Supreme Court Holds that Pharmaceutical Company Promotion Is Entitled to Full First Amendment Protection

On June 23, 2011, the US Supreme Court in *Sorrell* v. *IMS Health Inc.*, No. 10-779, held that Vermont violated the First Amendment by passing a law barring pharmaceutical manufacturers from promoting their drugs to doctors based on the use of the doctor's prescription history. In a 6-3 opinion authored by Justice Kennedy, the Court held that the Vermont law failed "heightened scrutiny" because it discriminated against the speech of pharmaceutical manufacturers based on the content of their speech, particularly speech promoting newer or branded drugs. The Court explained that the law banned manufacturers from marketing their drugs based on prescriber history information without prescriber consent but freely permitted insurance companies and the state itself to use such data to promote less costly or generic drugs without any restrictions. Thus, the Vermont law constituted an impermissible use of legislative power to burden disfavored speakers. Although the Court also held the law invalid under the less rigorous *Central Hudson*[1] test for restrictions on commercial speech, the decision paves the way for pharmaceutical companies to argue that their speech is protected by a more stringent test of heightened scrutiny.

The background of the case involves pharmaceutical manufacturers' practice of marketing branded drugs through one-on-one "detailing" visits by sales representatives to doctors' offices. Manufacturers use doctors' prescribing histories to make these visits more targeted and effective. Manufacturers purchase this data from data aggregation companies, which in turn acquire it from pharmacies. By using prescriber data, manufacturers focus on the medicines associated with conditions that a particular physician frequently treats and tailor their messages accordingly.

1 *Central Hudson Gas & Elec. Co.* v. *Pub. Serv. Comm'n*, 447 U.S. 557 (1980).

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Healthcare Reform Chart

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Several state legislatures sought to ban the use of prescriber data out of a perception that pharmaceutical marketing was too effective at persuading doctors to prescribe branded or newer drugs over generic or older drugs. Vermont enacted its so-called Prescription Confidentiality Law, or Act 80,[2] in 2007 in the wake of similar legislation passed by New Hampshire. Vermont's law contained two features. First, the law prohibited pharmacies, health insurers, and similar entities from selling prescriber data, absent a prescriber's consent, when such data was used for promoting or marketing drugs. Second, the law contained a variety of provisions expressly permitting the state itself, insurance companies, academia, and other entities to use prescriber data for a variety of purposes without obtaining prescriber consent. The law was accompanied by legislative findings proclaiming that, because pharmaceutical companies convey promotional messages that "are often in conflict with the goals of the state" of promoting cost containment and protecting patient health, the law was necessary to correct "the marketplace for ideas on medicine safety and effectiveness."[3]

Given the statutory purpose and effect, the Court held that the law imposed a content-based and viewpoint-based restriction of pharmaceutical company speech. The Court explained that the law "disfavors marketing, that is, speech with a particular content" and the statutory exceptions were "based in large part on the content of a purchaser's speech."[4] The law thus "disfavors specific speakers, namely pharmaceutical manufacturers" and "has the effect of preventing detailers—and only detailers—from communicating with physicians in an effective and informative manner."[5] The Court relied on the statute's facial discrimination, as well as the trial record and legislative findings, to conclude that the law's "express purpose and practical effect are to diminish the effectiveness of marketing by manufacturers of brand-name drugs."[6] Moreover, the Court observed, Vermont's law went beyond content discrimination to viewpoint discrimination.[7]

Because of these content-based burdens on protected speech, the Court found the Vermont law subject to "heightened judicial scrutiny."[8] This is a watershed moment in First Amendment doctrine because it is the first case applying this increased scrutiny to a restriction on so-called "commercial speech," which traditionally has received less protection under the First Amendment.[9] The Court emphasized that burdens on expression that are motivated by the government's substantive disagreement with the message are subject to intensive scrutiny no matter how the speech may be labeled.[10] Moreover, many consumers may care more about preserving the free flow of commercial information than of political dialogue, particularly "in the fields of medicine and public health, where information can save lives."[11]

The Court dismantled each of the state's arguments against heightened scrutiny. The Court first rejected the state's argument that the law was merely a commercial regulation, finding that it "imposes more than an incidental burden on protected expression."[12] The Court also rejected Vermont's argument that the law regulated only "access to information," because in operation it directly burdened speech based on content and speaker.[13] Vermont also took the position that the initial sale transfer of prescriber data is conduct outside the First Amendment's reach, likening the raw data about which physicians prescribe which medicines to a "mere commodity."[14] The Court expressed serious doubt about this argument, observing that "the creation and dissemination of information is speech" and "[f]acts . . . are the beginning point for much of the speech that is most essential to advance

2 Vt. Stat. Ann., Tit. 18, § 4631.
3 Slip op. at 9, 25 (quoting the statute).
4 *Id.* at 8.
5 *Id.* at 8, 9.
6 *Id.*
7 *Id.*
8 *Id.*
9 *See*, e.g., *Central Hudson*, 447 U.S. 557.
10 Slip op. at 11.
11 *Id.*
12 *Id.*
13 *Id.* at 12-14.
14 *Id.* at 15.

human knowledge and conduct human affairs."[15] In the end, however, the Court found it unnecessary to definitively resolve whether the data transmission is itself protected speech because it was so clear that the statute "impose[d] a speaker- and content-based burden on the availability and use of prescriber-identifying information" by pharmaceutical manufacturers, no different than if a state tried to prohibit certain magazines from purchasing or using ink.[16]

Although the Vermont law was subject to heightened scrutiny, the Court also held that the law would not survive review under the more traditional commercial speech test, known as *Central Hudson*.[17] Under that test, the state was required to "show at least that the statute directly advances a substantial governmental interest and that the measure is drawn to achieve that interest."[18] Vermont asserted two justifications for the law: (1) protecting "medical privacy, including physician confidentiality, avoidance of harassment, and the integrity of the doctor-patient relationship"; and (2) achieving policy objectives of "improved public health and reduced healthcare costs."[19] The Court rejected both.

