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LEGISLATING AROUND THE SUPREME COURT’S HOLDING THAT PRESCRIBER-IDENTIFYING DATA IS COMMERCIAL SPEECH

Jeff Gibellina*

INTRODUCTION

Pharmaceutical manufacturing is big business — really, really big business. Johnson & Johnson, a leader in the pharmaceutical manufacturing industry, generated $61.9 billion in revenue in 2009, resulting in $12.2 billion in profits.1 Pfizer, a similarly situated company, generated $50 billion in revenue in 2009, resulting in $8.6 billion in profits.2 Due to the Supreme Court’s ruling in Sorrell v. IMS Health, Inc.,3 those profits are unlikely to dip any time soon.4 On First Amendment grounds, the Sorrell court struck down a state statute and consequently allowed pharmaceutical manufacturers to continue using a particularly influential form of marketing called “detailing,” which entails the use of prescriber-identifying data typically obtained from pharmacies to better target physicians.5 After this ruling, a question remained: what could those states that restricted the use of prescriber-identifying data have done differently to lawfully curb the harmful marketing tactic? Regardless of the answer to this question, the Sorrell court erred in finding that the Vermont statute failed to sufficiently protect the state’s privacy interest.

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4. Kate Thomas, N.Y. TIMES, Pfizer Races to Reinvent Itself, May 01, 2012, http://www.nytimes.com/2012/05/02/business/pfizer-profit-declines-19-after-loss-of-lipitor-patent.html (Perhaps Pfizer’s profits will dip due to the expiration of its patent on Lipitor, which is completely unrelated to the Supreme Court’s ruling in Sorrell.).

5. Sorrell, 131 S. Ct. at 2659.
and should have upheld the constitutionality of the statute.

THE POWER OF "DETAILING"

One of the underlying forces behind such massive profit margins for pharmaceutical manufacturers is marketing. It is well documented that pharmaceutical companies spend billions of dollars on marketing annually, which includes millions of visits to physicians' offices by pharmaceutical sales representatives.\(^6\) Even in 2000, brand-name drug manufacturers spent $4 billion on these face-to-face interactions, also known as "detailing."\(^7\) The Maine legislature defined "detailing" as "one-to-one contact with a prescriber or employees or agents of a prescriber for the purpose of increasing or reinforcing the prescribing of a certain drug by the prescriber."\(^8\) Detailing is thought to be particularly effective in persuading physicians to prescribe "high-profit brand-name drugs protected by patent."\(^9\) Because the process of detailing is time-consuming and expensive, drug manufacturers use it to market only those drugs that generate significant profits.\(^10\) Those profitable drugs are as prevalent as ever, as 90,000 pharmaceutical sales representatives, also known as "detailers," make weekly or monthly trips to physicians' offices on an annual basis.\(^11\) To further emphasize the prevalence of detailing, the average primary-care physician meets with twenty-eight or more detailers every week while specialists meet with fourteen per week.\(^12\) Detailers who visit these physicians usually bring drug samples and medical studies that tout the advantages of their employer's pharmaceutical drugs.\(^13\) In addition to promotional materials and pamphlets highlighting the effectiveness of their pharmaceutical products, detailers distribute nearly $1 billion worth

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6. David Orentlicher, Prescription Data Mining and the Protection of Patients' Interests, 38 J.L. MED. & ETHICS 74 (2010) (citing Julie M. Donohue, et al, A Decade of Direct-to-Consumer Advertising of Prescription Drugs, 357 NEW ENG. J. MED. no.7, 673, 676 (2007) (reporting annual expenditures on detailing of about $7 billion between 2002 and 2005); David L. Coleman, et al, Guidelines for Interactions between Clinical Faculty and the Pharmaceutical Industry: One Medical School's Approach, 81 ACAD. MED. no. 2, 154 (2006) (reporting that pharmaceutical companies employ more than 80,000 sales representatives and that the average physician meets with a sales representative four times per month); John Russell, Lilly Changes Course as it Shrinks its Sales Force, INDIANAPOLIS STAR, Jan. 17, 2010, at A18 (reporting that drug companies appear to be reducing their sales forces.).
7. IMS Health Inc. v. Ayotte, 550 F.3d 42, 46 (1st Cir. 2008).
9. Sorrell, 131 S. Ct. at 2660 ("Once a brand-name drug's patent expires, less expensive bioequivalent generic alternatives are manufactured and sold.").
10. Ayotte, 550 F.3d at 46.
11. IMS Health Inc. v. Mills, 616 F.3d 7, 14 (1st Cir. 2010).
12. Ayotte, 550 F.3d at 47.
of free samples annually.\textsuperscript{14}

Detailers gain access to offices by offering physicians and staff objective information regarding the “latest pharmacological developments,” thereby saving the physicians’ time that would otherwise be used to educate themselves on such developments.\textsuperscript{15} Furthermore, detailers gain entry by bringing small gifts to physicians and staff, by hosting complimentary lunches, and by handing out the aforementioned complimentary drug samples.\textsuperscript{16} During these meetings, a physician can ask questions following a presentation and the detailer typically will establish a follow-up schedule with the physician.\textsuperscript{17} As the \textit{Mills} court correctly noted, “The central objective is to get prescribers to adopt the pharmaceutical product the detailer is marketing and to build brand loyalty.”\textsuperscript{18}

