2012

Marketing Pharmaceuticals: A Constitutional Right to Sell Prescriber-Identified Data?

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Georgetown Public Law and Legal Theory Research Paper No. 12-017
Georgetown Business, Economics and Regulatory Law Research Paper No. 12-003

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307 JAMA 787-788 (2012)

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Marketing Pharmaceuticals
A Constitutional Right to Sell Prescriber-Identified Data?

Lawrence O. Gostin, JD

Pharmaceutical companies have strong economic interests in influencing physician prescribing behaviors. They advertise directly to consumers and to physicians. Beyond general marketing, manufacturers promote their drugs to physicians through “detailing”—sales representatives (“detailers”) visiting medical offices to persuade physicians to prescribe their products.

By law, pharmacies receive specific information with every prescription, including the physician’s name, the drug, and the dosage. Pharmacies sell these records to prescription drug intermediaries (data miners), who use advanced computing to analyze prescriber-identified information (which physicians prescribe what drugs, in what dosages, and with what prescribing patterns). Data miners, in turn, lease sophisticated reports to pharmaceutical companies to refine detailers’ marketing tactics, armed with knowledge about physician prescribing practices—for example, who are high or low prescribers and early or late adopters of new drugs.

Detailing raises vital health policy questions, including its effects on clinical decision making (safety, quality, and cost) and the patient-physician relationship (privacy and professionalism). Yet private companies claim a First Amendment right to buy and use prescribing data for product marketing. The tensions between privacy and commercial speech have deep implications for public health regulation.

Commercial Speech: The Future of Public Health Regulation

In 2011, in Sorrell v IMS Health, the Supreme Court struck down Vermont’s prescription confidentiality law, which, absent the physician’s consent, prohibited the sale of prescriber-identifying information as well as the disclosure or use of that information for marketing purposes. Justice Kennedy’s 6-3 majority opinion held that Vermont’s law is subject to “heightened scrutiny” (a demanding level of judicial review) because the act restricts speech based on who the speaker is (marketers) and the content of the message (prescription data).

The First Amendment’s core purpose is to safeguard discourse in social affairs (politics, culture, and religion). For most of the nation’s history, the Supreme Court said that the Constitution afforded no protection for commercial speech—broadly defined as speech by a commercial enterprise for business purposes. By 1975, when the Court first recognized a constitutional right to market products, commercial speech was viewed as “lower-value” expression. The Roberts Court, however, has progressively increased protection for commercial speech, culminating in Sorrell’s “heightened scrutiny,” which is a rigorous standard of review for all “content and speaker-based” speech.

The standard for reviewing regulation of health information is critically important. The Court traditionally uses a “mid-level” 4-part test laid down in Central Hudson Gas v Public Service Commission: Is the message lawful and non-deceptive? Does the state have a “substantial interest” in curtailing the speech? Does the regulation “directly advance” that interest? Is the regulation “no more extensive than necessary?” Justice Breyer, dissenting in Sorrell, called for an even lower standard of review reserved for “mere economic regulation” that only incidentally affects speech. He observed that prescriber information exists only because the state requires reporting those data. Consequently, Breyer urged judicial deference to reasonable legislative judgments.

The prospect of enhanced judicial scrutiny casts a shadow over regulation of health information, including food, drugs, alcohol, and tobacco—almost all of which is speaker and viewpoint based. In today’s complex informational environment, government restricts the health claims that companies can make and compels the inclusion of safety warnings. Pharmaceutical companies must provide information about a drug’s risks and adverse effects and cannot promote off-label use of their products. If the Supreme Court uses a heightened standard of review, these public health regulations, and more, will be placed at risk.

A federal court recently found, for example, that the US Food and Drug Administration may have violated the First Amendment by requiring graphic images on tobacco packaging. The Supreme Court, moreover, has already used heightened scrutiny to invalidate California’s ban on violent video games to deter youth violence.

