Law and the Public's Health

One of the most important challenges facing public health agencies is how best to regulate health-care industry practices that carry public health implications. A crucial question, however, is the extent to which the U.S. Constitution imposes limits on the regulatory powers of public health, when the industry conduct in question involves what the law considers speech. The following article discusses the implications of a recent U.S. Supreme Court decision for public health policy and practice.

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SORRELL V. IMS HEALTH INC.: DATA MINING OF PHARMACY RECORDS AND DRUG MARKETING AS FREE SPEECH

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This installment of *Law and the Public's Health* reviews the U.S. Supreme Court decision in *Sorrell v. IMS Health Inc.*¹ and considers its implications for public health policy and practice. In *Sorrell*, the Court struck down Vermont's Prescription Confidentiality Law,² which prohibited pharmacies from disclosing—and pharmaceutical companies from using—physician-prescribing data for marketing purposes without physician consent. *Sorrell* changes the standard by which the Supreme Court has evaluated such state regulatory restrictions under the First Amendment during the past three decades. In this respect, *Sorrell* is consistent with perhaps the most famous First Amendment case involving corporate free speech in years, *Citizens United v. Federal Election Commission*,³ which extended free speech rights to corporations. *Sorrell* involves marketing rather than political speech, but it carries important implications for government efforts to curb the use of health information for commercial purposes.

BACKGROUND

Regulation of commercial speech

Sorrell involved a particular category of speech known as “commercial speech.” The Supreme Court has narrowly defined commercial speech as speech that does “no more than propose a commercial transaction.”⁴ Prior to 1976, Supreme Court precedent allowed states unlimited discretion to restrict commercial speech.⁵ In 1976, the Supreme Court modified its position in

Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council,⁶ holding that commercial speech should be afforded some First Amendment protection. The Court emphasized that commercial speech has social value and that the government cannot suppress such speech merely because of concerns regarding misleading information or the misuse of information.⁷

The evolution of the Court's commercial speech protection standard continued with its 1980 decision in *Central Hudson Gas v. Public Service Commission of New York*,⁸ establishing a four-prong test to measure the legality of commercial speech regulation. Under the first prong, the Court must determine whether the speech accurately informs the public about a lawful activity, as illegal or misleading statements are not protected.⁹ Second, if the speech is deemed protected, the courts must assess whether government has a substantial interest in regulating the speech in question.¹⁰ Third, courts must determine whether the regulation in question directly advances the government's asserted interest and is not ineffective or too remote from that interest.¹¹ Fourth, the Court must determine if the regulation is no more restrictive than necessary (i.e., is “narrowly tailored to achieve the desired objective”¹²). The *Central Hudson* test is considered by constitutional law scholars to establish an intermediate level of scrutiny for commercial speech regulations and was the standard in effect at the time *Sorrell* arose.

The Vermont law

When processing prescriptions, pharmacies collect prescriber-identifying information as required by law. These laws also permit pharmacies to sell this information to “data miners” who, in turn, produce reports on prescriber behaviors (de-identified with respect to patients but identifying the prescribing physician) and lease these reports to pharmaceutical manufacturers. Manufacturers then employ “detailers” (commonly

known as pharmaceutical sales representatives or, among physicians, as “drug reps”) who use the reports to strategically market and promote their drugs to physicians.

Concerned about the effects of this detailing process, Vermont passed the Prescription Confidentiality Law in 2007.¹³ The purpose of the law was to “advance the state’s interest in protecting the public health of Vermonters, protecting the privacy of prescribers and prescribing information, and to ensure costs are contained” in the health-care system.¹⁴ The law prohibited pharmacies and similar entities from selling or disclosing prescriber-identifying information for marketing purposes absent the prescriber’s consent.¹⁵ The law further prohibited pharmaceutical manufacturers and marketers from using prescriber-identifiable information for sales marketing and promotion practices. The law did not ban all disclosures; it prohibited disclosures for marketing purposes without physician consent while permitting the distribution and use of prescriber-identifying information for other purposes, such as research.¹⁶

Data miners, as well as brand-name drug companies, challenged the law’s constitutionality on free speech grounds. In separate cases, the same commercial interests had challenged similar laws enacted by Maine and New Hampshire. The U.S. Court of Appeals for the First Circuit, whose jurisdiction includes both New Hampshire and Maine, examined the laws of these states^{17,18} and concluded that the laws regulated economic conduct (i.e., actual marketing practices), not commercial speech. The court further held that even if such laws were considered laws reaching commercial speech, they satisfied the *Central Hudson* test. By contrast, the U.S. Court of Appeals for the Second Circuit, which has jurisdiction over Vermont, reversed a trial court ruling upholding the Vermont law. The Second Circuit concluded that the law did involve commercial speech (not just conduct) and that the state’s asserted physician privacy interest was too speculative. Therefore, the court held that the statute unconstitutionally burdened the pharmaceutical marketers and data miners’ speech.¹⁹ In the face of this split in the circuits, the U.S. Supreme Court granted Vermont’s appeal.