Detailing is used in a few scenarios, including when pharmaceutical manufacturers want physicians to understand why their brand-name drug is better than the generic drug or better than a competitor’s patented drug.\textsuperscript{19} Additionally, detailing maintains brand loyalty in anticipation of the patent expiration on a manufacturer’s brand-name drug and the physician has the opportunity to prescribe a generic version of the drug.\textsuperscript{20}

\section*{PRESCRIBER-IDENTIFYING INFORMATION}

The practice of detailing becomes far more profitable for pharmaceutical manufacturers with the availability of “prescriber-identifying information.” Such information is gathered by pharmacies (usually for insurance reimbursement purposes\textsuperscript{21}) each time they receive a prescription from a physician.\textsuperscript{22} Prescriber-identifying information is stored on pharmacies’ computerized databases and includes a “potpourri of information,”\textsuperscript{23} including the identity of the prescribing physician, the drug, the dosage, and the quantity dispensed.\textsuperscript{24} Pharmacies are able to generate vast amounts of data on individual physician’s prescribing habits

\begin{itemize}
\item \textsuperscript{14} \textit{Id.} at 8.
\item \textsuperscript{15} \textit{Id.}
\item \textsuperscript{16} \textit{Id.}
\item \textsuperscript{17} \textit{Sorrell,} 131 U.S. at 2659.
\item \textsuperscript{18} \textit{Mills,} 616 F.3d at 8.
\item \textsuperscript{19} \textit{Ayotte,} 550 F.3d at 46.
\item \textsuperscript{20} \textit{Id.}
\item \textsuperscript{21} 616 F.3d at 15.
\item \textsuperscript{22} \textit{Id.} at 12.
\item \textsuperscript{23} 550 F.3d at 45.
\item \textsuperscript{24} \textit{Id.}
\end{itemize}
over time, which eventually serve as an invaluable resource for detailers in crafting their marketing message toward a targeted audience. The information ultimately allows detailers to identify and subsequently target those physicians that consistently use a competitor’s drugs, physicians that prescribe large quantities of drugs for a particular condition, and physicians that have a propensity to use new drugs that have recently made their way to the market (“early adopters”).

Creating Prescriber-Identifying Information

The detailers’ use of prescriber-identifying information is actually the last step in a series of transactions that begins with gathering huge amounts of prescriber-identifying data. In order for detailers to obtain this information in such a way as to be useful to them, pharmaceutical manufacturers must purchase it from “data miners.” Data miners contract with pharmacies, insurance companies and other carriers to purchase their raw data. The contracts compel the pharmacies to send to the data miners the prescription data collected by the pharmacies’ computer software. To get an idea of the sheer volume of information exchanging hands, two of the more prominent data miners, IMS Health Inc. and Verispan LLC, organize information from several billion prescriptions annually. While the prescriber-identifying data does not include the patient’s name, data miners assign a unique number to the patient. With that ID number, data miners can determine how long a patient is on a drug, whether the physician prescribed a new drug and the name of that new drug, and if the physician discontinued drug therapy altogether on that particular patient. With the vast amount of data, data mining companies are able to create reports and databases that are more often than not tailored to sell or lease to pharmaceutical manufactures. With the drug manufacturers in mind, the data miners illustrate a prescribing-physician’s history by “cross

25. 616 F.3d at 12.
26. Id. at 14.
27. 550 F.3d at 48.
28. 616 F.3d at 15.
29. Id. at 16.
30. Id.
31. Id.
32. Ayotte, 550 F.3d at 45 (To ensure patient privacy, patients’ names are encrypted so it’s impossible to match particular prescriptions with particular patients.) (emphasis added.)
33. David Orentlicher, Prescription Data Mining and the Protection of Patients’ Interests, 38 J.L. MED. & ETHICS 74, 75 (2010).
34. Id.
35. Mills, 616 F.3d at 16.
referencing prescriber names with publicly available databases, including the [American Medical Association's] database of medical doctors' specialties." Data miners then sell or lease the prescriber-identifying data, subject to nondisclosure agreements, to pharmaceutical manufacturers who in turn give it to their sales representatives (detailers) who use it to determine which physicians to target in their marketing efforts. Similar to the pharmaceutical manufacturing industry, business is good for data miners. IMS Health earned $1.75 billion in revenue in 2005. That figure alone is a strong indicator of the value such information has for detailers and the impact it has on bottom lines for companies like Pfizer and Johnson & Johnson.

