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## Comments

### **AN ASSAULT ON THE BUSINESS OF PHARMACEUTICAL DATA MINING**

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#### INTRODUCTION

“Data mining” is a term used to describe “the process of discovering interesting patterns in databases that are useful in decision making.”<sup>1</sup> Data mining firms collect information, which is then resold to other companies for use in their business. As competition between firms in all areas of the economy increases, the need “to identify innovative ways to capture and enhance market shares while reducing cost” becomes more important than ever.<sup>2</sup>

Pharmaceutical data mining may be described, in part, as the business of collecting information relating to prescribers’ (e.g. doctors, dentists, and nurse practitioners) prescribing habits. This information is then sold to other companies that use the information in their business. A specific example of this practice entails pharmaceutical data mining companies<sup>3</sup> collecting prescribing data from pharmacies. The data mining companies then distill the data to determine the prescribing patterns of individual

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1. Indranil Bose & Radha K. Mahapatra, *Business Data Mining—A Machine Learning Perspective*, 39 INFO. & MGMT. 211, 211 (2001).

2. *Id.*

3. Pharmaceutical data mining companies prefer to be referred to as “health information publishers,” however, even though this characterization may be more precise, I will refer to them throughout this article as either pharmaceutical data mining firms, or simply data miners. See *IMS Health Corp. v. Rowe*, No. CV-07-127-B-W, 2007 U.S. Dist. LEXIS 94268, at \*3 (D. Me. Dec. 21 2007) (indicating that pharmaceutical data mining companies have a preferred nomenclature of “health information publishers”).

prescribers. Pharmaceutical companies then buy this information, which allow them to better target their sales force.<sup>4</sup> This specific data mining practice proliferated because it has shown great potential to allow pharmaceutical companies to increase their marketing efficiency and ultimately their profits.

As can be imagined, owing to the volatile public image of the pharmaceutical industry<sup>5</sup> coupled with the perceived importance of the privacy of health information by the general public, legislatures have found problems with this business practice. In June 2006, New Hampshire was the first state to pass a statute curbing this practice. The statute provided that “prescription information shall not be used, transferred, licensed, or sold for any commercial purpose.”<sup>6</sup> A sponsor of this bill opined that “[d]rug companies are peering into physician’s brains without any permission from them.”<sup>7</sup> It should be noted that the prescription information that was being bought and resold had no patient identifying features,<sup>8</sup> and that technically once a prescription is filled by a pharmacy it becomes the property of the pharmacy.<sup>9</sup> Furthermore, the data mining companies that purchased this information combined it with data (i.e., prescriber DEA numbers) voluntarily sold to them by the American Medical Association<sup>10</sup> (AMA) in order to “create detailed records on how 700,000 U.S. doctors prescribe any of 10,000 drugs.”<sup>11</sup> Despite the AMA’s acquiescence in this specific data mining practice, the New Hampshire statute became law and attached a possible criminal penalty.<sup>12</sup>

The data mining companies then filed a lawsuit to prevent this intrusion into their business. IMS Health and Verispan LLC contended that their First Amendment Rights were impermissibly restricted. In the first trial considering this issue, *IMS Health v. Ayotte*, the Honorable Judge Paul

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4. NAT’L CONF. OF STATE LEGISLATURES, 28 STATE HEALTH NOTES: VITAL SIGNS FOR POLICYMAKERS (2007), available at <http://www.ncsl.org/print/health/shn/shn496.pdf>.

5. See Doug Bandow, *Demonizing Drug Makers the Political Assault on the Pharmaceutical Industry*, 475 POL’Y ANALYSIS 1, 3 (2003), available at <http://www.cato.org/pubs/pas/pa475.pdf>.

6. See H.B. 1346, 2006 Gen. Court, 159th Sess. (N.H. 2006).

7. STATE HEALTH NOTES, *supra* note 4, at 1.

8. *IMS Health Inc. v. Ayotte*, 490 F. Supp. 163, 165 (D.N.H. 2007).

9. Therefore, because the prescription is not the property of the doctor, it seems unfair to characterize the conduct of the pharmaceutical companies as “peering into physician’s brains.” See *White v. McComb City Drug Co.*, 38 So. 739, 740-41 (Miss. 1905) (indicating that once a prescription has been filled the prescriber no longer has a property right to the prescription).

10. The American Medical Association has a stated mission of “promot[ing] the art and science of medicine and the betterment of public health.” AMA Mission, <http://www.ama-assn.org/ama/pub/category/1815.html>.

11. STATE HEALTH NOTES, *supra* note 4, at 1.

12. N.H. REV. STAT. ANN. § 358-A:6 (2008), available at <http://www.gencourt.state.nh.us/rfa/html/xxxi/358-a/358-a-mrg.htm>.

Barbadoro from the District of New Hampshire agreed, holding that “alternatives exist that would achieve the State’s interest as well as or better without restricting speech.”<sup>13</sup> This was not the end of the controversy. The New Hampshire Attorney General appealed to the First Circuit Court of Appeals, which heard the case during the summer of 2007, and overturned the District Court’s decision by finding that the law regulated “conduct, not speech.”<sup>14</sup>

During the summer of 2007, Maine passed a very similar statute, except that it allowed prescribers to opt out from allowing pharmaceutical companies to use their prescribing information to market their products.<sup>15</sup> IMS Health, Verispan LLC, and Source Healthcare Analytics promptly filed suit claiming a First Amendment violation, which has recently been resolved at the trial court level. Moreover, numerous other states have statutes that similarly restrict the sale of prescription drug data that are currently pending in legislative committees.<sup>16</sup> This issue will likely continue until states find an acceptable legal limit to place upon the data mining companies or a dramatic change in the culture of the medical community occurs.<sup>17</sup>

This comment will primarily focus on the nexus between the legal issues surrounding pharmaceutical data mining and the effect it may have on businesses that are closely connected to this practice, by using the New Hampshire case as the starting point in the analysis. The policy implications of protecting pharmacy related information, along with potential solutions to the perceived data mining problem, will also be discussed.

Part I will discuss data mining in general and the pharmaceutical industry in particular. Part II will discuss the legal issues surrounding data mining. More specifically, Part II will discuss commercial free speech, *IMS Health, Inc. v. Ayotte*, *IMS Health, Inc. v. Rowe*, and some state statutes designed to limit pharmaceutical data mining. Part II will comment on the data mining statutes, the outcome of the aforementioned cases, the potential effects of limiting data mining on pharmaceutical companies and potential Constitutional solutions to the data mining issue.

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13. *Ayotte*, 490 F. Supp. at 183.

14. *IMS Health v. Ayotte*, No. 07-1945, 2008 U.S. App. LEXIS 23701, at \*4 (1st Cir. Nov. 18, 2008).

15. See ME. REV. STAT. tit. 22, § 1711-E, 8704, 8713 (2007).

16. Electronic Privacy Information Center, *Additional State Information*, <http://www.epic.org/privacy/imshealth/>.

17. A “dramatic change in the culture of the medical community” specifically means that prescribers, if they truly do not wish to see pharmaceutical sales representatives, must make it apparent to the pharmaceutical industry by refusing to interact with the pharmaceutical sales representatives.

## I. DATA MINING AND ITS EFFECT ON BUSINESS

Data mining is typically thought of as essential to the modern day consumer-oriented business.<sup>18</sup> However, many other entities besides private firms pay for and use data that is compiled by data mining companies. For instance, the federal government uses data mining techniques to collect information from airlines concerning possible terrorist activity.<sup>19</sup> In fact, in 2000, the Justice Department and the Internal Revenue Service both had contracts with ChoicePoint<sup>20</sup> for at least eight million dollars.<sup>21</sup> Even the American Civil Liberties Union, a group that typically advocates for protection of consumer privacy, has engaged data mining firms to determine characteristics of their donors, such as “an individual’s wealth, holdings in public corporations, other assets, and philanthropic interests.”<sup>22</sup> Private companies also highly value consumer data. As of 2004, Wal-Mart had approximately 460 terabytes<sup>23</sup> of information stored at their Bentonville headquarters.<sup>24</sup> Target also amasses consumer data partly through the use of its proprietary Visa credit card.<sup>25</sup>

The trend towards increasing business efficiency and competitiveness by analyzing information has led to niche companies that provide analysis of the vast reams of data that firms gather throughout the course of their business. The need for this business service has in turn led to production of large profits for data collection and analysis companies. IMS Health, a company whose business model centers around health information, had a

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18. See Stacy Cowley, *Data Mining*, ITWorld.com (Aug. 5, 2005), available at <http://www.itworld.com/App/110/050805datamining/> (indicating that consumer focused companies with sizable caches of information on current and future customers, such as Wal-Mart and pharmaceutical companies, use data mining technology).

19. See Drew Shenkman, Comment, *Flying the Not-so-private Skies: How Passengers' Personal Information Privacy Stopped At The Airplane Door, And What (If Anything) May Be Done To Get It Back*, 17 ALB. L.J. SCI. & TECH. 667, 668-69 (2007).

20. ChoicePoint is a firm that “provides information, analysis and distribution solutions to advance the efforts of law enforcement, public safety, healthcare, child support enforcement, entitlement and other public agencies.” ChoicePoint, <http://www.choicepoint.com> (last visited May 11, 2009).

21. Daniel J. Solove, *Access and Aggregation: Public Records, Privacy and the Constitution*, 86 MINN. L. REV. 1137, 1151 (2002).

22. See Stephanie Strom, *A.C.L.U.'s Search for Data on Donors Stirs Privacy Fears*, N.Y. TIMES, Dec. 18, 2004, at A1 (noting that “the American Civil Liberties Union is using sophisticated technology to collect a wide variety of information about its members and donors in a fund-raising effort that has ignited a bitter debate over its leaders' commitment to privacy rights”).

23. For perspective, personal computers typically contain approximately 1-3 gigabytes, whereas, a single terabyte is 1 trillion bytes or 1000 gigabytes.

24. Constance Hays, *What They Know About You*, N.Y. TIMES, Nov. 14, 2004, at BU1.

25. *Id.*

revenue of \$1.96 billion in 2006;<sup>26</sup> ChoicePoint, which is a diversified data mining company, had a revenue of \$1.1 billion.<sup>27</sup> Furthermore, QForma Inc., a small start-up data collection company, has grown from a revenue of \$40,000 in 2000 to \$2.1 million in 2004.<sup>28</sup> In fact, the chairman of QForma noted that he has “12 large pharmaceutical companies as clients, up from two years ago.”<sup>29</sup> Moreover, as data mining technology advances and provides more accurate information, consumer sales companies such as Wal-Mart may benefit by instituting efficiency measures, such as scan based training.<sup>30</sup> Scan based training, which would represent a possible apex of efficiency, is a form of just-in-time product distribution, where Wal-Mart could theoretically make manufacturers of the products that they sell keep the cost of the products with their company until the product is sold. Therefore, Wal-Mart would “never take those products onto its books,” and decrease approximately “\$50 billion of inventory.”<sup>31</sup> This would be possible, in part, due to the business efficiencies that data-mining produces.