The Vermont law did not protect physician privacy because, as PhRMA argued and the Court agreed, the law made prescriber data "available to an almost limitless audience," other than "a narrow class of disfavored speakers."[20] The Court found that the law's capacious exceptions allowing prescriber data to be used by anyone other than a pharmaceutical manufacturer undermined any privacy argument that the state could conceivably advance. The Court further found that the provision allowing pharmaceutical companies to use prescriber data of a physician who affirmatively consented to such use did not save the law:

> 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.[21]

Notably, the Court suggested that revising Vermont's statute so that physicians had to affirmatively elect to have transfer of their data prohibited would not save the statute, reasoning that "reliance on a prior election would not suffice, for instance, if available categories of coverage by design favored speakers of one political persuasion over another."[22] This is significant because a separate challenge is pending against a Maine statute that is similar to Vermont's invalidated law except that it requires a physician to elect to be covered.[23]

Finally, the Court rejected the state's argument that pharmaceutical manufacturers' use of prescriber data undermines the doctor-patient relationship. The Court reasoned 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."[24]

As to Vermont's asserted goals of improving public health and reducing healthcare costs, the Court held that the law did "not advance them in a permissible way."[25] The Court explained, "fear that people would make bad decisions if given truthful information cannot justify content-based burdens on speech," and "[t]he 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."[26] These principles apply even more

15 *Id.*

16 *Id.* (citing *Minneapolis Star & Tribune Co.* v. *Minn. Comm'r of Revenue*, 460 U.S. 575 (1983)).

17 *Id.* at 15-24; *see Central Hudson*, 447 U.S. 557.

18 Slip op. at 16.

19 *Id.* at 17.

20 *Id.* at 18.

21 *Id.*

22 *Id.* at 19.

23 *See* Me. Rev. Stat. Ann. tit. 22, § 1711-E(2-A). In 2010, the First Circuit upheld the Maine statute against a constitutional challenge. *IMS Health Inc.* v. *Mills*, 616 F.3d 7 (1st Cir. 2010). After deciding *IMS Health*, the Supreme Court issued a summary disposition granting certiorari in *Mills*, vacating the First Circuit's judgment, and remanding the case for consideration in light of *IMS Health*. *See IMS Health, Inc.* v. *Schneider*, No. 10-984 (June 28, 2011).

24 Slip op. at 21.

25 *Id.*

26 *Id.* at 22 (internal quotation marks omitted).

so, according to the Court, "when the audience, in this case prescribing physicians, consists of sophisticated and experienced consumers."[27] While the state was free to disseminate its messages about pharmaceuticals through counter-detailing programs,[28] the Court said, "a State's failure to persuade does not allow it to hamstring the opposition. The State may not burden the speech of others in order to tilt public debate in a preferred direction."[29]

Not surprisingly, the most immediate repercussions of the *IMS Health* decision will be felt within the pharmaceutical industry. Both Maine and New Hampshire have enacted substantially similar statutes restricting use of prescriber data for marketing purposes.[30] Although the First Circuit previously upheld both laws,[31] the Supreme Court has now vacated the lower court's decision in the Maine case and remanded for review in light of *IMS Health*. Likewise, the *IMS Health* decision is likely to lead to repeal or invalidation of the New Hampshire law. Moreover, Vermont's petition for certiorari noted that 25 other states and the District of Columbia recently considered similar legislation restricting pharmaceutical manufacturers' use of prescriber data.[32] The Supreme Court's decision should stop this trend in its tracks.

The decision's likely implications are not limited to prescriber data legislation. As Justice Breyer stressed in dissent, "the same First Amendment standards that apply to Vermont here would apply to similar regulatory actions taken by . . . the Federal Government acting, for example, through Food and Drug Administration (FDA) regulation."[33] According to Justice Breyer, the Court's application of "heightened judicial scrutiny" to pharmaceutical company speech implicates the FDA's regulation of "off-label" promotion. Like the Vermont law, those regulations strictly apply to pharmaceutical company speech and regulate that speech based on its content.[34]

The decision also has implications beyond the pharmaceutical sector. As Justice Breyer explained, many other regulatory schemes (such as those applying to energy and financial institutions) include speaker-based and content-based restrictions on speech.[35] To be sure, Justice Breyer offered these examples to illustrate what he considered "a Pandora's Box of First Amendment challenges" opened by the majority's decision.[36] But, a company or industry that finds itself targeted by regulation of truthful communications may find support in the *IMS Health* decision in challenging those regulations.

27 *Id.*

28 *Id.* at 23.

29 *Id.*

30 Me. Rev. Stat. Ann. tit. 22, § 1711-E(2-A); N.H. Rev. Stat. Ann. §§ 318:47-f, 318:47g, 318-B:12(IV).

31 *See IMS Health Inc.* v. *Mills*, 616 F.3d 7 (1st Cir. 2010), *cert. granted, vacated, and remanded*, No. 10-984 (June 28, 2011); *IMS Health Inc.* v. *Ayotte*, 550 F.3d 42 (1st Cir. 2008), *cert. denied*, 129 S. Ct. 2864 (2009).

32 *See* Petition for a Writ of Certiorari at 26-27, *Sorrell* v. *IMS Health* Inc., No. 10-779 (filed Dec. 13, 2010).

33 Slip op. at 6 (Breyer, J., dissenting).

34 Slip op. at 10 (Breyer, J., dissenting).

35 Slip op. at 9-11 (Breyer, J., dissenting).

36 Slip op. at 24 (Breyer, J., dissenting).

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