Harmful Effects of Prescriber-Identifying Information

Due to a number of perceived adverse consequences, the use of prescriber-identifying information by detailers to influence physicians to buy or prescribe a pharmaceutical manufacturer's drugs has come under fire in several states. This has occurred most notably in Maine, New Hampshire, and Vermont. The New Hampshire legislature determined that prescriber-identifying information gave detailers too much bargaining power or leverage, which in turn had an inflationary impact on drug prices due to detailers' success in pushing more expensive brand-name drugs in lieu of cheaper generic drugs. The impact of such inflation results in increased healthcare costs, which hinders state Medicaid programs' ability to fund the needs of their beneficiaries. Additionally, this bargaining power held by detailers can lead to physicians' having an "overly enthusiastic view" on a particular brand-name drug, resulting in fewer prescriptions of cheaper, equally effective drugs. On a similar note, with prescriber-identifying information, detailers tend to become more "adversarial" in their presentation and focus on the negative effects of drugs that physicians are currently using in hopes that they will switch to the brand-name drug. Using this adversarial approach, detailers tend to

36. Id.
37. Sorrell, 131 S. Ct. 2653 at 2660.
38. See Orentlicher, supra note 30, at 74.
40. Ayoite, 550 F.3d at 54.
41. See Orentlicher, supra note 30, at 81.
42. Id. at 76 (citing Ashley Wazana, Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift? 283 JAMA 373, 378 (2000) ("After interactions with sales representatives, for example, physicians are more likely to prescribe expensive, new drugs instead of cheaper generic drugs, even when there is no medical advantage to the newer drug.").
43. 550 F.3d at 56.
ignore the virtues of their own drugs, focusing on the vices of competitors’
drugs, and therefore fail to adequately distinguish them from other
sometimes cheaper, generic drugs.\textsuperscript{44} Moreover, the New Hampshire
legislature found that detailers’ access to such information compromised
the decision-making of physicians who received most of their information
from brand-name-drug detailers.\textsuperscript{45} One study showed that physicians were
more likely to prescribe a drug that was heavily promoted over another
equally effective drug that was not promoted.\textsuperscript{46} Most physicians are
unaware of this propensity to lean toward the promoted drug even though
most claim that they strictly look at medical data.\textsuperscript{47}

Another concern is reciprocation with respect to the gifts that
detailers give to physicians during their one-on-one visits.\textsuperscript{48} Prescribing
physicians feel the need to reciprocate upon receiving a gift, and do so by
promoting the detailer’s drug.\textsuperscript{49} In fact, one study indicates that physicians’
prescribing practices are most influenced by the compulsion to
reciprocate.\textsuperscript{50}

In addition, physicians feel that detailers’ access to their prescribing
history is a violation of their privacy.\textsuperscript{51} Many physicians believe that
prescriber-identifying information increases the number of “unwanted
marketing calls.”\textsuperscript{52} Detailers also use such historical information to
confront physicians when they deviate from prescribing their brand-name
drugs.\textsuperscript{53} Physicians have been “outraged that people came into their office
and talked to them about how many times they prescribed a particular
drug.”\textsuperscript{54} Despite the widespread adversity to detailers’ access to

\footnotesize{\begin{flushleft}
\textsuperscript{44} Id.
\textsuperscript{45} Id. at 54.
\textsuperscript{47} Id.
\textsuperscript{48} See generally 38 J.L. MED. & ETHICS.
\textsuperscript{49} Id. at 76 (citing Manchanda & Honka, supra note 17, at 799-800; Council on Ethical and Judicial Affairs, \textit{supra} note 2, at 447-449; M. M. Chren, \textit{et al.}, \textit{Doctors, Drug Companies, and Gifts}, 262 JAMA 3448 (1989); J. Dana & G. Loewenstein, \textit{A Social Science Perspective on Gifts to Physicians from Industry}, 290 JAMA 252 (2003)).
\textsuperscript{50} Id.
\textsuperscript{51} Mills, 616 F.3d at 15.
\textsuperscript{52} Id.
\textsuperscript{53} Id.
\textsuperscript{54} Id. (citing Stephanie Saul, \textit{Doctors Object as Drug Makers Learn Who’s Prescribing What}, N.Y. TIMES, May 4, 2006, at A1).
\end{flushleft}
prescriber-identifying information, there are arguments to be made regarding its societal benefits.55

**Benefits of Prescriber-Identifying Information**

Detailers offer physicians information in a timely manner that they can immediately use to help their patients. There is a belief in the medical field, that the more information, the better, regardless of its source.56 The information that detailers offer physicians would often be expensive or take valuable time for physicians to obtain on their own.57 Such information includes “studies relevant to [a physician’s] practice, useful free samples, and targeted data about how widely certain drugs used to treat the same conditions and information about new drugs or more effective alternatives to the prescriptions they currently prescribe.”58 Moreover, physicians have found the comparisons that detailers make between drugs during their presentations to be immensely helpful.59 With respect to time, physicians appreciate that detailers are well-versed in their prescribing history and can therefore create efficient sales pitches that do not entail a lot of information-gathering during the detailers’ visits.60 Although there is arguably an upside to detailers possessing and using prescriber-identifying information, a group of New England states took action to curb the practice.

