HEALTH LAW, ETHICS, AND HUMAN RIGHTS

Restrictions on the Use of Prescribing Data for Drug Promotion

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Pharmaceutical manufacturers spend billions of dollars each year sending sales representatives, known as detailers, into physicians' offices. To promote their drugs, detailers show up at medical offices bearing product information and valuable drug samples. They also wield a third critical tool: reports about the doctor's prescribing history.

Pharmaceutical companies buy these reports from prescription drug intermediary (PDI) companies that obtain prescription records from pharmacies across the country and link them to physician information that they purchase from the American Medical Association (AMA) (Fig. 1).[1,2] Sales representatives can use the information to identify physicians who are high or low prescribers and early or late adopters, to decide which points to emphasize in their presentations, and to assess how effective their visits have been in modifying prescribing behavior.[3,4] This practice, known as data mining, enhances the effectiveness of sales calls. Although government agencies, researchers, and health insurers use prescribing databases, pharmaceutical manufacturers are the primary consumer.

Critics object that detailing — particularly detailing with prescribing information — raises health care costs by boosting the prescription of branded drugs[5-7] and their addition to hospital formularies,[7,8] jeopardizes patient safety by promoting new drugs for which safety and effectiveness data are limited,[6,7,9] and impinges on the privacy of both patients and physicians. Physicians tend to have mixed feelings about detailing. They recognize that sales presentations can be biased[7] and generally disapprove of the use of their prescribing data,[10,11] but many still find the presentations and free samples valuable.[12]

Concern about detailing has prompted at least 25 states to consider legislation to curtail it by restricting the transfer and use of physician-identifiable prescribing data.[13] Laws passed in 3 states — Vermont, New Hampshire, and Maine — were swiftly challenged by PDIs and a trade association of pharmaceutical manufacturers.[14-16] One of these challenges reached the nation's highest court this year, and on June 23, the Supreme Court struck down Vermont's statute by a vote of 6 to 3,[17] holding that in practical effect, the law unconstitutionally restricted the speech of pharmaceutical companies and PDIs on the basis of the viewpoint it expressed. In this article, we review the Court's reasoning and examine the implications of its holding.

VERMONT'S LAW

Vermont's law prohibited pharmacies and PDIs from selling, licensing, or exchanging prescriber-identifiable prescription information and from permitting its use for drug promotion. Pharmaceutical manufacturers and marketers were likewise prohibited from using the information for marketing purposes. The law contained an "opt-in" provision allowing the sale or use of data relating to physicians who consented. The Vermont statute[18] closely resembled the laws adopted in New Hampshire[19] and Maine[20] (Table 1). The central difference is that whereas Vermont barred the use of data unless a physician opted in, Maine allowed it unless a physician opted out, and New Hampshire imposed an unconditional ban.

In adopting its law, Vermont articulated three objectives: avoiding harm to the public health associated with the overprescription of new drugs, controlling costs by stemming practices that promote expensive, branded drugs over generics, and protecting physicians' privacy.[16] Unlike Maine and New Hampshire, Vermont did not emphasize the risks to patients' privacy even though data miners may be able to identify patients by triangulating information about patient sex and age and the drugs prescribed.[2,21]