Data mining not only produces business efficiencies, but it protects them as well. For example, by using data including 911 calls, police reports, neighborhood demographics, weather, traffic patterns, and the timing of sporting events, the Richmond police department was able to decrease robberies at payday check cashing stores.<sup>32</sup> Moreover, Capital One<sup>33</sup> uses data mining techniques to prevent fraudulent transactions,<sup>34</sup> and Harrah’s Casino uses it to identify people with criminal records.<sup>35</sup>

Data mining functions by employing what is generically known as “business intelligence software.”<sup>36</sup> Firms that are in the business of selling

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26. See IMS HEALTH, 2006 ANNUAL REPORT 5 (2007) (indicating that 1.96 billion was a twelve percent increase over the previous year).

27. See CHOICEPOINT, 2006 ANNUAL REPORT 3 (2007) (indicating that 1.1 billion was a four percent increase over the previous year).

28. Kevin Robinson-Avila, *Data Mining Firm Digs Roots in Pharmaceutical Industry*, N.M. BUS. WKLY., Dec. 15, 2006, available at <http://albuquerque.bizjournals.com/albuquerque/stories/2006/12/18/story11.htm>.

29. *Id.*

30. Hays, *supra* note 24.

31. *Id.*

32. See 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 institution of data mining techniques).

33. Capital One is a major banking corporation with \$178.6 million of revenue in 2006. See CAPITAL ONE, 2006 ANNUAL REPORT 8 (2007).

34. See Lohr, *supra* note 32.

35. *Id.*

36. Business intelligence (BI) software includes the computer programs and algorithms that are used to find correlations in the data that company’s collect. “Many products claim BI capabilities, but the end goal is to let users slice and dice the information from their organization’s numerous databases without having to wait for their IT departments to

“business intelligence software” are considered “one of the hot markets in technology.”<sup>37</sup> In fact, Microsoft has entered the business intelligence market,<sup>38</sup> and Oracle offered \$3.3 billion for Hyperion, which produces business intelligence software.<sup>39</sup>

These are just a few of the examples of the effect that data mining is having on business and economics. Data mining is becoming so pervasive in business that it has been noted that the only reason a company would not employ data mining techniques is if the executives do not understand its necessity.<sup>40</sup>

It is obvious that data mining is revolutionizing how businesses compete. Moreover, it is imperative that U.S. businesses be allowed to compete in an increasingly global marketplace and not be stifled by unneeded, over-reaching statutes, which increase inefficiencies without remedying the underlying problems that they were intended to solve. This is especially true in the pharmaceutical industry.

#### A. *Data Mining in the Pharmaceutical Industry*

It is estimated that every time a pharmaceutical sales representative visits a physician office it costs between \$100-\$150, without factoring in any free fringe benefits given to the physicians.<sup>41</sup> \$1.2 billion was spent on direct-to-consumer advertising for the first 11 months of 1998 alone.<sup>42</sup> These expenditures coupled with research and development costs<sup>43</sup> and the perceived failure of pharmaceutical companies to produce “blockbuster” drugs,<sup>44</sup> implies that efficient marketing strategies are highly sought after.

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develop complex queries.” The Free Online Encyclopedia, <http://encyclopedia2.thefreedictionary.com/BI+software>.

37. Lohr, *supra* note 32.

38. *Id.*

39. *Id.*

40. *Id.* (quoting *Competing on Analytics: The New Science of Winning* (Harvard Business School Press, 2007) as stating that data mining is “mainstream” and that “[t]he entry barrier . . . ‘is no longer technology, but whether you have executives who understand this’”); *see also id.* (indicating that “most companies now have the tools to do the kind of competitive analytics that only a relative handful of elite companies could do in the past”).

41. *Id.*

42. *Id.*

43. *See* Peter W. Huber, *Of Pills and Profits: In Defense of Big Pharma*, COMMENTARY 21, 22 (2006) (stating that “research and development costs for new drugs can approach \$2 billion”).

44. *See* Stephanie Saul, *More Generics Slow the Surge in Drug Prices*, N.Y. TIMES, Aug. 8, 2007, at A1 (indicating that consumers are spending less on drugs because “as nearly every big drug maker watches its best sellers fade away, there are fewer potential blockbuster drugs waiting to take their place”); *see also* Stephanie Saul, *Johnson & Johnson Plans to Cut 4,800 Jobs*, N.Y. TIMES, Aug. 1, 2007, at C2 (stating that “[w]ith generic competition looming for two of its blockbuster drugs and use declining for its drug-coated

Data mining is one example of how a firm in this industry can become more efficient.

The pharmaceutical industry uses data mining techniques in a variety of ways, including profiling, classification, clustering, prediction and data analysis.<sup>45</sup> However, due to the limited scope of this comment, only prediction and data analysis will be discussed. Prediction in the pharmaceutical context partly involves using past prescribing history of doctors to better predict future behavior.<sup>46</sup> Data analysis in the pharmaceutical context uses the inferences drawn from the data mining research to determine the optimal course of action regarding future business decisions.<sup>47</sup>

By determining prescribing patterns through prediction methods, pharmaceutical companies can see which doctors are writing the most prescriptions and what drugs they are prescribing. A former drug retailer at Eli Lilly described the data mining sales programs as giving “[doctors] a score of 1 to 10 based on how much they write. Once we have that, we know who our primary targets are. We focus our time on the big [prescription] writers—the 10s, the 9s, and then less so on the 8s and 7s.”<sup>48</sup> By targeting doctors in this way, Eli Lilly optimizes the use of their sales force by only “dealing with individual physicians who might give us the biggest dividend for our investment.”<sup>49</sup> More specifically, Eli Lilly used the collected data “to tout the virtues of [their] antidepressant Prozac to doctors who favored the rival drug Effexor.”<sup>50</sup> Through this process, it is apparent that pharmaceutical companies can achieve greater efficiency, which allows the companies to “do more targeted marketing, which lowers the total costs of its marketing.”<sup>51</sup>

This efficiency is particularly important when it is estimated to take ten to fifteen years and \$800 million to \$1 billion dollars to bring a compound through the research and regulatory process.<sup>52</sup> Even with these

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stents, Johnson & Johnson said yesterday that it would eliminate up to 4,800 jobs”).

45. See John J. Cohen & C. Olivia Parr Rud, *Data Mining of Market Knowledge in the Pharmaceutical Industry*, Proceeding of the Northeast Statistical Analysis Software Users Group, available at <http://nesug.org/proceedings/nesug00/ph/ph6007.pdf> (defining the various methods which the pharmaceutical industry employs data mining).

46. *Id.*

47. *Id.* at 1 (noting that data analysis is “an excellent tool for weighing risk and benefit”).

48. Christopher Lee, *Doctors, Legislators Resist Drugmakers’ Prying Eyes*, WASH. POST, May 22, 2007, at A1.

49. *Id.*

50. *Id.* Note that even though Eli Lilly is promoting their drugs, the prescriber makes, and is responsible for, the ultimate decision of which drug is prescribed to the patient.

51. *Id.*

52. See Next Generation Pharmaceutical, How Effective Document Management Helps Pharmaceutical Companies Accelerate Time to Market, available at

enormous costs and an obvious need for efficiency, “about half of [the money needed to bring a drug to market] is spent wooing legislators, regulators, academics, expert review boards, medical journals, doctors, patients, insurers, and jurors.”<sup>53</sup> The traditional counter-argument to this assertion is that putting price and efficiency restrictions (e.g. curbing data mining) on drug companies will have a chilling effect on the amount of research and development that occurs in the pharmaceutical industry. This may be true considering that private investment in pharmaceutical development firms only occurs because investors expect a high rate of return.<sup>54</sup> Without this investment, small pharmaceutical and biotechnology firms would likely decrease the amount of research they conduct,<sup>55</sup> unless the government made up for the shortfall by raising more revenues or diverting money from other sources. Therefore, even though drug pricing garners much media attention,<sup>56</sup> attempts at limiting data mining and the efficiencies that it produces could significantly add to the overall cost of development and the marketing of a drug, which in turn would decrease pharmaceutical company profits and may decrease investment in the industry.

Furthermore, because of the highly competitive nature of the pharmaceutical industry,<sup>57</sup> firms are cutting back the number of employees on their sales force.<sup>58</sup> This reduction of employees, coupled with the competitiveness of the industry, requires firms to maximize the efficiency of their sales force.<sup>59</sup> Data mining is a major tool for achieving this

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<http://www.ngpharma.com/pastissue/article.asp?art=271760&issue=225> (referring to data from the Pharmaceutical Research and Manufacturers of America (PhRMA)).

53. Huber, *supra* note 43, at 22; *see also id.* (indicating a perception that “[a] genuinely important new drug . . . sells itself” and that “Big Pharma ignores the drugs that matter, wastes huge amounts of money corrupting the market, and passes on the cost to patients”).

54. *See* Judith L. Wagner, *Should the Pharmaceutical Industry Be A Regulated Utility?*, 24 HEALTH AFFAIRS 289, 289 (2005) (stating a “basic economic principle” is that “private capital flows to R&D projects only when those projects offer expected financial returns high enough to justify their risks”).

55. *See id.* (holding as false one scholar’s view that the companies themselves will spend more money on development).

56. *See, e.g.,* Malcolm Gladwell, *High Prices: How to Think About Prescription Drugs*, NEW YORKER, Oct. 25, 2004, at 86 (stating that there is a “political uproar over prescription drug costs”).

57. *See* Evan H. Offstein & Devi R. Gnyawaldi, *CEO Compensation and Firm Competitive Behavior: Empirical Evidence from the U.S. Pharmaceutical Industry*, 22 J. ENG’G & TECH. MGMT. 201, 205 (2005) (stating that the U.S. pharmaceutical industry “operates in a fiercely competitive global market”).

58. *See* PFIZER 2006 ANNUAL REVIEW 40 (2006), *available at* <http://www.pfizer.com/files/annualreport/2006/annual/review2006.pdf> (stating that the field sales force was reduced by 20 percent).

59. *See, e.g.,* ELI LILLY AND COMPANY ANNUAL REPORT 2006 2 (2006), *available at* <http://files.shareholder.com/downloads/LLY/520676294x0x221585/4C4DCB78-EB45-4D3E-99C0-1C9ADC30A89E/English.PDF> (stating that “all of the major sales

objective.