**REGULATING PRESCRIBER-IDENTIFYING INFORMATION**

Maine, New Hampshire, and Vermont all passed legislation that virtually forbade pharmacies, insurance companies, or any other entity that possesses prescriber-identifying information from leasing, transferring, or selling that information to data miners.61 Rather than directly restricting detailers from using prescriber-identifying information, the statutes targeted data miners by seeking to prevent them from transmitting such information to the pharmaceutical manufacturers.62 By attempting to control the actions of data miners rather than legislating what detailers can

55. *Sorrell*, 131 S. Ct. at 2671.
56. *Id*.
57. 38 J.L. MED. & ETHICS at 77.
59. *Id*.
60. *Sorrell*, 131 S. Ct. at 2671.
62. *Id*.
and cannot say to physicians, the states were likely trying to avoid First Amendment challenges to the new laws. It was clear, however, that the legislatures wanted to prevent detailers from using prescriber-identifying information based on the stated legislative purposes of the laws. In Maine, the statute included a section that stated, “Restricting the use of prescriber-identifying information will act to decrease drug detailing that targets the prescriber, thus increasing decisions to prescribe lower priced drugs and decisions made on the basis of medical and scientific knowledge and driving down the cost of health care.” Under the Vermont statute, the legislation inserted a similar section to that found in the Maine statute: “The goals of marketing programs are often in conflict with the goals of the state. . .[the] marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that brand-name companies invest in expensive pharmaceutical marketing campaigns to doctors.”

THE COURTS STEP IN

Soon after the aforementioned states passed these laws, the big data mining companies brought suit against the states challenging the constitutionality of the laws. The Pharmaceutical Research and Manufacturers of America joined the data mining companies in their federal suit challenging the Vermont statute, which was eventually heard by the Supreme Court. The data miners claimed that the laws violated their First Amendment right to speech because of the statute’s restrictions on disseminating information and sought declaratory and injunctive relief. What ensued was an in-depth analysis by the federal district and circuit courts in an attempt to balance “the public’s desire for informational privacy and the First Amendment’s freedom to speak.”

The Courts’ Analysis

The first issue addressed by the courts was whether prescriber-identifying information was speech protected under the First Amendment. The First Circuit and the Second Circuit agreed that prescriber-identifying information was speech based on the longstanding precedent that

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64. Sorell, 131 S. Ct. at 2661.
65. Orentlicher, supra note 4, at 78-79.
66. Id.
67. Sorrel, 131 S. Ct. at 2661 (citing Vt. Acts No. 80 § 1).
68. Orentlicher, supra note 4, at 79.
“information” is protected under the First Amendment. However, they split on whether the sale or lease of prescriber-identifying information by data miners was conduct or speech. If, as the Second Circuit found, the data miner’s lease or sale of prescriber-identifying information was found to be commercial speech, then courts would apply intermediate scrutiny. Under the intermediate scrutiny standard as it relates to commercial speech, the government may regulate such speech if (1) “the communication is neither misleading nor related to unlawful activity;” (2) the government assert[s] a substantial interest to be achieved” by the regulation; (3) the restriction “must directly advance the state interest;” and (4) “if the governmental interest could be served as well by a more limited restriction on commercial speech, the excessive restrictions cannot survive.”

If, as the First Circuit found, the sale or lease of information by data miners is found to be merely business conduct as opposed to commercial speech then courts apply a rational basis review because such conduct falls under “economic regulation” rather than speech regulation.

Due to the split and ultimately the divergent rulings in the First and Second circuit courts, the Supreme Court granted certiorari to hear the case challenging the Vermont statute in the Second Circuit.

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69. Ayotte, 550 F.3d at 51 (“We recognize, of course, that pure informational data can qualify for First Amendment protection.”); IMS Health Inc. v. Sorrell, 630 F.3d 263, 271-72 (2d Cir. 2010) (“The First Amendment protects [e]ven dry information, devoid of advocacy, political relevance, or artistic expression.”) (citing Universal City Studios, Inc. v. Corley, 273 F.3d 429, 446 (2d Cir.2001)).

70. 550 F.3d at 53 (“This is a situation in which information itself has become a commodity. The plaintiffs, who are in the business of harvesting, refining, and selling this commodity, ask us in essence to rule that because their product is information instead of, say, beef jerky, any regulation constitutes a restriction of speech. We think such an interpretation stretches the fabric of the First Amendment beyond any rational measure.”); Sorrell, 630 F.3d at 272 (The legislative findings that prompted the Vermont statute clearly indicate that the statute’s purpose to influence the supply of information, “a core first amendment concern.”).


72. 131 U.S. at 275 (Intermediate scrutiny applies to commercial speech as opposed to strict scrutiny which applies to fully protected speech.).


74. There is no clear definition for what amounts to “business conduct.” The term itself is understood as a label for activity that cannot meet the threshold of commercial speech and therefore the regulation of that activity does not receive intermediate scrutiny, but rather rational basis review as an “economic regulation.”

75. 550 F.3d at 54 (This court still went ahead and applied the Central Hudson test, for argument’s sake, and still found the New Hampshire statute to be constitutional).

76. Id. at 64 (The First Circuit court reversed the district court and lifted the injunction against enforcement of the New Hampshire statute); Sorrell, 630 F.3d at 282 (The Vermont statute could not survive intermediate scrutiny and was found to be an unconstitutional regulation of commercial speech under the Central Hudson test.).

