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Prescription Data Mining and the Protection of Patients' Interests

David Orentlicher

Pharmaceutical companies have long relied on direct marketing of their drugs to physicians through one-on-one meetings with sales representatives. This practice of “detailing” is substantial in its costs and its number of participants. Every year, pharmaceutical companies spend billions of dollars on millions of visits to physicians by tens of thousands of sales representatives.¹

Critics have argued that drug detailing results in sub-optimal prescribing decisions by physicians, compromising patient health and driving up spending on medical care. In this view, physicians often are unduly influenced both by marketing presentations that do not accurately reflect evidence from the medical literature and by the gifts that sales representatives deliver in conjunction with their presentations.

Accordingly, public officials, professional societies and physicians have called for stricter regulation of the physician-sales representative relationship. Professional guidelines often include limits on gifts,² and medical schools may restrict contacts between sales representatives and physicians.³

This article considers the legislative efforts by states to address a long-standing, but increasingly refined practice that pharmaceutical companies use to enhance their drug-detailing efforts.⁴ Health care information organizations employ computer technology to collect and analyze data from prescriptions as they are filled at pharmacies. The organizations sell their analyses, which can include general prescribing trends as well as physician-specific data, to pharmaceutical companies so the companies' sales representatives can better target their marketing activities. This “data mining” has provoked concern because it can not only exacerbate the effects of drug detailing but also compromise other interests of patients.

In response, a few state legislatures have passed laws to prohibit or limit the use of data mining for marketing purposes.⁵ In turn, the laws have been challenged by the information organizations as violating their first amendment right to freedom of speech.

This article considers the policy arguments regarding legislative regulation of data mining. It also evaluates the constitutional implications of the regulations and concludes that the state provisions are desirable and should withstand constitutional challenge.

Data Mining

Given the high costs of their detailing efforts, drug companies are eager to employ the most efficient ways

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to identify physicians who might be persuaded to prescribe their drugs.

Consider the example of a pharmaceutical company launching a new calcium channel blocker to treat hypertension. Any internist could prescribe the drug to patients, but drug companies prefer knowing which internists prescribe anti-hypertensive drugs for a lot of patients, and which of those internists favor existing calcium channel blockers. Companies also like to know which physicians are quick to prescribe new drugs ("early adopters").⁶

For their existing drugs, companies like to know which physicians are already prescribing the drugs, so they can reinforce the physicians' preferences. In addition, companies like to know when a physician switches from the company's drug to a competing drug, so the company can encourage the physician to switch back.⁷

Given the high costs of their detailing efforts, drug companies are eager to employ the most efficient ways to identify physicians who might be persuaded to prescribe their drugs.

Drug companies can find all of this information by paying data miners who assemble information from individual prescriptions filled by pharmacies.⁸ When a prescription is filled, the data miners collect the name of the drug, the dose and quantity of the drug, the date of the prescription, and the physician's name.⁹ While the patient's name is not retrieved, the data miner does assign a unique number to the patient so that future prescriptions for the patient can be analyzed together.¹⁰ Thus, for example, the data miner can determine how long the patient remains on the drug, whether the physician substitutes a new drug or simply discontinues drug therapy, and which new drugs are prescribed for the patient. To ensure that they match each prescription to the correct physician and to increase their information about the prescribing physician, the data miners obtain data from other sources, particularly the American Medical Association (AMA)'s "Physician Masterfile," a database that includes all U.S. physicians, whether or not they belong to the AMA.¹¹

In addition to figuring out which doctors should be the focus of their detailing efforts, sales representatives can use data mining to tailor their presentations. If a physician already is using a competing drug, the

representative can highlight ways in which the representative's drug is superior to the competing drug.¹²

Opposition to Data Mining

Data mining is not condemned entirely. Researchers trying to understand the effects of marketing activities and other influences on physicians' prescribing decisions can learn a great deal from the data mining companies.¹³ Thus, even while New Hampshire prohibits data mining when used to promote prescription drug sales, it permits data mining when used to inform health care research.¹⁴

Data Mining Can Exacerbate the Problems with Drug Detailing

Critics have objected to data mining when used to enhance drug detailing because of the potential for harm to patients. When sales representatives meet with a physician, they tout the advantages of their drugs without trying to present a balanced assessment of the place for their products among a physician's options for treatment.¹⁵ As a result, physicians may develop an overly enthusiastic view of a drug's value and prescribe it when another drug or no drug would be more appropriate for the patient. If physicians prescribe the wrong drug, patient health may suffer.

This is problematic not only for the patient's well-being but also for society's health care spending — inadequate treatment may result in the need for costly, in-patient treatment at a hospital. Health care costs may be increased unnecessarily even if there is no detriment to patient health. A physician might be influenced to prescribe an expensive drug when an equally effective but lower cost alternative is available.

Because of these concerns, critics have argued, physicians should simply refuse to meet with sales representatives from pharmaceutical companies.¹⁶ Rather, when physicians need information about prescription drugs, they should be consulting objective and unbiased evaluations written by medical specialists.

But does drug detailing really influence prescribing decisions by physicians? Perhaps, as some argue, physicians base their decisions strictly on medical considerations and are not swayed by promotional pitches. In that regard, physicians tend to report a healthy dose of skepticism when surveyed about their attitudes toward drug company marketing. They are more likely to report negative rather than positive views about the accuracy and value of information from sales representatives.¹⁷ Still, some studies have found neutral attitudes by physicians toward sales representatives,

with the physicians reporting that the representatives provide useful information.¹⁸

While physicians may report a resistance to promotional efforts, evidence from physicians' actual practices indicates that drug detailing does influence prescribing decisions. Not only do visits from sales representatives increase drug sales, but they do so more than advertisements directed to physicians in professional journals or advertisements directed to consumers on television or in other media.¹⁹ Drug detailing also increases the likelihood that a physician will request the addition of a drug to a hospital's formulary.²⁰

More importantly, the influence on physician prescribing can compromise clinical decision-making. Researchers have found that the quality of prescribing decisions increases the more physicians rely on independent sources of information and decreases the more physicians rely on information from sales representatives.²¹ After interactions with sales representatives, for example, physicians are more likely to prescribe expensive, new drugs instead of cheaper generic drugs, even when there is no medical advantage to the newer drug.²² In one important study, researchers surveyed physicians' attitudes about two commonly prescribed drugs for which empirical studies found little benefit but promotional materials suggested substantially more benefit. While the physicians claimed to be influenced by the medical data, their attitudes in fact often were more consistent with the promotional claims.²³ Not only were the physicians making inappropriate prescribing decisions, they were unaware that they were doing so. This lack of awareness likely is being exploited by pharmaceutical companies for other drugs. Studies of promotional brochures and presentations by sales representative find selective or even inaccurate reporting of data that can mislead physicians into overestimating the efficacy and underestimating the side effects of the drugs being marketed.²⁴ The Food and Drug Administration (FDA) regularly cites pharmaceutical companies for promotional materials that exaggerate the benefits and/or minimize the risks of prescription drugs.²⁵

