⁶ and an association of pharmaceutical manufacturers⁶⁷ that produce brand-name drugs⁶⁸ challenged Section 4631(d) of the Vermont Act as an unconstitutional restraint on commercial speech.⁶⁹ The respondents sought declaratory and injunctive relief against the petitioners, the Attorney General, and other Vermont officials.⁷⁰

Section 4631(d) of the Vermont Act, the central provision at issue in the case, had three aspects.⁷¹ First, it prohibited pharmacies and other entities whose access to prescriber-identifying information is legal, from selling, licensing, or exchanging for value records containing such information.⁷² This prohibition prevented data miners and drug manufacturers, who do not have legal access to prescriber-identifying information, from purchasing prescriber-identifying information.⁷³ Second, it explicitly prohibited pharmacies and similar entities from selling prescriber-identifiable information to be used for marketing purposes unless the prescriber consents.⁷⁴ Significantly, prescriber consent was only required for marketing purposes, while consent was not required for prescriber-identifying information used in non-marketing purposes.⁷⁵ Finally, the statute explicitly

65. 131 S. Ct. 2653 (2011).

66. IMS Health, Inc., Verispan LLC (now owned by SDI Health), and Source Healthcare Analytics, Inc. are the three data mining firms that challenged the Vermont Act. See Initial Brief: Appellee-Respondent PhRMA, *supra* note 41.

67. The Pharmaceutical Research and Manufacturers of America (PhRMA) challenged the Vermont Act.

68. *Sorrell*, 131 S. Ct. at 2661. The *Sorrell* case consolidated the lawsuit brought by the three data mining firms and the lawsuit brought by PhRMA. *Id.*

69. Initial Brief: Appellee-Respondent PhRMA, *supra* note 41, at *7–*10 (arguing the Vermont Act furthers an improper goal, exclusively targets pharmaceutical manufacturers, and is overbroad); Initial Brief: Appellee-Respondent IMS Health Inc., Verispan, LLC, & Source Healthcare Analytics, Inc., *supra* note 56, at *10–*11 (arguing the Vermont government unconstitutionally restricted speech to prevent physicians from receiving information which the Vermont government disagreed with).

70. *Sorrell*, 131 S. Ct. at 2661 (noting that Appellee-Respondents sought declaratory and injunctive relief against the Appellant-Petitioners because the Vermont Act § 4631(d) violated their First Amendment rights; *see also* *IMS Health, Inc. v. Sorrell*, 631 F. Supp. 2d 434, 444 (D. Vt. 2009) (stating that Plaintiffs sought preliminary and permanent injunctive relief prior to the initial effective date of the Vermont Act), *rev'd*, 630 F.3d 263 (2d Cir. 2010), *aff'd*, 131 S. Ct. 2653 (2011).

71. VT. STAT. ANN. tit. 18, § 4631(d) (2012), *invalidated by Sorrell*, 131 S. Ct. 2653; *see also Sorrell*, 131 S. Ct. at 2660 (succinctly explaining the challenged provision of the Vermont Act).

72. § 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 containing prescriber-identifiable information...”).

73. *See Bibet-Kalinyak*, *supra* note 43, at 198 (explaining that preventing all entities with legal access to the information from selling the information effectively prevented data miners and drug manufacturers from being able to access it).

74. § 4631(d) (“A health insurer... shall not sell..., nor permit the use of regulated records containing prescriber-identifiable information for marketing or promoting a prescription drug, unless the prescriber consents.”); *see also Sorrell*, 131 S. Ct. at 2660 (explaining this prohibition effectively barred pharmacies from disclosing prescriber-identifying information for marketing purposes).

75. *Sorrell*, 131 S. Ct. at 2663 (highlighting that academic organizations could use prescriber-identifying information to promote generic drugs but that brand-name pharmaceutical manufacturers

prohibited pharmaceutical manufacturers and marketers from using prescriber-identifying information for marketing or promotional purposes unless the prescriber consents.⁷⁶ In sum, this section of the statute (1) prohibited entities authorized to obtain prescriber-identifiable information from selling, licensing, or exchanging it; (2) explicitly prohibited these entities from allowing prescriber-identifying information to be used for promotional purposes, unless the prescriber consents; and (3) explicitly prohibited pharmaceutical manufacturers and marketers from using prescriber-identifiable information for promotional purposes, unless the prescriber consents⁷⁷

Only Section 4631(d) of the Vermont Act, a two-sentence provision, was challenged. Unchallenged aspects of the Vermont Act include that the Vermont Attorney General could pursue civil remedies against violators.⁷⁸ Exceptions to the Vermont Act's prohibitions on sale, disclosure, and use of prescriber-identifying information included disseminating the information for use in health care research, educational communications to educate patients on treatment options, and for purposes "otherwise provided by law."⁷⁹ In addition, the Vermont Act authorized funding to educate prescribers "about commonly used brand-name drugs for which the patent has expired" or soon will expire and to promote the use of generic drugs, also known as "counter-detailing."⁸⁰

Following a bench trial, the U.S. District Court for the District of Vermont upheld the Vermont Act.⁸¹ The court applied the *Central Hudson Gas & Electricity Corp v. Public Service Commission* intermediate scrutiny framework⁸² for evaluating commercial speech regulations.⁸³ Concluding that legislative action was reasonable and based on substantial evidence, the court upheld the Vermont Act as

could not use such information to promote brand-name drugs). The consent requirement made the prescriber "the guardian of the [prescriber-identifying] information for marketing purposes." Bibet-Kalinyak, *supra* note 43, at 198.

76. § 4631(d) ("Pharmaceutical manufacturers and pharmaceutical marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents as provided in subsection (c) of this section.")

77. *Id.*

78. § 4631(f) (authorizing the attorney general to file a civil action for any violations of the Vermont Act and to investigate and obtain remedies).

79. § 4631(e).

80. § 4622(a)(2012); *Sorrell*, 131 S. Ct. at 2660–61 (also noting that "counterdetailers" use prescriber-identifying information to increase program effectiveness); *see also infra* Part IV.B.3.

81. *IMS Health, Inc. v. Sorrell*, 631 F. Supp. 2d 434, 440 (D. Vt. 2009) (stating that Plaintiffs sought preliminary and permanent injunctive relief prior to the initial effective date of the Vermont Act), *rev'd*, 630 F.3d 263 (2d Cir. 2010), *aff'd*, 131 S. Ct. 2653 (2011).

82. 447 U.S. 557 (1980) (promulgating the intermediate scrutiny test for commercial speech). Under *Central Hudson*, commercial information that is truthful and non-misleading may be limited if the restriction: (1) supports a substantial government interest; (2) directly advances the asserted interest; and (3) is narrowly tailored to serve that interest. *Id.* at 563–66.

83. *IMS Health, Inc.*, 631 F. Supp. 2d at 447–56. The court found the *Central Hudson* framework for intermediate scrutiny applied because the challenged provision of the Vermont Act strictly regulated the use of prescriber-identifying information in marketing, "a decidedly commercial use." *Id.* at 447.

an effective and targeted response to state interests in protecting the public against harmful drug practices and reducing prescription drug costs.⁸⁴ Specifically, the court found that the Vermont Act promoted the substantial government interests in cost containment and protecting public health in “a direct and material way” that was narrowly tailored because it exclusively targeted marketing using prescriber-identifying information.⁸⁵

The U.S. Court of Appeals for the Second Circuit reversed and remanded the District Court decision, holding that the Vermont Act violated the First Amendment by burdening speech of pharmaceutical marketers and data miners without adequate justification.⁸⁶ The Second Circuit agreed that the *Central Hudson* framework applied; however, it found the Vermont Act failed to meet the standard because it did not directly advance state interests in cost containment and public health.⁸⁷ The Second Circuit found the Vermont Act was not narrowly tailored to regulate “new and allegedly insufficiently tested brand-name drugs” where cheaper generic drugs existed because the statute targeted all brand-name prescription drugs, not only those for which generic alternatives existed.⁸⁸ This ruling was at odds with previous similar cases in the First Circuit.⁸⁹

Maine and New Hampshire had enacted legislation similar to the Vermont Act.⁹⁰ The First Circuit, however, upheld these similar laws on two separate occasions. In *IMS Health Inc. v. Ayotte*, the court found that prescriber-identifying information was conduct, not speech subject to regulation by the First Amendment.⁹¹ In *IMS Health Inc. v. Mills*, the court followed this precedent and upheld Maine’s Act to Amend the Prescription Privacy Law,⁹² a statute making

84. *Id.*

85. *Id.* at 450. The court did not consider whether protecting prescriber privacy was a substantial government interest because it had already accepted cost containment and protecting public health as legitimate ends. *Id.* The Second Circuit found protecting prescriber privacy was “too speculative to qualify as a substantial state interest under *Central Hudson*.” *IMS Health, Inc.*, 630 F.3d at 276.