Although the focus of this comment is on data mining in the context of the legality and policy considerations of pharmaceutical companies using prescriber information to better target their sales force, it should also be noted that generalized data mining techniques are also used by the health care industry to track adverse effects of drugs, interactions between drugs, and vaccine side-effects.<sup>60</sup>

### B. Backlash Against Pharmaceutical Data Mining

The conventional wisdom holds that “[d]octors object to gathering of drug data.”<sup>61</sup> Many others, including New Hampshire State Representative Cindy Rosenwald, have described pharmaceutical data mining as merely “a money issue.”<sup>62</sup> The money spent to gather information is purported to be wasteful because it encourages increased Medicaid spending on prescription drugs.<sup>63</sup> However, it is difficult to imagine how a technique designed to increase private firm efficiency, coupled with physicians’ ability to both choose whether to interact with pharmaceutical sales representatives and freely prescribe their drug of choice, can waste money

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organizations in our U.S. affiliate were newly constituted during 2006” in order to avoid “a system built around individual products and overlapping coverage of the same doctors”).

60. See Anne Trontell, *Expecting the Unexpected—Drug Safety, Pharmacovigilance, and the Prepared Mind*, 351 NEW ENG. J. MED 1385-1387 (2004) (discussing “pharmacovigilance” and the effect that data mining is having on reducing pharmaceutical related adverse effects in several countries); see also Lee, *supra* note 48, at A1 (indicating that the data may be used “to help determine whether physicians prescribing a particular high-risk drug have undergone required training about the medicine” and that “[t]he information helps companies, federal health agencies and others educate physicians about drugs, track whether prescribing habits change in response to continuing medical education programs, and promote higher-quality care”).

61. See Stephanie Saul, *Doctors Object to Gathering of Drug Data*, N.Y. TIMES, May 4, 2006, at BU1, available at <http://www.nytimes.com/2006/05/04/business/04prescribe.html> (describing how data mining is “virtually unknown to consumers” and “[a]rmed with such data, a drug sales representative can pressure a doctor to write more prescriptions for a name-brand medicine or fewer orders for a competitor’s drug”).

62. *Id.*

63. However, Medicaid maximization strategies that states employ to garner a higher federal match are likely to be more wasteful. See Teresa A. Coughlin et al., *Restoring Fiscal Integrity to Medicaid Financing?*, 26 HEALTH AFFAIRS 1469-80 (2007); see also Tim M. Henderson, *Financing: Intragovernmental Transfers and Other Special Financing Mechanisms* (American Academy of Family Physicians Memo), available at [http://www.aafp.org/online/etc/medialib/aafp\\_org/documents/policy/state/medicaid-financing-igt.Par.0001.File.tmp/stateadvocacy\\_MedicaidFinancingIGT.pdf](http://www.aafp.org/online/etc/medialib/aafp_org/documents/policy/state/medicaid-financing-igt.Par.0001.File.tmp/stateadvocacy_MedicaidFinancingIGT.pdf) (describing New Hampshire as one of sixteen states that had “some form of local financing matching requirement” which is a state Medicaid maximization policy to transfer federal Medicaid dollars for other uses, such as, to make up for “state budget shortfalls for other programs or to draw down additional federal Medicaid dollars”).

by “forcing” doctors to prescribe brand name medications. Nevertheless, the AMA continues to sell prescriber information to data collecting companies.<sup>64</sup> However, due to the aforementioned backlash, the AMA has instituted the Prescribing Data Restriction Program, which allows prescribers to request that their information not be transmitted to pharmaceutical companies (i.e., “opt out”).<sup>65</sup>

This means that physicians now have the option to request that their identifying information not be transmitted to pharmaceutical sales teams.<sup>66</sup> This program, coupled with physicians’ continued power to prescribe drugs that they alone choose and ability to limit pharmaceutical sales representatives from their office,<sup>67</sup> would seem to imply that doctors do not need additional legal protection that hinders pharmaceutical marketing efficiency and is arguably an unconstitutional violation of commercial free speech. Despite these institutional safeguards, some states have acted legislatively to protect their patients from the “abuses” of pharmaceutical data mining.<sup>68</sup>

## II. OVERVIEW OF RELEVANT FIRST AMENDMENT LAW

Commercial free speech can be narrowly defined as speech that “propose[s] a commercial transaction.”<sup>69</sup> Another definition of commercial speech is “expression related solely to the economic interests of the speaker and its audience.”<sup>70</sup> The Supreme Court has enumerated a test to determine whether speech is properly characterized as commercial or not. The three-part test asks: (1) whether the speech is an advertisement of some form; (2) whether it refers to a specific product; and (3) whether the speaker has an

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64. See Robert Restuccia & Lydia Vaias, *Prescription Mining Raises Millions for Doctors’ Group*, S.F. CHRONICLE, July 25, 2007, at B9 (noting that “[i]n 2005, the AMA made more than \$44 million from the sale of database products, approximately 16 percent of its budget”).

65. See *id.* (stating that “[t]he program does not bar the sale of prescriber information to pharmaceutical companies; it merely requests and then relies on the industry to prevent the transmission of this data to its sales teams”).

66. See *id.* (noting that the Prescribing Data Prescription Program is utilized by “less than 1 percent of doctors”).

67. See Benjamin Brewer, *Stopping Drug Reps At the Door*, WSJ, Aug. 16, 2005, available at <http://online.wsj.com/article/SB112405319132212657.html?mod=US-Business-News> (describing a physician that purposefully choose to ban pharmaceutical sales representatives from his office due to the increased amount of “unscheduled interruptions”). The physician also noted that “[o]ne down side to keeping drug salespeople out of my office is that I might get fewer samples to give out to my patients.” *Id.*

68. See H.B. 1346, 2006 Gen. Court, 159th Sess. (N.H 2006).

69. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 421 U.S. 748, 762 (1975).

70. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n.*, 447 U.S. 557, 561 (1980).

economic motivation for the speech.<sup>71</sup> While this may provide a framework for most cases, it may not help define commercial speech outside of advertising. The Court, however, has stated that the First Amendment protects speech that has scientific value<sup>72</sup> and contains factual information.<sup>73</sup> However, some forms of speech, including fighting words, can be regulated by statute because they are a form of speech that has only “slight social value.”<sup>74</sup>

Once speech has been accurately categorized as commercial, the next step is to determine whether it is constitutionally protected. The Supreme Court expressly held that the Constitution “accords a lesser protection to commercial speech than to other constitutionally guaranteed expression.”<sup>75</sup> In *Central Hudson*, the Court conveyed a four-part test to determine whether commercial speech warrants constitutional protection. The test asks: (1) whether the protected speech concerns lawful activity and is not misleading; (2) whether the government’s interest for regulating the speech is substantial; (3) whether the regulation directly advances the government’s asserted interest; and (4) whether the regulation is not more extensive than necessary to serve the government’s asserted interest.<sup>76</sup> The Court used intermediate scrutiny in the application of this test.<sup>77</sup>

When determining whether a stated interest is substantial under intermediate scrutiny, courts may not “supplant the precise interests put forward by the State with other suppositions.”<sup>78</sup> To establish whether regulation of commercial speech directly advances the government’s interest, the party attempting to sustain such a restriction must “demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.”<sup>79</sup> The Court has also clarified the fourth prong of the test by holding that governmental regulation of

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71. See *Bolger v. Youngs Drug Prod. Corp.*, 463 U.S. 60, 66-67 (1983).

72. *Miller v. California*, 413 U.S. 15, 34 (1973).

73. *Va. State Bd. of Pharmacy*, 421 U.S. at 763-64.

74. *Chaplinsky v. New Hampshire*, 315 U.S. 568, 571-72 (1942) (stating that “the right of free speech is not absolute at all times and under all circumstances” because “[t]here are certain well-defined and narrowly limited classes of speech, the prevention and punishment of which have never been thought to raise any Constitutional problem”). This reasoning is important because, as will be demonstrated *infra*, Judge Selya of the First Circuit Court of Appeals relies on *Chaplinsky* to determine that regulation of data mining firms’ activities is Constitutional. See *infra* note 115.

75. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 563 (1980).

76. *Id.* at 566.

77. See *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 623 (1995) (“we engage in ‘intermediate’ scrutiny of restrictions on commercial speech”).

78. *Edenfield v. Fane*, 507 U.S. 761, 768 (1993).

79. *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995).

commercial speech need not use the least restrictive alternative available.<sup>80</sup> More specifically, this prong requires “a ‘fit’ between the legislature’s ends and the means chosen to accomplish those ends, a fit that is not necessarily perfect, but reasonable.”<sup>81</sup>

A. *IMS Health Inc. v. Ayotte*<sup>82</sup>

*Ayotte* is the first case that demonstrates the arguable unconstitutionality of overbroad limits placed upon pharmaceutical data mining firms. In this case, the district court ultimately overturned the New Hampshire “Prescription Information Law” that barred the “transmission or use of both patient-identifiable data and prescriber-identifiable data for certain commercial purposes.”<sup>83</sup>

The legislative history of this statute indicated that it was intended “to protect patient and physician privacy and to save the State, consumers and businesses money by reducing health care costs.”<sup>84</sup> The healthcare costs that the legislature was attempting to reduce consisted primarily of the perceived overpayment by the state Medicaid program for branded drugs when generic alternatives were available.<sup>85</sup> Furthermore, the Attorney General, during the injunction hearing, further justified the statute by submitting to the court a report showing how pharmaceutical companies use prescribing data to target their sales force towards specific doctors, which causes “public mistrust of prescriber decisions, increased drug costs, and the provision of incomplete and/or misleading information to prescribers.”<sup>86</sup> Based upon these and other findings the New Hampshire Legislature concluded that the statute will “reduce the prescription drug costs for patients, employers [and] the State Medicaid program.”<sup>87</sup>

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80. *Bd. of Tr. of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989); *see also* *Greater New Orleans Broad-Casting Ass’n v. United States*, 527 U.S. 173, 177 (1999).

81. *Florida Bar*, 515 U.S. at 2380.

82. 490 F. Supp. 2d 163 (D.N.H. 2007). Note that the procedural posture of this case is an action by the data mining firms for declaratory relief and a permanent injunction concerning N.H. Rev. Stat. Ann. §§318:47-f, 318-B:12(IV) (2006), otherwise known as the Prescription Information Law. *See also* *IMS Health v. Ayotte*, No. 07-1945, 2008 U.S. App. LEXIS 23701 (1st Cir. Nov. 18, 2008). Note that this is the appeal from the District Court’s opinion.

83. *Ayotte*, 490 F. Supp. 2d at 170.

84. *Id.* at 171.

85. *See id.* at 171-72 (describing a state representative’s testimony that a one-year supply of Dynacirc, which is a branded medication, costs approximately \$1,047, whereas, Verapamil, which is a generic medication, would cost \$162).

86. *Id.* at 172.

