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IMS Health v. Ayotte: A New Direction on Commercial Speech Cases

Alexander D. Baxter

I. INTRODUCTION

The constant call of the pharmaceutical ad has become commonplace on radio and television. With less than twenty years to exploit a patent on a new drug or treatment, pharmaceutical companies are locked in an endless battle with their own past successes, forever trying to convince consumers that the latest patent-protected and profitable formulation is superior to older drugs that have lost patent protection. Although consumers can ignore drug ads at their own discretion in private venues, they are significantly less able to do so in their doctor’s office. Therefore, physicians are primary targets for pharmaceutical advertising. Company marketers ply them with free samples of the latest drug along with pens and paperweights, bagels and coffee, even reimbursement checks for travel expenses to educational conferences—all to convince the physicians to prescribe the company’s brand instead of a generic or a competitor’s product.

Pharmaceutical marketers are known as “detailers” because they provide doctors details on new medications. Detailers have access to a doctor’s prescription history, a valuable tool for pitching a drug to the physician and tracking the doctor’s decision to actually prescribe the marketed drug. Data mining companies, working closely with the pharmaceutical companies, collect, process, and sell these histories. To promote competition by curbing detailers’ success promoting brand-name drugs over generics, New Hampshire passed a law prohibiting the sale of prescription histories for commercial purposes in 2006, and other states have subsequently adopted similar legislation. Litigation against the New Hampshire Act, IMS Health v. Ayotte, arose quickly as the data mining companies challenged the Act on constitutional free speech grounds. In an unusual decision, the First Circuit Court of Appeals deemed the sale of prescription history information to be conduct rather than speech and therefore unprotected by the First Amendment.

Part I of the Note explains the background that prompted the New Hampshire law. Part II discusses the legislative response in New Hampshire.
and nearby states. Part III provides a brief overview of the relevant Supreme Court decisions regarding commercial speech. Part IV discusses the recent holdings in the *Ayotte* case as well as its counterpart cases in Maine and Vermont. Finally, Part V focuses on the court ruling in *Ayotte* and predicts that future courts handling commercial speech cases will not follow the First Circuit's departure from precedent.

II. DETAILING: A PART OF EVERY PHYSICIAN’S DAILY ROUTINE

Marketers of brand-name pharmaceuticals use a variety of methods to maximize their drugs’ market share. Along with marketing to consumers, pharmaceutical companies spend vast amounts of money selling brand-name drugs directly to physicians.¹ Marketers use the direct-to-physician approach, known as “detailing,” to encourage physicians to prescribe a particular brand-name drug over generic or competitor-brand drugs, or to maintain brand loyalty after a patent expires.² Pharmaceutical companies spend almost $16 billion a year advertising their products, $4 billion of which is used for direct-to-physician marketing.³ By purchasing data from “data mining” companies, detailers acquire a detailed knowledge of the prescription history of the physicians they advertise to.

Pharmacies store certain information when they fill a prescription: the name of the patient and physician, the drug, dosage, and quantity dispensed.⁴ Data mining companies purchase this information from the pharmacies to package for sale.⁵ They organize and cross-reference this information in a variety of ways, including combining it with reference information about prescribers from the American Medical Association’s Physician Masterfile.⁶ Data miners such as IMS Health Inc. (IMS) and Verispan, LLC (Verispan), the plaintiffs in the IMS Health cases,⁷ sell access to their information databases to pharmaceutical companies.⁸ Although IMS and Verispan have other customers and provide some information at little or no cost to researchers, pharmaceutical companies comprise up to ninety-five percent of

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² Id.
⁴ *Ayotte II*, 550 F.3d at 45.
⁵ *Ayotte I*, 490 F. Supp. 2d at 166.
⁶ Id.
⁷ See infra Part V.
their total business. IMS dominates the health care information market, and Verispan is approximately one-tenth IMS's size.

In compliance with patient privacy laws, IMS and Verispan install programs on pharmacy computers to encrypt the identity of the patient in each prescription record before the information is transferred from the pharmacy. However, after masking the patient's identity, the data miners assign a placeholder number to each patient in order correlate multiple prescriptions for the same patient.

Armed with a dataset describing various physicians, their specialties, and prescription histories, detailers have several marketing advantages. First, they can more accurately target drugs to the right audience. For instance, prescription information allows detailers to discover which physicians tend to adopt new drugs quickly. Such "early adopters" are more profitable advertising targets. Second, advertisers can tailor their pitches more accurately to individual physicians, improving the likelihood of success. Finally, the pharmaceutical companies can determine their advertising's success by tracking changes in a physician's prescription history and adjust their marketing strategies accordingly.

Almost all physicians report having some kind of relationship with pharmaceutical representatives. Usually this relationship includes small gifts to the office, free lunches or coffee, or samples of prescription drugs. Many physicians also report accepting compensation for attending medical conferences and continuing education programs, as well as payments for

9. Id. at 166.
10. Id. at 165.
13. Id. Importantly, the privacy of patients receiving and filling prescriptions was not a critical issue in the IMS Health cases because of IMS and Verispan's policies protecting their privacy. The litigation in the IMS Health cases thus focused instead on the effect that detailers have on health care costs as a result of their acquisition and use of prescription information linked to physicians. See infra, Part V.
15. Id.
16. Id.
17. Id.
19. Id. 83% of physicians reported being brought food or drink, while 78% reported receiving prescription samples. The free samples are of particular note, since they are often used for patients who are unable to afford the prescription drugs any other way.
consulting or speaking at conferences. Detailers utilize these gifts and reimbursements to influence physicians' prescription practices. Although most physicians deny being influenced by detailers, the vast amount of money that pharmaceutical companies spend on direct-to-physician marketing speaks to its efficacy.

