Sorrell v. IMS Health, Inc.: The Constitutionality of Restrictions on the Use of Data for Commercial Purposes

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Summary

Health related data can be very valuable to researchers, scientists, and other academics. It can be just as valuable to participants in the market for the provision of health care. For example, pharmaceutical manufacturers use a process known as detailing to market prescription drugs. Detailing involves sending representatives of the pharmaceutical manufacturers to individual doctors' offices with information about prescription drugs and their various uses. The more information a detailer has about the doctor (or medication prescriber) that he or she is planning to market to, the better targeted, and more effective, the detailing becomes. Consequently, information about the past prescribing practices of doctors can be valuable to detailers in designing their marketing strategies.

An industry has developed to collect, aggregate, and analyze these prescriber data. These data gatherers sell the information they collect from pharmacies and hospitals about prescriber practices to pharmaceutical manufacturers for use in marketing. They also sell the data to researchers and others that might use the data, but this market is far smaller than the market consisting of pharmaceutical manufacturers and marketers. Some doctors find better-targeted detailing to be useful. Other doctors find the sharing of their prescriber history without their consent, and its subsequent use as a marketing tool, to be an invasion of privacy.

Three states—Maine, New Hampshire, and Vermont—have enacted statutes to restrict the sale and use of prescriber history data for the purposes of marketing (though not for any other purpose) without the consent of the doctor. The states claimed to be protecting the privacy interest of the doctors. Also, the states were interested in lowering the costs of health care. Because detailing effectively encourages the prescription of more expensive, brand-name drugs, data suggest that health care costs are measurably increased by detailing. The states reasoned that if detailing were less effective, then doctors might be more likely to prescribe generic drugs, which are cheaper than brand-name drugs, and health care costs overall would go down.

The companies that collect, analyze, and sell these data challenged the laws, claiming that they were an unconstitutional restriction of their free speech rights under the First Amendment. The First Circuit Court of Appeals upheld the laws enacted by Maine and New Hampshire as restrictions on conduct rather than speech, and further found that even if the laws did restrict speech they were constitutional restrictions on commercial speech. The Second Circuit Court of Appeals struck down a functionally identical Vermont statute. The Second Circuit found that the Vermont law unconstitutionally restricted commercial speech. In order to resolve this split in the circuits, the Supreme Court granted certiorari in the Second Circuit Case. A divided Court affirmed the decision of the Second Circuit but applied a slightly different standard than the lower court.

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Introduction

In the information age, data of varying types have become increasingly valuable. Data can be used particularly to better target advertising and other forms of marketing to specific individuals. The preferences of individuals can be aggregated and analyzed in such a way as to better predict future habits. This general process is used across a wide array of industries, and it raises a number of First Amendment and privacy questions.[1] For example, courts have struggled with fundamental questions, such as whether the sale and aggregation of data is speech at all,[2] and, as discussed in the cases below, what standard of scrutiny to apply to restrictions on trade in data if it is speech.

These questions are particularly salient in the market for health related data. Health related data can be very valuable to researchers, scientists, and other academics.[3] It can be just as valuable to participants in the market for the provision of health care. For example, pharmaceutical manufacturers use a process known as detailing to market prescription drugs.[4] Detailing involves sending representatives of the pharmaceutical manufacturers to individual doctors' offices with information about prescription drugs and their various uses. Detailing is very expensive; as a result, pharmaceutical manufacturers only engage in detailing for more expensive (i.e., brand-name) prescription drugs.[5] The more information a detailer has about the doctor (or medication prescriber) that he or she is planning to market to, the better targeted, and more effective, the detailing becomes. Consequently, information about the past prescribing practices of doctors can be valuable to detailers in designing their marketing strategies.