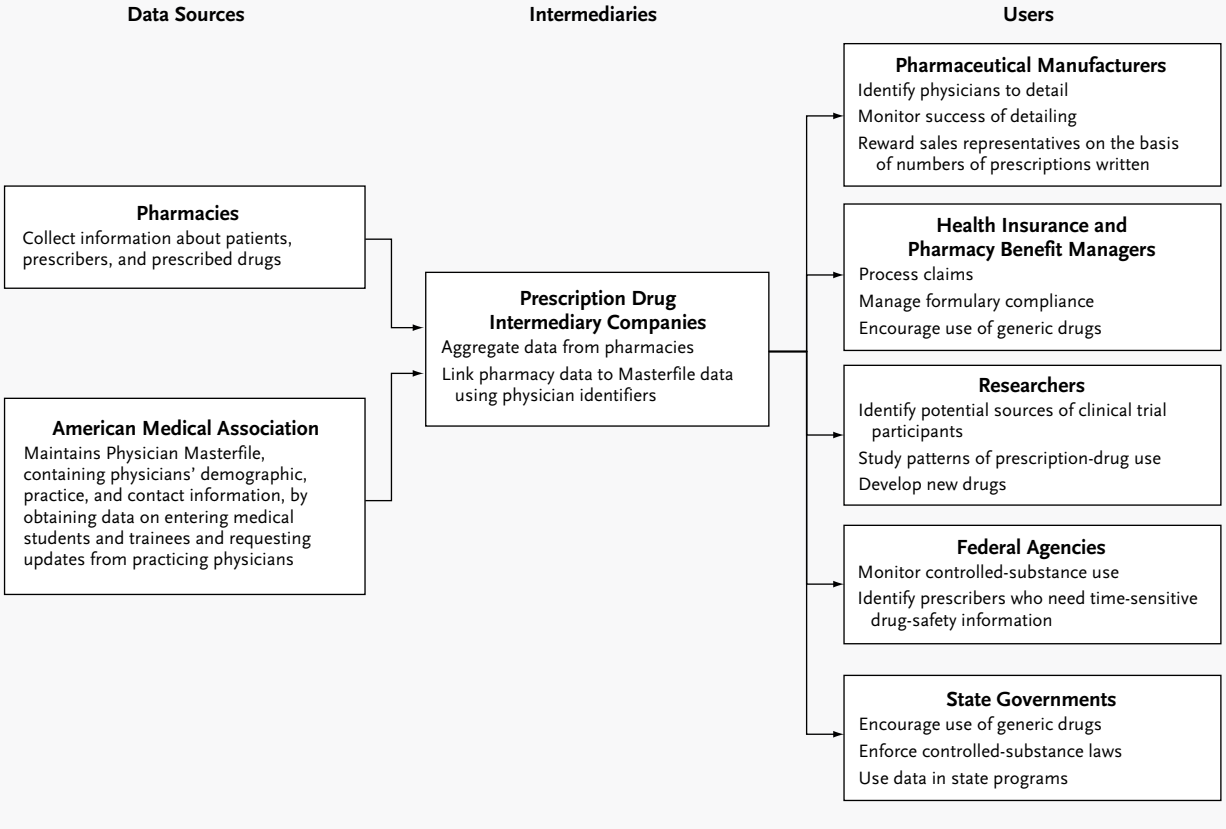

Figure 1. **The Data-Mining Process.**

CHALLENGES BASED ON THE FIRST AMENDMENT

The legal challenge to Vermont's statute alleged that the law trammeled rights to free speech: the data miners asserted the right to acquire information from pharmacies and communicate it, and the pharmaceutical companies asserted the right to use prescribing data to shape their conversations with physicians. Vermont argued that the sale of data involved not speech but a mere economic transaction akin to the sale of any other commercial product. Thus, Vermont asserted, the transfer of prescribing data could, with few limits, be regulated.

But both parties addressed a second argument: that the data transfers involved commercial speech — a hybrid of commerce (which states can generally regulate) and fully protected speech (which states usually cannot restrict). They disagreed, however, about the implications under the legal test that governs commercial speech. Entering this case, commercial speech was governed by a test that the Supreme Court introduced in 1980, known as the *Central Hudson* test.[22] The test provides that the government must show that regulations restricting commercial speech meet three requirements: they must serve a substantial state interest, must directly and materially advance that interest, and must be well "tailored" — meaning they are neither too narrow to address the problem nor broader than needed.

The data miners and pharmaceutical companies argued that Vermont's law could not withstand this test. They also argued that the Supreme Court should abandon the *Central Hudson* test and stop treating commercial speech as constitutionally inferior to political communications.[23] Under that approach, commercial speech would almost always fall beyond the government's regulatory reach.

Table 1. State Laws Restricting the Commercial Use of Physician-Identifiable Prescribing Data.*

State	Legal Case	Asserted State Interests	Entities Restricted	Prohibited Practices
Vermont[18]	*Sorrell* v. *IMS Health, Inc.*[17]	Health care cost containment, prescriber privacy, public health	Insurers and self-insured employers, PDIs, pharmacies, and other similar entities, pharmaceutical manufacturers, pharmaceutical marketers	Sell, license, or exchange data for value unless prescriber consents (opt in) Permit the use of data for "marketing or promoting a prescription drug" unless prescriber consents (opt in) Use data for "marketing or promoting a prescription drug" unless prescriber consents (opt in)
New Hampshire[19]	*IMS Health, Inc. v. Ayotte*[14]	Health care cost containment, prescriber privacy, patient privacy	Insurers, PDIs, pharmacy benefits managers, pharmacies, and other similar entities	Sell, license, transfer, or use data "for any commercial purpose" other than defined exceptions†
Maine[20]	*IMS Health, Inc. v. Mills*[15]	Health care cost containment, prescriber privacy, public health, patient privacy	Insurers and self-insured employers, pharmacies, PDIs	Sell, license, transfer, exchange for value, or use data "for any marketing purpose" if prescriber has filed for confidentiality protection (opt out)

* PDI denotes prescription drug intermediary.