Prescription drug costs, including increased costs from detailing, are an increasing portion of the similarly increasing cost of health care in the United States. Nationally, current estimates see health care costs rising from twelve percent of GDP in 2007 (itself nearly $1.8 trillion) to twenty-five percent in 2025, and almost fifty percent in 2082. The growth rate of medical costs far outstrips the growth rate of GDP. This relationship is present at the state level as well. Prescription drugs make up approximately fourteen percent of the total expenditure on medical services nationally, but drug expenditure is a strong growth area. The growth rate of brand-name prescription drug costs is between two and three times that of the inflation-tracking consumer price index, keeping total drug costs high despite the presence of cheaper

20. Id.
21. See IMS Health Inc. v. Ayotte (Ayotte II), 550 F.3d 42, 72 n.23 (1st Cir. 2008) (Lipez, J., concurring and dissenting). In one anecdote that Judge Lipez cites, a pharmaceutical marketing manager sent an email to her employees saying: Our goal is 50 more [prescriptions] per week for each territory. If you are not achieving this goal, ask yourself if those doctors that you have such great relationships with are being fair to you. Hold them accountable for all of the time, samples, lunches, dinners, programs and past [consulting engagements] that you have provided or paid for and get the business!! You can do it!!


22. See Natasha Singer, No More Goodies for Doctors from Drug Makers, N.Y. TIMES, Dec. 30, 2008, at A1 (“Dr. Phillip Freeman . . . said that physicians who contended the giveaways were benign might be suffering from denial. ‘The need to deny influence is damaging to the soul,’ Dr. Freeman said.’”).

24. Congressional Budget Office, The Long-Term Outlook for Health Care Spending 8 (2007). Excess cost growth in medical expenditure—the amount of cost growth in excess of GDP growth—was 2.1% in the 1975–2005 period; with a 2.2% annualized GDP growth, medical costs grew at nearly twice the rate of the national economy. Id.

27. See, e.g., Delay & Norton, supra note 25, at 5. But cf. PricewaterhouseCoopers, supra note 26, at 13 (noting that the acceleration in prescription drug cost growth has declined).
generic alternatives. With Medicare and Medicaid accounting for over forty percent of health care expenditures, rising drug prices have a serious effect on federal and state budgets.

Combined with these rising drug costs and pressures on state budgets, the pervasiveness of detailing makes the practice a common target for legislation. States have passed various laws attempting to restrict the effectiveness of detailing attempting to relieve some of the pressure on Medicare and Medicaid, hoping to contain at least one input to drug costs.

III. LEGISLATIVE AND PRIVATE RESPONSES TO DETAILING

A. INEFFECTIVE NON-LEGISLATIVE RESPONSES

In response to the effects of detailing on prescription practices, the American Medical Association (AMA) established the Prescribing Data Restriction Program (PDRP) in 2006. This program allowed doctors to opt in to prevent pharmaceutical companies from accessing their prescription records. If a physician registers, data mining companies may still collect and sell her prescription history information to pharmaceutical companies, but pharmaceutical companies are prohibited from giving the data to marketers for three years. Very few physicians signed up for the PDRP when it was first announced. The AMA also developed guidelines for the use of prescription data in order “to provide ethical guidance to the healthcare industry.”

In addition to the AMA’s efforts, many drug companies have voluntarily stopped providing small gifts such as pens and coffee mugs to physicians. However, because of the voluntary nature of the PDRP, the necessity to re-register every three years, and the commercial advantages of detailing, some

29. Id. at 13–14 (noting generics cost about 70% less than brand name drugs).
31. See infra Section III.B.
32. Id.
34. Ayotte II, 550 F.3d at 74 (Lipez, J., concurring and dissenting).
35. Herskovits, supra note 33.
36. Id.
37. Natasha Singer, No Mug? Drug Makers Cut Out Goodies for Doctors, N.Y. TIMES, Dec. 31, 2008, at A1. Given the small value of such gifts, the voluntary restrictions should have minimal effect on the total marketing effectiveness of detailing.
states deemed these efforts ineffectual and turned to legislation to regulate drug marketing and detailing in particular.\textsuperscript{38}

\textbf{B. LEGISLATIVE RESPONSES}

Considering the PDRP to be ineffectual in light of the high economic incentive for pharmaceutical marketing,\textsuperscript{39} several states placed restrictions on pharmaceutical advertisers, citing patient privacy, improved care, or reduction of costs associated with prescription drugs.\textsuperscript{40} Some states restricted the number, value, and quality of gifts that detailers could give to physicians.\textsuperscript{41} Others, including New Hampshire, Vermont, and Maine, passed laws prohibiting the use of prescriber-specific information in detailing,\textsuperscript{42} which spawned the litigation discussed, \textit{infra}, in Part V.

