Prescriptions, Privacy and the First Amendment

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On April 26, the Supreme Court heard oral arguments in a case that, when it is decided this spring, will have important repercussions for the practice of medicine. At issue in William H. Sorrell, Attorney General of Vermont, et al., Petitioners v. IMS Health Inc., et al.¹ is whether detailed information about prescriptions written by doctors, with the doctor identified, can be bought and sold. Currently, this practice is legal in almost every state, and the outcome of Sorrell v. IMS Health will signal whether states may restrict it.²

This is the way it works: Retail pharmacies retain information about all drug prescriptions that they fill, including the patient's name, the identification of the prescriber, the name, dosage, and quantity of the prescribed drug, and the date the prescription was filled. This information is collected, along with the patient's age, sex, and drug history, and sold, with the individual prescribing doctors identified but the patient's names encrypted, to data-mining companies (IMS Health is one such company). The data-mining companies then further process the information by collating each physician's prescribing history for each patient, and they sell it to pharmaceutical companies. The prescribing information of individual doctors can be linked to the Physician Masterfile of the American Medical Association (AMA), thereby enriching the data on prescribing physicians (the Masterfile, which is sold by the AMA, includes information on every physician's education, licensure, certification, hospital privileges, and practice details). The companies' marketing departments use the information to develop strategies to sell drugs to individual doctors, and the schemes are applied by pharmaceutical sales representatives (“detailers”) to make pitches to the doctors in their offices. These solicitations are not intended to communicate evidence-based information to doctors; they are intended to sell expensive drugs.³

It is a very successful business. When drug detailers have the prescribing history of the physicians they are visiting, they sell more drugs. This is one of the principal reasons why the Pharmaceutical Research and Manufacturers of America (PhRMA), the trade organization of the pharmaceutical industry, joined the data miners as a party to the lawsuit. It is quite clear who profits from the sale of the prescribing information: retail pharmacies, data-mining companies, drug companies, and the AMA. In the end, the costs are passed along to patients, and physicians' prescribing practices are manipulated by drug salespeople who know the details of their interactions with their patients.

Because of the concerns that many physicians have about the sale of their personal prescribing information, the AMA developed the Physician Data Restriction Program, which allows physicians to opt out of the use of their prescribing data by drug company salespeople (although doctors cannot opt out of the sale of the data to the drug companies themselves). However, the program seems to be minimally effective; data from the AMA itself indicate that less than 3% of prescribing physicians have elected to opt out through this program. According to the Electronic Privacy Information Center, this low opt-out rate may be due to the fact that the program is not well known,⁴ especially to the more than 80% of physicians who are not AMA members, but whose data are nonetheless sold by the AMA. (Physicians can register for the program on its Web site.⁵)

After receiving complaints from the Vermont Medical Society about data mining, the Vermont state legislature passed the Prescription Confidentiality Law, which required that data-mining...
companies obtain explicit permission from a physician before selling his or her prescriber-identifiable information to pharmaceutical companies for the commercial purpose of drug promotion (an “opt-in” requirement). However, the law permitted limited uses of the information for medical care, insurance payment, law enforcement, public health, and scientific research without obtaining physicians’ approval, just as HIPAA (the Health Insurance Portability and Accountability Act) does. The new law was thus narrowly tailored to achieve reasonable regulation in line with a compelling interest of the state of Vermont.

The constitutionality of the Prescription Confidentiality Law was challenged in a suit brought by leading data-mining companies, including IMS Health, and by PhRMA. Although the U.S. District Court ruled in favor of Vermont, this decision was overturned by the U.S. Court of Appeals for the Second Circuit and the law was struck down. Previously, similar data-mining laws in New Hampshire and Maine had been upheld by the U.S. Court of Appeals for the First Circuit. Owing in part to these conflicting rulings on similar laws, the Supreme Court agreed to hear the Vermont case.

At issue in this important case is the conflict between the privacy of physician-identified drug-prescribing information and the First Amendment right of a business to communicate about its products (“commercial speech”). In contrast to public discourse, which is protected by the First Amendment as a fundamental part of the democratic process, protection of commercial speech under the First Amendment is a relatively recent development in the law.6,7 According to the Supreme Court, government regulation of commercial speech must directly promote a substantial governmental interest and must be no more extensive than necessary to meet that interest.8 Regulation of commercial speech was recently discussed in the Journal by Robert Post, now the dean of Yale Law School, in relation to the New Hampshire version of the statute restricting the sale of physicians’ prescribing histories.7 Post agreed with the First Circuit that the New Hampshire statute was constitutional, but a divided panel of the Second Circuit came to the opposite conclusion about the constitutionality of the Vermont law.

In Sorrell v. IMS Health, we have sided with the state of Vermont, and we have filed a friend-of-the-court brief supporting the appropriateness of the statute to protect the privacy rights of physicians and patients.9 We do not believe that the organizations challenging the Prescription Confidentiality Law are engaging in speech that warrants First Amendment protection. Rather, they are selling highly sensitive medical information as a mere commodity without consent. We are concerned that such selling of prescribing data to pharmaceutical companies results in the manipulation of physicians’ drug-prescribing practices, unwarranted intrusion into the privacy of the doctor-patient relationship, and an increase in costs at a time when our health care system is under unprecedented financial strain. Furthermore, the technique used to de-identify patient information is flawed (and is often performed with the use of software provided by the data-mining companies themselves), and the risk of re-identification poses a serious threat to the confidentiality of patient information.3,10 A patient’s drug history provides clear insight into that patient’s medical history. Therefore, we believe a finding by the Supreme Court overturning the action of the Vermont legislature in this case would have serious negative consequences for the practice of medicine and for the public health. Such a finding could also open the door to legal challenges to other reasonable restrictions on the marketing practices of pharmaceutical companies, including the current prohibition of the promotion of off-label uses of prescription drugs.11

As medical journal editors committed to the open communication of medical knowledge, we are strong proponents of First Amendment protection for speakers who attempt to communicate important evidence-based health information or advocate for patients’ and physicians’ rights. But, the doctor–patient relationship is a sacred trust, and the sale of physicians’ confidential prescribing information puts patients’ highly private medical information at risk. Why should this information be sold to data-mining and drug companies as a commodity, when it offers no benefit to patients
and their physicians? This undesirable practice is nothing more than commercial conduct — not speech — and it is not in the best interest of the health of the American people.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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