77. See generally Sorrell, 131 S. Ct. at 2656.
The Supreme Court Ruling in *Sorrell*

The Supreme Court in *Sorrell v. IMS Health, Inc.*, ultimately held that the Vermont statute restricting the use of prescriber-identifying information by data miners was unconstitutional. The Court reached its holding by first determining that the prescriber-identifying information at issue in the statute was in fact speech. Moreover, the statute includes both content- and speaker-based restrictions on use of prescriber identifying information. The exceptions found in the statute for when the use of prescriber-identifying information is permissible illustrate the content-based restriction, seeing as data miners are prohibited from using it to sell or lease to pharmaceutical manufacturers when other entities can disseminate it for purposes that the state sees best fit. Furthermore, the second part of the statute prohibits pharmaceutical manufacturers from using the data for marketing purposes, thus disfavoring a particular content of speech in marketing. In terms of speaker-related restrictions, the Vermont statute disfavors pharmaceutical manufacturers, more specifically, detailers, from using the information in their pitches to physicians. The Court dispels of any notions that the statute only incidentally restricts the speech of detailers and pharmaceutical manufacturers by citing the legislative record. That record stated in part that detailers who promote brand-name drugs often convey messages that “are often in conflict with the goals of the state.”

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78. *Id.*
79. *Id.* at 2667 (citing *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 481 (1995)) (“If the acts of ‘disclosing’ and ‘publishing’ information do not constitute speech, it is hard to imagine what does fall within that category, as distinct from the category of expressive conduct.”); *Id.* (the Court makes no distinction between commercial speech or pure speech stating that the outcome would be the same either way.)
80. *Id.* at 2663. (A provision in the Vermont statute forbids pharmaceutical manufacturers from using prescriber identifying information for marketing, which qualifies as speech with a particular content. Moreover, the statute prevents detailers from obtaining such information even though several other speakers can use the same information.)
81. *Id.* at 2660 (citing *VT. STAT. ANN.*, tit. 18, § 4631(e)(4) (2009)) (“Prescriber-identifying information may be disseminated or used for ‘health-care research’; to enforce ‘compliance’ with health insurance formularies, or preferred drug lists; for care management educational communications provided to patients on such matters as ‘treatment options’; for law enforcement operations; and for purposes ‘otherwise provided by law.’”)
82. *Id.* at 2663. (For example, the statute allows speakers to purchase and use prescriber-identifying information for “educational communications” and academic research.)
83. *Id.*
84. *Id.*
85. *Id.*
86. *Id.*
87. *Id.* (citing 2007 *VT. No. 80*, §1(3))
whether regulations unduly burden First Amendment rights.\footnote{Id. (citing U.S. v. O'Brien, 391 U.S. 367, 384-88 (1968)).}

Having determined that prescriber-identifying information was speech, and that restrictions in the statute on such speech particularly target data miners and pharmaceutical manufacturers, the Supreme Court applied heightened scrutiny to the Vermont statute.\footnote{Id. at 2664 (citing Ward v. Rock Against Racism, 491 U.S. 781, 791 (1989) ("The First Amendment requires heightened scrutiny whenever the government creates a regulation of speech because of disagreement with the message it conveys."))}
The Court applied the \textit{Central Hudson} test in part to determine the constitutionality of the statute by asking whether the State met its burden in showing that the "statute directly advances a substantial governmental interest and that the measure is drawn to achieve that interest."\footnote{Id. at 2667-68 (citing Bd. of Trs. of State Univ. of N.Y. v. Fox, 492 U.S. 469, 474 (1989); Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 566 (1980)).}

Vermont's interests, similar to the interests in New Hampshire and Maine, were protection of medical privacy, which entailed physician confidentiality, avoidance of harassment, and the integrity of the doctor-patient relationship.\footnote{Id. at 2668.}

Secondly, the state asserted policy objectives in improving public health and reduced healthcare costs.\footnote{Id.}
The Supreme Court summarily dismissed the interest in protecting physician privacy by pointing out that the statute allows prescriber-identifying information to be used and studied by almost a "limitless audience" with the exception of data miners and pharmaceutical manufacturers.\footnote{Id. at 2669.}

If the State was truly interested in protecting physician privacy, it would have employed more far-reaching restrictions on access to prescriber-identifying information.\footnote{Id.}

As far as the avoidance of harassment interest of the state, the Court refused to accept that the statute at issue was necessary to accommodate a small group of physicians that may have felt harassed by detailers.\footnote{Id.}
The Court was also leery of the State's interest in protecting the integrity of the doctor-patient relationship by preventing detailers from unduly influencing the doctor's treatment decisions.\footnote{Id. at 2669 (citing Erznoznik v. Jacksonville, 422 U.S. 205, 210-11 (1975)) (Putting up with speech you do not like is the necessary cost of freedom.).}
The Court found that the statute could not protect such an interest because the detailer's speech was not misleading, but merely persuasive.\footnote{Id. at 2670.}

"Absent circumstances far from those [presented in the Court], the fear that speech might persuade provides no
lawful basis for quieting it."98 Regarding the public policy arguments made by the State, the Court returns to the legal conclusion that under almost any circumstance, a state cannot restrict persuasive speech via a statute in order to advance a legitimate interest.99 The Court offered several alternatives for the State to curb the practice of detailing.100 At the end of the day, the Court found the statute unconstitutional because it "burdened a form of expression that it found too persuasive," while allowing other speakers to convey messages using prescriber-identifying information that were "in accord with [the State's] view."101 Given the Supreme Court's ruling in Sorrell, the scope of the First Amendment's Freedom of Speech right has expanded in scope to the detriment of society. The holding begs the question: where did the state legislatures go wrong?