In 2006, the New Hampshire legislature passed the Prescription Information Confidentiality Act to restrict detailers' access to physicians' prescription histories and tendencies.\textsuperscript{43} The Act prohibits the licensing, transfer, use, or sale of patient-identifiable and prescriber-identifiable prescription records for most commercial purposes, and provides civil and criminal penalties for violations.\textsuperscript{44} This legislation has the practical effect of cutting data miners off from their primary source of revenue. Although data miners may still collect and analyze prescription data, any sale of such data to a pharmaceutical company for marketing purposes violates the law.\textsuperscript{45}

In 2007, two states followed New Hampshire's example. Maine passed "An Act to Amend the Prescription Privacy Law," which requires physicians to opt-in to have their records covered by the law.\textsuperscript{46} Vermont passed a similar

\begin{itemize}
  \item 38. IMS Health, Inc. v. Ayotte (\textit{Ayotte II}), 550 F.3d 42, 74 (1st Cir. 2008) (Lipez, C.J., concurring and dissenting).
  \item 39. \textit{Id.}
  \item 44. \textit{Id.} Data organized by less specific factors than prescriber, such as zip code, are explicitly permitted. \textit{Id.}
  \item 45. Sales to pharmaceutical companies comprise approximately 95\% of the data miners' businesses. IMS Health, Inc. v. Ayotte (\textit{Ayotte I}), 490 F. Supp. 2d 163, 166 (D.N.H. 2007).
\end{itemize}
law that protects physician records by default, but has an opt-out procedure to allow physicians to provide their records for collection.\cite{47}

Table 1: Summary of state statute opt in/out provisions

<table>
<thead>
<tr>
<th>State passing law</th>
<th>New Hampshire</th>
<th>Maine</th>
<th>Vermont</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date passed</td>
<td>2006</td>
<td>2007</td>
<td>2007</td>
</tr>
<tr>
<td>Physicians included by default</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Physicians may opt in</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Physicians may opt out</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

The legislation in New Hampshire had an immediate impact on co-plaintiffs IMS and Verispan.\cite{48} Both companies instituted procedures to remove New Hampshire records from their databases for sale.\cite{49} They also responded by challenging each of the laws on constitutional grounds, bringing IMS Health v. Ayotte in New Hampshire, IMS Health v. Rowe in Maine, and IMS Health v. Sorrell in Vermont (herein collectively referred to as “IMS Health cases”). All three cases challenged the respective state laws as overly restrictive of commercial speech in violation of the First Amendment. Before describing the court decisions in detail,\cite{50} Part IV provides a general legal background of the commercial speech doctrine.

IV. HISTORY OF THE COMMERCIAL SPEECH DOCTRINE

A. COMMERCIAL SPEECH DENIED PROTECTION IN FIRST HALF OF TWENTIETH CENTURY

The most common definition of commercial speech is speech proposing that the listener enter into a commercial transaction.\cite{51} Prior to 1976, commercial speech lacked clear constitutional protection and was occasionally denied First Amendment protection entirely by the Supreme Court.\cite{52} In 1946, the Court in Valentine v. Chrestensen upheld a New York law that prohibited the distribution of handbills and other advertisements on

\begin{itemize}
\item \cite{48} See supra Part II.
\item \cite{49} Ayotte I, 490 F. Supp. 2d at 173–74.
\item \cite{50} See infra Part V.
\item \cite{51} See id. at 176.
\item \cite{52} E.g., Breard v. Alexandria, 341 U.S. 622, 644–45 (1951).
\end{itemize}
public city streets. The Court determined that, while it would violate the First Amendment to ban the distribution of all handbills on the street, there was "no such restraint on government as respects purely commercial advertising." The Court later maintained that commercial speech was unprotected in *Breard v. Alexandria*, upholding a Louisiana law prohibiting door-to-door solicitation of magazine subscriptions. The Court distinguished *Breard* from a previous case striking down a conviction for door-to-door solicitation of a religious meeting, noting that the religious solicitation involved "no element of the commercial." Over the next two decades, however, the Court tended to soften its approach to cases involving commercial speech, either avoiding the issue or limiting the holding in *Valentine*.

B. COMMERCIAL SPEECH FIRST GRANTED PROTECTION IN VIRGINIA BOARD

In 1976, the Supreme Court swept away any previous notion that commercial speech was entirely unprotected by the First Amendment. In *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, the Court confronted a Virginia law declaring a pharmacist guilty of unprofessional conduct if she published or otherwise advertised the price of her drugs or any other commercial information related to their sale. After noting its past denials to extend First Amendment protection to commercial speech, the Court identified the pharmacists' speech as a communication of the idea: "I will sell you the X prescription drug at the Y price." This situation is similar to that surrounding the IMS Health cases, though in *Virginia Board*, the pharmacist advertised to the public at large, while in the IMS Health cases, the pharmaceutical companies advertise to physicians, a step removed from the public.

54. Id. at 54–55.
56. Id. at 642–43.
57. See, e.g., Bigelow v. Virginia, 421 U.S. 809, 819 (1975) (nothing that speech is not unprotected simply because it is part of a paid advertisement); Pittsburgh Press Co. v. Human Relations Comm’n, 413 U.S. 376, 385–86 (1973) (recognizing free expression interest in editorial decisions in newspaper advertising).
58. Va. Bd. of Pharm. v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 750 (1976). The restriction in *Virginia Board* was intended to buttress the public support and confidence in pharmacists, which might be damaged by the sense that they were excessively competing over price instead of focusing on patient health. Id.
59. Id. at 761.
60. See infra Part V.
The Court then noted that speech does not lose First Amendment protection because money is spent disseminating it, because the speech itself is in a form intended to make a profit, or because it involves a solicitation to purchase other things or contribute money. Therefore, if commercial speech were to be unprotected under the First Amendment, something about the content of the speech must make it unworthy. Because the public is, and should be, very much interested in the state of the commercial market, and because the free flow of information is likely to improve the public's decisions, the Court held that commercial speech "is not in itself harmful," and should not be denied constitutional protection. However, the Court noted that commercial speech had "commonsense differences" distinguishing it from other varieties of speech, and thus may be subject to regulation that the Constitution would not permit for non-commercial speech.