An industry has developed to collect, aggregate, and analyze these prescriber data.[6] Data gatherers collect information (by purchasing it) from pharmacies and other entities that have vast troves of prescriber history data. They then aggregate and analyze the data. The information they collect from pharmacies and hospitals about prescriber practices is then sold to pharmaceutical manufacturers for use in marketing. They also sell the data to researchers and others that might use the data for purposes unrelated to marketing, but this market is far smaller than the market consisting of pharmaceutical marketers. Some doctors find better-targeted detailing to be useful. Other doctors find the sharing of their prescriber history without their consent, and its subsequent use as a marketing tool, to be an invasion of privacy.[7]

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[1] See, e.g., CRS Report RL34693, *Online Data Collection and Disclosure to Private Entities: Selected Federal Laws and Self-Regulatory Regimes*, by (name redacted); CRS Report R40908, *Advertising Industry in the Digital Age*, by (name redacted); CRS Report RL30322, *Online Privacy Protection: Issues and Developments*, by (name redacted).

[2] See Sorrell v. IMS Health, Inc., 131 S. Ct. 2653, 2667 (2011) ("This Court has held that the creation and dissemination of information are speech within the meaning of the First Amendment."); but see IMS Health, Inc. v. Ayotte, 550 F.3d 42, 52 (1st Cir. 2008) (finding that the sale and distribution of information could be regulated similarly to the sale and distribution of any other commodity).

[3] See IMS Health, Inc. v. Sorrell, 630 F.3d 263, 268 (2d. Cir. 2010), *aff'd by* Sorrell v. IMS Health, Inc., 131 S. Ct. 2653 (2011) ("The state of Vermont itself uses [health related data] for law enforcement and other state programs. Researchers use [health related data] to identify overuse of a pharmaceutical ... ").

[4] Sorrell v. IMS Health, Inc., 131 S. Ct. 2653 (2011).

[5] *Id*.

[6] *Sorrell*, 131 S.Ct. at 2659 – 2662; *Ayotte*, 550 F.3d at 42 – 47.

[7] IMS Health, Inc. v. Mills, 616 F. 3d 7, 14-15 (1st Cir. 2010).

Three states—Maine,[8] New Hampshire,[9] and Vermont[10]—enacted statutes to restrict the sale and use of prescriber history data for the purposes of marketing (though not for any other purpose) without the consent of the doctor. As discussed below, the states claimed to be protecting the privacy interest of the doctors. Also, the states were interested in lowering the costs of health care. Because detailing effectively encourages the prescription of more expensive, brand-name drugs, data suggest that health care costs are measurably increased by detailing. The states reasoned that if detailing were less effective, then doctors might be more likely to prescribe generic drugs, which are cheaper than brand-name drugs, and health care costs overall would go down.

The companies that collect, analyze, and sell these data challenged the laws, claiming that they were an unconstitutional restriction of their free speech rights under the First Amendment, as incorporated against the states by the Fourteenth Amendment.[11]

Conflicting Appeals Court Decisions

The First and Second Circuit Courts of Appeals reached opposite conclusions regarding the constitutionality of the state laws that restricted the sale and use of prescriber data. The First Circuit, in two separate cases, found the laws to be constitutional, because they did not restrict "speech." The Second Circuit not only found a similar Vermont law to be a restriction of speech, but also found the law to be unconstitutional under the commercial speech standard of scrutiny, a standard considered to be less rigorous than the constitutional standard applied to fully protected speech.

First Circuit Cases

The first case, *IMS Health v. Ayotte*, was decided in 2008.[12] The First Circuit examined a New Hampshire law that made it a crime or a civil offense for entities, such as aggregators and sellers of prescriber-identifiable and patient-identifiable information, to sell that information for commercial purposes.[13] The court determined that this was primarily a regulation of conduct and not speech.[14] In the court's view, the law prohibited only the aggregation and transfer of certain information for a narrow purpose. The law thus sought to place restrictions on a class of speech to curb certain unwanted effects of the speech, and such regulation was not offensive to the First Amendment. The court likened the regulation of the distribution of this data to the prohibition on agreements in restraint of trade in the antitrust laws. The agreements to which the law applies may be speech, but the law actually seeks to prevent the conduct that is the unlawful restraint of trade. According to the First Circuit, prescriber-identifiable information had become a

[8] Me. Rev. Stat. Ann. tit. 22 § 1711-E.

[9] N.H. Rev. Stat. Ann. § 318:47-f.

[10] Vt. tit. 18 § 4631 (2007).

[11] See Sorrell, 131 S.Ct. 2653; IMS Health v. Mills, 616 F. 3d 7 (1st Cir. 2010); Ayotte, 550 F.3d at 42.