It may be that drug detailing alone does not influence physician prescribing decisions. Rather, sales representatives may exert their influence through a combination of promotional information and the giving of gifts. When physicians receive a gift, they may feel the normal and important social obligation to reciprocate, and they may do so by prescribing the promoted drugs.²⁶ Indeed, in a study that involved the audio-taping of detailing visits from sales representatives, researchers reported that acts of reciprocation were

the most commonly observed way in which physicians were influenced in their prescribing practices.²⁷

Data Mining Unfairly Exploits Patient-Physician and Patient-Pharmacist Relationships

If data mining is problematic because it intensifies the problems created by drug detailing, why not regulate drug detailing directly? There are two important reasons that can explain why the legislative efforts have focused on data mining.

First, pharmaceutical companies manufacture legal — indeed socially important — products, and they are entitled to cultivate potential customers of those products. The Supreme Court has recognized this interest through a first amendment right for businesses to advertise and solicit clients for their goods and services (the “commercial speech” doctrine). If marketing activities have harmful effects, first amendment principle instructs society to counter the harmful effects with counter-speech, not by prohibiting pharmaceutical companies from promoting their drugs.²⁸ Indeed, some medical schools and health care organizations have done exactly that. By using “academic detailing,” universities, professional societies and others can encourage physicians to base their prescribing on medical evidence rather than drug company promotions.²⁹

Legislative efforts have focused on data mining also because data mining directly invades the interests of patients in a way that drug detailing does not. In particular, it involves an expropriation of information created in the privacy of patient-physician and patient-pharmacist relationships.³⁰

Confidentiality Interests of Patients

Information about a patient's health is highly sensitive. It can cause embarrassment and result in stigmatization and discrimination. Consider in this regard the implications when family, friends, acquaintances, or employers find out that a person has a drug abuse problem, a sexually-transmitted disease, a mental illness, or a cancer. While a prescription may provide only indirect evidence of a patient's health, it can provide fairly clear evidence of illness. If a patient fills prescriptions for efavirenz (Sustiva) and tenofovir/emtricitabine (Truvada), people can readily conclude that the patient is being treated for an HIV infection.³¹ If a patient fills a prescription for olanzapine (Zyprexa), others can reasonably suspect that the patient is being treated for mental illness.³²

Physicians, pharmacists and other health care professionals therefore promise strict rules of confidentiality. Indeed, the duty to protect patient confidentiality has been a hallmark of medical codes of ethics throughout

While concerns about patient confidentiality have been voiced about data mining, data mining companies strip their records of information that can identify patients and indeed are required to do so by HIPAA.

history.³³ Moreover, the government reinforces ethical principles of confidentiality with legal safeguards, including the Health Information Portability and Accountability Act (HIPAA) and state law provisions.³⁴

While concerns about patient confidentiality have been voiced about data mining,³⁵ data mining companies strip their records of information that can identify patients and indeed are required to do so by HIPAA.³⁶

Advocates of data mining laws have invoked the privacy interests of physicians, but identifying the prescribing practices of physicians does not entail disclosure of the kind of sensitive information that privacy safeguards are designed to protect. Accordingly, even when a federal court of appeals upheld New Hampshire's data mining law, it did not invoke the privacy concerns of physicians in doing so.³⁷

Property Interests of Patients

As the entire data mining enterprise reflects, information can have substantial economic value. Data mining companies pay pharmacies for the right to extract information about prescriptions, and pharmaceutical companies pay the mining companies for information about individual physicians' prescribing practices.

This use of prescription information for economic purposes has troubling implications for patients. In effect, data mining companies exploit the relationships between patients and their physicians or pharmacists for the pecuniary benefit of pharmacies, pharmaceutical manufacturers, and the mining companies themselves. To be sure, the practice of medicine regularly entails the realization of profit by pharmacies and pharmaceutical manufacturers, as well as physicians and hospitals. But ethical principle justifies the ability of health care providers and companies to profit from patient care because economic incentives are necessary to ensure high quality care. Capable people will not pursue the practice of medicine or pharmacy if they are not compensated for doing so, and industry will not develop new therapies if they are not compensated for doing so.

It is difficult, however, to justify the mining of prescription data in terms of the interests of patients. As discussed above, drug detailing encourages physicians to prescribe a drug even when scientific evidence indicates that the prescription is not desirable. Patients may receive a drug when one is not needed, they may

receive a drug that is less effective or that has greater side effects than an alternative, or they may receive a drug that is more expensive than an equally effective alternative.

And while drug detailing poses risks to patient welfare, it does not offer offsetting benefits. Arguably, patients might benefit when a sales representative apprises a physician of a therapeutic alternative of which the physician was unaware.³⁸ Obtaining information can be costly in terms of time or financial expense, and sales representatives may overcome the cost barriers to physicians educating themselves about pharmaceutical options. However, it is very easy for physicians to obtain timely and accurate information about new (and existing) drugs without listening to sales representatives. For \$98 a year, for example, physicians can subscribe to *The Medical Letter on Drugs and Therapeutics*, a respected and independent, biweekly newsletter that provides evaluations of prescription (and over-the-counter) drugs.³⁹ And Internet searches or medical information programs for personal digital assistants (PDAs) make it much easier today for a physician to find useful and trustworthy information on drugs.

Professional Response to Data Mining

All of these considerations suggest that as an ethical matter, physicians should eliminate the incentive for data mining by refusing to meet with drug company sales representatives.⁴⁰ Medical schools do not permit sales representatives to participate in the instruction of students; physicians also should not turn to sales representatives for their post-graduate education.