C. THE COURT PROVIDES THE COMMERCIAL SPEECH TEST IN CENTRAL HUDSON

In 1980, the Supreme Court clarified the differences between commercial and non-commercial speech and established a test for permissible regulation of commercial speech. The Court in Central Hudson Gas & Electric Co. v. Public Service Commission of New York reviewed a New York restriction on the advertisement of electricity usage, which the state had initially adopted as a response to the inadequate fuel stock in the winter of 1973–74. The state continued to enforce the ban after the pressure on fuel had eased, and Central Hudson Gas & Electric Co. challenged the law on First Amendment grounds.

The Court identified two content-neutral features of commercial speech that allowed its regulation: the commercial speakers' ability to control the accuracy and lawfulness of their messages, and a profit motive that makes commercial speech "hardy" and less likely to be suppressed completely by regulation. The Court accorded commercial speech First Amendment protection, but the protection is somewhat limited. Thus the Court reviews commercial speech cases under a type of intermediate scrutiny.

61. Virginia Board, 425 U.S. at 761.
62. Id. at 761–62.
63. Id. at 770.
64. Id. at 771 n.24.
66. Id.
67. Id. at 564 n.6.
68. Id. at 563–64.
The *Central Hudson* rule for reviewing commercial speech restriction proceeds in two stages. First, because commercial speech is afforded less protection than regular speech, the government may proscribe misleading or illegal commercial speech, such as speech proposing an illegal transaction.\(^6^9\) If the government regulation does not address illegal or misleading speech, then the government must prove that it passes a three part test: (1) the government must show a substantial interest in regulating the speech, (2) the regulation must directly advance the substantial interest, and (3) the regulation must not be more restrictive than it needs to be to serve the substantial government interest.\(^7^0\) The Court in *Central Hudson* found the New York law to be unconstitutionally broad. Although New York's interest in conservation that prompted the ban on electricity advertising was substantial and the ban advanced that interest, the Court concluded that the law failed the final aspect of the test because it was overly restrictive.\(^7^1\)

Although the *Central Hudson* three part test has provided guidance for how courts structure their analyses of commercial free speech, it has by no means provided a bright line rule on the constitutionality of commercial speech restrictions.\(^7^2\) Many commercial speech cases hinge on whether or not the government regulation is overly restrictive, the third factor in the three-part test. While lower court rulings tend to be very fact-intensive and difficult to predict, Supreme Court precedents offer a few benchmark cases that provide a sliding scale of constitutional scrutiny. Thus, the more restrictive of speech a law is, the more compelling a state interest it must serve in order to pass constitutional muster. First, a law entirely suppressing the dissemination to the public of truthful, non-misleading commercial speech faces exacting (though not *strict*) scrutiny, and "rarely survive[s] constitutional review."\(^7^3\) These types of bans are nearly always found to be overbroad and more restrictive than necessary. Second, a ban that is less complete, such as prohibiting the in-person solicitation of business by lawyers or accountants, faces more relaxed scrutiny. These bans often target a certain form or venue

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69. *Id.* at 578–79.
70. *Id.* at 561–66.
71. *Id.* at 570–71.
73. 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 502–03 (1996). The Court in *Liquormart* did carve out a small space where such a blanket ban may be acceptable, when such bans are enacted to preserve a fair bargaining process. *Id.* at 502. Though the First Circuit in *Ayotte II* did not hold so, this line of reasoning parallels the court's "felt sense" argument about which types of speech are denied First Amendment protection. *See* IMS Health, Inc. v. Ayotte (*Ayotte II*), 550 F.3d 42, 52 (1st Cir. 2008).
of advertising, so-called “time and place” restrictions.\textsuperscript{74} Such bans “need only be tailored in a reasonable manner to serve a substantial state interest.”\textsuperscript{75} Third, speech that is related solely to the commercial interests of the speaker and its specific business audience warrants the most relaxed constitutional scrutiny, because the public has the smallest interest in the particular information.\textsuperscript{76} Restrictions on the transfer of a person’s credit history, when used to compile an advertising list, fall into this final category.\textsuperscript{77}

The Court has noted that when it strikes down a restriction of commercial speech, it is almost always because the restrictions are substantially excessive.\textsuperscript{78} In contrast, a regulation need not be the least restrictive option to be upheld; the Court requires only a “reasonable fit” between the restriction of commercial speech and the legislative goal, and will defer somewhat to legislative findings.\textsuperscript{79} Whether the New Hampshire law transgresses the First Amendment, assuming it regulates speech, depends heavily on the category into which the restriction of detailing falls.\textsuperscript{80}

V. THE IMS HEALTH CASES

IMS and Verispan filed a civil action seeking declaratory and injunctive relief in the District Court of New Hampshire against the Attorney General of New Hampshire Kelly Ayotte.\textsuperscript{81} Their constitutional challenge alleged that the Prescription Information Confidentiality Act (the New Hampshire Act) “transgressed the Free Speech clause of the First Amendment, was void for vagueness, and offended the Commerce Clause.”\textsuperscript{82} This Note only addresses the plaintiffs’ First Amendment challenge.