86. *IMS Health, Inc.*, 630 F.3d at 267.

87. *Id.* at 277.

88. *Id.* at 279.

89. *IMS Health, Inc. v. Mills*, 616 F.3d 7, 13 (1st Cir. 2010) (upholding ME. REV. STAT. ANN. tit. 22, § 1711-E(2-A) (2007), a Maine statute making prescriber-identifying information unavailable for use in brand-name prescription drug marketing, and after finding that prescriber-identifying information is not a form of speech). This decision echoed the First Circuit’s earlier decision concerning the New Hampshire Prescription Information Law, N.H. REV. STAT. ANN. §§ 31847-f, 318:47-g, 318-B:12(IV) (2006). *IMS Health, Inc. v. Ayotte*, 550 F.3d 42, 45 (1st Cir. 2008).

90. ME. REV. STAT. ANN. tit. 22, § 1711-E(2-A) (2007); N.H. REV. STAT. ANN. §§ 31847-f, 318:47-g, 318-B:12(IV) (2006).

91. 550 F.3d 42, 52–53 (1st Cir. 2008) (holding that the law addresses the transferring and aggregating prescriber-identifying information for commercial ends which is conduct, not protected speech). The court explained, “[t]he plaintiffs, who are in the business of harvesting, refining, and selling this commodity, ask us in essence to rule that because their product is information instead of, say, beef jerky, any regulation constitutes a restriction on speech. We think that such an interpretation stretches the fabric of the *First Amendment* beyond any rational measure.” *Id.* at 53.

92. ME. REV. STAT. ANN. tit. 22, § 1711-E(2-A) (2007).

prescriber-identifying information unavailable for use in brand-name prescription drug marketing, after reiterating that prescriber-identifying information is conduct, not speech, and therefore not subject to First Amendment protections.⁹³

The First Circuit and Second Circuit came to different conclusions regarding whether prescriber-identifying information and the transfer of such information is conduct or speech. The U.S. Supreme Court granted certiorari on January 7, 2011 to settle this split in the circuits and, if prescriber-identifying information is speech, to determine whether the Vermont Act and similar legislation violated the First Amendment by improperly burdening protected commercial speech.⁹⁴

II. LEGAL BACKGROUND

A. *For Decades, Vermont Used Legislative Tools to Protect the Health and Privacy of Its Citizens and to Combat Rising Prescription Drug Costs*

Vermont is a prescription drug cost-containment leader and aggressively fought to lower drug costs and increase pharmaceutical marketing transparency in its Medicaid program.⁹⁵ Since 1894, Vermont has regulated “every aspect of the profession, including licensing, physical space, security, staff, recordkeeping, reference materials, and advertising.”⁹⁶ Vermont’s regulations supplement federal regulations of the industry, including the FDA’s approval of new drugs and the Health Insurance Portability and Accountability Act (HIPAA) concerning privacy in the health industry.⁹⁷

Vermont’s efforts to regulate the pharmaceutical industry and protect the public health of its citizens⁹⁸ include a law enacted in 1978 which requires pharmacists to dispense the generic form of a drug (1) if it was available and (2) unless the prescriber requested the brand-name drug.⁹⁹ Vermont also attempted to

93. *Mills*, 616 F.3d at 18–23.

94. *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2662 (2011).

95. 2007 Vt. Acts & Resolves 80. Vermont aggressively sought to lower drug costs in the state Medicaid program by enacting pharmacy best practices, cost control programs, mandatory generic substitution, and mail order purchasing. *Id.*

96. Initial Brief: Appellant-Petitioner, *supra* note 13, at *4. *See generally* 04-030 VT. CODE R. § 230 (2009).

97. Initial Brief: Appellant-Petitioner, *supra* note 13, at *3–*6; *see also* Health Insurance Portability and Accountability Act (HIPAA) of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of U.S.C.) (creating privacy measures in the medical field); Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended in scattered sections of 21 U.S.C.) (giving the FDA authority to oversee the safety of food, drugs, and cosmetics).

98. *See infra* Part I (explaining that brand-name prescription drug use implicates public health concerns because new brand-name drugs may have unknown harmful side effects that could lead to black box warnings and voluntary withdrawals).

99. Initial Brief: Appellant-Petitioner, *supra* note 13, at *4; *see* VT. STAT. ANN. tit. 18, §§ 4605, 4606 (2012) (requiring pharmacists to dispense the lowest priced bioequivalent generic drug unless the prescriber indicates that a brand-name drug is necessary).

require pharmaceutical marketers to disclose marketing costs and drug pricing information to doctors during marketing visits.¹⁰⁰

Vermont argued that the Vermont Act was a lawful exercise of its regulatory authority and a continuation of state efforts to regulate the medical and pharmaceutical fields.¹⁰¹ The Vermont legislature created the Vermont Act in response to legislative findings that marketing program goals “are often in conflict with the goals of the state” and that pharmaceutical marketing campaigns resulted in a “one-sided” marketplace for ideas.¹⁰² By eliminating pharmaceutical marketers’ access to prescriber-identifying information, Vermont sought to remedy doctors’ reliance on biased information, prevent detailers from harassing doctors with marketing campaigns, protect prescriber privacy, and reduce state spending on brand-name drugs when generic alternatives exist.¹⁰³ Although Vermont’s regulatory efforts may have been legitimate, the Vermont Act was invalidated as a violation of the First Amendment commercial speech doctrine.¹⁰⁴

B. The Extent of the First Amendment’s Commercial Speech Protection Was Disputed as it Was Unclear Whether Prescriber-Identifying Information Was Speech and Whether Vermont’s Policy Goals Justified Burdens on Speech

The primary disagreement in *Sorrell* concerned the proper standard for adjudicating the First Amendment’s commercial speech protections.¹⁰⁵ Vermont asserted that the First Amendment permits government restrictions on access to or use of non-public information and also argued that information use is conduct, not speech.¹⁰⁶ The respondent pharmaceutical manufacturers and marketers argued that

100. 2007 Vt. Acts & Resolves 80. The American Medical Association established the Prescribing Data Restriction program in 2006, which allowed doctors to opt in to prevent pharmaceutical companies from accessing their prescription records. See Alexander D. Baxter, *IMS Health v. Ayotte: A New Direction on Commercial Speech Cases*, 25 BERKELEY TECH. L.J. 649, 653 (2010). Data mining companies could still collect and sell doctors’ prescription history to pharmaceutical companies, but pharmaceutical companies were prohibited from giving the data to marketers for three years. *Id.* This program was deemed ineffective by some states because it was voluntary, required doctors to re-register every three years, and did not stop the commercial advantages of detailing. *Id.* at 653–54.

101. Initial Brief: Appellant-Petitioner, *supra* note 13, at *10–*11.

102. 2007 Vt. Acts & Resolves 80. Prescribing physicians’ practices reflect that detailing by pharmaceutical representatives increases drug sales more so than advertisements in professional journals, and physicians are more likely to prescribe newer expensive drugs despite no medical advantage over the generic version. Orentlicher, *supra* note 17, at 75–76.

103. Brief for Michael A. Scodro et al., *supra* note 31, at 2.

104. *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2668 (2011) (holding that Vermont’s justifications for the Vermont Act, namely protecting medical privacy, improving public health, and reducing health care costs, do not withstand the heightened scrutiny required for First Amendment commercial speech protection).