Even if they continue to meet with sales representatives, physicians can prevent the representatives from using information about their prescribing practices from the data mining companies. The American Medical Association established the Physician Data Restriction Program in May 2006, and any physician can opt out of data mining by registering with the Program.⁴¹ For registered physicians, pharmaceutical companies still have access to prescriber data for marketing and research purposes and also for making compensation decisions for their employees. However, the companies agree to withhold individual prescriber information from their sales representatives.⁴²

Pharmacy companies also should take steps to prevent prescription information from being used

to enhance drug detailing. To comply with state and federal privacy laws, pharmacies require patient-identifiable information to be stripped from prescription records before the records are retrieved by health information organizations.⁴³ The pharmacies also should require physician-identifiable information to be stripped.

Legal Response to Data Mining

While professional self-regulation can increase adherence to ethical norms, legal mandates often are necessary to ensure that professionals meet their moral obligations.⁴⁴ Accordingly, it is important to consider the role of legislative action to regulate data mining.

The empirical evidence suggests that legislation may be needed to prevent the use of prescription information for drug detailing activities. Through April 2009, the AMA's Physician Data Restriction Program had enrolled 22,000 of roughly 650,000 actively prescrib-

ing behavior" of a physician.⁴⁹ However, there are two important exceptions to the restriction. If the information is "de-identified" with respect to the physician (and patient), it can be used when aggregated by zip code, geographic region, or medical specialty.⁵⁰ Thus, a data mining company can analyze the overall prescribing of a calcium channel blocker by internists in a particular zip code, but the company cannot analyze the prescribing of a calcium channel blocker by a particular internist.⁵¹ In addition, prescription information can be used for purposes more directly connected to the patient's care or to public welfare. For example, permissible uses include pharmacy reimbursement, care management, utilization review, or health care research.⁵²

Maine and Vermont also have adopted statutes limiting the efforts of data miners. In Vermont, the miners must obtain the consent of the prescribing physician before using "prescriber-identifiable" information

Even if the sale of information constitutes commercial speech, government may be able to regulate the sale if it can satisfy the Supreme Court's *Central Hudson* test. Under *Central Hudson*, a regulation of commercial speech is permissible if it (1) supports a substantial government interest, (2) directly advances that interest, and (3) is no more extensive than necessary to serve the interest.

ing physicians, or less than 4 percent of those who can enroll.⁴⁵ According to Dr. Robert Musacchio, who oversees the Program, the AMA has strongly promoted the opt-out option, but few physicians have demonstrated interest.⁴⁶ This supports the view of the courts that physician privacy is not a serious concern with data mining.⁴⁷ However, it also may reflect the fact that physicians tend not to appreciate the extent to which they are influenced by the promotional activities of sales representatives.⁴⁸ In any event, while it makes sense to rely on physicians to protect their own privacy interests, they should not have sole authority for protecting the privacy interests of patients.

Legislative Approaches

In response to the concerns with the mining of prescription records, three states have enacted statutes that prevent the mining. New Hampshire passed the first such law with its Prescription Confidentiality Act of 2006. According to the Act, prescription information cannot be used or sold for "advertising, marketing, promotion," or other activities that involve efforts by drug companies to "influence or evaluate the prescrib-

from prescription records for marketing or promoting a drug.⁵³ In Maine, physicians can register with the state to prevent companies from using prescriber-identifiable information for marketing or promoting a drug.⁵⁴ Thus, Vermont requires a physician to "opt in" to data mining activity, while Maine requires a physician to "opt out."

In listing the purposes of its statute, the Maine State Legislature expressed its concern about patient confidentiality and physician privacy. The legislators also stated their desire to promote the state's compelling interests in containing health care spending, by encouraging the substitution of generic and therapeutically equivalent alternatives for more expensive brand name drugs, and in improving the public's health.⁵⁵ The legislative history for the New Hampshire and Vermont statutes includes the same concerns.⁵⁶

Judicial Response

The leading data mining companies launched legal challenges in federal court to the legislation in Maine, New Hampshire, and Vermont, and were joined in their challenge to the Vermont law by the Pharmaceu-

tical Research and Manufacturers of America. While the companies scored initial successes in the Maine and New Hampshire district courts,⁵⁷ the U.S. Court of Appeals for the First Circuit rebuffed their claims in upholding the New Hampshire statute.⁵⁸ The district court in Vermont followed the lead of the First Circuit in backing Vermont's data mining provisions.⁵⁹

In their responses to data mining legislation, the federal courts waded into an important and unsettled area of law — how to resolve the conflict between the public's desire for informational privacy and the first amendment's freedom to speak. On one hand, people may be dismayed to discover that information about their prescriptions is being packaged and sold by data mining companies for commercial purposes. On the other hand, first amendment advocates worry when government tries to block the free flow of information.⁶⁰

In sorting out this issue, an important first step is to decide whether the sale of information from a database even constitutes "speech" for purposes of the first amendment. According to all three of the district courts, the states were restricting speech because they were interfering with the transfer of information from data mining companies to pharmaceutical companies — the data mining companies could not speak freely to the pharmaceutical companies.⁶¹ Moreover, by blocking the information transfer, the states were interfering with the ability of pharmaceutical sales representatives to speak with physicians.⁶² The district courts therefore analyzed the state statutes under the Supreme Court's commercial speech doctrine.⁶³ In the view of the court of appeals, on the other hand, the sale of prescription information is principally commercial conduct, just as is the sale of beef jerky, and the first amendment does not protect commercial conduct from regulation.⁶⁴ In this view, providing first amendment protection for commercial conduct merely because a business is selling words rather than other products would entail the resurrection of economic substantive due process.⁶⁵ The court of appeals recognized that there is an element of speech in the sale of information, but concluded that there is "scant societal value" to the use of prescriber-identifiable data in drug detailing.⁶⁶

Even if the sale of information constitutes commercial speech, government may regulate the sale if it can satisfy the Supreme Court's *Central Hudson* test. Under *Central Hudson*, a regulation of commercial speech is permissible if it (1) supports a substantial government interest, (2) directly advances that interest, and (3) is no more extensive than necessary to serve the interest.⁶⁷ The Maine and New Hampshire district courts concluded that the data mining legisla-

tion failed to satisfy the second and third requirements of the *Central Hudson* test.⁶⁸ While the appeals court did not need to reach the *Central Hudson* test since it held that data mining does not involve speech, it did supply an alternative basis for its holding by deciding that the legislation constituted a permissible regulation of commercial speech.⁶⁹ In particular, wrote the court of appeals, the New Hampshire law served the important state interest of cost containment: drug detailing armed with data mining encourages physicians to prescribe costly brand-name drugs instead of less expensive but equally effective generic drugs.⁷⁰ The Vermont district court agreed with the First Circuit in concluding that data mining legislation serves the state's interest in cost containment.⁷¹ The court also concluded that the regulation serves the state's interest in protecting the public's health by limiting the overuse of new drugs like Vioxx with their potentially serious side effects.⁷²