WHAT STATE LEGISLATURES LEARNED FROM SORRELL

The First Circuit made a compelling argument that the data mining statutes in New Hampshire and Maine were in fact regulating conduct rather than speech.102 After all, the statutes regulated the sale or lease of prescriber-identifying data by data miners. As such, the data mining laws were merely regulating an economic transaction (a sale) between data miners and their customers—not an expression protected under the First Amendment.103 Moreover, the statutes were not prohibiting detailers from meeting with physicians or placing limits on what detailers could say to the physicians, only prohibiting them from using one of many marketing tools.104 However, like the Supreme Court found in Sorrell, it was obvious that the statute indirectly targeted detailers and the content of their

98. Id. (citing Brandenburg v. Ohio, 395 U.S. 444, 447 (1969)).
99. Id. at 2671. (The state may not seek to remove a popular but disfavored product from the marketplace by prohibiting truthful, misleading advertisements that contain impressive endorsements or catchy jingles. That if the state finds expression too persuasive, that does not permit it to quiet the speech or to burden its messengers.);
100. Id. at 2668-2672. (The State could assert its privacy interest by allowing the information's sale or disclosure in only a "few narrow and well-justified circumstances." The State could encourage doctors to refuse to meet with detailers, which is well within doctors' rights. Additionally, the State could use counter-speech to inform the public of the harmful effects that prescriber-identifying information can have on patients and the State as a whole.)
101. Id. at 2672.
102. See generally Ayotte, 550 F.3d at 42; Mills, 616 F.3d at 7.
104. Orentlicher, supra note 4, at 80.
presentations to physicians. The dissent in Ayotte questioned why the New Hampshire state legislature was able to regulate the speech of detailers indirectly by placing heavy regulations upon data miners rather than directly placing restrictions on detailers’ speech, which would clearly amount to a First Amendment violation. The legislative findings associated with the statutes left little doubt that the driving force behind the laws was to curb the widespread practice of detailing. The Supreme Court noted that the Vermont legislature found that the “goals of marketing programs are often in conflict with the goals of the state...[the] marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that brand-name companies invest in expensive pharmaceutical marketing campaigns to doctors.” With such language available to the Court, it was clear that the states wanted to regulate detailing while avoiding constitutional challenges related to First Amendment rights. The Court was well within its right to consider the statute’s state purpose and in doing so struck down the Vermont statute as a thinly veiled infringement on the detailers’ fundamental right to free speech. If the states could have avoided such explicit references to detailing when drafting their statutes, then the underlying purpose of the statute would likely not have been so abundantly clear and as a result may have passed constitutional muster.

Another hurdle that Vermont and the other states could not overcome was the scant evidence to support the assertion that their statutes directly advanced a substantial governmental interest as required by the Central Hudson test. As previously stated, Vermont contended, as did New Hampshire and Maine, that its statute was necessary to protect medical privacy, specifically physician confidentiality, avoidance of harassment, and the integrity of the doctor-patient relationship. Furthermore, Vermont claimed that the data-mining statute furthered policy objectives

105. See generally, Sorrell, 131 S. Ct. 2653.
106. Ayotte, 550 F.3d at 79-84 (Lipez, J., concurring in part and dissenting in part). One of the First Circuit judges in fact dissented from the court’s opinion because he viewed the regulation of data mining as effectively a regulation of drug detailing. Accordingly, he concluded that the provision involved the regulation of commercial speech.
108. Sorrell, 131 S. Ct. at 2661 (citing 2008 Vt. Acts No. 80 §§ 1(3), (4)).
109. Id. at 2663 ("Formal legislative findings accompanying [Vermont’s data mining statute] confirm that the law’s express purpose and practical effect are to diminish the effectiveness of marketing by manufactures of brand-name drugs.").
110. Id. (citing United States v. O’Brien, 391 U.S. 367, 384 (1968)).
111. Id. at 2672.
112. Id. at 2668.
such as improved public health and reduced healthcare costs. The Sorrell court rejected each connection the state attempted to establish between the statute and governmental interests. The Court reasoned that the connections between the statute and the harassment, privacy, and doctor-patient interests were too tenuous and were only invoked to get around impermissible First Amendment regulations pertaining to pharmaceutical marketing. Given the Supreme Court’s ruling and reasoning on data-mining statutes, do states have any recourse in legislating around the Court’s decision in order to regulate detailing?

WHERE DO STATE LEGISLATURES GO FROM HERE?

In passing legislation similar to the Vermont statute, but that can withstand a First Amendment challenge, states may simply have to wait. Under the Central Hudson test, states need to show that a statute that regulates commercial speech directly advances a substantial governmental interest. However, the concern regarding the ill-effects of detailing is a fairly recent phenomenon and as such, there are few studies or reports out there to establish that detailing threatens governmental interests by inflating healthcare costs or by having a detrimental impact on public health. As time passes, there will likely be more evidence to establish a stronger cause-and-effect relationship between data-mining or detailing statutes and governmental interests that are threatened by detailing.