105. *Id.*

106. Initial Brief: Appellant-Petitioner, *supra* note 13, at *22–*27. Vermont cited the First Circuit decisions and a Supreme Court decision, *Los Angeles Police Dept’t v. United Reporting Publ’g Corp.*, as the applicable precedents. *Id.* In *United Reporting*, the Court had held that a plaintiff could not raise a

the correct standard was heightened scrutiny as promulgated in *Central Hudson* because communicating aggregated data and marketing to prescribing physician are protected forms of speech.¹⁰⁷ *Sorrell* settled the dispute and contributed to First Amendment commercial speech jurisprudence by establishing that the use of prescriber-identifying information for marketing is speech¹⁰⁸ and that the Vermont Act's regulation of prescriber-identifying information amounted to a regulation of commercial speech, which warranted a heightened judicial scrutiny analysis.¹⁰⁹

The Supreme Court found in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council* that commercial speech is protected by the First Amendment, and this basic tenet remains good law.¹¹⁰ The more significant inquiries are what constitutes "commercial speech" and how it should be safeguarded.¹¹¹ The main case addressing these two questions is *Central Hudson*, which defined "commercial speech" and articulated a test for when the government may regulate it.¹¹²

Central Hudson defined "commercial speech" as "expression related solely to the economic interests of the speaker and its audience."¹¹³ This definition attempted to remedy the over- and under-inclusive nature of *Virginia State Board of Pharmacy*'s definition of "commercial speech" as an expression that "proposes a

prima facie challenge to a content-based regulation barring access to information held by the government. 528 U.S. 32, 48 (1999).

107. Initial Brief: Appellee-Respondent PhRMA, *supra* note 41, at *12, *18.

108. *Sorrell*, 131 S. Ct. at 2667 (reaching the conclusion that using prescriber-identifying information for marketing was a form of speech without much pageantry, simply noting that previous Supreme Court cases established "that the creation and dissemination of information are speech within the meaning of the First Amendment"). *See also* Bartnicki v. Vopper, 532 U.S. 514, 527 (2001) (noting that "it is hard to imagine" what would constitute speech if disclosing and publishing information are "expressive conduct" and not speech) (quoting Bartnicki v. Vopper, 200 F.3d 109, 120 (3d Cir. 1999)).

109. *Sorrell*, 131 S. Ct. at 2666–67.

110. 425 U.S. 748, 770 (1976). Interestingly, *Virginia State Board of Pharmacy* involved a government regulation preventing pharmacists from advertising prescription drug prices because the government feared pharmacies would go out of business in an effort to keep up with aggressive price lowering practices. *Id.* at 767–69. Regular prescription drug consumers, "the poor, the sick, and particularly the aged," challenged the regulation because they were spending a "disproportionate" amount of money on prescription drugs and would benefit from the advertisements. *Id.* at 763. The Court held that a pharmacist's communication of what he charges for a prescription drug is commercial speech protected by the First Amendment because society has "a strong interest in the free flow of commercial information." *Id.* at 764.

111. *Id.* at 770–73 (clarifying that the Court's holding only protects "commercial speech" where "commercial speech" is "the dissemination of concededly truthful information about entirely lawful activity").

112. 447 U.S. 557 (1980). *See also* Martin H. Redish, *The First Amendment in the Marketplace: Commercial Speech and the Values of Free Expression*, 39 GEO. WASH. L. REV. 429, 433 (1971) (analyzing the justifications for omitting commercial speech from First Amendment protection and exploring how the judiciary has dealt with the problem of commercial speech).

113. 447 U.S. at 561.

commercial transaction.”¹¹⁴ Both definitions have been criticized as being ambiguous, and the Supreme Court has yet to focus on what “commercial speech” fully entails.¹¹⁵ For now, *Central Hudson* guides courts to find the speech is “commercial speech” protected by the First Amendment if it concerns lawful activity and is not misleading.¹¹⁶

Once speech is found to be protected commercial speech, the *Central Hudson* test for determining whether the government may regulate the speech involves three additional inquiries.¹¹⁷ First, the government’s restriction must be justified by a substantial interest.¹¹⁸ Second, the law must directly advance the government’s interest.¹¹⁹ Third, the regulation of speech must be narrowly tailored to achieve the government’s interest.¹²⁰ This *Central Hudson* framework of narrowly tailored regulations substantially related to achieving an important government goal was relied on by the Court to invalidate governmental restrictions on commercial speech in subsequent cases.¹²¹

114. *Virginia State Board of Pharmacy*, 425 U.S. at 762. The Court examined whether speech which merely “propose[s] a commercial transaction” and does not promote ideas, truth, science, morality, or art lacks protection, ultimately holding that commercial speech does not lack protection. *Id.* (citations omitted).

115. Nat Stern, *In Defense of the Imprecise Definition of Commercial Speech*, 58 MD. L. REV. 55, 79–87 (1999) (describing the Court’s various imperfect definitions of “commercial speech” and the criticism of the Court’s inconsistency and lack of clarity in this regard).

116. 447 U.S. at 566–68 (finding advertising is commercial speech because, even in monopoly markets, it increases the amount of information available to consumers for making decisions). The *Central Hudson* Court found the government ban on utility advertising violated the First Amendment right to free speech because the State’s asserted substantial interests were not narrowly tailored to the advertising restrictions. *Id.* at 570–71.

117. *Id.* at 566 (“In commercial speech cases, then, a four-part analysis has developed. At the outset, we must determine whether the expression is protected by the *First Amendment*. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.”).

118. *Id.* at 568–69 (finding that the State had substantial interests in energy conservation and maintaining fair energy rates).

119. *Id.* at 569 (finding that the State’s interest in energy conservation was directly advanced by the advertising ban, but that the State’s interest in fair and efficient energy rates was not sufficiently linked to the speech restriction).

120. *Id.* at 566 (finding the complete advertising ban “more extensive than necessary” to further the State’s interest in energy conservation).

121. *See, e.g.*, *Greater New Orleans Broad. Ass’n, Inc. v. United States*, 527 U.S. 173, 176 (1999) (finding prohibitions on gambling advertisements unconstitutional); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360 (2002) (invalidating restrictions on advertisements for “compounded drugs” as unconstitutional).

III. THE COURT'S REASONING

The Supreme Court invalidated the Vermont Act as an unconstitutional attempt to prohibit a protected form of expression.¹²² Justice Kennedy, joined by Justices Scalia, Thomas, Alito, Sotomayor, and Chief Justice Roberts, applied a heightened scrutiny analysis to the Vermont Act upon a finding that content- and speaker-based restrictions were enacted by Vermont to burden pharmaceutical marketing because the State disagreed with the message pharmaceutical marketing conveys.¹²³ The Court found that Vermont's contentions that the Vermont Act was necessary to protect medical privacy and was integral to achieving policy objections related to public health care and cost containment could not justify burdening the speech under the required heightened scrutiny analysis.¹²⁴

Examining the Vermont Act on its face, the Court found that the Act placed content- and speaker-based burdens on the sale, disclosure, and use of prescriber-identifying information, namely that this information could not be sold or given away for marketing purposes or used by pharmaceutical detailers for marketing purposes.¹²⁵ Marketing is speech with a particular content, and the Vermont Act restricted pharmaceutical marketing by forbidding the sale of prescriber-identifying information; therefore, the Vermont Act disfavored a particular type of content.¹²⁶ The Vermont Act also explicitly disfavored particular speakers, the pharmaceutical manufacturers and marketers.¹²⁷ Detailers were prohibited from using prescriber-identifying information for marketing, yet a wide range of other speakers, such as academic organizations, could use the information to market generic drug prescriptions.¹²⁸

The Court next examined the purpose and practical effect of the law, emphasizing that a prima facie neutral regulation would be unconstitutional if its purpose was to suppress commercial speech and if it placed unjustified burdens on such expression.¹²⁹ The Court explained that the record and formal legislative

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

123. *Id.* at 2663–64 (explaining that heightened scrutiny is warranted when the government places content-based burdens on speech because the government seeks to suppress a particular viewpoint).

124. *Id.* at 2667–68 (concluding that the Vermont Act failed to “directly advance” and was not narrowly drawn to achieve the government’s interests).

125. *Id.* at 2663 (highlighting that the Vermont Act explicitly singled out pharmaceutical detailers from using the information or conveying an effective pharmaceutical marketing message).