That the different courts came to different conclusions on the application of *Central Hudson* is not surprising. The Supreme Court has sometimes implemented the *Central Hudson* test rigorously and sometimes more flexibly.⁷³ Similarly, the Maine and New Hampshire district courts applied *Central Hudson* rigorously to strike down the New Hampshire and Maine laws, and the First Circuit and Vermont district court applied the *Central Hudson* test more flexibly to uphold the New Hampshire and Vermont laws. As mentioned, the second prong of *Central Hudson* requires a direct connection between the state's regulation and the substantial interest that the regulation is designed to serve. The New Hampshire and Maine district courts did not believe there was a strong enough empirical link between drug detailing and harm to patients,⁷⁴ while the First Circuit and the Vermont district court found the empirical evidence sufficient.⁷⁵ Under the third prong of *Central Hudson*, the state regulation must limit speech no more than necessary to serve the state's interests. The Maine and New Hampshire district courts felt that alternative approaches, like restrictions on gifts from drug companies to physicians, were available to serve the state's interests without restricting speech,⁷⁶ while the First Circuit considered alternative approaches either inadequate or infeasible.⁷⁷ The Vermont district court observed that the Vermont statute was a targeted response to the problem because it simply allowed physicians the opportunity to opt out of detailing based on data mining without interfering in any other way with the sales efforts of drug companies.⁷⁸

Does judicial precedent better support either the Maine and New Hampshire district courts or the First Circuit and Vermont district court? In all of the

Supreme Court's cases in which it has recognized first amendment protection for commercial speech, the regulations involved restrictions on advertising or other kinds of solicitation.⁷⁹ In other words, the Court has invoked the first amendment to protect the ability of businesses to speak to potential customers. In none of the cases did the Court interfere with government regulation of transactions between two businesses.⁸⁰

While helpful, Supreme Court doctrine does not settle the matter. If one agrees with the court of appeals and views the sale of information by one business to another business as a commercial transaction, then the data mining statutes should not raise first amendment concerns. On the other hand, if one agrees with the district courts and views the state statutes as interfering with the ability of a business to speak to potential customers, then the statutes constitute commercial speech and must satisfy the Court's *Central Hudson* test for permissible commercial speech.

Lower court decisions on related issues send a mixed message as well. On one hand, courts have recognized that the Food and Drug Administration should be able to regulate the promotion of "off-label" uses of approved drugs, even though independent physicians are free to encourage off-label use, and all physicians are free to prescribe approved drugs of off-label uses.⁸¹ Restrictions on the discussion of off-label uses involve a far greater intrusion on speech than restrictions on the transfer of prescription information. On the other hand, the Tenth Circuit struck down a federal restriction on the use of customer information by telecommunications companies.⁸² The D.C. Circuit also concluded that a telecommunication company's use of customer information constitutes commercial speech, even though that court upheld a regulation of customer information as a permissible regulation of commercial speech.⁸³

First Amendment Principle and Regulation of Data Mining

If the case law is indeterminate, we may be able to sort things out better by considering first amendment principles. From that perspective, data mining legislation should be upheld.

To be sure, the arguments for first amendment protection are significant. As the Maine and New Hampshire district courts observed, the data mining provisions interfere with speech between the data mining companies and potential customers. Just as newspapers sell information to readers, data miners sell prescriber information to pharmaceutical companies. Moreover, restrictions on data mining are essentially indirect efforts to regulate the speech of sales representatives engaged in drug detailing. States that regulate data

mining are driven by concerns that drug detailing can result in inappropriate prescribing, which in turn can cause harm to patient health and increases in health care costs. But if states cannot modify the message of sales representatives directly because doing so would infringe the first amendment rights of drug companies to speak to potential customers, why should they be able to regulate drug detailing indirectly?⁸⁴

But there are real problems with the analogy between a data mining company and a newspaper in terms of their role in informing the public and in terms of the kind of information they provide. When government regulates a newspaper, we rightly worry whether the government is trying to suppress a disfavored viewpoint. When government regulates a data mining company, on the other hand, we can be more confident that the government is trying to protect the public from misleading promotional messages or from paying too much for their medical treatment.⁸⁵

And even if limits on data mining indirectly affect the speech of sales representatives, the limits do not raise the kinds of concerns that drive much of first amendment law. The states do not restrict what the sales representatives can say, nor do they require the sales representatives to make any specific disclosures. Sales representatives in Maine, New Hampshire, and Vermont can make the same presentations to physicians that they make in any other state. Moreover, they can deliver their presentations to any physician who will meet with them, just as they can do so in the rest of the country.

In contrast, when the Supreme Court has struck down a regulation of pharmaceutical promotion, it has been concerned about a broad restriction of speech. Consider in this regard the Court's decision in *Thompson v. Western States Medical Center*.⁸⁶ In that case, the Court rejected a limitation on the advertising of drug compounding by pharmacies.⁸⁷ Pharmacies could advertise the fact that they provided compounding services, but they could not "advertise or promote the compounding of any particular drug, class of drug, or type of drug."⁸⁸ The provision entailed a broad ban on speech, in contrast to the data mining provisions' lack of interference with what sales representatives can say to physicians.

The data mining laws do make it more difficult for sales representatives to predict where their efforts will yield the most impact. Without the data mining, the representatives will not know which physicians write the most prescriptions for calcium channel blockers, anti-depressants or anti-histamine drugs.⁸⁹ As the First Circuit observed, however, what is at stake is not whether people can speak but on whether they can turn a profit.⁹⁰

The district court in New Hampshire cited another important strand of first amendment principle. If the government is troubled by the effects of speech, its remedy generally is to rely on counter-speech, not the suppression of speech.⁹¹ In this view, states concerned about the effects of speech by drug company sales representatives should counter the speech rather than try to block it. States can encourage physicians to register with the AMA's Physician Data Restriction Program, or they can fund physician-education programs that provide accurate information about prescription drugs. In fact, several states, including Maine and Vermont, do just that.⁹² However, as the First Circuit wrote, states do not have the funds to meaningfully counter the speech of pharmaceutical companies.⁹³ As mentioned, drug companies spend billions of dollars each year on their detailing efforts.⁹⁴

Moreover, when the government is speaking itself or funding the speech of private citizens, it enjoys greater freedom to regulate the content of speech. Thus, for example, the federal government can prevent physicians from discussing abortion at clinics that receive federal funding;⁹⁵ the government also can consider the extent to which art funded by federal grants reflects the "diverse beliefs and values of the American public."⁹⁶ While the analogy is not perfect since government does not directly fund pharmaceutical company marketing efforts, a key justification for regulating data mining lies in the impact of drug detailing on the public fisc. If inappropriate prescribing decisions drive up health care costs, state Medicaid programs will find it increasingly difficult to fund the needs of program beneficiaries. States may be limited in their ability to regulate drug detailing when only private dollars are at stake, but the analysis should change when the government is footing the bill.