THE SUPREME COURT DECISION

By a 6–3 decision, the Supreme Court affirmed the Second Circuit decision. Writing for the majority and joined by Chief Justice Roberts and Justices Scalia, Thomas, Alito, and Sotomayor, Justice Kennedy

concluded that the Vermont statute violated the First Amendment Free Speech Clause. In ruling for the companies, the majority rejected Vermont’s argument that conduct (not speech) was involved and that, therefore, a less demanding standard similar to that used for state regulation of economic activity was appropriate. Instead, siding with IMS Health, the majority concluded that the statute imposed a content- and speaker-based burden on protected speech, thereby restricting both who can communicate and what may be communicated; thus, it should be subject to heightened judicial scrutiny.²⁰

The Court rejected the state’s assertion that the statute’s restrictions were necessary to advance a “substantial government interest” in protecting physician privacy and reducing health-care costs. The majority concluded that the information was not in fact completely private, and indeed could be used for nonmarketing purposes by a variety of audiences (e.g., researchers). As a result, the state’s purported justification failed; therefore, the statute “imposes more than an incidental burden on protected expression.”²¹ Although the Court found the state’s interests to be proper, it found that the law advanced the state’s law in an impermissible way. In the majority’s view, even a substantial state interest cannot justify the censorship of speech involving reliable and truthful information out of “fear that people will make bad decisions if given truthful information.”²² It was this effort to curb speech involving accurate information that led to the law’s downfall. In light of this decision, the Maine and New Hampshire laws were likewise overturned because of the *Sorrell* ruling. (The First Circuit’s decision regarding the Maine law was vacated and remanded for further consideration in light of *Sorrell*.²³ In New Hampshire, the District Court reinstated its 2007 opinion invalidating the New Hampshire law.²⁴)

Justice Breyer, joined by Justices Ginsburg and Kagan, filed a dissenting opinion. In their view, Vermont’s law regulated commercial activity rather than speech and, thus, imposed no significant burden on free speech.²⁵ The dissent argued that just because the statute implements a speaker-based ban does not change the fact that the law is aimed at a commercial activity, not at speech; therefore, no heightened scrutiny is necessary. Arguing that the majority’s opinion was inconsistent with precedent, Justice Breyer further expressed concern that the majority had substituted its judgment for that of state legislators²⁶ and that its action would open a “Pandora’s box of First Amendment challenges to ordinary regulatory practices.”²⁷

IMPLICATIONS FOR PUBLIC HEALTH POLICY AND PRACTICE

The creation and use of health information are fundamental tools of health reform efforts that aim to improve the quality and cost-effectiveness of health care. Federal and state governments will seek to regulate the use of the information that is created under their reform efforts, particularly information that can be applied to advance commercial interests. The lesson of *Sorrell* is that government cannot stop commercial interests from using legal, accurate, and available information to advance their interests through speech. Of course, government could bar the creation or disclosure of identifiable information regarding health-care providers, just as it has restricted the disclosure of individually identifiable patient information under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. The majority opinion in *Sorrell* does not in any way affect the power of government to create vital health information, nor does it affect government's power to use information. However, by classifying commercial practices as speech rather than conduct, the decision makes clear that the courts will closely scrutinize efforts to censor the use of information, once created, by commercial interests.

As with marketing restrictions for pharmacy data, various state and federal laws regulate the use and disclosure of health information contained in medical records or insurance records that is indisputably truthful and potentially useful to other parties (e.g., health insurers, life insurers, employers, retailers of medical equipment, and lobbyists). State laws requiring disclosures for quality measurement or reporting of communicable diseases may restrict the use of that information for marketing purposes while allowing various entities to access the data for public health surveillance, oversight, research, and other noncommercial purposes. State disease registries may authorize the collection of information for public health and research purposes but prohibit commercial uses. In the past, such limitations would be considered part of a state's legitimate regulatory objectives, particularly where the information in question is created only because of a government mandate. The *Sorrell* decision carries implications for these laws in cases in which a commercial interest seeks to buy the data and use them for marketing reasons, treating such restrictions as subject to heightened First Amendment scrutiny, rather than the lower standard of scrutiny typically applied to laws regulating economic conduct.

Of course, an important underlying question is whether government can prohibit the commercial sale or lease of public health information altogether. *Sorrell* does not address this question, but one could easily anticipate enormous resistance to a law barring the commodification of accurate health-care information, and there are important reasons why such information should be available in the marketplace. The immediate lesson of *Sorrell* is that the goal of high-quality, cost-effective health care cannot be achieved through efforts to ban marketing practices. Instead, achieving this goal will depend on the degree to which providers are educated about and the health-care system supports and rewards appropriate health-care practice. In this context, initiatives to engage health-care providers, consumers, and payers regarding the use of medical resources become even more vital to the national goal of health reform.

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