87. *Id.* at 171. It should also be noted that while this law may in fact help to minimize Medicaid costs in the short term, the New Hampshire Legislature is discounting the effect that an inefficient and less profitable pharmaceutical industry may have an innovation and therefore drug prices in the future. These facts were brought to the attention of the court by

Contrary to the State Legislature's position, the New Hampshire Association of Chain Drug Stores "expressed concern that the bill struck too broadly and, among other problems, would prevent prescriptions from being transferred from one pharmacy to another."<sup>88</sup>

The plaintiffs (i.e., the data mining firms) proffered several arguments in an effort to save their business model. First, they argued that the statute is subject to strict scrutiny because it is a content-based restriction on non-commercial speech. Alternatively, the plaintiffs argued that the statute is subject to intermediate scrutiny as commercial speech, and consequently is not narrowly tailored to directly advance a substantial governmental interest. The Attorney General, on the other hand, argued that the statute does not regulate speech and therefore does not violate the First Amendment. In addition, the Attorney General argued that even if the statute does regulate speech, it is subject to immediate scrutiny and passes the aforementioned test.<sup>89</sup>

The court responded to the Attorney General's arguments by establishing that the First Amendment protects speech consisting of factual information,<sup>90</sup> despite the Attorney General's contention that the statute "targets unprotected factual information, rather than constitutionally protected speech."<sup>91</sup> The court concluded that the law "restricts the transmission of truthful information concerning the prescribing practices of New Hampshire's health care providers" and "is not exempt from First Amendment review merely because it targets factual information."<sup>92</sup> The court went on to note that the statute prevents pharmaceutical companies from using prescriber-specific data to direct their sales force towards specific prescribers. Therefore, the First Amendment analysis was particularly applicable because the statute "affect[s] both the speaker's

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representatives from IMS Health and Verispan. *See id.* at 173.

88. *Id.* at 173. Furthermore, the AMA expressed an opinion that "[t]he unintended consequence of restrictive legislation is that companies that collect and process this information may no longer be willing to spend the resources necessary to maintain these data. Therefore, these data would no longer be available for those public benefits." The public benefits of information provided by data mining firms include, "(1) promoting public health policy, (2) accelerating healthcare innovation, (3) driving best clinical practice, and (4) monitoring drug safety and (5) clinical trial recruitment." *See American Medical Association, The Unintended Consequences of Proposals to Restrict Disclosure of Physician Prescribing Data, available at <http://www.ama-assn.org/ama1/pub/upload/mm/432/rxamapositionmarch07.pdf>.*

89. The Attorney General also argued that the plaintiff lacked standing to sue. However, the court dismissed this argument in part because the plaintiffs are "plainly subject to prosecution as conspirators if they conspire with covered entities to violate the law." *Ayotte*, 490 F. Supp. 2d at 174 n.9.

90. *Id.* (citing several cases including *Va. Bd. of Pharmacy*, 425 U.S. at 762).

91. *Id.*

92. *Id.* at 175.

ability to communicate with his intended audience and the audience's right to receive information."<sup>93</sup>

After the statute was shown to inhibit speech under the First Amendment, the court had to determine the level of scrutiny. The court rejected the plaintiffs' argument that the statute regulated non-commercial speech, and hence should be subject to strict scrutiny, because the statute only restricted the use of prescriber-identifiable data for certain limited commercial purposes (i.e., re-sale to pharmaceutical companies). Due to prior precedent, the court then applied the *Central Hudson* definition of commercial speech.<sup>94</sup> In sum, the court held that "the [Prescription Information Law] is a commercial speech restriction under *Central Hudson* because it restricts only speech that is 'solely in the individual interest of the speaker and its specific business audience.'"<sup>95</sup>

Once it was determined that the law affected commercial free speech, intermediate scrutiny was applied under the *Central Hudson* test.<sup>96</sup> The Attorney General argued that protecting prescriber privacy is a substantial governmental interest because "the State has a substantial interest in lowering health care costs and limiting unwarranted intrusions into the decision making process of prescribing physicians."<sup>97</sup> The court made an important observation that the Attorney General could not have claimed that the statute protected a substantial information privacy interest. This is for two reasons: First, "most information privacy laws protect the privacy of personal information"<sup>98</sup> and the state's interest in the protection of business information is not equivalent to the state's interest in protecting personal information. Second, prescribers cannot claim an expectation of privacy in their prescribing practices because they are well aware that this information is transmitted to many different parties, including, "patients, pharmacies, insurance companies, medical review committees, and government agencies."<sup>99</sup> This intuitively means there is no protectable privacy interest in prescriber data that does not identify patients' identities.

The Attorney General, in arguing that the state's substantial interest is comprised of lowering health care costs, claimed "that pharmaceutical

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93. *Id.* Note that the speaker referred to is the pharmaceutical data mining firms and the audience consists of the prescribers.

94. The Supreme Court defined commercial speech in *Central Hudson* as speech "related solely to the economic interests of the speaker and its audience." 447 U.S. 557, 561 (1980). Furthermore, the Court in *Central Hudson* held that commercial speech regulations ordinarily are "subject to an intermediate level of scrutiny." *Id.* at 573.

95. *Ayotte*, 490 F. Supp. 2d at 176. The court also noted in dicta that the same result would be warranted even if a narrower definition of commercial speech were to be used. *Id.*

96. See *supra* note 77 and accompanying text.

97. State's Trial Memorandum at 20, *Ayotte*, 490 F. Supp. 2d 163 (D.N.H. 2007).

98. *Ayotte*, 490 F. Supp. 2d at 179 n.13.

99. *Id.*

companies use prescriber-identifiable data to ‘pressure’ health care providers.”<sup>100</sup> However, there was no proof that the “pressure” being applied to health care providers was inappropriate.<sup>101</sup> Indeed, the court noted that the Attorney General was not claiming that the pharmaceutical sales representatives were using the data to relay deceitful information to prescribers.<sup>102</sup> Therefore, the statute did not support a substantial government interest.

The next issue, despite the lack of a substantial governmental interest, was whether the statute directly advanced the state’s interests in enhancing public health and restraining health care spending. The Attorney General argued that prescription data mining makes pharmaceutical sales more efficient, which allows pharmaceutical companies to have an easier time selling their products (i.e., name brand drugs). Therefore, the sales of branded medications will increase (which also increases pharmaceutical company profits), and the state will end up spending more than necessary on healthcare costs. This assumes, as the court correctly pointed out, that “any increase in the number of prescriptions written for brand-name drugs when compared to generic alternatives harms the public health and increases health care costs because branded drugs often turn out to be more harmful than generic alternatives.”<sup>103</sup>

However, the court reasoned that the Attorney General’s argument was a “general claim” dependent upon the “unproven proposition” that branded medications cause more injury relative to generic drugs.<sup>104</sup> Moreover, the Attorney General’s argument that prescriber data was being used to target physicians who were prone to prescribe newer drugs was “unpersuasive” and the argument that the statute contains health care costs assumes a proposition that “is far from self evident.”<sup>105</sup> Finally, the court insisted that even if the unproven allegations of the Attorney General were true, the statute would still not advance the state’s interest in protecting the public’s health. The court reasoned, “health care providers are highly trained professionals who are committed to working in the public

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100. *Id.* at 179.

101. *Id.* However, the court did note that the law’s legislative history indicated possible prescriber coercion. This evidence of coercion was in part from a nurse practitioner who received free coffee and donuts from a pharmaceutical sales representative. The Attorney General did not present this evidence at trial and the court held that there was no “credible evidence in the record that supports the notion that pharmaceutical companies are routinely using prescriber-identifiable data to coerce health care providers.” *Id.* at 180 n.14.

102. *Id.* at 181.

103. *Id.* at 180.

104. *Id.*

105. *Id.* The proposition that the court was referring to was that the health care savings resulting from the statute will not simultaneously compromise patient care in some circumstances.

interest.”<sup>106</sup> Therefore, prescribers are unlikely to act irrationally when confronted with the truthful commercial speech that the statute targeted.<sup>107</sup>

After rejecting the Attorney General’s claims regarding the first two elements of the *Central Hudson* test, the court analyzed the third prong of the test to determine whether the statute was more extensive than necessary to achieve the state’s asserted interests. The court that noted the statute does not differentiate between using the prescriber data to target physicians based upon the need to deliver factual pharmaceutical information and the use of the information to coerce physicians into prescribing certain drugs. Because the statute lacked this distinction, it was overbroad and served to impose “a sweeping ban on the use of prescriber-identifiable information to enhance the effectiveness and efficiency of all detailing.”<sup>108</sup> The court went further by offering several ways that the state could achieve their asserted interests, while not unconstitutionally restricting commercial speech. For example, the state legislature could limit gift-giving from pharmaceutical companies, require more continuing education for prescribers describing better prescribing practices, or implement a prior authorization or preferred drug list for the state’s Medicaid formulary.<sup>109</sup> The court’s proposed alternatives center around the fundamental flaw in Cindy Rosenwald’s and the rest of the New Hampshire State Legislature’s reasoning. The court reasoned that in order to advance the state’s proposed interests, “the remedy to be applied is more speech, not enforced silence.”<sup>110</sup>

Despite the thorough analysis of the district court, the case was reversed on appeal.<sup>111</sup> The Honorable Judge Bruce Selya of the First Circuit Court of Appeals wrote the majority opinion. Judge Selya first discussed whether the data mining companies had standing. The court concluded that the data mining firms’ standing was restricted to the data mining firms’ specific activities, which included “the acquisition, aggregation, and sale of prescriber-identifiable data.”<sup>112</sup>

In deciding whether the aforementioned activities were speech or

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106. *Id.* at 181.

107. *See id.* (quoting the Supreme Court in *Va. State Bd. of Pharmacy* that “[B]ans against truthful, non-misleading commercial speech . . . usually rest solely on the offensive assumption that the public will respond ‘irrationally’ to the truth. The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.”).

108. *Id.* at 182.

109. *Id.*

110. *Id.* at 181 (citing *Whitney v. California*, 274 U.S. 357, 377 (1927)).

111. *Ayotte*, 2008 U.S. App. LEXIS 23701, at \*59.