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The Lower-Value Content of Detailing

Detailer sales calls may benefit some physicians who learn useful information and receive generous product samples. Yet the source of medical information is vital. Detailers’ primary goal is to sell more brand-name products rather than to educate physicians by providing objective scientific evidence. Some physicians may rely on these accounts rather than delving into the peer-reviewed medical literature. The informational deficits resulting from detailing could pose health and safety risks, increase health care costs, and affect privacy and professional practice.

Patient Health and Safety. Although most physicians recognize detailers’ self-interest, sales calls significantly alter prescribing practices. Physicians may prescribe medications that are not needed or that are newly marketed without an adequate safety record. Detailing, for example, increased Vioxx and Baycol prescriptions before these drugs were withdrawn from the market because of inordinate safety risks.

Health Costs. Pharmaceutical companies spend billions of dollars on detailing, primarily for brand-name patented drugs for which prices are higher. The detailers’ aim is to convince physicians to prescribe their products and add them to hospital formularies. Generic drug manufacturers, in contrast, engage in far less marketing, leading to an informational imbalance that contributes to driving up health care costs. Studies point to the savings that would be generated by the increased use of generics and suggest ways to incentivize physicians to prescribe generics.

Patient Privacy. Prescriber information is not usually considered a privacy concern because patients are not personally identified. However, theoretically, cross-matching prescriber information with multiple databases could reveal a patient’s identity, although there are no reported instances of this occurring. Consequently, companies that possess prescriber records must ensure the privacy and security of potentially identifiable patient data.

Professionalism. Because privacy traditionally safeguards patients rather than health care professionals, prescriber-identified information is not usually thought of as a privacy invasion. Yet sales visits designed to influence treatment are professionally intrusive, interfering with the patient-physician relationship. Although physicians can opt out of detailing, the presence of private marketing in physician offices is common, which could potentially undermine physician objectivity and impartiality.

Regulation in a Post-Sorrell Environment

Although Sorrell’s heightened scrutiny poses considerable challenges, government could find creative ways to regulate drug detailing. Existing laws in Maine and New Hampshire probably will be invalidated, but more than 25 additional states have proposed detailing regulations. The Court offered states pathways to constitutionally viable laws, ironically by enacting more systematic restrictions on prescriber information.

Vermont’s law permitted prescriber information to be disclosed for health care research, compliance, education, or law enforcement. The Court said that these broad exceptions showed that Vermont was not truly interested in protecting privacy. The courts would probably uphold future laws if states more uniformly restricted prescriber information, with narrow exceptions such as for health care research.

Even absent strict regulation, states could significantly reduce detailing by informing physicians of their right to opt out or by requiring an “opt in,” which would affirmatively require physician consent to sales visits. For example, the American Medical Association launched its Physician Data Restriction Program in 2006 to allow prescribers to opt out of having their prescription information shared.

Rather than restricting the use of prescriber-identified information, states could increase the information available to physicians. For example, states have supported “academic detailing” or “counterdetailing” to inform physicians about generic and lower-cost alternatives to brand-name pharmaceuticals. The Supreme Court views more information in the marketplace as constitutionally preferable to restricting information.

Although “more” information may be constitutionally preferred, it is nearly impossible for public health agencies to match the marketing resources of private businesses. Companies spend countless billions of dollars to influence consumer purchasing decisions throughout the marketplace. Consequently, there remains an important role for public health regulation, such as restrictions on marketing potentially harmful products, disclosure of health and safety risks, and instructions for safe use.

Whether the product is intended to promote health (vaccines, drugs, or medical devices), poses hidden risks (food or alcohol), or is inherently dangerous (tobacco), government has a solemn responsibility to ensure fair and balanced health information rather than leaving consumer safety to an unregulated private market.

Conflict of Interest Disclosures: The author has completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

Additional Contributions: I thank Katie Stewart, JD, MPH, O’Neill Institute fellow, for her assistance with the manuscript. No compensation was received.

REFERENCES