Conclusion

When people develop relationships with their physicians and pharmacists, they are entitled to the assurance that information about their medical condition will be used for their benefit and not to place their health at risk or to increase their health care costs. In the case of drug detailing and data mining, legislative regulation is needed to provide that assurance.

While an extended and stringently applied commercial speech doctrine could block government regulation, such an approach would not be justified by first amendment principle and should not be employed to strike down statutes that prevent drug companies from using physician-identifiable prescription drug records to fashion their promotional activities.

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References

1. J. M. Donohue, M. Cevalco, and M. B. Rosenthal, "A Decade of Direct-to-Consumer Advertising of Prescription Drugs," *New England Journal of Medicine* 357, no. 7 (2007): 673-681, at 676 (reporting annual expenditures on detailing of about \$7 billion between 2002 and 2005); D. L. Coleman, A. E. Kazdin, L. A. Miller, J. S. Morrow, and R. Udelsman, "Guidelines for Interactions between Clinical Faculty and the Pharmaceutical Industry: One Medical School's Approach," *Academic Medicine* 81, no. 2 (2006): 154-160, 154 (reporting that pharmaceutical companies employ more than 80,000 sales representatives and that the average physician meets with a sales representative four times per month). Drug companies appear to be reducing their sales forces. J. Russell, "Lilly's Shrinking Sales Force," *Indianapolis Star*, January 17, 2010, at A18.
2. Council on Ethical and Judicial Affairs, "Guidelines on Gifts to Physicians from Industry: An Update," *Food & Drug Law Journal* 47, no. 4 (1992): 445-458 (establishing the American Medical Association's restrictions on gift-giving); S. L. Coyle, and the Ethics and Human Rights Committee, American College of Physicians-American Society of Internal Medicine, "Physician-Industry Relations, Part 1: Individual Physicians," *Annals of Internal Medicine* 136, no. 5 (2002): 403-406; Institute of Medicine, *Conflict of Interest in Medical Research, Education and Practice* (Washington, D.C.: National Academies Press, 2009). The American Medical Association's gifts guidelines evolved into the guidelines of the Pharmaceutical Research and Manufacturers of America. T. Randall, "AMA, Pharmaceutical Association Form 'Solid Front' on Gift-Giving Guidelines," *JAMA* 265, no. 18 (1991): 2304-2305. See also J. Zweifler, S. Hughes, S. Schafer, B. Garcia, A. Grasser, and L. Salazar, "Are Sample Medicines Hurting the Uninsured?" *Journal of the American Board of Family Practice* 15, no. 5 (2002): 361-366 (expressing concerns with free drug samples).
3. See Coleman, et al., *supra* note 1.
4. J. A. Greene, "Pharmaceutical Marketing Research and the Prescribing Physician," *Annals of Internal Medicine* 146, no. 10 (2007): 742-748 (describing the history of data mining from its origins in the mid-twentieth century).
5. 22 Me.Rev.Stat. § 1711-E(2)-(2.A); N.H. Rev. Stat. Ann. § 318:47-f; 18 Vt. Stat. Ann. § 4631(d). Legislators in a number of other states have introduced bills to regulate data mining. K.B. O'Reilly, "New Hampshire Ban on Sale of Prescribing Data Upheld," *American Medical News*, December 22/29, 2008.
6. *IMS Health, Inc. v. Ayotte*, 490 F. Supp. 2d 163, 170 (D.N.H. 2007).
7. J. L. Klocke, Comment, "Prescription Records for Sale: Privacy and Free Speech Issues Arising from the Sale of De-Identified Medical Data," *Idaho Law Review* 44, no. 2 (2008): 511-536, 515. The Prescription Project provides excellent materials on data mining, available at <www.prescriptionproject.org/newscenter/fact_sheets> (last visited December 10, 2009).
8. *IMS Health, Inc.*, 490 F. Supp. 2d at 166; *IMS Health Corp. v. Rowe*, 532 F. Supp. 2d 153, 158 (D.Me. 2007).
9. *IMS Health, Inc.*, 490 F. Supp. 2d at 165.
10. *IMS Health, Inc.*, 490 F. Supp. 2d at 166.
11. *IMS Health, Inc.*, 490 F. Supp. 2d at 166; Greene, *supra* note 4, at 744; R. Steinbrook, "For Sale: Physicians' Prescribing Data," *New England Journal of Medicine* 354, no. 26 (2006): 2745-2747, 2745. Data mining companies do not need to purchase access to the AMA's Physician Masterfile to obtain the information that they need about physicians. However, it would be more costly to use other sources since they would