\begin{itemize}
\item \textsuperscript{74} Edenfield v. Fane, 507 U.S. 761, 767–74 (1993).
\item \textsuperscript{75} Compare id. (striking down a law prohibiting in-person solicitation by professional accountants) with Ohralik v. Ohio State Bar Ass’n, 436 U.S. 447, 465–66 (1978) (upholding a ban on solicitation of injury clients by attorneys, because of the heightened stress placed on the lay audience of the solicitation by “a professional trained in the art of persuasion”).
\item \textsuperscript{76} See Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc., 472 U.S. 749, 760–63 (1985) (holding that the delivery of credit reports to business audiences warranted reduced Constitutional protection).
\item \textsuperscript{77} Id. at 789.
\item \textsuperscript{78} Bd. of Trustees of State Univ. of New York v. Fox, 492 U.S. 469, 479–81 (1989). The substantially excessive standard is itself rather vague.
\item \textsuperscript{79} Fox, 492 U.S. at 480. The Court notes that the “reasonable fit” doctrine is still substantially more strict than the “rational basis” doctrine applied to some Fourteenth Amendment equal protection cases. Id. at 480–81.
\item \textsuperscript{80} See infra Part VI.
\item \textsuperscript{81} IMS Health Inc. v. Ayotte (Ayotte I), 490 F. Supp. 2d 163 (D.N.H. 2007).
\item \textsuperscript{82} IMS Health Inc. v. Ayotte (Ayotte II), 550 F.3d 42, 48 (1st Cir. 2008).
\end{itemize}
A. THE LOWER COURT DECISION IN AYOTTE

The Ayotte district court first considered whether IMS Health and Verispan’s actions constituted speech at all. Ayotte advanced two arguments that the New Hampshire Act prohibiting the sale or use of prescription data for commercial purposes did not regulate speech: (1) it regulated factual rather than expressive information, and (2) it regulated the use of the information rather than its disclosure. The court rejected both arguments: the first by noting that the Supreme Court in Va. Board protected purely factual information, and the second by observing that the New Hampshire Act expressly prohibited the transmission, and thus disclosure, of prescriber records. The court added that even if it did not prohibit transmission of records directly, it still regulated speech because it affected the downstream speech of pharmaceutical marketers.

After establishing that the plaintiffs’ actions constituted speech, the court characterized the restricted speech as commercial under the Central Hudson formulation. The court held that the law specifically prohibited the use and transmission of prescriber information for commercial purposes but did not regulate non-commercial disclosures. The district court proceeded to evaluate the constitutionality of the New Hampshire Act based on the Central Hudson test: whether it concerned a substantial state interest, effectively promoted that interest, and was no more restrictive than necessary in light of the state interests it promoted.

The state asserted that the New Hampshire Act advanced two substantial interests: the protection of prescriber privacy and the reduction of state health care costs. The state argued the first interest on very narrow grounds. The state argued that detailers invaded the privacy of prescribers not by acquiring the prescription information (professional information which the physicians likely did not have a right to keep private), but by intruding into the physician’s decision-making process. The court rejected this argument because the detailer-prescriber relationship did not meet the level of

84. Id.
85. Id. at 176.
86. That is, the pharmaceutical companies’ ability to speak would be affected by the lack of prescription history information. Id.
87. Id.
88. Id. at 177–83.
89. Id. at 179.
90. Id. at 179 n.13.
91. Id. at 179.
intrusiveness required to invoke a privacy interest. The court found that preventing detailers from using prescription data to persuade doctors to make “inadvisable prescribing decisions” was not a compelling state interest.

On the other hand, the court held that the state’s interest in reducing health care costs was clearly substantial. However, the court ultimately determined that the New Hampshire Act failed the second and third parts of the Central Hudson test. The state argued that detailing would become less effective without access to prescription records, thereby causing physicians to prescribe more generic drugs, which in turn would cut the state’s Medicare and Medicaid expenses. The court rejected this argument. Citing cases wherein patients had to be treated with brand-name drugs due to negative physical reactions to generics, the court reasoned that less expensive generic drugs are not always as medically efficacious as their brand-name counterparts. Thus, the initial savings in state expenditures might come at the cost of health care quality, leading to more treatments and more expense. Unwilling to balance the cost savings with the chance of losing care quality, the court held that the state had not met its burden in proving that the New Hampshire Act effectively advanced the goal of cost savings.

Finally, the district court held that the law was more restrictive than necessary. In doing so, the court appeared to use a “least restrictive means” test for this analysis instead of the “reasonable fit analysis” that the Supreme Court has advanced. The court presented three alternatives that the state could employ to reduce health care costs related to prescribing brand name drugs that did not involve restricting speech: (1) restricting detailers’ gift giving, as in other states, (2) instituting a state-sponsored advertising campaign for generic drugs, and (3) requiring prescription of generic rather than brand-name drugs to Medicaid patients unless the prescriber determines

92. The state argued by analogy to previous cases, showing that there was a substantial state interest in: (1) preserving the tranquility of the home, Carey v. Brown, 447 U.S. 455, 471 (1980); (2) preventing harassment or intimidation in advertising services, Edenfield v. Fane, 507 U.S. 761, 769 (1993); and (3) preventing the willing affront to the tranquility of bereaved individuals, Fla. Bar v. Went For It, Inc., 515 U.S. 618, 630 (1995).


94. Id. at 178–80.

95. Id. at 180.

96. Id.

97. Id.

98. Id. at 181.

99. Id. at 181–83.

100. See supra Section IV.C.
the brand-name drug to be medically necessary. However, the court did not directly consider whether the restriction on prescription information was a "reasonable fit" to the state interest.

The court thus determined the state could not justify the New Hampshire law under either of the interests that it advanced. The first interest of prescriber privacy, preventing the "intrusion" of detailers into the doctor-patient relationship, was not a substantial state interest. The second interest in cost reduction was a substantial interest, but the court held that the law did not successfully advance it and was overly restrictive of speech. After dismissing both justifications, the court struck the New Hampshire Act as unconstitutional and issued an injunction preventing its enforcement.