112. *Id.* at \*19. Note that this does not include “the use of that information by pharmaceutical company detailers to promote particular products to physicians,” which is surely commercial activity. *Id.* at \*14-15.

conduct, the court noted that “[t]he challenged portions of the statute principally regulate conduct, and to the extent that the challenged portions impinge at all upon speech, that speech is of scant societal value.”<sup>113</sup> The court conceded that the statute implicated speech, but only speech that is primarily between doctors and detailers. This reasoning was enough to doom the fate of the data mining firms because the regulation of conduct (not speech) falls within “other species of speech-related regulations that effectively lie beyond the reach of the First Amendment.”<sup>114</sup> It is important to note that conduct that falls within the category of “other species of speech related regulations” has a common underlying feature. This type of statutorily regulated conduct originates “from a felt sense that the underlying laws are inoffensive to the core values of the First Amendment.”<sup>115</sup> Furthermore, the court defined their use of the word “inoffensive” as meaning that the “other species” primarily “regulate conduct and, to the extent that they regulate speech at all, that putative speech comprises items of nugatory informational value.”<sup>116</sup> In other words, the data mining firms’ business did not have to undergo First Amendment scrutiny because Judge Selya had a “felt sense” that the New Hampshire Legislature was merely regulating conduct, and that prescriber information has “nugatory” value.<sup>117</sup>

The court did not stop there. In an analysis of a hypothetical, the court assumed, “arguendo, that the acquisition, manipulation and sale of prescriber-identifiable data comes within the compass of the First Amendment.”<sup>118</sup> Despite this hypothetical situation, the court ultimately

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113. *Id.* at \*26. The court further noted that “the challenged elements of the Prescription Information Law principally regulate conduct because those provisions serve only to restrict the ability of data miners to aggregate, compile, and transfer information destined for narrowly defined commercial ends.” *Id.*

114. *Id.* at \*23. The court noted that the “other species” include restraints of trade, communications in furtherance of crimes, statements or actions creating hostile work environments, and promises of benefits made by an employer during a union election. *Id.* at \*24.

115. *Id.* at \*25. Note that Judge Selya relies on *Chaplinsky v. N.H.*, 315 U.S. 568, 572 (U.S. 1942), to make the point that the data miners’ commercial speech is not protectable. However, *Chaplinsky* involves the Constitutionality of the regulation of “fighting words” and is only tangentially applicable to the commercial free speech at issue in the present case. In addition, comparing the value of “fighting words” relative to prescription information seems spurious at best.

116. *Id.*

117. *Id.* It should be noted that Judge Selya left the door open for pharmaceutical companies to sue claiming a First Amendment violation. The court stated that, “[a]lthough speech, protected or not, is implicated by the Prescription Information Law, it consists primarily of communications between detailers and doctors—but no detailer or doctor is a plaintiff here. Therefore, an adjudication of that aspect of the law must await a proper plaintiff.” *Id.* at \*28-29.

118. *Id.* at \*31.

held that “even if one assumes that those provisions to some extent implicate commercial speech, they do not violate the First Amendment.”<sup>119</sup> In reaching this decision, the court applied *Central Hudson*. First, the court indicated that New Hampshire had three stated interests, which included, “maintaining patient and prescriber privacy, protecting citizens’ health from the adverse effects of skewed prescribing practices, and cost containment.”<sup>120</sup> In finding that cost containment was a substantial state interest, the court dramatically reasoned that “[f]iscal problems have caused entire civilizations to crumble.”<sup>121</sup> Therefore, the State had met part of the *Central Hudson* test.

For the next part of the *Central Hudson* test, the court had to decide whether the Prescription Information Law directly advanced the goal of cost containment. Judge Selya found that the State provided sufficient evidence to show that the statute leads to better healthcare cost containment.<sup>122</sup> He then rebutted the district court’s reasoning<sup>123</sup> by concluding that, even though some branded pharmaceuticals may produce better clinical results, this, in and of itself, is “too flimsy a hook on which to hang a conclusion that a decrease in the prescription of brand-name drugs would be unlikely to yield a net diminution in health care costs.”<sup>124</sup> In chastising the district court’s insistence that the New Hampshire Attorney General actually present solid evidence on the Prescription Information Law net health care costs, Judge Selya noted that New Hampshire was in the “vanguard” when “formulating public policy . . . to deny detailers access to prescribing histories,” and therefore the District Court was found “to demand too much.”<sup>125</sup> Despite the lack of evidence

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119. *Id.* at \*49-50.

120. *Id.* at \*33. It is important to note that the court decided to restrict their analysis to only cost containment. *Id.*

121. *Id.* at \*33.

122. More specifically, Judge Selya stated that there was “competent evidence that detailing increases the prescription of brand-name drugs, that brand-name drugs tend to be more expensive, that detailers’ possession of prescribing histories heightens this exorbitant effect, that many aggressively detailed drugs provide no benefit vis-à-vis their far cheaper generic counterparts, and that detailing had contributed to pharmaceutical scandals endangering both the public health and the public coffers.” *Id.* at \*41.

123. Recall that the district court concluded that the Attorney General made a flawed assumption that “any health care cost savings that will result from a ban on the use of prescriber-identifiable data can be achieved without compromising patient care.” *Id.* at \*39.

124. *Id.* at \*41.

125. *Id.* at \*42-43. It should be noted that it seems inappropriate, over the long-term, for a state legislature to routinely pass new legislation that lacks substantial evidentiary support (although, according to Judge Selya it is legally sufficient when a state is in the “vanguard”). Furthermore, as the New Hampshire Legislature garners the appropriate evidence to support their new policy (which they will presumably accomplish), it is not apparent they will alter the Prescription Information Law if the evidence proves contradictory.

supporting the cost containment theory, the court decided to give the New Hampshire Legislature sufficient “elbow room” to find that the “Prescription Information Law is reasonably calculated to advance its substantial interest in reducing overall health care costs.”<sup>126</sup>

For the final *Central Hudson* question, the court had to determine whether the regulation is not more extensive than necessary to serve the government’s interest. To justify the New Hampshire Legislature, the court stated that “[t]he Prescription Information Law was a targeted legislative response to a particular problem that had proven resistant to a number of different regulatory approaches.”<sup>127</sup> In particular, Judge Selya thought that it was impractical for New Hampshire “to retool” its Medicaid formulary to make brand name drugs non-preferred and available only if a physician consults with a pharmacist. Furthermore, the court noted that this policy would “make no inroads with respect to privately insured patients.”<sup>128</sup> What the court apparently failed to realize is that the New Hampshire Medicaid system already has a preferred and non-preferred formulary, which is segregated precisely as the district court suggested.<sup>129</sup> Moreover, private insurance plans follow the same structure in order to minimize cost. Finally, when a doctor prescribes a non-preferred drug, the pharmacist and doctor typically consult as to what other options are available and whether or not a prior authorization<sup>130</sup> needs to be obtained from the insurer.<sup>131</sup> Therefore, the court failed to realize that the “crude attempt to remedy the compromised prescribing habits of physicians after the fact” is the precise system that doctors and pharmacists already operate in.<sup>132</sup> However, the court tried to explain itself by noting that even though

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126. *Id.* at \*45.

127. *Id.* at \*46. However, this only begs the question as to why a regulatory approach was needed at all.

128. *Id.* at \*48.

129. New Hampshire Department of Health and Human Services Preferred Drug List, *available at* <http://www.dhhs.state.nh.us/NR/rdonlyres/eenpdx5ovw5xeniv65oe5fdha56vob2enswz2bsmpvjhcgzmedmzaxc6m4kbcmbhlzg6sn3lh3mywotimde>. Notice that the preferred drugs are predominantly generic and the non-preferred are predominantly brand.

130. A prior authorization is, “[i]n pharmacy, a cost-containment procedure that requires a prescriber to obtain permission to prescribe a medication prior to prescribing it.” MedicineNet.com, <http://www.medterms.com> (last visited Jan. 27, 2009).

131. “When a private insurance company or Medicaid rejects a prescription I will call the doctor. Sometimes the doctor and I will discuss changing the prescription to a drug that is covered, and other times the doctor will submit a prior authorization form in order to get the private insurer or Medicaid to cover the drug. Either way, under the present system, the doctor has to take extra time to deal with the prescribed drug that is not covered by the patient’s insurance due to the private insurer or Medicaid having a preferred and non-preferred drug list.” Interview with Dr. Katie Wang, Pharmacy Manager, CVS (Nov. 20, 2008).

132. *Ayotte*, 2008 U.S. App. LEXIS 23701, at \*48.

a preferred and non-preferred formulary, which is already in place, would presumably contain costs, the Prescription Information Law was enacted “not only to lower costs but also to prevent detailers from exerting so much influence over physicians’ prescribing habits.”<sup>133</sup> With this justification, the court erratically departed from their cost containment analysis and presumably provided a sufficient justification as to why the Prescription Information Law is no more restrictive than necessary. It should be noted that the court may have veered from the cost containment analysis because the district court suggested several adequate remedies for the over-breath of the Prescription Information Law and exposed the government’s asserted cost containment interest as merely nugatory.

The court continued to summarily reject the plaintiff’s contention that the statute was void for vagueness and unconstitutional under the dormant commerce clause. In their analysis, several concessions were made to the data mining firms. First, the court noted that data mining firms may sell prescriber data to pharmaceutical firms “for research or for recruiting physicians to participate in clinical trials of newly developed drugs.”<sup>134</sup> Therefore, if data mining firms sell the prescriber data for permissible purposes, they cannot be held liable for impermissible uses of the data further downstream by the pharmaceutical companies. Nevertheless, the court provided a caveat that data purchased by pharmaceutical companies for research purposes cannot then be used for targeted detailing.<sup>135</sup> However, the court refused to address whether a pharmaceutical company can be liable for data properly acquired, which is then used to target physicians.<sup>136</sup> Thus, data mining firms will not be held liable if prescribing data is collected for permissible uses. However, using permissibly collected data for impermissible uses is a violation of the Prescription Information Law, yet the court did not address pharmaceutical company liability. Consequently, it is a mystery as to who is liable for impermissible uses of permissibly collected data.

Second, while rejecting the plaintiff’s dormant commerce clause argument, the court noted that the Prescription Information Law “may not accomplish very much” because prescriber data is permitted to be transferred “to out-of-state facilities where it can then be aggregated and sold legally to others.”<sup>137</sup> The court then punted the ultimate question as to whether that information can then be used in New Hampshire to other courts.<sup>138</sup> Therefore, based upon the court’s analysis, data mining firms can

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133. *Id.* at \*49.

134. *Id.* at \*53.

135. *Id.* at \*52.

136. *Id.* at \*55 n.10.

137. *Id.* at \*60.

138. *Id.* at \*60 n.11.

still sell prescriber information for permissible purposes, even if it is ultimately used for impermissible purposes and can sell data for impermissible purposes if it is sold outside of New Hampshire.