- have to invest the time and expense to recreate the information in the Masterfile. Personal communication, Robert A. Musacchio, Ph.D, Senior Vice President, Publishing and Business Services, American Medical Association (May 5, 2009).
12. IMS Health, Inc., 490 F. Supp. 2d at 170.
 13. D. Grande and D. A. Asch, "Commercial versus Social Goals of Tracking What Doctors Do," *New England Journal of Medicine* 360, no. 8 (2009): 747-749, at 748.
 14. N.H. Rev. Stat. Ann. § 318:47-f. Other uses of the data are also permitted, including pharmacy reimbursement, care management and utilization review. *Id.*
 15. R. Cardarelli, J. C. Licciardone, and L. G. Taylor, "A Cross-sectional Evidence-Based Review of Pharmaceutical Promotional Marketing Brochures and Their Underlying Studies: Is What They Tell Us Important and True?" *BMC Family Practice* 7, no. 13 (2006): 1-6 (finding that promotional brochures discussed alternative treatments 40 percent of the time).
 16. H. Brody, "The Company We Keep: Why Physicians Should Refuse to See Pharmaceutical Representatives," *Annals of Family Medicine* 3, no. 1 (2005): 82-86.
 17. P. Manchanda and E. Honka, "The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review," *Yale Journal of Health Policy Law & Ethics* 5, no. 2 (2005): 785-822, 788-791.
 18. *Id.*, at 788-791, 793-795; T. S. Caudill, M. S. Johnson, E. C. Rich, and W. P. McKinney, "Physicians, Pharmaceutical Sales Representatives, and the Cost of Prescribing," *Archives of Family Medicine* 5, no. 2 (1996): 201-206, 205.
 19. See Manchanda and Honka, *supra* note 17, at 800-804.
 20. M. M. Chren and C. S. Landefeld, "Physicians' Behavior and Their Interactions with Drug Companies: A Controlled Study of Physicians Who Requested Additions to a Hospital Drug Formulary," *JAMA* 271, no. 9 (1994): 684-689, at 687; N. Lurie, E. C. Rich, D. E. Simpson, J. Meyer, D. L. Schiedermayer, J. L. Goodman, and W. P. McKinney, "Pharmaceutical Representatives in Academic Medical Centers: Interaction with Faculty and Housestaff," *Journal of General Internal Medicine* 5, no. 3 (1990): 240-243.
 21. A. Figueiras, F. Caamano, and J. J. Gestal-Otero, "Influence of Physician's Education, Drug Information and Medical-Care Settings on the Quality of Drugs Prescribed," *European Journal of Clinical Pharmacology* 56, nos. 9-10 (2000): 747-753, 750 (studying practices of primary care physicians and using three measure of quality - whether the physicians prescribed drugs that had been shown to be effective, that were suitable for use in primary care settings, or that were included in the formulary of the Spanish National Health Service).
 22. A. Wazana, "Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?" *JAMA* 283, no. 3 (2000): 373-380, at 378.
 23. J. Avorn, M. Chen, and R. Hartley, "Scientific versus Commercial Sources of Influence on the Prescribing Behavior of Physicians," *American Journal of Medicine* 73, no. 1 (1982): 4-8. To be sure, not all studies find that drug detailing distorts physician prescribing decisions. J. M. Donohue, E. R. Berndt, M. Rosenthal, A. M. Epstein, and R. G. Frank, "Effects of Pharmaceutical Promotion on Adherence to the Treatment Guidelines for Depression," *Medical Care* 42, no. 12 (2004): 1176-1185, 1182 (finding "no evidence . . . that detailing affected rates of adherence to guideline treatment of depression.")
 24. See Cardarelli et al., *supra* note 15, at 4; J. Lexchin, "What Information Do Physicians Receive from Pharmaceutical Representatives?" *Canadian Family Physician* 43, no. 5 (1997): 941-945; M. Sernyak and R. Rosenheck, "Experience of VA Psychiatrists With Pharmaceutical Detailing of Antipsychotic Medications," *Psychiatric Services* 58, no. 10 (2007): 1292-1296; M. G. Ziegler, P. Lew, and B. C. Singer, "The Accuracy of Drug Information from Pharmaceutical Sales Representatives," *JAMA* 273, no. 16 (1995): 1296-1298.
 25. The FDA posts its warning letters to pharmaceutical companies on its website, *available at* <www.fda.gov/cder/ddmac/lawsregs.htm> (last visited December 16, 2009).
 26. See Manchanda and Honka, *supra* note 17, at 799-800; Council on Ethical and Judicial Affairs, *supra* note 2, at 447-449; M. M. Chren, C. S. Landefeld, and T. H. Murray, "Doctors, Drug Companies, and Gifts," *JAMA* 262, no. 24 (1989): 3448-3451; J. Dana and G. Loewenstein, "A Social Science Perspective on Gifts to Physicians from Industry," *JAMA* 290, no. 2 (2003): 252-255.
 27. E. E. Roughead, K. J. Harvey, and A. L. Gilbert, "Commercial Detailing Techniques Used by Pharmaceutical Representatives to Influence Prescribing," *Australian & New Zealand Journal of Medicine* 28, no. 3 (1998): 306-310, 308.
 28. *New York Times v. Sullivan*, 376 U.S. 254, 270 (1964) (observing that "the fitting remedy for evil counsels is good ones").
 29. S. D. Graham, "Effect of an Academic Detailing Intervention on the Utilization Rate of Cyclooxygenase-2 Inhibitors in the Elderly," *Annals of Pharmacotherapy* 42, no. 6 (2008): 749-756; S. B. Soumerai and J. Avorn, "Principles of Educational Outreach (Academic Detailing) to Improve Clinical Decision Making," *JAMA* 263, no. 4 (1990): 549-556.
 30. Had the Supreme Court ruled in favor of federal preemption in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), that might have given state legislatures an additional reason to eschew direct regulation of drug detailing. In *Wyeth*, the Court rejected a claim that compliance with Food and Drug Administration (FDA) regulations should insulate pharmaceutical manufacturers from state tort law claims. *Id.*, at 1190. If the Court had sided with the drug companies, state legislatures might worry that the Court would view regulation of drug detailing as falling within the sole purview of the FDA.
 31. Panel on Antiretroviral Guidelines for Adults and Adolescents, *Guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents*, Washington D.C., Department of Health and Human Services, November 3, 2008, at 38, *available at* <<http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>> (last visited December 16, 2009).
 32. S. Dando and M. Tohen, "Olanzapine - Relapse Prevention Following Mania," *Journal of Psychopharmacology* 20, no. 2 Suppl. (2006): 31-38, at 31.
 33. D. Orentlicher, "Genetic Privacy in the Patient-Physician Relationship," in M. Rothstein, ed., *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (New Haven: Yale University Press, 1997): 77-91, at 77-78.
 34. M. A. Hall, M. A. Bobinski, and D. Orentlicher, *Health Care Law and Ethics*, 7th ed. (New York: Aspen Publishers, 2007): at 175-185.
 35. See Klocke, *supra* note 7, at 518-521; IMS Health, Inc., 490 F. Supp. 2d at 171.
 36. See Greene, *supra* note 4, at 747; Steinbrook, *supra* note 11, at 2746. To be sure, patient confidentiality can be compromised. It is often possible to deduce a patient's identity from de-identified prescription records, particularly in small towns. Klocke, *supra* note 7, at 520-521; D. E. Zoutman, B. D. Ford, and A. R. Bassili, "The Confidentiality of Patient and Physician Information in Pharmacy Prescription Records," *Canadian Medical Association Journal* 170, no. 5 (2004): 815-816. But the risk to patient privacy is created by the existence of the prescription records, whether or not they are mined for physician prescribing information.
 37. *IMS Health, Inc. v. Ayotte*, 550 F.3d 42, 55 (1st Cir. 2008). See also *IMS Health, Inc.*, 490 F. Supp. 2d at 178-180 (rejecting the argument based on prescriber privacy).
 38. *IMS Health Corp.*, 532 F. Supp. 2d at 163.
 39. The author relied on *The Medical Letter* during his years as a practicing physician. *The Medical Letter* describes itself as follows:
The Medical Letter on Drugs and Therapeutics is an independent, peer-reviewed, nonprofit publication that offers unbiased critical evaluations of drugs, with special emphasis on new drugs, to physicians and other members of the health professions. It evaluates virtually all new drugs and reviews older

