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Perspective

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In 2007, Vermont enacted the Prescription Confidentiality Law, prohibiting pharmacies from selling "prescriber-identifiable" prescription information to data-mining companies such as IMS Health and Verispan. These companies aggregate such data and sell them to many groups, including drug companies, so when drug sales representatives visit a physician, they can know exactly what prescriptions the physician has written.

The companies, joined by the trade association Pharmaceutical Research and Manufacturers of America, sued Vermont to block the law. Vermont won in federal district court but lost on appeal. In June, the U.S. Supreme Court ruled in *Sorrell v. IMS Health*,[1] holding six-to-three against Vermont. As Mello and Messing describe, the decision considers drug marketing using prescriber-identifiable prescription data to be speech protected by the First Amendment, and it implicates similar New Hampshire and Maine laws and a Massachusetts regulation.

Vermont's statute had a fatal self-inflicted wound. By prominently announcing that the state intended to tip the balance in the "marketplace for ideas" against drug companies, the law dug itself into a constitutional hole: state interference with that marketplace was likely to provoke the ire of a majority of the Supreme Court. Writing for the Court, Justice Anthony Kennedy stated, "[t]he more benign and, many would say, beneficial speech of pharmaceutical marketing is also entitled to the protection of the First Amendment."

Instead of dealing with this statute under existing precedent, Kennedy seized the opportunity to expand the First Amendment's reach and power to strike down government regulation of health care information. The Court's opinion raises serious questions for some public health rules and the regulation of drug marketing. Justice Stephen Breyer, writing in dissent, charged that the Court added an unprecedented constitutional standard that would hinder consumer-protection regulations, including Food and Drug Administration (FDA) restrictions against off-label marketing.

Although the First Amendment's core is the protection of religious freedom and political speech, in recent decades, federal courts have expanded its application to business-related or "com-

mercial" speech. In the 1970s, the Court used the commercial speech doctrine to reach state laws prohibiting advertising by professionals such as lawyers, accountants, pharmacists, and physicians. These professions had been self-regulating, following ethical rules that limited market competition. The Supreme Court struck down the prohibitions, using a standard of review that reserved some deference to the state legislature. By 1980, this "intermediate-scrutiny" standard was encapsulated in the *Central Hudson* decision, and until now, the *Central Hudson* test — whereby it's considered constitutional to regulate commercial speech only if doing so "directly advances" a "substantial" government interest in a way that "is not more extensive than is necessary" — has been the operative standard.

Kennedy applied a more stringent "heightened-scrutiny" standard to the Vermont law, seeing the additional burden as justified because the law regulated specific conduct (drug marketing) and specific persons (data miners and drug companies). Under this standard, the Court didn't carefully weigh the health care cost savings described by Vermont and gave short shrift to physicians' confidentiality in patient-related decision making, claiming that prescriber-identifiable information was widely available in the marketplace. The majority dismissed Vermont's concerns about data mining as "nothing more than a difference of opinion," without considering seriously the peer-reviewed evidence on marketing's effect on prescribing choices. Indeed, experts' testimony to the Vermont legislature was offered as evidence of the state's bias.

In his dissent, Breyer noted that many well-established FDA regulations could fall if heightened scrutiny were applied. In fact, it's difficult to identify an FDA regulation that does not target specific conduct and specific persons. For example, the FDA restricts off-label promotion by drug and device companies,[2] and regulations specifically target food and cigarette advertising. And indeed, drug companies have recently raised First Amendment challenges to enforcement actions against off-label promotion.[3] In a prominent case involving Allergan's promotion of onabotulinumtoxin A (Botox) for unapproved indications including headache, pain, muscle spasticity, and cerebral palsy in children,[4] one of Allergan's defenses was a First Amendment challenge against the regulation prohibiting off-label promotion. Ultimately, Allergan pled guilty to a misdemeanor misbranding charge and paid the U.S. government $600 million, but in announcing this settlement, the company expressed regret that the First Amendment issue had not been litigated to a final conclusion. After *Sorrell*, we can expect similar challenges to FDA marketing rules. In fact, Allergan and six other pharmaceutical and device companies recently filed a petition calling for clarifications of the FDA's regulation of off-label promotion and warning that "important constitutional concerns arise out of the regulatory scheme."

In *Sorrell*, the Court suggested that the Constitution might be more flexible regarding FDA regulations protecting consumers rather than physicians. The Court reaffirmed that "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. . . . These precepts apply with full force when the audience, in this case prescribing physicians, consists of 'sophisticated and experienced' consumers." Thus, FDA regulation of direct-to-consumer advertising could be given more leeway than marketing to physicians, especially if medical education programs focused on helping physicians evaluate such claims. Similarly, more leeway could be given under special circumstances, such as if the FDA restricted direct-to-consumer advertising as part of a Risk Evaluation and Mitigation Strategy.

Outside the pharmaceutical realm, this decision also bodes ill for marketing regulation of food, tobacco, alcohol, and other products with important public health effects. Kennedy's opinion notes that "the State may not seek to remove a popular but disfavored product from the marketplace by prohibiting truthful, nonmisleading advertisements that contain impressive endorsements or catchy jingles. That the State finds expression too persuasive does not permit it to quiet the speech or to burden its messengers." One could surmise from this position that cigarette manufacturers might have a First Amendment right to broadcast TV advertisements or target young prospective smokers with cartoons. By contrast, regulations requiring additional speech — such as menu and food-labeling laws — might better survive First Amendment review.

With respect to data mining, states have several options going forward. The majority opinion provides a road map for a law focused on patient privacy. States

may supplement the Health Insurance Portability and Accountability Act (HIPAA), the federal privacy statute, to add protections for prescriber-identifiable data. The Court indicated that HIPAA would survive a First Amendment challenge: "For instance, 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. . . . A statute of that type would present quite a different case than the one presented here." Under HIPAA, Vermont has authority to adopt such an amendment.

One major factual disagreement on the Court relates to the breadth of exceptions under the Vermont law: the majority thought prescriber-identifiable data were ubiquitous in the marketplace, whereas Breyer believed the law operated more like HIPAA, with such data assumed to be confidential unless a clear exception applies. Under HIPAA, the state could extend the federal Privacy Rule to cover prescriber-identifiable data in Vermont, and the Supreme Court would apparently approve.

In addition, as Vermont transitions to single-payer health care, Green Mountain Care will become the sole authority contracting with all providers. Vermont could use Green Mountain Care's pharmacy–provider contracts to restrict the sale of prescriber-identifiable data without running afoul of the First Amendment. Similarly, other public and private health plans could refuse to sign contracts with pharmacies that sell prescriber-identifiable data.

The commercial speech doctrine is a modern invention. In 1942, the Supreme Court unanimously held that whereas the First Amendment protected political protest, "the Constitution imposes no such restraint on government as respects purely commercial advertising."[5] Today's Court has come to a quite different conclusion, raising new constitutional hurdles for myriad FDA and public health regulations.

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