126. *Id.*

127. *Id.*

128. *Id.* The Court emphasized the Vermont Act’s flaw in solely prohibiting pharmaceutical manufacturers and detailers from acquiring prescriber-identifying information and using the information for marketing when other parties could acquire the information and use the information for marketing. The Court explained, “[f]or example, it appears that Vermont could supply academic organizations with prescriber-identifying information to use in countering messages of brand-name pharmaceutical manufacturers and in promoting the prescription of generic drugs.” *Id.*

129. *Id.* at 2663. The Court cited *United States v. O'Brien*, 391 U.S. 367, 384 (1968), for the proposition that the effect and purpose of a statute may render it unconstitutional. *Id.*

findings made it clear that the purpose of the Vermont Act was to target speakers and their messages for disfavored treatment, even reaching the level of viewpoint discrimination in its application.¹³⁰ Pharmaceutical manufacturers and detailers are essentially the only customers seeking prescriber-identifying information from data mining vendors like IMS Health, and detailing is in support of brand-name drugs.¹³¹ The Vermont legislature found that detailers convey messages that “are often in conflict with the goals of the state” and designed the Vermont Act to restrict these brand-name pharmaceutical marketing messages.¹³² The Court found that detailers and their message were the Vermont Act’s exclusive target.¹³³

Because the Court found that the Vermont Act imposed specific, content-based burdens on commercial speech, which is a protected expression, and did so because the State disagreed with the message conveyed by it, the Court applied heightened judicial scrutiny.¹³⁴ The Court additionally noted that the free flow of commercial speech is of great importance to a consumer, and it can save lives in the fields of medicine and public health.¹³⁵

The Court disagreed with Vermont’s contention that the Vermont Act was a commercial regulation that did not warrant heightened judicial scrutiny, explaining that the Vermont Act imposed more than an incidental burden on protected expression.¹³⁶ The Court explained that “Vermont’s law does not simply have an effect on speech, but is directed at certain content and is aimed at particular speakers.”¹³⁷

130. *Id.* at 2663. The Court cited *R.A.V. v. St. Paul*, 505 U.S. 377, 391 (1992), which invalidated an ordinance that prohibited display of a symbol known to arouse alarm in others on the basis of race as improper viewpoint discrimination because displays containing “fighting words” that promote racial equality were protected while displays advocating the opposite viewpoint were prohibited. *Id.*

131. *Id.* at 2663. The District Court found as fact that pharmaceutical marketers are the only paying customers and that detailing by pharmaceutical manufacturers is by “almost invariable rule” in support of brand-name drugs. *IMS Health, Inc. v. Sorrell*, 631 F. Supp. 2d 434, 451 (D. Vt. 2009) (stating that Plaintiffs sought preliminary and permanent injunctive relief prior to the initial effective date of the Vermont Act), *rev’d*, 630 F.3d 263 (2d Cir. 2010), *aff’d*, 131 S. Ct. 2653 (2011).

132. 2007 Vt. Acts & Resolves 80.

133. *Sorrell*, 131 S. Ct. at 2663–64 (“Given the legislature’s expressed statement of purpose, it is apparent that § 4631(d) imposes burdens that are based on the content of speech and that are aimed at a particular viewpoint.”).

134. *Id.* at 2664. *See also* *Ward v. Rock Against Racism*, 491 U.S. 781, 791 (1989) (holding that the First Amendment requires heightened judicial scrutiny whenever the government creates “a regulation of speech because of disagreement with the message it conveys”).

135. *Sorrell*, 131 S. Ct. at 2665. The *Virginia State Board of Pharmacy* Court similarly considered the need for the speech’s intended audience to have access to speech, namely that ill consumers who regularly take prescription drugs would benefit from pharmacy advertisements telling them the prices of prescription drugs. 425 U.S. 748, 763–64 (1976).

136. *Sorrell*, 131 S. Ct. at 2665. The First Amendment does not prevent restrictions directed at commerce from imposing incidental burdens on speech, however the Act imposes more than incidental burdens on speech. *Id.*; *see* *Rumsfeld v. Forum for Academic and Institutional Rights, Inc.*, 547 U.S. 47, 62 (2006) (holding that a ban on race-based hiring may require employers to remove “White Applicant Only” signs).

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

The Court also disagreed with Vermont's argument that the Vermont Act regulates access to information, not speech, and that such regulation is supported by *Los Angeles Police Dept. v. United Reporting Publishing Corp.*¹³⁸ The *United Reporting* Court held that a plaintiff could not raise a prima facie challenge to a content-based regulation barring access to non-public information held by the government, and the Court did not rule on the merits of any First Amendment claim.¹³⁹

The *Sorrell* Court characterized *United Reporting* as "a case about the availability of facial challenges" and distinguished the regulation in *United Reporting* from the current Act on two grounds.¹⁴⁰ First, the *United Reporting* regulation prohibited access to non-public information in the government's hands, which is distinct from the Vermont Act's restrictions on the use of information already in the private speaker's hands.¹⁴¹ The Vermont Act involved the government prohibiting a speaker from conveying information that the speaker already possesses, thus it implicated an individual's right to speak because the information possessed was subject to use and dissemination restraints.¹⁴² Second, the current plaintiffs argued that the Vermont Act burdened their own speech;¹⁴³ the plaintiffs in *United Reporting* had not suffered a personal First Amendment injury and had to invoke the rights of others through a facial challenge.¹⁴⁴

Ultimately, the Court found that the use of prescriber-identifying information is speech, not conduct as Vermont contended.¹⁴⁵ This holding overruled the First Circuit characterization of prescriber-identifying information as a "mere commodity" that lacks First Amendment protection.¹⁴⁶ The Court reasoned that "Vermont's statute could be compared with a law prohibiting trade magazines from

138. *Id.*

139. 528 U.S. 32, 40–41 (1999) (finding that a California regulation, which required parties who obtained arrestees' addresses to declare the information would not be used for promotional purposes, could not be subjected to a First Amendment prima facie challenge because the regulation did not abridge speech rights, did not prohibit speakers from conveying information in the speaker's possession, and did not create penalties for using information in violation of the regulation).

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

141. *Id.* at 2665–66. The Court noted that even though Respondent-data miners do not have the information, the information is in the hands of private entities, as opposed to government entities, and the "threat of prosecution... hangs over [Respondents'] heads." *Id.* at 2666 (citing *United Reporting*, 528 U.S. at 41).

142. *Sorrell*, 131 S. Ct. at 2666.

143. Amended Complaint for Declaratory and Injunctive Relief at 2, *IMS Health, Inc. v. Sorrell*, 631 F. Supp. 2d 434, 451 (D. Vt. 2009) (No. 1:07 Civ. 00220), 2008 WL 7311222.

144. *Sorrell*, 131 S. Ct. at 2666. The regulation in *United Reporting* required parties interested in the information to qualify for the information; the plaintiffs did not even attempt to qualify and invoked a facial challenge without suffering an injury. *Id.*

145. *Id.* at 2666–67.

146. *Id.* at 2667; see also *IMS Health, Inc. v. Ayotte*, 550 F.3d 42, 53 (1st Cir. 2008) (reasoning that the Vermont Act regulates "the ability of data miners to aggregate, compile, and transfer information," which is "a restriction on the conduct, not the speech, of data the miners").

purchasing or using ink.”¹⁴⁷ Where the lower courts viewed the sale of prescriber-identifying information as akin to the sale of “cookbooks, laboratory results, or train schedules,” the Supreme Court upheld the precedent that the sale of prescriber-identifying information was the creation and dissemination of information and therefore speech within the meaning of the First Amendment.¹⁴⁸

Vermont’s restrictions on the availability and use of prescriber-identifying information imposed content and speaker based restrictions on speech, specifically singling out detailers and pharmaceutical marketing as targets of the prohibition.¹⁴⁹ As such, heightened scrutiny was warranted and Vermont had to show that the Vermont Act directly advanced a substantial governmental interest and the measure was drawn to achieve that interest.¹⁵⁰

The Court generalized Vermont’s justifications for the Vermont Act as “necessary to protect medical privacy,” including doctor-patient confidentiality, and “integral to the achievement of policy objectives,” specifically improved public health and reduced health care costs.¹⁵¹ The Court found that neither justification withstood heightened scrutiny because both rationales hinged on “a difference of opinion” between the detailers and the State, and a state cannot quiet speech or burden messengers solely on this basis.¹⁵²

The Court contended that Vermont’s stated purpose of protecting physician privacy did not justify the Vermont Act because pharmacies could still share prescriber-identifying information with anyone and for any reason except to detailers or for marketing purposes.¹⁵³ Had Vermont advanced its legitimate interest in protecting patient and doctor confidentiality by allowing prescriber-identifying information disclosures in narrow and well-justified circumstances, then the Vermont Act would be justified.¹⁵⁴ As it currently stood, however, the Vermont Act explicitly disfavored a specific purpose and speaker, and this burden was not justified by the State.¹⁵⁵

Similarly, Vermont’s purpose to advance public policy goals by lowering health care costs and promoting public health were legitimate, but the Vermont Act

147. *Sorrell*, 131 S. Ct. at 2667.