[12] 550 F.3d at 42.

[13] N.H. Rev. Stat. Ann. § 318:47-f.

[14] 550 F.3d at 51-54.

commodity, akin to beef jerky, and regulation of its distribution for commercial purposes was similarly a regulation of conduct and not speech under the Constitution.[15]

In the alternative, the court also found that if this was in fact a regulation of speech rather than conduct, the law was a regulation of commercial speech, subject to intermediate scrutiny, and that the law passed constitutional muster under that test.[16] Commercial speech is most often defined as speech that primarily concerns the economic interests of the speaker, or speech that proposes a commercial transaction.[17] Since the New Hampshire law regulated only the transmission of data for commercial purposes, the court found the law regulated commercial speech.

In order for a restriction on commercial speech to be constitutional it must serve a substantial interest of the government, directly advance that interest, and be no more burdensome than necessary on protected speech.[18] New Hampshire asserted three interests in enacting the law: protecting prescriber and patient privacy, protecting patients from skewed prescription practices, and cost containment.[19] The court analyzed only cost containment and found it to be a substantial interest. The court also found that the law directly advanced that interest. The court found evidence that the inability to use prescriber identifiable information to detail decreases the effectiveness of detailing. If detailing is less effective, fewer expensive brand-name drugs will be prescribed, and the cost of health care would therefore decrease in the aggregate.[20] Finally, the court found that there were no viable alternatives for reaching the state's goal without restricting speech, and that the law was no more restrictive than necessary to achieve that state's goals because it restricted only speech made for commercial purposes.

In 2010, the First Circuit considered a Maine law that was similar to the statute enacted by New Hampshire and upheld in *Ayotte*.[21] The Maine law prevented pharmacies and other prescription drug intermediaries from licensing, selling, or otherwise transferring prescriber identifiable information to data aggregators for marketing purposes for prescribers that have filed for confidentiality protection.[22] In other words, the Maine statute created an opt-out system for prescribers. If prescribers informed the state that they no longer wished that their data be shared by pharmacies and others in possession of the raw data for marketing purposes, the data could no longer be shared for that purpose. Though the system for achieving the state's goal was somewhat different than the New Hampshire statute, the First Circuit reached the same conclusion it had in *Ayotte*.[23] The court found that the statute regulated conduct rather than speech, and that even if it regulated speech the regulation was constitutionally permissible pursuant to the Supreme Court's commercial speech case law. The court also found that the law constitutionally protected the privacy of physicians and prescribers that did not wish to allow their prescriber information to be shared and protected them from unwanted solicitations on that basis.[24]

[15] *Id*. at 53.

[16] *Id*. at 55-61.

[17] Central Hudson Gas and Electric Corp. v. Public Service Comm'n, 447 U.S. 557, 567 (1980).

[18] *Id*.

[19] Ayotte, 550 F. 3d at 55.

[20] *Id*. at 55-58.

[21] Mills, 616 F.3d at 7.

[22] *Id*. at 16.

[23] *Id*. at 13.

[24] *Id*.

Second Circuit Decision

By contrast, the Second Circuit Court of Appeals reached the opposite conclusion when it considered a similar Vermont law.[25] The court found that the law regulated speech, thus implicating the First Amendment. The Second Circuit applied the constitutional test for regulations of commercial speech and found that the law could not survive constitutional scrutiny because it did not directly advance the state's interests.

The Vermont statute in question banned the "sale, transmission, or use of prescriber-identifiable data for marketing or promoting a prescription drug unless the prescriber" consented.[26] This meant it prohibited data miners from selling the information for commercial purposes without consent and it prohibited pharmaceutical manufacturers in possession of the data from using it to market prescription drugs without consent. The statute expressly permitted the sale or transfer of the data for other purposes including pharmacy reimbursement, other health insurance related transfers, health care research, and care management. In its legislative findings, the state listed a number of interests that it sought to advance by enacting this statute.[27] Taken together, the court found that the findings expressly stated Vermont's intent "to interfere with the marketplace of ideas to promote the interests of the state."[28] The idea behind the statute, the state seemed to make clear, was to handicap detailers by denying them access to information that would improve their message. This handicap would "even the playing field" in a marketplace where speech about brand-name drugs is far more accessible to prescribers than speech about generic drugs. The court found this reasoning particularly troublesome.