A more palatable alternative for states that want to minimize the adverse effects of detailing may be to focus on the physician’s privacy interest. The Supreme Court accepted Vermont’s assertion that physician privacy was a substantial interest. However, because of the way the Vermont data mining statute was structured, it allowed “information to be studied and used by all, but a narrow class of disfavored speakers.”

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113. Id.
114. Sorrell, 131 S. Ct. at 2668-2672.
115. Id. at 2668-2670. (With respect to the harassment interest, the Court found it “doubtful that concern for ‘a few’ physicians who may have ‘felt coerced and harassed’ by pharmaceutical marketers can sustain a broad content-based rule like [found in the Vermont statute].” The privacy interest was rejected because under the Vermont law, “pharmacies may share prescriber-identifying information with anyone for any reason save one: They must not allow the information to be used for marketing.” Regarding the State’s concern that the doctor-patient trust is undermined by the influential nature of prescriber-identifying information used by detailers, the Court stated “if pharmaceutical marketing affects treatment decisions, it does so because doctors find it persuasive. Absent circumstances far from those presented here, the fear that speech might persuade provides no lawful basis for quieting it.” (citing Brandenburg v. Ohio, 395 U.S. 444, 447 (1969)).
117. Id. at 2668.
118. Id. (“Given the information’s widespread availability and many permissible uses, the state’s asserted
Supreme Court went as far as to suggest “The state might have advanced its asserted privacy interest by allowing the information’s sale or disclosure in only a few narrow and well-justified circumstances.”119 In order for states to have a shot at passing future legislation that regulates detailing, they must create statutes with limited exceptions as to when it is permissible to use prescriber-identifying data. States need to convey how serious they are about protecting their physician privacy interest, which according to the Supreme Court, the Vermont statute failed to do. That said, following the Sorrell decision, courts will be skeptical of such legislation and are likely to apply heightened scrutiny. Nonetheless, the Court seems receptive to such legislation. However, the Court in Sorrell should have upheld Vermont’s privacy interest with slight, if any, modification of the statute.

THE STATE’S PRIVACY INTEREST IN SORRELL

The Sorrell court stated that the state of Vermont indeed has an interest in maintaining the confidentiality of prescription decisions made by physicians.120 However, the Court reasoned that the State’s statute was not narrowly tailored and thus underinclusive because it allowed pharmacies to “share prescriber-identifying information with anyone for any reasons save one: They must not allow the information to be used for marketing.”121 The Court elaborated on its finding by stating that the "Exceptions [in the Vermont statute] further allow pharmacies to sell prescriber-identifying information for certain purposes, including ‘health care research.’”122 Furthermore, the Court claimed the statute permitted "insurers, researchers, journalists, the State itself, and others to use the information.”123 The Court grossly overstated the accessibility of prescriber-identifying information outside of detailers and thus wrongly decided that the state’s privacy interest was not adequately protected under the statute. At no point, under the “exceptions” section of the statute, does the statute indicate that prescriber-identifying information is accessible to “anyone for any reason save one.”124 In fact, subsection (d) of the statute,

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119. Id.
120. Sorrell, 131 S. Ct. at 2668.
121. Id.
122. Id.
123. Id.
124. Sorrell, 131 S. Ct. at 2668; See, VT. STAT. ANN. tit. 18, § 4631(d).

(e) The prohibitions set forth in subsection (d) of this section shall not apply to the following:
forbids the sale or marketing of prescriber-identifying information to anyone unless the sale or marketing meets the criteria set forth in subsection (e) or if a prescriber consents to such a sale.125

The Exceptions

Contrary to what the Supreme Court said in Sorrell, the exceptions to the prohibition of the sale of prescriber-identifying information by pharmacies are narrowly tailored. The exceptions strictly relate to the administrative side of prescription information, to promoting the knowledge and well-being of healthcare patients, and to federal law enforcement regulations. Few would argue against the need for disclosure of prescriber-identifying data under these circumstances and the inherent privacy associated with each exception.

Administrative Exceptions

The exceptions for administrative functions under the Vermont statute apply to (1) pharmacy reimbursement, (2) prescription drug formulary compliance, (3) patient-care management, (4) utilization review by a health care professional, the patient's health insurer, or the agent of either, (5) the dispensing of prescription medications to a patient or to the patient’s authorized representative, and (6) the transmission of prescription information

(1) the sale, license, exchange for value, or use, of regulated records for the limited purposes of pharmacy reimbursement; prescription drug formulary compliance; patient care management; utilization review by a health care professional, the patient's health insurer, or the agent of either; or health care research;
(2) the dispensing of prescription medications to a patient or to the patient's authorized representative;
(3) the transmission of prescription information between an authorized prescriber and a licensed pharmacy, between licensed pharmacies, or that may occur in the event a pharmacy's ownership is changed or transferred;
(4) care management educational communications provided to a patient about the patient's health condition, adherence to a prescribed course of therapy and other information relating to the drug being dispensed, treatment options, recall or patient safety notices, or clinical trials;
(5) the collection, use, or disclosure of prescription information or other regulatory activity as authorized by chapter 84, chapter 84A, or section 9410 of this title, or as otherwise provided by law;
(6) the collection and transmission of prescription information to a Vermont or federal law enforcement officer engaged in his or her official duties as otherwise provided by law; and
(7) the sale, license, exchange for value, or use of patient and prescriber data for marketing or promoting if the data do not identify a prescriber, and there is no reasonable basis to believe that the data provided could be used to identify a prescriber.