Several points of the dissent bear note. First, the dissent disagreed with the majority's standing analysis. The dissent believed that pragmatic principles should aid in determining standing because the data mining firms have every reason to aggressively litigate this case, even in the absence of a pharmaceutical company as a plaintiff.<sup>139</sup>

Second, the dissent questioned, "how can the majority make a judgment about the low value of that speech in deciding that the Act regulates only conduct and not speech?"<sup>140</sup> The low value speech referred to is the acquisition, aggregation and sale of prescriber identifiable data, which the majority deemed conduct, not speech. Therefore, it seems paradoxical that the majority can "make a judgment about the low value of that speech in deciding that the Act regulates only conduct and not speech," without considering the First Amendment implications.<sup>141</sup> Furthermore, the dissent correctly indicated that the majority "never actually identifies the specific speech component . . . from pharmacies to data miners and from data miners to pharmaceutical companies."<sup>142</sup>

Third, the dissent held that, although the data mining companies have standing, the Prescription Information Law does not violate the First Amendment. The dissent agreed with the majority that the district court held the New Hampshire Attorney General to a higher standard of proof relative to prior precedent.<sup>143</sup> Moreover, the dissent agreed with the New Hampshire Attorney General that cost containment was a substantial interest that was advanced by the statute.<sup>144</sup> Interestingly, however, the dissent concluded that the benefits that pharmaceutical representatives provide are "largely achievable in other ways."<sup>145</sup> For instance, "[n]ews reports . . . would highlight truly groundbreaking new therapies,"<sup>146</sup> and a representative from the New Hampshire Medical Society stated that "the vast majority of physicians" become quickly aware of any "new miracle

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139. *Id.* at \*65-66. The dissent also notes that "[n]othing in the extensive record even hints that the plaintiffs were unable or unwilling to aggressively litigate the *First Amendment* issues at stake in the 'downstream' transactions between the detailers and physicians." *Id.*

140. *Id.* at \*71.

141. *Id.* at \*71. The dissent also indicates that "[t]he very elimination of the detailers' ability to use 'a particular informational asset' restricts the message they are allowed to disseminate and implicates the free speech concerns of the *First Amendment*." *Id.* at \*72.

142. *Id.* at \*73-74 n.14.

143. *Id.* at \*146.

144. *Id.* at \*151.

145. *Id.* at \*154.

146. *Id.*

drugs.”<sup>147</sup>

The dissent’s analysis misses the larger point. The vast majority of new pharmaceuticals are not “miracle drugs,” which would indicate that many physicians would not be aware of the benefits of these new therapies. Furthermore, only incompetent prescribers would be unaware of “truly groundbreaking new therapies.”<sup>148</sup> It is much more likely that a competent physician would be unaware of a new branded medication that benefits a relatively small group of patients, compared to an older generic medication that benefits the population as a whole.<sup>149</sup> This is precisely why doctors and pharmaceutical companies need efficient marketing strategies—to get the correct message to the correct prescribers.

*B. IMS Health Corp. v. Rowe*

*IMS Health Corp. v. Rowe* was decided before the First Circuit Court of Appeals overturned the district court’s opinion in *IMS Health v. Ayotte*.<sup>150</sup> This case involves a statute similar to the New Hampshire Prescription Information Law. The Maine statute differs in that it featured an ‘opt-out’ provision.<sup>151</sup> This provision allows prescribers to file for confidentiality protection.<sup>152</sup> If a prescriber chooses to opt out, pharmacies, data-mining firms and other carriers are prohibited from using or selling their information for marketing purposes.<sup>153</sup> The opt out feature does not restrict data-mining firms from purchasing and selling prescriber information for any purpose other than marketing.<sup>154</sup>

The issues before the District Court of Maine were very similar to the New Hampshire case.<sup>155</sup> In fact, the Maine court agreed with the New

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147. *Id.* at 155 n.64.

148. *Id.* at \*154.

149. See Huber, *Curing Diversity*, 18 CITY J. 4 (2008) (describing how the pharmaceutical industry is increasingly producing drugs that are targeted towards smaller, biochemically diverse subsets of patients).

150. No. CV-07-127-B-W, 2007 U.S. Dist. LEXIS 94268 (D. Me. Dec. 21, 2007) (*amended*, 523 F. Supp. 2d 183 (D. Me. 2008)).

151. *Id.* at \*24.

152. *Id.*

153. *Id.* Marketing is defined as advertising, publicizing, promoting, selling a prescription drug, influencing market share of a prescription drug or prescribing pattern of prescribers, a detailing visit or a personal appearance, evaluating or improving the effectiveness of a professional detailing sales force or a brochure, media advertisement or announcement, poster or free sample of a prescription drug. P.L. 2007, Ch. 460, § 1711-E(1)(F-1) (Me. 2007).

154. *Id.* at \*25.

155. Indeed, the court opined that “[h]aving reviewed Judge Barbadoro’s well-reasoned opinion, the Court concludes that it ‘should refrain from writing at length to no other end than to hear its own words resonate.’” *Rowe*, 2007 LEXIS 94268, at \*31 (quoting in part *Lawton v. State Mut. Life Assurance Co.*, 11 F.3d 218, 220 (1st Cir. 1996)).

Hampshire court's reasoning concerning the restriction of commercial speech and the application of intermediate scrutiny.<sup>156</sup> The remaining issue was whether the aforementioned opt-out feature passed constitutional muster. The court applied the *Central Hudson* test<sup>157</sup> to decide whether the opt-out statute was constitutionally sound.<sup>158</sup>

Upon enacting the statute, the Maine legislature asserted the government's interests, which included improving public health, limiting the increasing cost of healthcare, and protecting the privacy of patients and prescribers.<sup>159</sup> The court specifically agreed that patient privacy, decreasing the influence of drug representatives, ending the use of prescriber comparisons for manufacturer profitability and efficiency purposes, and enhancing the effectiveness of other laws were all substantial governmental interests.<sup>160</sup> However, the goal of protecting prescribers' prescribing patterns was described as "narrow."<sup>161</sup> The court, holding that prescriber privacy was not a substantial state interest, noted that "[p]rescribers' prescribing patterns are . . . dissimilar to the traditional areas of privacy" and that prescribers already know that they "cannot prevent a host of entities from reviewing their prescribing patterns."<sup>162</sup> The Attorney General countered that Maine has a right to recognize new privacy rights.<sup>163</sup> This argument did not sway the court because the statute is "essentially protecting prescribers from truthful information" and "there is no evidence that by using this information, the detailers intimidate prescribers or that the prescribers are vulnerable victims."<sup>164</sup>

Afterwards, the court analyzed whether the statute directly advanced the government's asserted interests. Even though the statute was found to directly advance patient confidentiality, data mining firms were already prohibited from selling patient-identifiable information.<sup>165</sup> Therefore, even

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156. *Id.* at \*31.

157. *See supra* note 76 and accompanying text.

158. *Rowe*, 2007 LEXIS 94268, at \*32.

159. The Maine Legislature specifically listed the purposes of the law: (1) patient privacy; (2) prescriber privacy; (3) decreasing the influence of drug representatives; (4) ending the use of prescriber comparisons for purposes related to manufacturer profitability and decreasing unnecessary marketing costs; and (5) enhancing the effectiveness of other laws. P.L. 2007, Ch. 460, § 1711-E(1-B) (Me 2007).

160. *Rowe*, 2007 LEXIS 94268, at \*45.

161. *Id.* at \*44.

162. *Id.* at \*39-40. These other entities are composed of pharmacies, insurance companies, patients, etc. It should also be noted that this argument is very similar to the district court's reasoning in *Ayotte*.

163. *Id.* at \*41.

164. *Id.* at \*42-43. The court also noted that the prescribers are "well educated professionals" and "highly trained professionals" who are "entrusted to make complex and dispassionate medical decisions based upon a plethora of information." *Id.* at \*42.

165. Moreover, the court noted that "[r]egardless of the opt-out provisions of the new law, personal patient information has been and will continue to be encrypted and there is no

though patient confidentiality was a substantial state interest that was directly advanced, it was a moot point because the challenged provisions of the statute did not affect patient privacy.

The court next addressed whether prescriber privacy was directly advanced. In holding that the statute “only marginally advances the governmental interest in prescriber privacy” the court noted that “the Law does not restrict access to the opt-out prescribers’ prescription history.”<sup>166</sup> Therefore, the impact on prescriber privacy, namely prescribers who would opt out, is “oblique.”<sup>167</sup>

The statute did not directly advance the state’s interest of decreasing the influence of drug representatives because “[a] Law that penalizes one person for the misconduct of another cannot be using the most direct approach to achieve its purpose.”<sup>168</sup> The court was referring to the fact that the statute punishes data mining firms for the alleged indiscretions of pharmaceutical companies. The court further noted that overly aggressive marketing may already be covered under other Maine laws prohibiting unfair trade practices.<sup>169</sup> Furthermore, the court recognized two seemingly obvious facts that may have escaped the Maine Legislature. First, the “most effective tool that the prescriber possesses to reduce the influence of detailers is to refuse to see them.”<sup>170</sup> Second, the Maine statute will not stop pharmaceutical companies from targeting physicians who use the opt-out provision, which will only make the pharmaceutical companies “resort to more general, less tailored marketing, which was the source of prescriber complaint[s].”<sup>171</sup>

The asserted governmental interest of ending prescriber comparisons for manufacturer profitability and decreasing unnecessary marketing costs was not directly advanced because not all prescribers will opt out. Therefore, even with the statute in place, prescriber comparisons will continue and marketing inefficiencies and costs will rise due to the need to “resort to more general, less tailored marketing.”<sup>172</sup>

The asserted interest of enhancing other statutes received a mixed reception. Specifically, the court found that the statute would encourage prescribing on the Maine Medicaid formulary, but that the patient

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evidence that the current practices of the PDIs [i.e. data mining firms] and the pharmaceutical companies have had or realistically could have any effect on patient confidentiality.” *Id.* at \*48.

166. *Id.* at \*49-50.

167. *Id.* at \*49.

168. *Id.* at \*54.

169. *Id.* at \*53. In fact, the Maine unfair trade practices statute was used to stop inappropriate marketing of the drug Oxycontin. *Id.*

170. *Id.* at \*50.

171. *Id.* at \*52.

172. *Id.*

confidentiality statutes were unlikely to be affected.<sup>173</sup> For many other laws which the legislature claimed would see enhanced effectiveness, the court simply did not have enough evidence to pass judgment.<sup>174</sup>

In summary, the court determined that the statute directly advanced the government's interest in advancing utilization of the Maine Medicaid formulary. The court rejected the Attorney General's arguments that the statute advanced the state's interests of prescriber privacy, the influence of drug representatives, prescriber comparisons, and marketing costs.<sup>175</sup> The court also held that patient privacy was unaffected by the new law because patients were already adequately protected.<sup>176</sup>

Finally, the court analyzed whether the statute was narrowly tailored to meet its stated objectives.<sup>177</sup> First, patient and prescriber privacy was discussed. It was once again emphasized that the patient confidentiality protections were "redundant" because of other laws providing the same protection.<sup>178</sup> Moreover, the patient confidentiality provisions were not being challenged by the plaintiffs, and "once the patient confidentiality provision is excluded, the provisions of the Law that are constitutionally challenged prohibit the sale of prescriber information, not patient specific information, for marketing purposes."<sup>179</sup> As for prescriber privacy, the statute did not prevent dissemination of prescriber information; it merely prevented one type of entity (i.e., pharmaceutical companies) from having access to this information.<sup>180</sup> Therefore, the statute did not serve the purpose for which it was intended.