† Exceptions listed in New Hampshire's statute are pharmacy reimbursement, formulary compliance, patient care management, utilization review by a health care provider or the patient's insurer, health care research, information transfers between pharmacies or from providers to pharmacies, educational communications to patients (including information about clinical trials), "or as otherwise provided by law." Vermont's statute also lists these exceptions, along with "certain law enforcement purposes as otherwise authorized by law." These exceptions are merely implicit in Maine's statute.

THE SUPREME COURT DECISION

In striking down Vermont's statute, the majority, led by Justice Anthony Kennedy, held that the statute unconstitutionally enacted "content- and speaker-based restrictions" on speech. In plain terms, the law restricted only data sales related to a specific topic (marketing) and only when certain parties (such as pharmaceutical manufacturers) were involved. Furthermore, in practice, the law targeted only companies that were expressing a specific viewpoint — advocating the prescribing of branded drugs.[17] These biases did not doom Vermont's law, but they caused the Court to assess it with a beady eye, which Justice Kennedy called "heightened scrutiny."

The term "heightened scrutiny" is critical and pointedly ambiguous. It might be a mere synonym for the midlevel scrutiny applied under the *Central Hudson* test — but it might mean far more. In a prior opinion, Justice Kennedy cited First Amendment cases that applied "strict scrutiny," the most rigorous kind, as examples of "heightened scrutiny,"[24] suggesting that he may have intended this meaning when he used the same term in *Sorrell v. IMS Health, Inc.* Furthermore, just 4 days after the *Sorrell* decision, the Court opined (in a decision striking down a law banning the sale of violent video games to minors) that all content-based speech restrictions require strict scrutiny.[25] *Sorrell* might thus portend that commercial speech will no longer receive lesser protection than political and social speech.

But the Court dodged the need to resolve which species of scrutiny should apply. Instead, it held that under either the intermediate approach represented by the *Central Hudson* test or the stricter test applied by the Court, the First Amendment barred Vermont's law. Although the state's asserted interests were plausible, Vermont had pursued them in a constitutionally infirm way.

As to Vermont's first policy concern — physician privacy — the Court found that the statute was "not drawn to serve that interest" because pharmacies could share prescribing information "with anyone for any reason" except marketing. Nor could the statute's opt-in provision save it, since the provision created a "contrived choice" under which Vermont forced doctors to allow either everyone to use their prescribing data or everyone who Vermont supported — but gave them

no option to curtail the use of their data by Vermont's favored speakers.

The Court next rejected Vermont's cost-control argument, adopting the appellate court's conclusion that Vermont's approach to cost containment was too indirect and chastising Vermont for seeking to influence commercial conduct by stifling speech. As to Vermont's final interest — protecting public health — the Court elided the core issue, noting that other parties had found that detailing could benefit public health. The Court did not confront the evidence Vermont had introduced showing that detailing had boosted the prescribing of newly approved, brand-name drugs, including Vioxx and Baycol.[26] The Court also did not address concerns about patient privacy that third-party *amici* (interested third parties) had raised in briefs submitted to the Court.

The Court rejected a potentially powerful argument that Vermont had not raised in earlier stages of the litigation: the plain language of the statute barred pharmacies, which the state had entrusted to gather sensitive data, from selling the data to anyone (unless specifically exempted in the statute). Thus, the law banned sales, not sales related to marketing. That subtle but vital difference had rattled several justices during oral arguments because when viewed in this light, Vermont's law looked more like an ordinary regulation of commerce than an objectionable restriction on speech. Nevertheless, the majority found that Vermont exempted so many parties from the ban on the sale and use of data that the restriction burdened only marketers. The Court also hinted that this portion of Vermont's statute was a pretext for the state's real motive: stifling detailers' speech.

Thus, the Court held, the law was biased against detailers, discriminating on the basis of both content and — given how the law worked in practice — viewpoint. That bias triggered heightened scrutiny, which Vermont's law could not survive.