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

(d) A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity shall not sell, license, or exchange for value regulated records containing prescriber-identifiable information, nor permit the use of regulated records containing prescriber-identifiable information for marketing or promoting a prescription drug, unless the prescriber consents as provided in subsection (c) of this section. Pharmaceutical manufacturers and pharmaceutical marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents as provided in subsection (c) of this section.
information between an authorized prescriber and a licensed pharmacy, between licensed pharmacies, or that may occur in the event a pharmacy's ownership is changed or transferred. All of the administrative exceptions carved out in the Vermont statute are necessary for the orderly operation of pharmacies, insurers and doctor's offices. Furthermore, these exceptions are critical to the efficient flow of information between the aforementioned parties.

The Exceptions for the Benefit of Healthcare Patients

In addition to the administrative exceptions, the Vermont statute contains exceptions that relate to the well being of patients. Pharmacies are allowed to sell, license, or exchange for value, or use, of regulated records for (1) healthcare research; (2) care management educational communications provided to a patient about the patient's (a) health condition, (b) adherence to a prescribed course of therapy and (c) other information relating to the drug being dispensed, treatment options, recall or patient safety notices, or clinical trials; and (3) to assist a specified state program in compiling healthcare information. For the most part, these exceptions only result in the disclosure of prescriber-identifying information to patients and a specific state agency, which is necessary in order for patients to receive the best treatment.

However, the Court presented a valid point in finding that the exception of "healthcare research" was too broad to adequately protect the State's privacy interest. This exception is the only phrase in section (e) that could be interpreted as being too broad for giving a wide spectrum of people access to prescriber-identifying information. Though the Court's belief is speculative, because it lacks evidence to support such widespread accessibility, Vermont and other states could easily get around such a finding by including qualifiers or strict parameters relating to healthcare research to ensure that only a small, definable group has access to prescriber-identifying information under such an exception. An example of such a parameter would be to make access to such information available only to certain certified institutions, which would ensure that the information was not available to an almost "limitless audience" as the Court stated and that appropriate measures were taken to keep such

126. See generally, VT. STAT. ANN. tit. 18, § 4631(e).
127. See generally, VT. STAT. ANN. tit. 18, § 4631(e).
128. Id. ("Exceptions further allow pharmacies to sell prescriber-identifying information for certain purposes, including 'healthcare research.' And the measure permits insurers, researchers, journalists, the State itself, and others to use the information.")
129. Id. ("Vermont made prescriber-identifying information available to almost a limitless audience.")
information private.

The Federal Law Enforcement Exception

The final category of exceptions is the use of prescriber-identifying information to facilitate enforcement of law. Section 4631(e)(6) of the Vermont statute states that "the collection and transmission of prescription information to a Vermont or federal law enforcement officer engaged in his or her official duties as otherwise provided by law."130 Because of the narrow exception under this subsection and its support (or lack of pretext) for the State’s privacy interest, the Court expressed no opinion on this particular exception.

The categories in the exceptions section in the Vermont statute allow pharmacies to sell or disclose prescriber-identifying information to insurers, physicians, other pharmacies, a state agency, federal law enforcement officials, and patients.131 All of these potential recipients need the information for administrative purposes, to improve the well being of patients, or to enforce laws. The State clearly made an effort to narrowly tailor the exceptions so only those that absolutely needed such information could obtain it. The statute unequivocally denies the distribution of prescriber-identifying data to the general population in which a very small fraction of that group are pharmaceutical manufacturers. This fact alone disproves the Supreme Court’s assertions that "share prescriber-identifying information with anyone for any reasons save one: They must not allow the information to be used for marketing."132 Admittedly, the State’s inclusion of "healthcare research" as an exception may have been too broad, but a narrower description of what amounts to healthcare research, if needed, should overcome the Court’s skepticism toward whether the State was adequately protecting a privacy interest.

CONCLUSION

The Supreme Court once again established that it is almost never permissible to restrict an entity’s First Amendment right to free speech even if that entity is a juggernaut in the pharmaceutical manufacturing industry. As a result, companies like Pfizer and Johnson & Johnson will continue to reap the massive financial benefits of detailing while states

130. VT. STAT. ANN. tit. 18, § 4631(e).6.
131. See generally, VT. STAT. ANN. tit. 18, § 4631(e).
132. Sorrell, 131 S. Ct. at 2668.
continue to try to minimize the influence and subsequent harmful effects of pharmaceutical marketing. States that want to control detailing through the Central Hudson test under the Commercial Speech doctrine have an uphill battle. The Supreme Court in Sorrell makes it perfectly clear that an airtight, direct connection is required between the statute at issue and the governmental interests. Anything less will leave state legislatures with unconstitutional statutes. The state of Vermont established such a connection when it raised its privacy interest, but the Supreme Court erroneously and unfairly rejected it as underinclusive.