148. *Id.* at 2666–67; *see also* *Bartnicki v. Vopper*, 532 U.S. 514, 527 (2001) (noting that it is “hard to imagine” what would constitute speech if disclosing and publishing information are “expressive conduct” and not speech) (quoting *Bartnicki v. Vopper*, 200 F.3d 109, 120 (3d Cir. 1999)).

149. *Sorrell*, 131 S. Ct. at 2667.

150. *Id.* at 2667–68.

151. *Id.* at 2668.

152. *Id.* at 2671–72 (“That the State finds expression too persuasive does not permit it to quiet the speech or to burden its messengers.”).

153. *Id.* at 2668.

154. *Id.* (comparing HIPAA, which only allows disclosures in a few instances, with the Vermont Act, which allows disclosures for all instances save pharmaceutical detailing).

155. *Id.*

improperly advanced these goals in an indirect way.¹⁵⁶ The Vermont Act restricted prescriber-identifying information from being sent to data miners so that data miners could not transfer the information to pharmaceutical manufacturers to prevent the pharmaceutical manufacturers from using the information for marketing purposes, which “cannot be said to advance the state’s interests . . . in a direct and material way.”¹⁵⁷ The Court also found the Vermont Act’s restrictions to be especially suspect because the pharmaceutical marketing at issue contains truthful information and the audience, prescribing physicians, are “sophisticated and experienced” consumers, many of whom found detailing helpful because the marketing pitch was directed at the physician’s specific practice.¹⁵⁸

The Court invalidated the Vermont Act as an unconstitutional restriction on commercial speech because the use of prescriber-identifying information for marketing was speech and the Vermont Act failed the requisite heightened scrutiny analysis.¹⁵⁹ The dissent, however, disagreed with the application of First Amendment heightened scrutiny analysis by reasoning that the Vermont Act’s “effect on expression . . . is a lawful governmental effort to regulate a commercial enterprise.”¹⁶⁰

The dissent, written by Justice Breyer and joined by Justices Ginsburg and Kagan, applied the *Glickman v. Wileman Bros. & Elliott, Inc.*¹⁶¹ standard of giving significant weight to legitimate commercial regulatory objectives,¹⁶² noting that the Court normally gives leniency to legislative judgment for commercial or regulatory legislation that indirectly affects commercial speech.¹⁶³ The dissent also disagreed with the application of the heightened scrutiny analysis because precedent dictates that “sales practices” that are “misleading, deceptive, or aggressive” lack a

156. *Id.* at 2670; *see also* *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 566 (1980) (explaining that the act at issue must advance the government interest in a direct way).

157. *Sorrell*, 131 S. Ct. at 2670 (discussing the Second Circuit’s decision).

158. *Id.* at 2671–72. The Court emphasized that “open channels of communication” and making information available, as opposed to suppressing information that may be harmful, helps physicians and lawyers alike make informed decisions as to what is in their best interest. *Id.* at 2671.

159. *Id.* at 2672.

160. *Id.* at 2673.

161. 521 U.S. 457, 469–77 (1997) (holding that Department of Agriculture regulations requiring California tree-fruit growers to finance generic advertising as part of a program for collective action in the tree-fruit market did not violate the First Amendment because the marketing orders did not restrain the growers’ speech, did not compel the growers to engage in speech, and did not compel the growers to endorse political views).

162. *Sorrell*, 131 S. Ct. at 2673. The *Glickman* Court performed a searching analysis of the regulatory objectives and explained, “[w]hether the benefits from the advertising justify its cost is a question that not only might be answered differently in different markets, but also involves the exercise of policy judgments that are better made by producers and administrators than by judges.” *Glickman*, 521 U.S. at 476.

163. *Sorrell*, 131 S. Ct. at 2674; *Glickman*, 521 U.S. at 475–77 (finding that the *Central Hudson* heightened scrutiny test places too high a burden on the marketing regulation at issue and explaining that the courts should respect Congress’s power to regulate commerce).

heightened level of protection.¹⁶⁴ Under this deferential approach, the dissent found the Vermont Act a lawful exercise of state regulatory power which advanced the legitimate state interests of protecting public health, reducing health care spending, and protecting patient and physician privacy.¹⁶⁵

IV. ANALYSIS

Maryland was among the states that contemplated an act similar to the Vermont Act.¹⁶⁶ In light of the *Sorrell v. IMS Health* ruling, this bill should not be revived because only futile, toothless revisions would survive judicial review under the heightened scrutiny approach to analyzing commercial speech regulations. To promote its interests in protecting the general welfare and reducing “spiraling costs”¹⁶⁷ of health care, Maryland can continue, and perhaps strengthen, its current measures of encouraging pharmacies to dispense generic drugs and curbing prescription drug abuse.¹⁶⁸ Maryland should also develop an educational “counter-detailing” program to teach physicians about the benefits of generic drugs.¹⁶⁹

A. Maryland Should Not Attempt to Revise or Revive the Prescription Privacy Act

Maryland should not attempt to revise or revive the Maryland Prescription Privacy Act, hereinafter the “Maryland Act,” proposed in 2007,¹⁷⁰ because the *Sorrell* Court explicitly held it unconstitutional to statutorily bar pharmaceutical marketers from gaining access to patient and prescriber information and using that information for brand-name pharmaceutical detailing purposes.¹⁷¹ Any revisions to the Maryland Act would be futile because the intended effect of the Maryland Act was to stop the unauthorized use of personal information by pharmaceutical

164. *Sorrell*, 131 S. Ct. at 2674–75 (citations omitted). The dissent does not explicitly state that pharmaceutical marketing is misleading or aggressive but relies on the “reasonableness of the legislature’s belief in the existence of evils.” *Id.* at 2675.

165. *Id.* at 2681–83.

166. See Heesters, *supra* note 19, at 815 (reporting that Arizona, Illinois, Kansas, Massachusetts, Nevada, New York, Rhode Island, Texas, Washington, and West Virginia also considered bills to restrict data mining firms from having access to certain health care information).

167. See Brief for Maryland et al., as Amici Curiae Supporting Petitioners at 1, Nat’l Fed’n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566 (2012) (No. 11-398) (addressing the Minimum Coverage Provision of the recently passed Patient Protection and Affordable Care Act and noting that “spiraling costs” are among the “extraordinary problems associated with the current system of healthcare delivery in the United States”).

168. See *infra* Part IV.B.1–2.

169. See *infra* Part IV.B.3.

170. Maryland Prescription Privacy Act, S.B. 266, 423d Gen. Assemb., Reg. Sess. (Md. 2007) (attempting to prohibit the transfer of prescriber or patient information on a prescription).

171. *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2663 (2011) (explaining that courts can consider the statute’s language on its face, practical effects, and stated purpose when evaluating its constitutionality).

marketers,¹⁷² and the Supreme Court found that the practical effect of such a law is to restrict speech in violation of the First Amendment.¹⁷³

Any legislative attempt to prevent only marketers from obtaining prescriber information, regardless of whether the statute explicitly prohibits or has the practical effect of restricting pharmaceutical marketing speech, would be an unconstitutional restraint on commercial speech, preventing Maryland and other States from passing such acts.¹⁷⁴ The Maryland Act does not contain language similar to the Vermont Act's explicit prohibition of pharmaceutical manufacturers and pharmaceutical marketers from using prescriber-identifying information for marketing prescription drugs unless the prescriber consents,¹⁷⁵ but the usefulness and effectiveness of such an act rests on its ability to prevent pharmaceutical marketers from using the information for detailing purposes. The *Sorrell* Court noted that pharmaceutical manufacturers are "essentially the only paying customers of the data vendor industry,"¹⁷⁶ therefore the Vermont Act had the effect of "preventing detailers—and only detailers—from communicating with physicians."¹⁷⁷ Even without similarly explicit language, the Maryland Act would likely be found unconstitutional for having the purpose and practical effect of singling out pharmaceutical manufacturer and marketer speech, regardless of whether or not the act blatantly excluded data miners and detailers from accessing and using the information for marketing purposes.¹⁷⁸

The proposed Maryland Act would prohibit pharmacies and "data transfer intermediaries" from transferring prescriber-identifying information unless no payment is received and the recipient is the patient, the prescribing or treating physician, a government inspector using the information for official business or law enforcement, a person authorized by court order, a researcher with written authorization signed by the patient, another pharmacy for the limited purpose of

172. The Maryland Act's stated purpose is "prohibiting the transfer by certain persons of information that identifies a specific prescriber or patient on a prescription," but, like the Vermont Act, it allows all conceivable interested parties access to prescriber-identifying information except data miners and detailers. Md. S.B. 266.