In dissent, three justices dismissed the majority's conclusion that Vermont's law appreciably burdened speech. Rather, Vermont's law was a mere quotidian regulation of economic activity — just as Vermont had argued. It affected speech incidentally — and only by depriving "pharmaceutical and data-mining companies of data, collected pursuant to the government's regulatory mandate, that could help pharmaceutical companies create better sales messages." The dissent would have reviewed the law under a standard more lax than that of the *Central Hudson* test, but it would also have upheld the statute even under the majority's stricter test, because "Vermont compiled a substantial legislative record to corroborate" its policy concerns and because Vermont had tailored its law sensibly. The dissent warned that the majority's opinion might empower judges to strike down ordinary economic regulations under the guise of protecting fundamental rights.

A DEFEAT FOR PUBLIC HEALTH?

The *Sorrell* litigation has been closely watched by opponents of detailing, and the Court's decision hinders their cause. Yet the decision is not an unequivocal defeat for public health. If laws like Vermont's were to become widespread, they would undercut pharmaceutical companies' ability to detail physicians effectively, with the probable consequence that detailing would be greatly reduced. Although this outcome might well reduce the cost of prescription drugs, it would also reduce the amount of information that doctors receive. Indeed, all the justices in *Sorrell* agreed that detailing can have educational value. For all its problems, detailing — like its troublesome cousin, direct-to-consumer advertising — is probably of some benefit to patients.

A ruling in Vermont's favor also could have substantially changed the financial landscape for PDIs. Legislators in other, larger states might have passed data-mining laws, which might have caused PDIs to stop building prescribing databases. These databases are used for purposes that benefit public health, such as pharmacoepidemiologic research, as well as for marketing.[1] Although researchers are typically interested in prescription volume and cost data rather than physician-identifiable prescribing data, PDIs might not invest in building prescription databases at all if their primary market evaporated.

A broader question is whether *Sorrell* will vitiate restrictions on the commercial sale and use of other kinds of identifiable health information, such as information from electronic health records.[27,28] *Sorrell* did not reach that far. On the contrary, the Court defended the patient privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, noting

that HIPAA imposed a general ban on disclosure except in "a few narrow and well-justified circumstances." Although the Court did little to define the boundary between unconstitutional laws such as Vermont's and sacrosanct ones such as HIPAA, it is clear that some restrictions on data sales will, if tailored finely and fueled by strong governmental interests, survive.

Sorrell may also affect the government's ability to regulate in other areas of public health. The dissenters feared that the majority's reasoning could expand judicial power to invalidate a wide range of regulatory actions on the basis that they burden speech. The dissent warned that the majority opened "a Pandora's Box of First Amendment challenges to many ordinary regulatory practices that may only incidentally affect a commercial message." Most actions taken by regulatory agencies target specific commercial practices or specific commercial actors; the majority categorized such actions (assuming that they affect speech) as "content-based" and "speaker-based" restrictions, respectively.

Public health advocates and regulators may worry, with reason, that the government will now have less latitude to make policy decisions in the interest of public health without fear of judicial reversal. For example, the Food and Drug Administration has interpreted two provisions of the federal Food, Drug, and Cosmetic Act to prohibit the advertising and promotion of off-label uses of drugs.[29-32] Other regulations, adopted in 2010, restrict tobacco advertising — for instance, barring manufacturers, distributors, and retailers of tobacco products from marketing nontobacco products that bear the brand name or logo of a tobacco product.[33] The Supreme Court struck down California's ban on the sale of violent video games, rejecting the state's claim that the ban advanced its interest in the prevention of youth violence.[25] All these speech restrictions target a particular type of business that delivers marketing messages, and all are motivated by the government's view that the marketing is bad for public health.

CAN DATA-MINING LAWS BE SAVED?

The Court's decision formally applies only to Vermont's data-mining law. However, on June 28, the Court vacated the decision by a federal appellate court to uphold Maine's law, ordering that court to reconsider the case in light of *Sorrell*.[34] The speech restrictions in Maine's law are narrower in that they are triggered only when a physician files for confidentiality protection. This opt-out feature makes the law more like the regulations creating a national Do Not Call Registry for consumers, which a federal court of appeals upheld and the Supreme Court declined to review.[35,36] And Maine pressed a concern that Vermont disregarded — the need to protect patient privacy — which might provide a way to distinguish the two laws. Still, the law targets data miners and drug sellers, raising the same concerns about speaker-based discrimination and tailoring that preoccupied the Court in *Sorrell*. Maine's law will probably fall.

Sorrell also renders the New Hampshire law unenforceable. The law contains the same constitutional infirmity as Vermont's — the restriction on data mining is limited to commercial uses of the data and to specific types of speakers. Indeed, it is even more objectionable, from the Court's perspective, because it offers no options for physician privacy, such as an opt-out provision.