The Second Circuit found that the First Amendment protects even "dry information, devoid of advocacy, political relevance, or artistic expression."[29] It was clear to the court that Vermont sought to restrict speech, because the legislation stated that "the marketplace for ideas on medicine safety and effectiveness is frequently one-sided."[30] The state also attempted to argue that, pursuant to Supreme Court precedent in *Los Angeles Police Department v. United Reporting Publishing Corp.*,[31] the pharmaceutical manufacturers had no right to access non-public health related records without consent. The court found that the precedent cited was distinguishable.[32] In *United Reporting*, the Supreme Court had held that there was no First Amendment right to access information held by the government.[33] The statute in this case prevented private parties from accessing information in the hands of other private entities, and the private entities in possession of the information were more than willing to provide it to those who sought it.[34] In other words, it was a statute that restricted the communication of information between private parties, a very common restriction on speech that should be subject to review under the First Amendment, in the court's view.

[25] Sorrell, 630 F.3d at 263.

[26] Vt. tit. 18 § 4631 (2007).

[27] Sorrell, 630 F.3d at 270.

[28] *Id*.

[29] *Id*. at 271 (quoting Universal City Studios, Inc. v. Corley, 273 F.3d 429, 446 (2d Cir. 2001).

[30] *Id*. at 272.

[31] 528 U.S. 32 (1999).

[32] Sorrell, 630 F.3d at 273.

[33] 528 U.S. at 34-37; Sorrell, 630 F. 3d at 273.

[34] Sorrell, 630 F. 3d at 273.

Like the First Circuit's alternative view of the restriction, the Second Circuit agreed that the restrictions placed on the ability of pharmaceutical marketers to use this data for detailing was a restriction on commercial speech, because the speech restricted concerned the economic interests of the speakers (i.e., pharmaceutical marketers). The restrictions on the sale of the information by data miners presented a closer question as to whether it was commercial speech. Because speech is not commercial merely because it is sold, a closer look was required.[35] The court found the data miners' sale of the data could arguably be commercial speech because it is a step in a chain created primarily to influence marketing. However, the court assumed without deciding that the restriction on the sale of the data was a restriction on commercial speech. The court found that the regulation would fail under the commercial speech test; therefore, examination under a stricter standard, if the information was fully protected, would have yielded the same result.

Like New Hampshire in *Ayotte*, Vermont claimed to be advancing three substantial interests: protecting public health, protecting physician and patient privacy, and containing health care costs.[36] First, the court noted that the statute does not protect physician privacy. "Physician privacy might be protected if the statute prohibited the collection and aggregation of [physician identifiable] data for any purpose, or if the use of such data were permitted only in rare and compelling circumstances."[37] However, Vermont only restricted the collection and aggregation of data for marketing purposes. It could be collected and aggregated for virtually any other reason, and could be used for nearly any reason, including general publication. It simply could not be used for marketing. If the data could be made publicly available under the statute, then, in the court's view, "privacy" could not reasonably be said to be an interest protected by the statute. Though the court did not find that the statute protected the state's asserted privacy interests, the states asserted interests in protecting public health and containing health care costs were found to be substantial.[38]

The court then had to consider whether the statute directly advanced the state's legitimate interests. The court found it did not.[39] In order for the statute to actually contain costs, the reasoning necessarily took a particularly circuitous route, in the court's estimation. Essentially, according to the court, the state was trying to bring about indirectly a social good that it apparently could not bring about directly, because the state would not restrict the prescribing practices of doctors or the marketing practice of drug manufacturers. Instead, Vermont chose to hamstring the drug manufacturers' access to and use of information in the hope that their marketing would thereby be less effective, which would then cause doctors to prescribe more generic drugs, which would then lower the cost of healthcare, which would benefit the public health.[40] This appears to be similar to the reasoning accepted by the First Circuit as a direct advancement of the state's goals in *Ayotte*, but the Second Circuit found the argument to be lacking. Furthermore, the court found that the state's tactic of limiting the amount of information available to people providing information to physicians was antithetical to the core principles of the First Amendment, which is founded upon the idea that the more truthful information that exists in the marketplace the better off the people are.[41] The court took particular issue with what

[35] *Id*. at 275 (citing Universal City Studios, 273 F. 3d at 446).