173. *Sorrell*, 131 S. Ct. at 2672 (finding that Vermont enacted the Vermont Act for the purpose of burdening pharmaceutical marketing which that state "found too persuasive").

174. *Id.* at 2663, 2672 (noting that content-based restrictions are sometimes permissible, but not, as here, when the government fails to show the law has a neutral justification).

175. VT. STAT. ANN. tit. 18, § 4631(d) (2012), *invalidated by Sorrell*, 131 S. Ct. 2653 ("Pharmaceutical manufacturers and pharmaceutical marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents."). The Maryland Act lacks this explicit prohibition, but it does effectively prevent only data miners and detailers from accessing prescriber-identifying information which would almost certainly be used for detailing purposes. Md. S.B. 266.

176. *Sorrell*, 131 S. Ct. at 2663 (quoting the District Court decision below).

177. *Id.* at 2663.

178. *Id.* at 2663–64 ("Even if the hypothetical measure on its face appeared neutral as to content and speaker, its purpose to suppress speech and its unjustified burdens on expression would render it unconstitutional.").

preventing falsified prescription forms, or the patient's insurer for reimbursement purposes.¹⁷⁹ Violators of the Maryland Act are punishable by fines of up to \$25,000 and three years of imprisonment.¹⁸⁰ The Maryland Act practically, although not explicitly, prevents only pharmaceutical manufacturers and marketers from using the information because virtually no other party would want or need it. Because the practical effect of the law is to target a specific group whose speech the government disfavors, the Maryland Act would be found unconstitutional.

Maryland also cannot revise the Act to create a more narrowly tailored approach to protect medical privacy.¹⁸¹ The *Sorrell* Court noted that the Vermont Act may have been upheld if it allowed disclosure in only a few instances, similar to the design of the federal Health Insurance Portability and Accountability Act (HIPAA), as opposed to Vermont's approach of forbidding access to and use of information by a specific industry wishing to convey a specific message.¹⁸² Attempts to protect patient privacy would likely be ineffective because (1) the law would be a redundant affirmation of current privacy laws at best,¹⁸³ and (2) current data mining practices already encrypt patient identifying information.¹⁸⁴ Adjusting the statute to protect prescribing-physician is also likely to be impractical because the *Sorrell* Court found that prescriber-identifying information is accessible to a number of other parties, including "insurers, researchers, journalists, and the State itself;" unless Maryland is willing to significantly limit the availability of prescriber-identifying information to all of these parties, then the modified statute would likely still be struck down for solely targeting a specific speaker with a specific message.¹⁸⁵

179. Md. S.B. 266.

180. *Id.*

181. *Sorrell*, 131 S. Ct. at 2668 (explaining that the Vermont Act was not drawn to serve the privacy interest, as evidenced by the legislative history, language, and practical effect of the Act).

182. *Id.*

183. See e.g. MD. CODE ANN., HEALTH-GEN. § 4-301 (2009) (regulating the confidentiality of medical records in Maryland); MD. CODE ANN., HEALTH OCC. § 12-403(18) (2009) (promulgating that pharmacies can keep records of prescriptions requested to be filled but must keep the patient's social security number, illness, condition, and type of drug confidential). In addition, the Maryland Act did not create a significant financial benefit for Maryland. DEP'T OF LEGISLATIVE SERVS., FISCAL & POLICY NOTE, S. 423-266, Reg. Sess. (Md. 2007), available at http://mgaleg.maryland.gov/2007RS/fnotes/bil_0007/sb0277.pdf (noting that fiscally, the effect of the Act would be "none").

184. See *infra* Part I.A (discussing the privacy implications of data mining and detailing).

185. But see Jeff Gibellina, *Legislating Around the Supreme Court's Holding that Prescriber-Identifying Data is Commercial Speech*, 14 DEPAUL J. HEALTH CARE L. 341, 354-55 (2012) (arguing that the Vermont Act was narrowly tailored to protect prescriber privacy and that the Court "grossly overstated the accessibility of prescriber-identifying information outside of detailers").

B. To Battle Increasing Prescription Drug Costs, Maryland Should Bolster Current Measures and Educate Prescribing Physicians About the Benefits of Generic Drugs

1. Maryland Should Continue to Encourage Generic Drug Use

Rather than pursuing modifying the Maryland Act, Maryland should focus on continuing, and strengthening, the Maryland Pharmacy Act's encouragement of generic drug use.¹⁸⁶ The Maryland Pharmacy Act requires pharmacists to inform consumers about the availability of a generic drug and the approximate cost difference as compared to the brand-name drug.¹⁸⁷ Section 12-504(c) of the Maryland Pharmacy Act allows a pharmacist to substitute a generic drug for a brand-name drug unless the prescribing physician affirmatively indicates that the brand-name drug must be prescribed.¹⁸⁸ Generic medical devices may also be substituted for brand-name devices.¹⁸⁹

Encouraging the use of generic drugs over brand-name prescription drugs saves a significant amount of money because the retail price of a generic drug is, on average, seventy-five percent less than the retail price of a brand-name drug.¹⁹⁰ In a study completed by IMS Health for the Generic Pharmaceutical Association, it was found that generic substitution saved the U.S. health care system over \$1 trillion between 1999 and 2010, with \$157 billion saved in 2010 alone.¹⁹¹ Maryland should continue encouraging the use of generic drugs over brand-name drugs when possible because this data proves that using generic drugs saves government money.¹⁹²

186. Maryland Pharmacy Act, MD. CODE ANN., HEALTH OCC. § 12-101 (2009) (regulating the pharmacy-related occupations, prescription drugs, and the acts involved with filling prescriptions).

187. § 12-504(b)(1).

188. *See* *Pediamed Pharms., Inc., v. Breckenridge Pharm., Inc.*, 419 F. Supp. 2d 715, 720 (D. Md. 2006) (noting that a pharmacist may substitute a lower priced generic equivalent for the brand-name drug unless the prescribing physician affirmatively indicates that the prescription is to be dispensed as written).

189. § 12-504(d).

190. CONG. BUDGET OFFICE, *EFFECTS OF USING GENERIC DRUGS ON MEDICARE'S PRESCRIPTION DRUG SPENDING* 8–9 (2010) (noting that this statistic is based on the National Association of Chain Drug Stores nationwide average of prescription drug costs in 2007).

191. GEN. PHARM. ASS'N, *SAVINGS: AN ECONOMIC ANALYSIS OF GENERIC DRUG USAGE IN THE U.S.* 1, 3, 5 (2011), *available at* <http://patentdocs.typepad.com/files/gpha-ims-study-web-sep20-11.pdf> (highlighting that “a greater reliance on the use of generic drugs” is one method states can use to reduce government overspending in Medicare and Medicaid). *See generally* Letter from John E. Dicken, Dir., Health Care, U.S. Gov't Accountability Office, to Sen. Orrin G. Hatch, Ranking Member, Comm. on Fin. (Jan. 31, 2012) (on file with author) (giving a summary of similar studies on savings generated by generic drug use and substitution).

192. *See* Duff Wilson, *Generic Drug Savings Promoted by Industry Group*, N.Y. TIMES (Sept. 21, 2011), <http://prescriptions.blogs.nytimes.com/2011/09/21/generic-drug-savings-promoted-by-industry-group/> (noting that over \$931 billion was saved by consumers and the government over the past decade from using generic drugs).