Another related law has thus far avoided a legal challenge. In 2008, Massachusetts required pharmaceutical manufacturers to provide prescribers with the opportunity to prevent their data from being used for marketing purposes.[37] The law is vulnerable — governments generally cannot force private parties to do to themselves what the government cannot impose upon them. But data miners and drug companies may refrain from challenging this law because its effects are too minimal to warrant risking an adverse court ruling. Seemingly, companies can satisfy the law by responding to physician requests to opt out — they are not required to publicize the availability of that option.

There are two avenues along which data-mining laws could be recrafted so that they might survive judicial scrutiny. First, the Court suggested that a broader ban on the use of prescribing data might be acceptable — provided that the state showed no animus toward drug marketers. The majority wrote that if Vermont's law had "provided that prescriber-identifying information could not be sold or disclosed except in narrow circumstances then the State might have a stronger position." For example, disclosure might be limited to purposes related to law enforcement and public health activities. Such a policy would be better tailored to protect physician privacy.

At first blush, this proposed solution seems

counterintuitive: the Court implied that a law restricting more speech would better comport with the First Amendment. But that solution is common in First Amendment jurisprudence, which aggressively polices viewpoint discrimination. The Court, in other words, is especially concerned about governmental attempts to silence speakers expressing messages with which the government disagrees, and it demands similar treatment for speakers with different viewpoints. A broader ban on disclosure of prescribing information would place all (or most) speakers on similar footing.

Such a law, however, would probably become ensnared in a trap inherent in the Court's tailoring analysis. To be well tailored to protect physician privacy, the ban on disclosing prescribing data needs to be broad. But a statute restricting disclosure to a broad range of parties would probably provoke the Court to conclude that the law was broader than necessary to advance the state's other interests — promoting public health and reducing health care costs. Indeed, a ban on disclosure for the purposes of research and public health surveillance would work against both these interests. States, in short, will be whipsawed when their interests demand inconsistent remedies.

A second potential approach to future data-mining laws would be to give physicians a menu of privacy options. Allowing physicians to select which uses of their prescribing data to permit would avoid a blanket ban on all disclosures, maximize the law's responsiveness to physicians' privacy concerns, and give equal treatment to various viewpoints on detailing. The majority noted that simply converting the statute to a Maine-style opt-out model "would not necessarily save" it, but hinted that a broader range of privacy options might.

ALTERNATIVES TO DATA-MINING LAWS

The Court's decision may lead states and private parties to consider alternative means of addressing concerns about detailing. The Court suggested two of them: physicians can simply close their doors to detailers and states can vigorously pursue "counterdetailing." The latter suggestion reflects the Court's general preference for policies that lead to more, rather than less, speech in the information marketplace.

The PDIs in the *Sorrell* litigation suggested that Vermont pursue a third approach to achieve its public health and cost-control objectives: adopting policies that promote the use of generic drugs. States and private payers could strengthen initiatives such as prior authorization requirements for branded drugs, mandatory generic substitution, tiered formularies, and educational outreach to physicians.

Notably, the Court did not mention the AMA's Physician Data Restriction Program (PDRP) as an effective alternative to Vermont's law. Launched in 2006, the PDRP allows physicians to withhold their prescribing data from pharmaceutical sales representatives while still sharing it for research purposes.[38] To date, few physicians (approximately 4%) have signed up for the PDRP,[4] perhaps because the AMA's financial interests cut against strongly promoting the program.[1,39] The AMA realizes substantial revenue from the sale of physicians' professional data, and widespread physician opt-out would reduce the usefulness of the data to PDIs. Nevertheless, the PDRP is a potentially powerful tool, and as a voluntary private initiative, it poses no constitutional concerns.

States could also combat the worst excesses of detailing by passing laws that directly regulate detailing practices. A ban on detailing would be unconstitutional, but nothing in the First Amendment prevents the government from prohibiting untruthful or misleading statements in detailing conversations, since such speech receives no First Amendment protection. The District of Columbia has already enacted such a law.[40] States could also probably require detailers to disclose to doctors what sources of data they are relying on in making claims about their products — another "more speech" solution that would appeal to courts.

CONCLUSIONS

The *Sorrell* decision impedes states' efforts to curb detailing. Clever lawmakers may, however, be able to write their way around the Court's ruling. The decision might also offer an unexpected dividend to opponents of data mining: the surrounding publicity might alert physicians to their right to opt out of sharing their prescribing information through the PDRP. Although the Supreme Court swept aside data-mining laws with the stroke of a pen, physicians who object to data sharing can escape it with the click of a mouse.

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