[36] *Id*. at 275.

[37] *Id*.

[38] *Id*. at 276.

[39] *Id*. at 277.

[40] *Id*.

[41] *Id*. at 278.

it saw as the state putting its "thumb on the scales of the marketplace of ideas in order to influence conduct."[42] The court also found that the statute was not narrowly tailored enough to survive review, even assuming that it did directly advance the state's interest, because it bans the use of information for the marketing of all prescription drugs regardless of whether there is a viable alternative that would be more cost effective.[43] Consequently, the Second Circuit struck down the Vermont law as unconstitutional. Vermont appealed and the Supreme Court agreed to hear the case.

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The Supreme Court affirmed the decision of the Second Circuit, but did so using what appeared to be a different standard of review that the Court called "heightened judicial scrutiny."[44] As noted above, the Vermont law in question operated to restrict the sharing and use of prescriber-identifiable information in three ways. First, it prohibited pharmacies, health insurers, and others in possession of or gathering prescriber-identifiable information from selling that information without the consent of the prescriber. At the Second Circuit level, it was assumed that only sales for marketing purposes were restricted without consent, but at the Supreme Court level Vermont argued that all sales were prohibited without consent.[45] Second, pharmacies, health insurers, and similar entities were prohibited from allowing prescriber-identifiable information to be used for marketing purposes without prescriber consent. Lastly, marketers and pharmaceutical manufacturers were barred from using prescriber-identifiable information in their marketing, without the prescriber's consent.

The Court began its analysis of the law by addressing Vermont's arguably new interpretation of the statute.[46] Below it had been argued that the ban on the sale of prescriber-identifiable information was only a ban on the sale for marketing purposes. Vermont argued to the Court that the statute banned all sales of such information that occurred without consent. The Court noted that it might be too late in the game for Vermont to change its interpretation of the law, but, ultimately, the shift in interpretation would not matter analytically. The Court found that the provision was unsustainable even under Vermont's new interpretation, because the sale of the information was prohibited without prescriber consent, except in certain enumerated circumstances.[47] These exceptions, in the Court's estimation, were very broad. For example, under the exemption the prescriber-identifiable information could be given away or sold to academic researchers without consent, but not to pharmaceutical marketers. The rest of the statute prohibited the use and disclosure of the prescriber-identifiable information only for marketing.

The Court held that the Vermont statute should be subject to "heightened judicial scrutiny," because it placed both content- and speaker-based restrictions on speech.[48] The statute was a content-based restriction on speech because it placed burdens on speech with a particular content

[42] *Id*.

[43] *Id*. at 279.

[44] Sorrell, 131 S.Ct. at 2653.

[45] *Id*. at 2662.

[46] *Id*. at 2663.

[47] *Id*.

[48] *Id*. at 2663-2664.

(i.e., pharmaceutical marketing). However, it placed no burdens on speech for an academic purpose, or other routine sharing of the information outside marketing purposes.

The statute was found to make speaker-based distinctions, because it burdened particular speakers—pharmaceutical marketers—while allowing other speakers an informational and communicational advantage.[49] Vermont was free, for example, to provide academic researchers with prescriber-identifiable information in order for the researchers to craft a message that would counter the message of pharmaceutical manufacturers and promote generic alternatives. The Court seemed to take issue with the intentional handicapping of the speech of pharmaceutical marketers. The Court referenced Vermont's stated desire to "level the playing field" and the legislative finding that pharmaceutical marketers often communicate messages that "are in conflict with the goals of the state."[50] The Court found that the Vermont law seemed to be designed to make the message of pharmaceutical marketers less effective in an effort to bring down the costs of prescription drugs, and thereby advantage the communication of state-supported content.