B. AYOTTE ON APPEAL

In 2008, Ayotte appealed on behalf of New Hampshire to the Court of Appeals for the First Circuit. The court of appeals overturned the district court in a split decision. The court's analysis differed significantly from the district court's, eventually determining that the New Hampshire law did not regulate speech. However, the court first identified three information transactions that occur before a detailer makes her marketing pitch: (1) the plaintiffs' acquisition of prescriber-specific information, (2) the sale of processed information to pharmaceutical companies for use in detailing, and (3) the use of that information by detailers to promote products. The court then established that it would consider only the rights of the plaintiffs, the data miners, and not those of detailers or pharmaceutical companies. This restricted the court's analysis to "whether . . . the acquisition, aggregation, and sale of prescriber-identifiable data constitute[s] speech or conduct and whether New Hampshire's legitimate governmental interests are sufficient to counterbalance any speech rights inherent therein." The following Sections consider the court's holdings that (1) the data miners' activity constituted conduct, not speech, and (2) even if it was speech, the state had sufficient justification for restricting it.

102. Id. at 183.
103. IMS Health v. Ayotte (Ayotte II), 550 F.3d 42 (1st Cir. 2008).
104. Id. at 48-49.
105. Id. at 49. Judge Lipez noted in his concurring and dissenting opinion that the pharmaceutical companies were intimately involved in the overall IMS Health litigation, and that because the law squarely targeted their practices, their rights should not be ignored in adjudicating the case. Id. at 65-69 (Lipez, C.J., concurring and dissenting).
106. Id. at 50 (majority opinion).
1. The Act Constitutes Regulation of Conduct

The court began its analysis with the observation that making a course of conduct illegal does not necessarily abridge freedom of speech simply because that conduct is carried out through language, whether spoken or written. The court then noted that there were categories of speech to which the Supreme Court had not granted First Amendment protection. The unprotected categories included lewd and profane speech, libel, “fighting words,” agreements restraining trade, speech furthering crime, and speech such as sexual harassment that creates hostile work environments. While noting that no doctrinal aggregation and explanation of these exceptions exists, the court identified a “felt sense” that laws proscribing such categories primarily regulated conduct rather than speech, or that the speech they regulated was of little to no societal value.

Turning to the New Hampshire Act, the court determined that it primarily regulated conduct: information that the data miners used was more akin to a commodity that was purchased, processed, and re-sold, and the law only restricted to whom and for what purpose the data miners could sell it. The court also noted that the law did not exist to protect particular businesses, and that the free development (through collection and processing) of prescription history information was still legal—only sale for use in detailing was proscribed. Actors in the information market were still free to create and disseminate the underlying information for other purposes.

107. Id. at 51.
108. Id. at 51–52. (noting examples of the categories of speech).
110. Ayotte II, 550 F.3d at 52 (1st Cir. 2008).
111. Id. at 53 (“The plaintiffs . . . ask us in essence to rule that because their product is information instead of, say, beef jerky, any regulation constitutes a restriction of speech. We think that such an interpretation stretches the fabric of the First Amendment beyond any rational measure.”).
112. Id. ("[T]he First amendment [sic] does not safeguard against changes in commercial regulation that render previously profitable information valueless.") (quoting Wine & Spirits Retailers, Inc. v. Rhode Island, 418 F.3d 36, 49 (1st Cir. 2005)).
113. Id. The New Hampshire Act targets the conduct of detailers, but the information they use to convince doctors to purchase their drugs can also be used for more laudatory research activities. Id.
such as research. The court thus held that the New Hampshire Act did not violate the Free Speech Clause and that the law was constitutional.

Circuit Judge Lipez, though ultimately concurring that the law was constitutionally permitted, penned a forceful dissent on the speech or conduct issue. Lipez reasoned that the law had to be a regulation of speech because of it affected how pharmaceutical companies are allowed to advertise. Lipez further noted that even if the “upstream” conduct of data mining companies and pharmacies was not speech, the New Hampshire Act targeted the “downstream” speech of pharmaceutical companies advertising to physicians. Since the law was designed to limit speech, Lipez concluded, it had to be analyzed as a restriction on speech under the *Central Hudson* test.

2. The Act Would Meet Free Speech Scrutiny

Although the court held that the New Hampshire Act did not regulate First Amendment-protected speech, it assumed *arguendo* that it did to analyze the law as a commercial speech restriction subject to *Central Hudson*. As the district court had done below, the court first found that health care cost containment satisfied the first prong of the test as a substantial government interest.

The court then analyzed the connection between regulating detailing and the stated interest of containing health care costs by looking at the evidence the state presented: (1) detailing increases the cost of prescription drugs, (2) prescriber history information increases the success of detailing, and (3) detailing does not contribute to improved patient health. The court concluded that the evidence, while not iron-clad, was “competent,” and that it was unreasonable to require more concrete evidence where New Hampshire was the first state to restrict detailing in this manner. Thus, the New Hampshire Act was “reasonably calculated to advance [the state’s] substantial interest in reducing overall health care costs within New Hampshire.”

114. *Id.*
115. *Id.* at 68–69 (Lipez, C.J., concurring and dissenting).
116. *Id.*
117. *Id.*
118. *Id.*
119. *Id.* at 54 (majority opinion).
120. *Id.* at 55.
121. *Id.* at 55–58.
122. *Id.* at 58.
123. *Id.* at 59.
Finally, the court turned to whether the New Hampshire law was no more extensive than necessary to serve the state’s interest. The Court of Appeals considered the district court’s three alternatives to restricting the use of prescription histories: restricting gifts to physicians, providing competing advertising for cheaper methods, and re-tooling the state Medicaid program to aggressively promote generic drugs and make it more difficult to prescribe brand-name drugs. The court dismissed each in turn, finding that there was little efficacy in restricting gifts (and that gifts of drugs were gratefully used to treat patients unable to pay for their prescriptions), that it was unfeasible for the state to compete with the huge advertising budget of the pharmaceutical industry, and that the Medicaid proposal was impractical, incomplete, and improperly placed in the prescription process. The court thus held that there was no identifiable alternative to achieving the goals of the New Hampshire Act without restricting speech and that it was no more restrictive than it had to be. With this conclusion, the state had met its burden under all three parts of the Central Hudson test, and the Court of Appeals therefore upheld the New Hampshire Act as constitutionally permissible.