Maryland's efforts to encourage generic drug use are supplemented by federal efforts to encourage generic drug use.¹⁹³ In July 2011, the Affordable Medicines Utilizations Act was introduced by Senator Scott Brown of Massachusetts in Congress to encourage States to utilize generic drugs in State Medicaid programs and for other uses.¹⁹⁴ The National Association of Chain Drug Stores (NACDS) supports the Affordable Medicines Utilizations Act as a way to reduce health care costs and ensure that Medicaid patients have continued access to affordable treatment.¹⁹⁵

Another recently proposed federal measure to encourage generic drug use is the Generic Drug User Fees program initiated by the FDA in January 2012.¹⁹⁶ The program amendments proposed would charge application fees to drug manufacturers for review of traditional drugs, generic drugs, and new generic biotech drugs in order to address the backlog of generic drug applications awaiting FDA approval.¹⁹⁷ The Generic Drug User Fees program is designed to generate additional revenue that the FDA can use to hire more staff and improve systems to support the generic drug review process, with the goal being to improve the average review time of generic drugs from thirty months to ten months, the same amount of time it takes to review new drugs.¹⁹⁸ Combined with these recent federal efforts, Maryland's efforts to encourage generic drug use as a cost containment measure may continue to slow increasing health care costs.

2. *Maryland Should Continue Programs to Combat Drug Abuse*

Curbing prescription drug abuse is essential to societal wellbeing as well as cost control. For example, prescription drug abuse cost the U.S. economy \$180.9 billion in 2002.¹⁹⁹ This economic cost translated into \$15.8 billion spent on substance abuse-related health care spending in the same year.²⁰⁰

193. See, e.g., Brief of the United States as Amici Curiae in Support of Petitioners, Caraco Pharm. Lab., Ltd. v. Novo Nordisk A/S, 601 F.3d 1359 (E. D. Mich. 2010) (No. 10-844) (arguing that brand-name drug patents that contain inaccuracies should be able to be efficiently challenged to prevent delay of FDA approval of generic drugs).

194. Affordable Medicines Utilization Act of 2011, S. 1356, 112th Cong. (2011). This proposed act encourages generic drug use without restricting brand-name drug manufacturer or marketer speech, thus it likely does not raise First Amendment implications. *Id.*

195. See John Schultz, *NACDS Backs Bill to Spur Generics Use in Medicaid*, CHAIN DRUG REV., Nov. 21, 2011, at 6 (noting that seventy percent of Medicaid prescriptions are filled by chain pharmacies).

196. Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, §§ 301–08, 126 Stat. 993, 1008–26 (referred to as the “Generic Drug User Fee Amendments of 2012”).

197. See Matthew Perrone, *FDA Unveils User Fee Program For Generic Drugs*, USA TODAY, Jan. 13, 2012, <http://usatoday30.usatoday.com/news/health/healthcare/health/healthcare/story/2012-01-13/FDA-unveils-user-fee-program-for-generic-drugs/52538458/1>.

198. *Id.*

199. OFFICE OF NAT'L DRUG CONTROL POLICY, EXECUTIVE OFFICE OF THE PRESIDENT, PUB. NO. 207303, THE ECONOMIC COSTS OF DRUG ABUSE IN THE UNITED STATES: 1992–2002 vii (2004). “Economic cost” was divided into three major components: (1) health care, including the use of

In Maryland, prescription drug abuse admissions to the Alcohol and Drug Abuse Administration-funded treatment programs doubled between the fiscal years of 2007 and 2011, reflecting a prescription drug abuse problem that needed attention for public health and cost reasons.²⁰¹ In 2011, the Maryland legislature proposed the Prescription Drug Monitoring Program, a program designed to help medical professionals identify prescription drug abuse by monitoring the prescribing and dispensing of commonly abused prescription drugs.²⁰² This program seeks to prevent drug abusers from exploiting the prescription system, which lacks integration and tracking capabilities, thus allowing drug abusers to solicit different physicians and pharmacies in pursuit of prescription drugs.²⁰³ Under the new program, prescription drug dispensers electronically submit data whenever a monitored prescription drug is dispensed.²⁰⁴

The results of similar programs in other states are encouraging.²⁰⁵ For example, a similar Wyoming program resulted in reduced costs related to prescriptions, addiction, and abuse because prescription monitoring reports reduced the availability of prescription drugs to “doctor shopping” patients.²⁰⁶ Also, prescription monitoring programs led to reduced costs of law enforcement related to drug abuse in Nevada and Maine, and reduced the drug diversion investigation time in Kentucky.²⁰⁷ By instituting a prescription monitoring program, Maryland will similarly be able to reduce costs related to prescription drug use and abuse.²⁰⁸

In a similar vein, Corrective Managed Care programs are another way that Maryland can battle prescription drug abuse and overuse.²⁰⁹ Part of Maryland's

resources to address the health consequences of drug abuse, (2) lost productivity due to disability, death, and withdrawal from the workforce, and (3) other impacts, notably criminal justice consequences. *Id.* at III-1.

200. *Id.* at IV-1. This data was compiled by the Centers for Medicare and Medicaid Services. *Id.*

201. MD. DEP'T. OF HEALTH & MENTAL HYGIENE, A COMPREHENSIVE APPROACH TO PRESCRIPTION DRUG ABUSE AND DIVERSION: PRESCRIPTION DRUG MONITORING PROGRAM FACTSHEET 1 (2011).

202. Prescription Drug Monitoring Program, S.B. 883, 428th Gen. Assemb., Reg. Sess. (Md. 2011). The program was posted in the Maryland Register for public comment. 39 Md. Reg. 801–06 (June 29, 2012).

203. J. JOSEPH CURRAN, JR., MD. OFFICE OF THE ATT'Y GEN., PRESCRIPTION FOR DISASTER: THE GROWING PROBLEM OF PRESCRIPTION DRUG ABUSE IN MARYLAND 21–22 (2005), available at <http://www.oag.state.md.us/Reports/PrescriptionDrugAbuse.pdf>.

204. Md. S.B. 883.

205. See ALLIANCE OF STATES WITH PRESCRIPTION MONITORING PROGRAMS, <http://www.pmpalliance.org/> (last visited Apr. 17, 2013) (compiling information on prescription monitoring programs in forty-eight states and one territory).

206. See PRESCRIPTION MONITORING PROGRAM CTR. OF EXCELLENCE, BRIEFING ON PMP EFFECTIVENESS 3 (2011), available at http://pmpexcellence.org/sites/all/pdfs/pmp_effectiveness_brief_final.pdf.

207. *Id.* at 4.

208. See *Maryland State Profile*, ALLIANCE OF STATES WITH PRESCRIPTION MONITORING PROGRAMS, <http://www.pmpalliance.org/content/maryland-state-profile> (last visited Apr. 17, 2013).

209. See MD. MEDICAID PHARM. PROGRAM, MD. DEPT. OF HEALTH & MENTAL HYGIENE, ADVISORY: CORRECTIVE MANAGED CARE PROGRAM AND MISUSE OF CONTROLLED SUBSTANCES

Medicaid program, Corrective Managed Care programs target Medicaid recipients determined by the Department of Health and Mental Hygiene to have abused the prescription drug services provided by Medicaid.²¹⁰ These recipients must obtain all services from a single primary medical provider and can only obtain prescription drugs from a single designated pharmacy provider.²¹¹ The purpose of the program is to ensure recipients get the medications they need without overusing controlled substances.²¹²

Curbing prescription drug abuse also reduces other health care costs to the State.²¹³ In addition to the cost of the prescription drugs, prescription drug abuse costs include doctor's visits, emergency room treatment, rehabilitation services, and other health care costs.²¹⁴ About one half million hospital emergency visits every year are attributed to prescription drug abuse, making prescription drug abuse an area that demands continued attention when working to reduce health care costs and improve the public welfare.²¹⁵

3. *Maryland Should Initiate an Educational Program to Teach Prescribing Physicians About the Benefits of Generic Drugs*

Because Maryland cannot silence pharmaceutical detailers due to the *Sorrell v. IMS Health*²¹⁶ decision, Maryland should join the discussion and launch a marketing program of its own. Vermont originally created such a “counter-detailing”²¹⁷ program in the Vermont Act, granting the Vermont Department of Health authority to establish “an evidence-based prescription drug education program for health care professionals designed to provide information and education on the therapeutic and cost-effective utilization of prescription drugs to

(2011), available at http://mmcp.dhmh.maryland.gov/pap/docs/Advisory_94.pdf (advising the Medicaid community about the new Corrective Managed Care Program); *Corrective Managed Care*, MD. MEDICAID PHARMACY PROGRAM, <http://www.emdhealthchoice.org/mpap/correctivecare.htm> (last visited Apr. 17, 2013) (briefly explaining the program and providing referral forms to keep a recipient “locked-in” to one particular pharmacy).

210. MD. CODE REGS. 10.09.24.14-1 (2012).

211. *Id.*

212. *Corrective Managed Care*, *supra* note 209.

