Sorrell v. IMS Health Inc. — Supreme Court Strikes Down Law Restricting Pharmaceutical Manufacturers' Speech

On Thursday, the Supreme Court issued its decision in *Sorrell v. IMS Health Inc.*, a case testing the constitutional limits of governmental restrictions on the speech of pharmaceutical manufacturers. By a vote of 6-3, the Court held that the law at issue — a Vermont statute that prohibits pharmaceutical manufacturers from obtaining or using "prescriber-identifiable information" collected from pharmacists for the purposes of "marketing or promoting a prescription drug" — is a "speaker- and content-based burden on protected expression" that cannot survive "heightened judicial scrutiny." In stressing that "[s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment," *Sorrell* may set the stage for a constitutional challenge to what is arguably the most draconian governmental restriction on healthcare related speech: the Food and Drug Administration's web of regulations that make it a federal crime for a pharmaceutical manufacturer to engage in truthful, non-misleading speech about off-label uses of its FDA-approved products.

In 2007, Vermont enacted the Prescription Confidentiality Law, commonly referred to as "Act 80," in response to the concern that pharmaceutical manufacturers were having too much success in persuading doctors to prescribe brand-name drugs rather than cheaper drugs promoted by generic manufacturers as alternatives. The Vermont legislature had concluded that manufacturers' successes in marketing brand-name drugs were largely the result of their ready access to so-called "prescriber-identifiable information," publicly available information from which individual doctors' prescribing practices could be discerned. According to the Vermont legislature, manufacturers had been using prescriber-identifiable information to help their sales representatives "shape their messages [to doctors] by 'tailoring' their 'presentations to individual prescriber styles, preferences, and attitudes.'" As its chosen solution to this problem, the Vermont legislature included in Act 80 the following provision: "Pharmaceutical manufacturers and pharmaceutical marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents . . . ." The Vermont legislature intended the provision to make it more difficult for manufacturers to steer doctors toward brand-name drugs and, thereby, to help reduce the overall cost of health care in the state.

Convinced that Act 80's speech restriction violated the First Amendment, an association of brand-name pharmaceutical manufacturers and a data-collection firm brought suit in federal court seeking declaratory and injunctive relief against Vermont's attorney general William Sorrell. The plaintiffs lost in the district court but prevailed on appeal in the Second Circuit, with a split panel holding that Act 80 "violates the First Amendment by burdening the speech of pharmaceutical marketers . . . without an adequate justification." When the Supreme Court granted certiorari just two months later, it was clear that the case had the potential to be one of the most important First Amendment cases of the October 2010 Term.

Writing for a six-member majority, Justice Kennedy had little trouble affirming the Second Circuit's decision. Justice Kennedy emphasized over and over again that Act 80's provision was a "content- and speaker-based restriction" on speech that even Vermont conceded is neither false nor misleading: "The statute . . . disfavors marketing, that is, speech with a particular content. More than that, the statute disfavors specific speakers, namely pharmaceutical manufacturers. . . . The law on its face burdens disfavored speech by disfavored speakers." In fact, Justice Kennedy pointed out, "'[i]n its practical operation,' Vermont's law 'goes even beyond mere content discrimination, to actual viewpoint discrimination.'" Accordingly, even if viewed as a restriction solely on "commercial speech," the provision "imposes a speaker- and content-based burden on protected expression, and that circumstance is sufficient to justify application of heightened scrutiny." After all, a "'consumer's concern for the free flow of commercial speech often may be far keener than his concern for urgent political dialogue,'" and "[t]hat reality has great relevance in the fields of medicine and public health, where information can save lives."

Justice Kennedy easily rejected Vermont's argument that Act 80 could survive heightened scrutiny. He began by reiterating that "[i]n the ordinary case it is all but dispositive to conclude that a law is content-based and, in practice, viewpoint-discriminatory," suggesting that "whether a special commercial speech inquiry or a stricter form of judicial scrutiny is applied" is essentially immaterial in such circumstances. He then explained why Vermont's asserted justifications for Act 80's speech restrictions — namely, shielding doctors from the "harassment" of pharmaceutical sales representatives and improving public health by lowering healthcare costs — were woefully inadequate: First, "if pharmaceutical marketing affects treatment decisions, it does so because doctors find it persuasive," and "the fear that speech might persuade provides no lawful basis for quieting it." And, second, noting that Act 80 has "the effect of preventing detailers — and only detailers — from communicating with physicians in an effective and informative manner," Justice Kennedy explained that the Constitution does not allow the government to "achieve its policy objectives through the indirect means of restraining certain speech by certain speakers," nor does "the 'fear that people would make bad decisions if given truthful information' . . . justify content-based burdens on speech," particularly "when the audience, in this case prescribing physicians, consists of 'sophisticated and experienced' consumers." In sum, Vermont had "burdened a form of protected expression that it found too persuasive" yet, at the same time, "left unburdened those speakers whose messages are in accord with its own views. This the State cannot do."

Although the statute directly at issue in *Sorrell* concerned pharmaceutical manufacturers' marketing generally, the decision will almost certainly have a significant impact on future challenges by pharmaceutical manufacturers to the array of speech restrictions that both the federal government and the states have placed upon them, in particular the FDA's so-called "off-label promotion" regulations. To that extent, the fact that the Court issued a broad, full-throated condemnation of Vermont's paternalistic rationales for selectively burdening the speech of pharmaceutical manufacturers — repeatedly calling Act 80 a "content- and speaker-based" restriction on speech and notably declining to apply the "intermediate" scrutiny called for by Justice Breyer in dissent — is particularly noteworthy. The dissent specifically observed that the majority's analysis called into question many existing regulatory restrictions on speech, identifying in particular FDA's restrictions on "what a pharmaceutical firm can, and cannot, tell potential purchasers about its products." The majority nowhere disavowed that likely logical extension of its holding.

For many years, pharmaceutical manufacturers and their counsel have been arguing, in court briefs, legal and other publications, and before the FDA and Department of Justice, that laws restricting the truthful and non-misleading speech of pharmaceutical manufacturers regarding new uses of their approved products are unconstitutional content- and speaker-based restrictions on First Amendment rights. The opinion of the six-member *Sorrell* majority plants a stake in the ground firmly on the side of First Amendment rights: content- and speaker-based restrictions on truthful and non-misleading speech, commercial or otherwise, will not likely survive constitutional challenge.

It might not take long before *Sorrell*'s impact is felt in connection with FDA's off-label speech restrictions: another case that is currently pending in the Second Circuit is United States v. Caronia, which involves a First Amendment challenge to the misdemeanor criminal conviction of a pharmaceutical sales representative for promoting the prescription drug Xyrem for off-label uses. Caronia was argued on December 2, 2010, but the court has not yet issued an opinion. It is entirely possible that the panel has been waiting for the Supreme Court's decision in *Sorrell*. Now that the *Sorrell* decision has issued, it will undoubtedly provide further support for the defendant's First Amendment challenge.

The full text of the Supreme Court opinion is available here.

If you have any questions about this alert, please contact Joan McPhee, Douglas Hallward-Driemeier, Brien O'Connor, Alan Bennett, Stephen Warnke, or Aaron Katz.