The majority on the Court of Appeals took two different approaches to arrive at the same conclusion. While its decision ultimately rested on the determination that the New Hampshire Act regulated conduct and not speech, the court also provided Central Hudson analysis to conclude that even if it did regulate speech, it would nevertheless be permitted under First Amendment jurisprudence. This dual structure is a new wrinkle in commercial speech cases, and the First Circuit is currently the only court to declare that an information-regulating law like New Hampshire’s regulates conduct rather than speech.

C. Litigation in Maine and Vermont

Maine and Vermont passed legislation similar to the New Hampshire Act concerning physician records, but the laws differ regarding the presence of opt-out and opt-in provisions. In Maine, a physician must request that his or her records not be used for commercial purposes. This request is made when applying for a medical license. In Vermont, as in New Hampshire, the

124. Id. at 59–60.
125. Id.
126. Id. at 60.
127. Id. at 64.
law covers prescriber data by default, but prescribers may opt out of coverage.\footnote{129}{See 18 Vt. Stat. Ann. § 4631 (2008).}

There was litigation in both states paralleling the case in New Hampshire. \textit{IMS Health v. Rowe}, in Maine, was decided after the district court issued its decision in \textit{Ayotte}, but before the Court of Appeals had reviewed the case. As such, the \textit{Rowe} court cited the \textit{Ayotte} district court decision approvingly and only discussed whether the opt-in provision in the Maine law made enough of a difference to save the law from constitutional violation.\footnote{130}{IMS Health Corp v. Rowe, 532 F. Supp. 2d 153 (D.Me. 2007).} The court concluded that, though the opt-in provision made it a closer case, the law still violated the First Amendment.\footnote{131}{Id.}

The case in Vermont, \textit{IMS Health v. Sorrell}, was decided after the \textit{Ayotte} appeal came down. Though not bound by \textit{Ayotte}'s First Circuit precedent, the \textit{Sorrell} court cited the \textit{Ayotte} appeal approvingly and followed its commercial speech analysis.\footnote{132}{See IMS Health Inc. v. Sorrell, 631 F. Supp. 2d 434 (D.Vt. 2009).} Noticeably lacking in the \textit{Sorrell} court's analysis, though, was any discussion of \textit{Ayotte}'s distinction between conduct and speech. The \textit{Sorrell} court held that the Vermont law squarely targeted speech and proceeded accordingly, upholding the law on \textit{Central Hudson} grounds.\footnote{133}{Id. at 446–47.}

\section{VI. ANALYSIS: THE NEW HAMPSHIRE LAW REGULATES SPEECH, NOT CONDUCT, BUT IN A CONSTITUTIONALLY PERMISSIBLE MANNER}

The litigation in \textit{Ayotte} invoked two competing interests: the right to speak freely and disseminate information, and the need to contain drug expenditures and preserve the sanctity of the doctor-patient relationship. Although both are important, the First Circuit made the correct decision—even if for an unexpected reason—to allow for regulation of selling prescription information in light of the massive drain on public finance that drug prices and drug detailing cause. Section V.A is a critical examination of the court's finding that the Prescription Information Law regulated conduct, not speech.\footnote{134}{See N.H. Rev. Stat. Ann. § 318:47-f (2006). For a description of the court’s opinion, see \textit{supra} Section V.B.} The Section concludes that the First Circuit's finding is unsustainable and that plaintiff's conduct should have been categorized as speech. Section V.B explores the options of how data mining can be regulated if it is considered speech.
A. THE COURT'S ODD DECISION: CONDUCT, NOT SPEECH

The Ayotte court's primary basis for upholding the New Hampshire Act was that it regulated the conduct of the plaintiffs, not their speech.135 However, this determination jumps over a few important gaps. First, the first stage of the commercial speech regulation test the Supreme Court set out in Central Hudson reasonably covers the categories that the court identified as exempt from First Amendment protection—"fighting words" and agreements in restraint of trade, for example. These are categories of speech that facilitate or promote otherwise illegal activity, permissible under the test. The "downstream" speech that the New Hampshire law targets—pharmaceutical marketing to physicians by detailers—is not made illegal by the law. It is only weakened. Because the data mining does not facilitate an illegal activity, it is strange to deem the data mining without First Amendment protection.

Furthermore, the existence of a market for the manipulated data belies the court's supposition that it is only of "nugatory informational value."136 Though the court notes that drying up a market is not a reason to strike down a regulation of speech,137 the market (which ranges from encouraged research to disfavored marketing) for IMS's services differentiates their commercial activities from non-protected speech-like agreements to restrain trade or "fighting words." Finally, the court recognizes that there is a public interest in disseminating the prescription information, but that research rather than detailing serves that interest.138 Nevertheless, the information itself has value, both social and economic. The court's determination that the transfer of information for one purpose (research) is permissible conduct but transfer for a different purpose (pharmaceutical marketing) is of little or no value is difficult to reconcile in a stable framework.