213. Ctr. for Program Integrity, *Drug Diversion in the Medicaid Program: State Strategies for Reducing Prescription Drug Diversion in Medicaid*, CTR. FOR MEDICARE & MEDICAID SERVS. 1 (Jan. 2012), <https://www.cms.gov/MedicaidIntegrityProgram/Downloads/drugdiversion.pdf> (noting that “drug diversion,” a form of prescription drug abuse involving the use of licit drugs for illicit purposes, is often associated with high cost prescription antipsychotic and mental health drugs).

214. *Id.*

215. *Model Initiatives: Restraining Prescription Drug Costs*, DEMOCRATIC LEADERSHIP COUNCIL (June 30, 2008), http://www.dlc.org/ndol_ci6496.html?kaid=139&subid=275&contentid=253949. This statistic refers to nationwide hospital visits and is not Maryland-specific. *Id.*

216. 131 S. Ct. 2653, 2671–72 (2011).

217. “Counter-detailing” is defined as, “[a]ny effort by managed care organizations to control drug costs by educating prescribing physicians on less expensive equivalent or generic alternatives. J. C. SEGAN, *CONCISE DICTIONARY OF MODERN MEDICINE* (2006).

physicians, pharmacists, and other health care professionals authorized to prescribe and dispense prescription drugs.”²¹⁸ This aspect of the Vermont Act was not challenged, and the legislative action creating the program became effective in July 2011.²¹⁹ Maryland should follow Vermont’s example and create a counter-detailing program of its own.

Counter-detailing is also known as “academic detailing” because the purpose of the marketing program is to educate physicians about the pharmaceutical marketplace, not to promote the brand-name drug produced by the manufacturer that the detailer works for.²²⁰ Academic detailing is designed to counter the biased information presented by detailers, and this “noncommercial education of health professionals” is typically given by physicians, pharmacists, nurses, or other health professionals.²²¹ Currently, the Agency for Healthcare Quality and Research (AHQR), part of the U.S. Department of Health and Human Services (HHS), is spending \$300 billion on an Academic Detailing Initiative.²²² Part of AHQR’s initiative is signing three-year contracts with organizations to perform counter-detailing programs while AHQR studies program effectiveness.²²³ Although this comprehensive study is not yet completed, Maryland should join AHQR, Vermont, and other states²²⁴ in similar efforts to educate physicians because there is a need for physicians to learn unbiased information.²²⁵

Maryland needs a counter-detailing program to educate physicians, who lack the time to research the pharmaceutical market and consequently may rely on information presented by detailers.²²⁶ Following the Vermont example, Maryland’s

218. VT. STAT. ANN. tit. 18, § 4622(a)(1) (2012).

219. *Id.*

220. See Mike Mitka, *New Physician Education Initiatives Seek to Remove the Devil from the Detailing*, 306 JAMA 1187, 1187 (2011).

221. *Id.*

222. *Id.*

223. *Id.*

224. The District of Columbia, Idaho, Maine, Massachusetts, New Hampshire, New York, Oregon, Pennsylvania, and South Carolina all have academic detailing programs. WELLS WILKINSON, COMMUNITY CATALYST, INDEPENDENT PRESCRIBER EDUCATION FUNDED THROUGH PRESCRIPTION DRUG SETTLEMENTS 3 (2010), available at http://www.prescriptionaccess.org/docs/Funding_Prescriber_Education_thru_Settlements.pdf.

225. Pennsylvania found that reminding doctors that Nexium often has equally effective generic alternatives saved the State \$572,000 a year on acid-reflux drug costs. See Thornburgh, *supra* note 27. South Carolina has a similar counter-detailing program called SCORxE, which is a joint program between the South Carolina College of Pharmacy and the State Medicaid Program. See Thornburgh, *supra* note 27.

226. See 2007 Vt. Acts & Resolves No. 8 (finding physicians rely on marketing campaigns presented by pharmaceutical manufacturers because they lack the time to research and assess whether these campaigns present full and accurate information). Physicians may also be motivated by financial gain. Thirty-seven percent of Maryland internists surveyed in a 2004 study by the Journal of General Internal Medicine reported that they engaged in pharmaceutical sponsored clinical trials and/or lectures to supplement their incomes. See Thomas L. Hafemeister et al., *Beware Those Bearing Gifts: Physicians’ Fiduciary Duty to Avoid Pharmaceutical Marketing*, 57 U. KAN. L. REV. 491, 498 (2009).

counter-detailing educational program should involve collaboration between the Department of Health and Mental Hygiene and the University of Maryland Medical System to develop a drug education program.²²⁷ The focus of the program should be to notify prescribers about soon-to-expire and recently expired patents on commonly used brand-name drugs.²²⁸ The information provided must be supported by evidence and independent research of the effectiveness of the drugs.²²⁹

Awards from suits brought by the Attorney General against pharmaceutical manufacturers may be used to fund the counter-detailing program.²³⁰ Funds arising from lawsuits could take two distinct forms: (1) explicitly allocated funds from lawsuits alleging illegal promotion charges, such as off-label promotions, as a corrective remedy for the illegal conduct on behalf of pharmaceutical manufacturers, or (2) residual funds from class action settlements.²³¹ For example, a 2004 lawsuit against pharmaceutical manufacturer Warner-Lambert regarding illegal and fraudulent promotion of the drug Neurontin resulted in a \$430 million settlement, \$38 million of which was allocated to fund an academic detailing program to counter the effects of the improper off-label marketing of Neurontin conducted by Warner-Lambert.²³² Maryland prosecutors could similarly find creative ways to structure settlements resulting from lawsuits with pharmaceutical manufacturers to fund counter-detailing programs.

Generic drugs save money for the patient and the State without sacrificing treatment effectiveness, and counter-detailing programs can educate, and remind, physicians about the existence and benefits of generic drugs.²³³ By spending time and money to create and initiate a counter-detailing program, Maryland can help its prescribing physicians understand the pharmaceutical marketplace and make educated, unbiased prescribing decisions.

V. CONCLUSION

Maryland and other States attempted to combat increasing prescription drug costs by using legislation to silence detailers and brand-name pharmaceutical marketing.²³⁴ *Sorrell v. IMS Health*, however, found that state statutes burdening

227. VT. STAT. ANN. tit. 18, § 4622 (2012). The Vermont program involves collaboration between the Vermont Department of Health, the Attorney General, the University of Vermont area health education centers program, and the Department of Vermont Health Access. *Id.*

228. *Id.*

229. *Id.*

230. *Id.*

231. WILKINSON, *supra* note 224.

232. Press Release, Dept. of Justice, Warner-Lambert to Pay \$430 Million to Resolve Criminal and Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004) (on file with author).

233. See Mark E. Greg, *Confessions of a Counter-Detailer*, DRUG TOPICS, Apr. 2011, at 16 (explaining the detailing and pharmaceutical industries from the perspective of a counter-detailer who works with Advocate Physician Partners in Illinois and noting that many prescribing physicians are surprised at how many brand-name prescriptions they wrote).

234. See *supra* Part I.B.

such speech violates the commercial speech doctrine of the First Amendment;²³⁵ therefore such statutes are no longer an option. To reduce prescription drug costs and protect the public health, Maryland should not attempt to revive or revise its version of the Vermont Act because the purpose and practical effect of such an act would be unconstitutional.²³⁶

Maryland should fight increasing prescription drug costs by continuing and strengthening the current measures of encouraging pharmacies to prescribe generic drugs and creating programs to battle prescription drug abuse.²³⁷ In addition, Maryland should create a prescribing-physician “counter-detailing” educational program to teach physicians about the benefits of generic drugs.²³⁸ Maryland cannot silence the biased messages of pharmaceutical detailers, but Maryland can and should join the discussion and teach prescribing physicians about the benefits of generic drug use.²³⁹ Combined with federal efforts to encourage generic drug use, Maryland and other States have an arsenal of tools to battle increasing prescription drug costs.

235. 131 S. Ct. 2653 (2011).

236. Maryland Prescription Privacy Act, S.B. 266, 423d Gen. Assemb., Reg. Sess. (Md. 2007); *see supra* Part IV.A.

237. *See supra* Part IV.B.1–2.

238. *See supra* Part IV.B.3.

239. In addition to proven effectiveness and lowered costs, generic drugs may improve patient compliance with treatment because generic drugs are more affordable for patients. Greg, *supra* note 233.