Second, the statute was found to be more extensive than necessary regarding the need to decrease the influence of drug company representatives and to end the use of prescriber comparisons relating to manufacturer profitability and marketing costs.<sup>181</sup> The court stated that "[t]he Maine Law does not, however, 'discriminate between beneficial detailing and harmful detailing.'"<sup>182</sup> Furthermore, "[t]he law does not prevent a detailer from giving gifts, even expensive gifts, to prescribers, whether they opt out or not."<sup>183</sup> This implies that the alleged influence of

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173. *Id.* at \*57.

174. *Id.*

175. *Id.* at \*62

176. *Id.* at \*57.

177. *Id.*

178. *Id.*

179. *Id.* at \*58.

180. *Id.*

181. *Id.* at \*62.

182. *Id.* at \*63 (quoting in part *Ayotte* 490 F. Supp. 2d at 182). The court noted further that "because some detailing is harmful and increases costs, the Law allows the restriction of the use of truthful information that can be applied for beneficial and cost effective detailing." *Id.*

183. *Id.* at \*58-59.

drug company representatives could be lessened by measures outlawing specific sales practices that are particularly egregious.<sup>184</sup> By doing so, the Maine Legislature would achieve the same goal of minimizing pharmaceutical company influence over physician prescribing, without restricting commercial free speech.

Then the court proceeded to discuss the statute's impact. The plaintiffs argued that the cost of complying with the statute will be "hundreds of thousands of dollars" and that "about 10,000 hours" had already been expended to comply.<sup>185</sup> In addition, once in compliance, doctors who opt out under the statute may be omitted from data collected by the plaintiffs for investigative and regulatory purposes.<sup>186</sup> The Maine Legislature apparently thought that the plaintiffs would continue collecting information on all prescribers but differentiated between the information sold for marketing purposes and the information sold for regulatory and investigative purposes or both. However, due to the increased cost to the data mining firms, "the likelihood also increases that the [plaintiffs] will not collect any data on opt-out prescribers."<sup>187</sup> The Maine Attorney General argued that this is irrelevant because of the small number of doctors that practice in Maine relative to the rest of the country.<sup>188</sup> Despite this shortsighted argument, the court correctly noted that even though the national impact would be slight, "the potential impact within the state of Maine itself would be significant."<sup>189</sup> Therefore, the court held that the statute would have a significant impact on the data mining firms and that the opt-out provision does not affect the constitutionality of the statute relative the New Hampshire Prescription Information Law.

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184. In fact, the court specifically indicated that Maine may consider enacting statutes that restrict pharmaceutical sales representatives from giving free gifts to doctors. *See id.* at \*59.

185. *Id.* at 67.

186. *See* FDA NEWS RELEASE, *FDA and Lincoln Technologies, Inc. to Collaborate on Developing Tools for Safety Data Mining*, May 1, 2003, available at <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00899.html> (describing how the FDA will use data mining techniques to extract safety information concerning drug related adverse effect patterns); *see also* IMS HEALTH PRESS RELEASE, *IMS HEALTH ACQUIRES DATA NICHE ASSOCIATES; COMBINATION CREATES COMPREHENSIVE SOURCE OF PRESCRIPTION INFO FOR MEDICAID AND MANAGED CARE MARKETS*, March 3, 2003, available at <http://www.imshealth.com> (follow "Press Room" hyperlink; then follow "News Releases" hyperlink; then follow "March 3, 2003" hyperlink) (detailing IMS Health's acquisition of a smaller data mining firm that specializes in validating government-mandated rebates).

187. *See Rowe*, 2007 U.S. Dist. LEXIS 94268, at \*71.

188. However, it seems unlikely that patients who reside and use physicians located in Maine would feel the same way.

189. *Id.* Moreover, it seems unlikely that the Maine Legislature intended adverse reaction data to not be collected from residents of Maine, despite the Attorney General's argument.

### C. Potential Statutes Affecting Commercial Free Speech

Several other states are considering restricting data mining firms from having access to certain healthcare information. For example, the New York Legislature has a bill in committee that prohibits the sale of prescription information that identifies either patients or prescribers.<sup>190</sup> A Texas state senator offered a bill modeled after the New Hampshire statute, but this law did not make it out of committee.<sup>191</sup> Illinois also has a similar bill that is stuck in the Rules Committee as of March 2007.<sup>192</sup> Other states that have statutes pending include Arizona,<sup>193</sup> Kansas,<sup>194</sup> Maryland,<sup>195</sup> Massachusetts,<sup>196</sup> Nevada,<sup>197</sup> Rhode Island,<sup>198</sup> Vermont,<sup>199</sup> Washington,<sup>200</sup> and West Virginia.<sup>201</sup>

Many of the statutes are stalled in their respective state legislatures. This may be due in part to the state legislatures awaiting the final disposition of the two cases previously discussed. However, now that First Circuit Court of Appeals upheld the New Hampshire Prescription Information Law, it is only a matter of time before other states enact unneeded regulation that will decrease the efficiency of pharmaceutical marketing in an attempt to control an uncontrollable activity.

### III. LIMITATIONS ON SELLING PRESCRIPTION INFORMATION INHIBITS SPEECH AND WILL ADVERSELY AFFECT THE HEALTHCARE INDUSTRY

Laws that restrain prescription information inhibit commercial free speech. Notwithstanding the First Circuit Court of Appeals, two independent district courts have determined that statutes that prevent the sale of non-patient specific prescription information are unconstitutional.

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190. S.B. A07645, State Assem. (N.Y. 2007). As of February 2009, the bill was in the ways and means committee.

191. S.B. 1620, 80th Leg. (Tx. 2007) available at <http://www.legis.state.tx.us/tlodocs/80R/billtext/html/SB01620I.htm>; see also *Minutes of the S. Comm. on Health & Human Svcs* (April 24, 2007), available at <http://www.legis.state.tx.us/tlodocs/80R/minutes/html/C6102007042409001.HTM>; TEXAS HEALTHCARE & BIOSCIENCE INSTITUTE, 80TH LEGISLATURE END OF SESSION SUMMARY, available at <http://biodfw.com/portals/0/EndofSessionReport80thSession.pdf> (stating that Senate Bill 1620 “died in committee”).

192. H.B. 1459, 95th Gen. Assem. (Ill. 2007).

193. S.B. 1518, 48th Leg. (Ariz. 2007).

194. S.B. 229, 2007 Leg. Sess. (Kan. 2007).

195. S.B. 266, 2007 Gen. Assem., Reg. Sess. (Md. 2007).

196. H.B. 1005, 2007-2008 Sess. (Mass 2007).

197. S.B. 231, 74th Leg. (Nev. 2007).

198. S.B. 0653, 2007 Gen. Assem., Reg. Sess. (R.I. 2007).

199. H.B. 92, 2007 Gen. Assem. (Vt. 2007).

200. H.B. 1850, 60th Leg., Reg. Sess. (Wash. 2007).

201. S.B. 434, 2007 Reg. Sess. (W.Va. 2007).

First, the prescription drug information collected by data mining firms is factual,<sup>202</sup> and “related solely to the economic interests of the speaker and its audience.”<sup>203</sup> Admittedly, the Supreme Court has used varying definitions of commercial free speech, but prescriber-identifiable prescription information is precisely the information that has economic value to prescription data miners. Therefore, data mining firms target the sale of prescriber identifiable information to firms that purchase it for completely economic reasons. Without prescriber identification, the information would be worth much less to pharmaceutical companies, and the economic interests of the speaker (i.e., the data mining firms), and the audience (the pharmaceutical companies) would be inhibited. Furthermore, even though the First Circuit Court of Appeals determined that the New Hampshire statute regulated conduct and not speech, the appellate court’s opinion was supposedly limited to only the data mining firms’ actual use of the information (which includes aggregation, compilation and transfer of such information). Therefore, inhibition of the use of the information by pharmaceutical companies and individual detailers may, and is likely, to be considered a restraint on commercial speech.

Even if prescription data is considered commercial speech, it does not necessarily follow that it deserves constitutional protection.<sup>204</sup> Commercial speech may be regulated if there is a substantial interest and the regulatory technique is proportional to that interest.<sup>205</sup> Furthermore, “if the governmental interest could be served as well by a more limited restriction on commercial speech, the excessive restrictions cannot survive.”<sup>206</sup>

Data mining firms have a protectable interest because state legislatures that enacted the aforementioned statutes arguably did not articulate sufficiently important interests (i.e., ends) to justify the overbroad means (i.e., the statutes).<sup>207</sup> Both the New Hampshire and Maine Legislatures claimed that they were instituting restrictions upon pharmaceutical data mining in an effort to reduce the expenses of their Medicaid programs. At first glance, as the First Circuit Court of Appeals decided, the statutes may reduce healthcare costs.<sup>208</sup> However, another way to achieve the same

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202. *See Va. State Bd. of Pharmacy*, 425 U.S. at 763-64 (describing commercial free speech as having a factual aspect).

203. *Central Hudson*, 474 U.S. at 661.

204. *See id.* at 563 (noting that commercial speech receives less protection relative to other types of speech under the First Amendment).

205. *Id.* at 564.

206. *Id.*

207. This is meant to imply that the states’ stated interests were, for the most part, substantial, but the statutes in question were significantly broader than necessary to achieve the same policy endpoints.

208. This is primarily because if the statute works as planned, fewer brand name drugs will be prescribed. Therefore, the savings will result from the difference between the price

outcome would be to have a Medicaid formulary composed primarily of generic drugs and mandate prior authorizations on whichever branded drugs were offensive to the Legislatures.<sup>209</sup> More importantly, it is less burdensome for those physicians who wish to keep pharmaceutical sales representatives from visiting them to merely refuse to see them.<sup>210</sup> For example, Cindy Rosenwald, the sponsor of the New Hampshire legislation, is married to a cardiologist who apparently “had long known that he was being targeted specifically by drug representatives to change his prescribing habits.”<sup>211</sup> As a cardiologist being “targeted” it seems reasonable that excluding pharmaceutical sales representatives from his practice would produce a less intrusive result relative to passage of an arguably unconstitutional statute that will make pharmaceutical sales even less “targeted” and more chaotic.<sup>212</sup> It should also be noted that any competent prescriber would not be coerced by free coffee and donuts from a pharmaceutical sales representative.<sup>213</sup> Therefore, cardiologists, along

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of the brand name drugs promoted by the pharmaceutical companies and the generic drugs that the doctors would prescribe in their place. This savings is conditioned on the assumption that if physicians are subject to less advertising of brand name drugs, they will prescribe generic drugs, but it is also possible that physicians will merely prescribe other brand name drugs.