- drugs when important new information becomes available on their usefulness or adverse effects. Published every other week in a four-page newsletter format, it carries no advertising and is supported entirely by subscription fees. A typical issue appraises two or three new drugs in terms of their effectiveness, toxicity, cost and possible alternatives. Occasionally, *The Medical Letter* publishes an article on a new non-drug treatment or a new diagnostic aid. Available at <www.medicalletter.org/html/who.htm#about_newsletters> (last visited December 16, 2009).
40. See Brody, *supra* note 16.
 41. See Greene, *supra* note 4, at 742.
 42. R. A. Musacchio and R. J. Hunkler, "More Than a Game of Keep Away," *Pharmaceutical Executive*, May 1, 2006, available at <http://pharmaexec.findpharma.com/pharmaexec/article/articledetail.jsp?id=323311> (last visited February 16, 2010); Steinbrook, *supra* note 11, at 2745-2746. (Initially, the program was called the Prescribing Data Restriction Program, but the name was changed to Physician Data Restriction Program since the AMA maintains physician data rather than prescribing data.)
 43. IMS Health, Inc., 490 F. Supp. 2d at 166.
 44. D. Orentlicher, "The Influence of a Professional Organization on Physician Behavior," *Albany Law Review* 57, no. 3 (1994): 583-605.
 45. Personal communication with Mark Frankel, American Medical Association (April 26, 2009) (reporting the 22,000 figure for enrollment); Greene, *supra* note 4, at 746 (estimating at 650,000 the number of physicians who actively prescribe drugs).
 46. Personal communication, *supra* note 11.
 47. See, *supra*, text accompanying note 37.
 48. See, *supra*, text accompanying notes 23-24.
 49. N.H. Rev. Stat. Ann. § 318:47-f.
 50. *Id.*
 51. See Klocke, *supra* note 7, at 524.
 52. N.H. Rev. Stat. Ann. § 318:47-f.
 53. 18 Vt. Stat. Ann. § 4631(d).
 54. 22 Me.Rev.Stat. § 1711-E(2)-(2.A).
 55. 22 Me.Rev.Stat. § 1711-E(1-B).
 56. IMS Health, Inc., 490 F. Supp. 2d at 171-173; 18 Vt. Stat. Ann. § 4631(a).
 57. IMS Health, Inc., 490 F. Supp. 2d at 183; IMS Health Corp., 532 F. Supp. 2d at 182-183.
 58. IMS Health, Inc., 550 F.3d at 64. The court of appeals reviewed only the New Hampshire district court decision, but because the First Circuit encompasses Maine as well as New Hampshire, its holding that data mining constitutes commercial conduct should clear the Maine data mining provision for implementation. As this article is being written, the First Circuit has been briefed on Maine's appeal of the district court, but oral arguments has not been scheduled. Personal communication with Nancy Macirowski, Assistant Attorney General, State of Maine, January 22, 2010. Although legitimate disagreement may exist regarding the constitutionality of the New Hampshire statute, it is difficult to make sense of the district court's decision in Maine. That statute does not prohibit drug companies from selling the information that they create from data mining. Rather it simply permits physicians to maintain the confidentiality of their own prescription practices, and the Supreme Court has permitted the public to opt out when it does not want to be involved in the speech of others. See, e.g., *Rowan v. Post Office Department*, 397 U.S. 728 (1970) (permitting individuals to direct the postal service not to deliver pornographic mail from a particular person or organization).
 59. *IMS Health v. Sorrell*, 631 F. Supp. 2d 434 (D. Vt. 2009).
 60. For useful treatment of this issue by legal scholars, see, N. M. Richards, "Reconciling Data Privacy and the First Amendment," *U.C.L.A. Law Review* 52, no. 4 (2005): 1149-1222; F. Schauer, "The Boundaries of the First Amendment: A Preliminary Exploration of Constitutional Science," *Harvard Law Review* 117, no. 6 (2004): 1765-1809; E. Volokh, "Freedom of Speech and Information Privacy: The Troubling Implications of a Right to Stop People from Speaking About You," *Stanford Law Review* 52, no. 5 (2000): 1049-1124.
 61. *IMS Health, Inc.*, 490 F. Supp. 2d at 175; *IMS Health Corp.*, 532 F. Supp. 2d at 167 (adopting the reasoning of the New Hampshire district court); *IMS Health, Inc.*, 631 F. Supp. 2d at 445-44.
 62. *IMS Health, Inc.*, 490 F. Supp. 2d at 175.
 63. *IMS Health, Inc.*, 490 F. Supp. 2d at 175-183. *IMS Health, Corp.*, 532 F. Supp. 2d at 169-183. There have been decisions by courts of appeal that characterize transmission of data as commercial speech. See, e.g., *U.S. West, Inc. v. FCC*, 182 F.3d 1224 (10th Cir. 1999); *Nat'l Cable & Telecomms. Ass'n v. FCC*, 555 F.3d 996 (D.C. Cir. 2009).
 64. *IMS Health, Inc. v. Ayotte*, 550 F.3d at 52-53.
 65. See T. H. Jackson and J. C. Jeffries, Jr. "Commercial Speech: Economic Due Process and the First Amendment," *Virginia Law Review* 65, no. 1 (1979): 1-41. Economic substantive due process has been rejected by the Supreme Court since 1937 as a basis for finding laws unconstitutional, although it has been used to limit the amount of punitive damage awards. E. Chemerinsky, *Constitutional Law: Principles and Policies*, 3rd ed. (New York: Aspen Publishers, 2006): at 625-629.
 66. *IMS Health, Inc.*, 550 F.3d at 52-53.
 67. *IMS Health, Inc.*, 490 F. Supp. 2d at 177. Under *Central Hudson*, speech does not qualify for first amendment protection under the commercial speech doctrine if it is false or misleading. *Central Hudson Gas v. Public Service Commission of New York*, 447 U.S. 557, 566 (1980).
 68. *IMS Health, Inc.*, 490 F. Supp. 2d at 180-183; *IMS Health, Corp.*, 532 F. Supp. 2d at 168-180.
 69. *IMS Health, Inc.*, 550 F.3d at 54-60.
 70. *IMS Health, Inc.*, 550 F.3d at 55-59.
 71. *IMS Health, Inc.*, 631 F. Supp.2d. at 451-453.
 72. *IMS Health, Inc.*, 631 F. Supp.2d. at 453-455.
 73. *Compare Florida Bar v. Went for It*, 515 U.S. 618, 628 (1995) (upholding a restriction on attorney solicitation of clients and observing that restrictions on commercial speech could be justified "by reference to studies and anecdotes pertaining to different locales altogether") with *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 563 (2001) (striking down restrictions on tobacco advertising in part because the effect of the regulations would "vary based on whether a locale is rural, suburban, or urban"). See also R. Post, "Prescribing Records and the First Amendment—New Hampshire's Data-Mining Statute," *New England Journal of Medicine* 360, no. 8 (2009): 745-747, 746.
 74. *IMS Health, Inc.*, 490 F. Supp. 2d at 180-181; *IMS Health Corp.*, 532 F. Supp. 2d at 172-176.
 75. *IMS Health, Inc.*, 550 F.3d at 55-59; *IMS Health, Inc.*, 631 F. Supp.2d. at 453-454.
 76. *IMS Health, Inc.*, 490 F. Supp. 2d at 181-183 (also suggesting that New Hampshire's Medicaid program could contain health care costs by requiring prior authorization before physicians could prescribe an expensive drug in lieu of a cost-effective alternative); *IMS Health Corp.*, 532 F. Supp. 2d at 176-178.
 77. *IMS Health, Inc.*, 550 F.3d at 59-60.
 78. *IMS Health, Inc.*, 631 F. Supp.2d. at 454-455.
 79. Chemerinsky, *supra* note 65, at 1091-1109 (discussing cases involving advertising or solicitation of clients by accountants and attorneys, advertising for gambling, alcohol or tobacco and solicitation of students for commercial transactions on a college campus).
 80. Government regulation of business activity does not enjoy constitutional protection. Under the Supreme Court's fourteenth amendment jurisprudence, economic substantive due process places little constraint on the state. See *supra* note 65.