Ultimately, it is unlikely that Ayotte's characterization will be widely adopted by other courts. Perhaps recognizing the disconnect between its holding and First Amendment precedent, the Ayotte court offered an alternative explanation for upholding the New Hampshire Act.139 The Sorrell district court, not bound by the First Circuit precedent, characterized the prescriber-identifiable information as "plainly commercial [and] possessing a degree, however debatable, of social importance," and held that the Vermont

135. See supra Section V.A.
136. See IMS Health v. Ayotte (Ayotte II), 550 F.3d 42, 52 (1st Cir. 2008).
137. Id. at 53.
138. Id.
139. Id. at 54.
law regulated speech and not conduct.\textsuperscript{140} If more states seek to curb pharmaceutical detailing, it is likely that the other federal circuits will analyze those laws as regulating speech as well.

\textbf{B. What kind of speech is regulated, and at what level of scrutiny?}

Assuming that data collection, analysis, and resale should fall under the limited constitutional protection offered by the commercial speech doctrine, the next question is at what level of scrutiny a court should examine data regulations. As discussed previously, the Supreme Court has drawn out three rough categories of commercial speech and three corresponding levels of intermediate scrutiny: (1) complete bans on the dissemination of commercial information which rarely survive constitutional review, (2) less than complete restrictions that must reasonably comport with their legislative goal, and (3) restrictions of information of little public interest that are examined in a more relaxed manner.\textsuperscript{141}

The New Hampshire Act and its counterparts do not appear to fit into the first category of restrictions—complete bans on the spread of commercial information. As the First Circuit Court of Appeals noted, nothing prohibits data mining companies from collecting and analyzing prescription histories, as long as they do not sell them to those who use them for a commercial purpose.\textsuperscript{142} However, there is some danger to this line of reasoning. Given that sales to pharmaceutical companies account for the vast majority of revenue for data mining companies, a country-wide replication of the New Hampshire Act would threaten to force companies like IMS and Verispan out of business. Although preservation of business models is not normally a factor in First Amendment analysis, the same data miners who sell to pharmaceutical companies also distribute their databases to researchers without a profit expectation.\textsuperscript{143} Consequently, making data mining companies unprofitable by criminalizing their most important revenue stream could effectively cripple dissemination of prescription information for useful research purposes and thus harm the public interest.

Though the New Hampshire Act is not a complete ban on a type of commercial information, it might fit under either of the two remaining categories: (1) restrictions on time, place, or manner of spreading information, or (2) restrictions on information relevant only to the speaker

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\textsuperscript{141} See supra Section IV.C.
\textsuperscript{142} Ayotte II, 550 F.3d at 53.
\textsuperscript{143} Id. at 74.
\end{flushleft}
and its specific business audience. If a less than complete restriction on the spread of commercial information (the second category), the New Hampshire Act meets the “reasonable fit” analysis used to evaluate the level of speech restriction and the governmental interest behind it. The district court in Ayotte seemed to apply a test more like the “least restrictive means” test for restrictions on expressive speech, offering several alternatives that might further the New Hampshire state legislature’s goal of restricting the effectiveness of detailing while causing less harm to the dissemination of information. The court of appeals was correct to reject that framework. The existence of less restrictive alternatives does not mean that the New Hampshire law was unreasonable. The legislature’s goal, restraining rapidly growing health care costs based in part on the expense of brand-name drugs,144 is substantial enough to sustain a restriction on the commercial use of certain information. The court of appeals was correct to offer New Hampshire some leeway in charting a course that may reduce state medical expenses at the cost of some dissemination of commercial information.145

Finally, the New Hampshire law likely meets the most relaxed test for restraints on commercial speech: if prescription histories are commercial information of importance only to the speaker and its specific business audience, then their transfer warrants reduced constitutional protection. The cases that federal courts have decided on these grounds are similar to the Ayotte case—in Dun & Bradstreet v. Greenmoss, the Supreme Court found that credit histories delivered by credit reporting companies to a business audience were this type of information.146 Similarly, the Court of Appeals for the District of Columbia held that a marketing list based on credit reports, which helped buyers target consumers for advertising, was a matter of no public concern.147 The sale of prescription histories seems to fit this general category. Certainly most arguments that prescription histories are matters of public concern—that they are subject to research, are needed for professional review, and are useful for measuring various aspects of the economy—could also apply to credit reports. Under this more relaxed framework, the New Hampshire Act and others like it easily pass constitutional muster.

Thus, the New Hampshire Act does not fit into the strictest category of commercial speech restrictions but would survive the lower constitutional

144. Prescription drugs make up 14% of health care expenditures, and brand-name drugs are increasing in price at nearly three times the rate of inflation. See supra Part II.
145. See Ayotte II, 550 F.3d at 58.
scrutiny if it fit into either of the other two categories. Because of its reasonably limited scope (prohibiting only one type of informational transaction) and the strong legislative goal behind it, the New Hampshire Act is a “reasonable fit” as an attempt to control health care costs, despite the as-yet unknown ultimate effect. Despite the implication for free speech, New Hampshire and the other states enacting laws like New Hampshire’s should be able to attempt to control health care costs in this manner.

VII. CONCLUSION

The New Hampshire legislature faced a difficult problem prevalent throughout the United States—rising drug prices impacting the state budget through Medicare and Medicaid—and came up with an imperfect solution. Although the New Hampshire Act regulates protected speech and impinges upon the free flow of information (commercial or not), ultimately the substantial state interest in reducing medical costs is paramount. The First Circuit Court of Appeals, in a break from every other court handling this type of issue, deemed the sale of prescription information conduct and not speech. It is unlikely that this idea will be carried forward for long. At least one district court has already decided the exact same issue under a speech analysis, and similar decisions will surely come if more states pass laws similar to the New Hampshire Act.