The Court seemed particularly concerned with Vermont's attempt to favor its own message by disadvantaging the speech of a particular group. The "First Amendment requires heightened scrutiny whenever the government creates 'a regulation of speech because of disagreement with the message it conveys.'"[51] Burdens on commercial speech are not excepted from this rule, according to the Court. Often citizens may have more of an interest in hearing truthful commercial speech than even highly valued political dialogue. "That reality has great relevance in the fields of medicine and public health, where information can save lives."[52]

The Court also disagreed with Vermont's argument that the statute was merely a regulation of commerce.[53] As before the Second Circuit, Vermont again argued that precedent in *United Reporting*, which upheld a regulation of access to information held by the government, applied in this case, because the Vermont statute also regulated access to information. The Supreme Court agreed with the Second Circuit. Access to information held by the government is distinguishable from regulations on the exchange of information between private parties. "This Court has held that the creation and dissemination of information are speech within the meaning of the First Amendment.... Facts, after all are the beginning point for much of the speech that is most essential to advance human knowledge and conduct human affairs."[54] As a result, the Court found that the Vermont statute implicated the First Amendment and should be subject to heightened scrutiny, despite the state's objections.

Under usual circumstances, it would be enough to say that the law discriminated based upon content on its face, and viewpoint in practice, but because this law arguably burdened only commercial speech, the Court acknowledged that a different standard might apply.[55] Nonetheless, the Court found that "the outcome is the same whether a special commercial inquiry or a stricter

[49] *Id*. at 2664.

[50] *Id*. at 2663.

[51] *Id*. (citing Ward v. Rock Against Racism, 491 U.S. 781, 791 (1989).

[52] *Id*.

[53] *Id*. at 2665.

[54] *Id*. (quoting Bartnicki v. Vopper, 532 U.S. 514, 527 (2001)).

[55] *Id*. at 2667-2668.

form of judicial scrutiny is applied."[56] In order to survive constitutional review under the commercial speech standard, Vermont was required to at least show that the statute directly advanced the interests it sought to protect, and that there was a reasonable fit between the means chosen and the ends sought to be achieved.

Similar to the reasoning of the Second Circuit, the Supreme Court found that the statute did not advance the interest of protecting physician privacy.[57] The prescriber-identifiable information could be distributed widely, so long as it was not being distributed for a marketing purpose. It could also be used for myriad purposes without permission. The Court found that "Vermont has given its doctors a contrived choice: Either consent, which will allow your prescriber-identifying information to be disseminated and used without constraint; or, withhold consent, which will allow your information to be used by those speakers whose message the State supports."[58] While the law did offer physicians limited privacy from the use and disclosure of their information, it only did so by requiring that physicians also support the state's interests.

Vermont also argued that detailing undermines the doctor-patient relationship, because it interferes with doctors' treatment decisions, and burdens on detailers' speech work to protect the doctor-patient relationship. The Court dispensed with this argument by noting that "[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."[59]

As to Vermont's interest in lowering the cost of health care, the Court, like the Second Circuit, was not persuaded that restricting the use of prescriber-identifiable information directly advanced the state's interest in lowering healthcare costs. The Court was also cautious of a regulation that sought to keep truthful information from people. "The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good."[60] Fearing that expression is too effective is not a permissible reason to restrict it or burden it, even if it somehow may lower healthcare costs.[61] The state is, of course, free to attempt to argue its own point of view. For example, the state might also launch a campaign to educate doctors about generic alternatives to brand-name drugs, and it may use prescriber-identifiable information in order to better target its messaging. "However, the state cannot engage in content-based discrimination to advance its own side of a debate."[62]

Fundamentally, the Court seemed to be particularly concerned that the government, in this case, had burdened a message simply because the government did not approve of the message, and found it to be too effective. The government also left unburdened the speech of speakers with whom the government agreed or whose message the government supported. "This the State

[56] *Id*.
[57] *Id*. 2668-2669.
[58] *Id*.
[59] *Id*. at 2670.
[60] *Id*. at 2671.
[61] *Id*.
[62] *Id*. at 2672.

cannot do."[63] As a result the Court affirmed the decision of the Second Circuit striking down the law.

Three Justices dissented.[64] Those Justices would have applied *Central Hudson's* intermediate commercial speech standard, and would have found that Vermont's law withstood scrutiny under that standard.

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[63] *Id*.

[64] *Id*. at 2673.