209. See Mark V. Siracuse & Phillip J. Vuchetich, *Impact of Medicaid Prior Authorization Requirement for COX-2 Inhibitor Drugs In Nebraska*, 43 HEALTH SERVICES RES. 435, 445-48 (2008) (indicating that a Medicaid prior authorization program successfully reduced prescription expenditures on COX-2 inhibitors). It should be noted that Maine is already employing “prior authorization as an incentive or a leverage device for extracting supplemental rebates from manufacturers.” Jagan Nicholas Ranjan, *Medicaid and the Unconstitutional Dimensions of Prior Authorization*, 101 MICH. L. REV. 602, 603 (2002).

210. Furthermore, residency programs can limit access of pharmaceutical sales representatives from meeting with the residents or institute greater prescribing controls upon their residents. See Peter J. Peraud & Eric B. Kulstad, *Another Resident Perspective: Resident Education and the Pharmaceutical Industry*, 45 ANNALS OF EMERGENCY MED. 32, 33 (2005) (indicating that the “restriction or prohibition of pharmaceutical company representatives is based on ethical standards,” but that this is a “paternalistic view” because “research shows little difference in the degree of industry influence on residents versus faculty”).

211. Sean Flynn, *The Constitutional Battle Over State Regulation of Data Mining*, THE PRESCRIPTION PROJECT LEGAL ANALYSIS (August 30, 2007) available at [http://www.wcl.american.edu/pijip/reglation\\_of\\_prescription.cfm](http://www.wcl.american.edu/pijip/reglation_of_prescription.cfm) (search for article under PIJIP documents).

212. See Rowe, 2007 Lexis 94268, at \*50-51 (indicating both that “the most effective tool that the prescriber possesses to reduce the influence of detailers is to refuse to see them” and that a prohibition on sales of prescriber information “does not prevent the pharmaceutical companies from marketing their products and the companies may resort to more general, less tailored marketing”).

213. But see *supra* note 101 (noting that there may have been evidence available, but not presented in *Ayotte*, that a nurse practitioner was coerced by coffee and donuts). Moreover, if a prescriber is allowing himself or herself to be coerced by mere coffee and donuts, the primary issue seems to be with the prescriber and not the pharmaceutical companies.

with most other doctors, may experience even more visits from sales representatives if the “privacy” statute is upheld. This is precisely due to the shortsightedness of legislation that does not prevent sales representatives’ visits, but prevents access to doctors’ prescribing patterns. Without access to sufficient information, the pharmaceutical industry may resort to indiscriminate canvassing of all doctors in a particular geographic area, instead of only sending sales representatives to specific doctors.<sup>214</sup> Moreover, despite Cindy Rosenwald’s opinion, the AMA has warned of the possible negative externalities associated with statutes that limit pharmaceutical data mining. Specifically, the AMA has expressed their opinion that “[r]estrictions on the use of prescription information could disrupt health care research and its corresponding benefits for patients, government agencies, health planners, academicians, businesses and others,” and that it is important to “not confuse confidential patient data with physician prescribing data.”<sup>215</sup>

Another problem with the Maine statute, as noted in *Rowe*, is that pharmaceutical companies can bypass the statute by simply paying prescribers to not opt out.<sup>216</sup> Therefore, if pharmaceutical companies instituted this practice, it is probable that only prescribers that found themselves excessively besieged by sales representatives would opt out. This is yet another reason why the statute is overbroad and arguably unconstitutional.

Proponents of anti-pharmaceutical data mining legislation also fail to realize the alleged influence of sales representatives is diminishing, without statutory manipulation, due to the changing dynamics of the pharmaceutical marketing industry. For example, pharmaceutical firms are already reducing their generalized marketing effort directly to physicians. This is due to several non-regulatory factors, including the increasing influence of payers, expiring patents, fewer new drugs with broad indications, and more specialty drugs.<sup>217</sup> This is even more evidence that Cindy Rosenwald’s legislation was, like so much other unneeded

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214. The court noted the potential for this wasteful effect in *Rowe*. 2007 Lexis 94268, at \*50-51.

215. See American Medical Association, *The Unintended Consequences of Proposals to Restrict Disclosure of Physician Prescribing Data*, available at <http://www.ama-assn.org/ama1/pub/upload/mm/432/rxamapositionmarch07.pdf> (stating further that “[t]he AMA believes that physician prescribing data do not undermine patient confidentiality laws because all patient data have been de-identified prior to collection and aggregation of this information”).

216. *Rowe*, 2007 Lexis 94268, at \*54 n.30.

217. Michael Steiner et al., *The Continuing Evolution of the Pharmaceutical Industry: Career Challenges and Opportunities*, Regent Atlantic Capital White Paper, 1, 3-4 (Dec. 2007), available at <http://www.pharmawealthmanager.com/pdf/Pharma%20Paper%20ADVANCE%20PUBLIC%20COPY%20Nov-30-2007.pdf>.

regulation, too late.

One final point bears noting. As healthcare receives more and more attention,<sup>218</sup> it is increasingly important for the federal government and individual state legislatures to refrain from infringing on the rights of businesses that provide healthcare services in a hasty or ill-conceived manner.<sup>219</sup> The statutes discussed in this paper exemplify how a good policy objective (i.e., the need to control healthcare costs) can be followed by overzealous attempts at mitigation. Healthcare is made up of a diverse group of businesses that attempt to provide patient care efficiently in the face of vast amounts of regulation.<sup>220</sup> Therefore, healthcare businesses should not face *non-safety* regulation in excess of any other types of businesses.<sup>221</sup> Haphazard regulation of data mining is an example of how healthcare regulation has the potential to increase inefficiencies.<sup>222</sup> Moreover, state legislatures should be more concerned with incompetent prescribers who prescribe drugs merely because they were advertised to them, and not on the basis of a sufficient, medically valid diagnosis. Curtailing data mining firms is not a way to correct this more serious underlying problem.

The question then becomes how to efficiently limit pharmaceutical data mining firms from allegedly interfering with prescribers and possibly increasing healthcare expenditures. A potential solution is a cultural opt out policy. For example, if a physician's practice is affected by

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218. This is due in part to the aging of the American population coupled with the policy debate concerning healthcare financing. See, e.g., Centers For Disease Control and Prevention, *Public Health And Aging: Trends in Aging—United States and Worldwide*, available at <http://www.cdc.gov/MMWR/preview/mmwrhtml/mm5206a2.htm> (stating that “[i]n the United States, the proportion of the population aged  $\geq 65$  is projected to increase from 12.4% in 2000 to 19.6% in 2030”); Lawrence D. Brown, *The Amazing Noncollapsing U.S. Healthcare System*, 358 NEW ENG. J. MED. 325, 325-27 (noting that the “U.S. healthcare costs have been in crisis for roughly 40 years . . . for several reasons, including administrative overhead, high payments to providers and the practice of defensive medicine”).

219. Note that even the First Circuit Court of Appeals commented that the New Hampshire statute “may not accomplish very much.” *Ayotte*, 2008 U.S. App. LEXIS 23701, at \*60.

220. Editorial, *An Unhealthy Burden*, ECONOMIST, June 28, 2007, available at [http://www.economist.com/finance/displaystory.cfm?story\\_id=9407716](http://www.economist.com/finance/displaystory.cfm?story_id=9407716) (subscription required) (indicating that as a result of federal and state regulation, the United States approach to healthcare regulation results in a “massive drag” of \$169 billion annually).

221. It can be argued that healthcare is different from other businesses, namely due to the asymmetric information qualities inherent in the healthcare industry. However, this is hardly an argument for preventing an efficient dissemination of pharmaceutical information from reaching physicians by sales representatives.

222. See, e.g., Jonathan Klick & Thomas Stratmann, *Diabetes Treatments and Moral Hazard*, 50 J.L. & ECON. 519, 537 (2007) (demonstrating how a diabetes mandate regulation creates an inefficient moral hazard situation where “the passage of diabetes benefit mandates worsens the health of diabetics relative to non-diabetics within mandate states”).

pharmaceutical sales representatives and the physician does not wish to see them, the physician should opt out by informing the sales representatives that they are not welcome in his or her office.<sup>223</sup> If enough doctors become upset at the pharmaceutical industry's advertising model, a culture of defiance will be directed towards pharmaceutical sales representatives, which in turn will cause the pharmaceutical industry to respond by advertising in an alternative way. However, the fact is that most prescribers tolerate pharmaceutical sales representatives because of the education provided concerning new therapeutic options and the provision of free drug samples to hand out to patients. It should be further noted that pharmaceutical companies have already begun moving away from directing their marketing efforts to prescribers despite an unwise regulatory attack on the business of pharmaceutical data mining.<sup>224</sup> In short, only social norms within the medical and pharmaceutical community itself, not overzealous and arguably unconstitutional regulation, will be truly effective in preventing the alleged bombardment of sales representatives that physicians supposedly encounter.

#### CONCLUSION

Data mining has been occurring in one form or another in many industries without many consumers realizing it. Data mining firms are continuously responding to marketplace demands<sup>225</sup> by developing more powerful information-collecting technologies. However, a backlash may occur as more and more consumers become aware of the information that data mining firms collect. Data mining firms may be viewed with contempt as consumers realize they are being specifically targeted due to information collected from their economic activities. However, it is naïve to think that the actions of pharmaceutical data mining firms can be significantly curtailed without impinging on the First Amendment or making the healthcare marketplace less efficient. As a result, state

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223. There is already evidence that this is happening without any regulation. *See* SK&A Patient Access Survey Press Release (Feb. 10, 2009), *available at* [http://www.skainfo.com/press\\_releases.php?article=71](http://www.skainfo.com/press_releases.php?article=71) (indicating that between June and December of 2008, physicians who forbid sales representative visits rose from 22.3% to 23.6% and physicians requiring sales representatives to make appointments rose from 31.4% to 38.5%). As for prescribers that work in settings other than individual practices, particularly hospitals, a drug formulary can be strictly enforced or the hospital can opt out of pharmaceutical sales representatives visits, with the exceptions of specified times.

224. *See* Steiner et al., *supra* note 217, at 38 (describing how “the shift from the “physician-prescriber” to a “stakeholder-payer” model will make the ability to influence payers of paramount importance to pharmaceutical companies. It also will cause these companies to lessen, though not eliminate, their marketing efforts to physicians”)

225. This demand occurs due to the ever-increasing competition between firms and the resulting need to achieve as high a rate of efficiency as possible.

legislatures should not act rashly when responding to the public's concerns about data miners. Furthermore, state legislatures must be vigilant to avoid imputing a backlash against data mining firms that is not actually present. As legislatures try to strike an appropriate balance, it must be remembered that "our brilliant Constitution made us free enough to develop and democratize free-speech technologies so cheap and powerful they can now be controlled only by property rights and local culture."<sup>226</sup>

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226. Peter Huber, *Smile, You're On Googcam*, FORBES, July 2, 2007, at 110.