81. Off-label uses refer to uses of the drug that have not been approved by the FDA even though they might be justified by clinical studies. After a drug has been approved for a particular use (or uses) by the FDA, new indications for the drug may be discovered, but the drug company may not seek approval for the new indications.
While this area of law is unsettled, the predominant judicial view appears to be that the FDA must have some authority to regulate the promotion of off-label uses of approved drugs, even if the first amendment sets limits on the FDA's authority to do so. *United States v. Caronia*, 576 F. Supp. 2d 385 (E.D. N.Y. 2008); *United States v. Caputo*, 517 F.3d 935, 939-940 (7th Cir. 2008). See also J. Rogers, Essay, "Freedom Of Speech & The FDA's Regulation Of Off-Label Drug Uses," *George Washington Law Review* 76, no. 5 (2008): 1429-1443; R. F. Hall and E. S. Sobotka, "Inconsistent Government Policies: Why FDA Off-Label Regulation Cannot Survive First Amendment Review Under Greater New Orleans," *Food & Drug Law Journal* 62, no. 1 (2007): 1-48.
82. *U.S. West, Inc. v. FCC*, 182 F.3d 1224 (10th Cir. 1999).
83. *Nat'l Cable & Telecomms. Ass'n v. FCC*, 555 F.3d 996 (D.C. Cir. 2009).
84. One of the First Circuit judges in fact dissented from the court's opinion because he viewed the regulation of data mining as effectively a regulation of drug detailing. Accordingly, he concluded that the provision involved the regulation of commercial speech. *IMS Health, Inc.*, 550 F.3d at 79-84 (Lipez, J., concurring in part and dissenting in part). Nevertheless, he concurred in the decision on the ground that the New Hampshire law also constituted permissible regulation of commercial speech. *Id.* at 84-100.
To be sure, the Supreme Court has permitted indirect regulation of speech even when direct regulation would not be permissible in other contexts. For example, while the press enjoys a strong first amendment right to publish news, the state has considerable leeway to erect barriers to the press' ability to gather news. G. R. Stone, L. M. Seidman, C. R. Sunstein, M. V. Tushnet, and P. S. Karlan, *The First Amendment* 3rd ed. (New York: Aspen Publishers, 2008), at 495-517. Similarly, the Court might conclude that the right to speak to potential customers does not include a right to gather information that will enhance the speech. But this is a doctrinal argument, not an argument from theory.
85. S. Shiffrin, "The First Amendment and Economic Regulation: Away from a General Theory of the First Amendment," *Northwestern University Law Review* 78, no. 5 (1983): 1212-1283, 1256-1265.
86. 535 U.S. 357 (2002).
87. As the Supreme Court wrote, "drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient. Compounding is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product. It is a traditional component of the practice of pharmacy." *Id.*, at 360.
In 1997, Congress exempted drug compounding from the Food and Drug Administration's drug approval process but only if several requirements were met, including the restriction on advertising.
88. *Id.*, at 365 (citing 21 U.S.C. § 353a(c)).
89. Of course, sales representatives can find out some of the information from other sources that they ordinarily obtain from data mining. If they want to know whether a physician prescribes a competing drug, they can ask the physician.
90. *IMS Health, Inc.*, 550 F.3d at 53.
91. *IMS Health, Inc.*, 490 F. Supp. 2d at 182.
92. See 22 Me. Rev. Stat. § 2685; 18 Vt. Stat. Ann. § 4622; W. Va. Code § 5-16C-9(a)(5); G. Lavine, "Pharmacists Provide Academic Detailing to South Carolina Health Care Providers," *American Journal of Health-System Pharmacy* 65, no. 24 (2008): 2312-2314; C. Guadagnino, "Pa. Launches Academic Drug Detailing," *Physician's News Digest*, December 2005, available at <www.physiciansnews.com/spotlight/1205.html> (last visited February 11, 2010).
93. *IMS Health, Inc.*, 550 F.3d at 60.
94. See Donohue et al., *supra*, note 1.
95. *Rust v. Sullivan*, 500 U.S. 173 (1991).
96. *National Endowment for the Arts v. Finley*, 524 U.S. 569 (1998).