The Emerging Legal Regime

Managing Physician-Company Conflict of Interest

By David L. Ferrera and Dawn M. Curry

The need to justify medical care as cost-effective raises concerns about how physician-company relationships may affect approvals of certain drugs and devices.

Pharmaceutical and medical device companies cannot exist without physicians to prescribe their products. But what happens when an intermediary becomes a collaborator? The law of conflict of interest as it affects drug and medical device companies and physicians spans multiple practice areas that clients and counsel alike should understand to ensure a uniform approach to business and litigation decisions.

Disclosure of the close connections between the pharmaceutical and medical device industries and physicians has spurred growing federal and state level backlashes against such relationships. Actions by Congress, the U.S. Department of Justice, several state legislatures and attorneys general, and civil courts have all contributed to a new legal framework governing financial relationships between physicians and drug and medical device companies.

This framework increasingly emphasizes complete disclosure of all ties between doctors and manufacturers of drugs and medical devices, aggressive government enforcement against improper relationships between physicians and these companies, and new claims in civil product liability litigation that call into question physicians' roles in clinical research, in dispensing medical advice, and in providing treatment to patients. As the legal framework unfolds, physicians and drug and medical device companies can expect to face heightened scrutiny and increased risks of civil and criminal legal actions.

Federal Government Enforcement

Federal prosecutors have become much more aggressive in employing a number of legal tools and in casting an ever wider net to punish and deter perceived corruption among physicians and pharmaceutical and medical device companies. This aggression comes amid escalating concerns over whether and how relationships between companies and physicians compromise a doctor's ability to render clinical care, conduct impartial research, and impart unbiased advice to peers.

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Within the last decade, prosecutors have actively pursued pharmaceutical and medical device companies for alleged kickback and off-label promotional activities. Not fully satisfied with the many millions of dollars paid by these companies to settle these actions, prosecutors have attempted to hold individuals accountable for such activities with expanding government resources.

Federal health and legal officials are increasingly interested in how financial relationships between drug makers and physicians may impact physician off-label prescribing practices.

The federal government has prosecuted individual physicians and, more often, pharmaceutical and device company employees, more recently based solely on an employee's status as a "responsible corporate officer" under the *Park* doctrine.

Actions Against Drug and Medical Device Companies

The antikickback statute, 42 U.S.C. §1320a-7b(b), makes it a criminal offense to offer, pay, solicit, or receive knowingly or willingly any remuneration to induce use of products or services reimbursed by any federal health care program. In its first few decades of operation, federal prosecutors confined application of the anti-kickback statute largely to situations involving explicit schemes to increase physician prescriptions of certain drugs or referrals. These prosecutions primarily targeted drug and medical device companies while—despite the statute's broad language—largely immunizing doctors.

Over the past decade, the federal government has targeted an array of practices employed by drug and medical device manufacturers, including lavishing physicians with expensive lunches, exotic trips, and lucrative consulting arrangements without requiring significant work product in return, and unrestricted educational grants. Many of these practices had become the industry standard by the late 1990s.

The government's efforts in the area of kickbacks have resulted in staggering fines and settlements borne by a number of companies, including TAP Pharmaceutical for $875 million, Serono for $705 million, AstraZeneca for $355 million, and Schering-Plough for $350 million.

The U.S. Department of Justice (DOJ) has also used means other than prosecutions to hold pharmaceutical and medical device companies responsible for their actions. In the wake of an investigation into the financial relationships of five orthopedic device manufacturers with orthopedic surgeons, the DOJ executed deferred prosecution agreements with four of the companies, and the DOJ executed a non-prosecution agreement with the fifth. The agreements resulted in financial settlements amounting to $310 million, federal oversight of the companies for an 18-month period, and full, public disclosure by the companies of the names and amounts that they paid to physicians.

Off-label marketing is another area of growing scrutiny. In 2009, federal prosecutors scored record fines in the area of off-label promotion, including $1.4 billion from Eli Lilly to settle federal criminal charges that it illegally marketed Zyprexa, and $2.3 billion from Pfizer to settle illegal marketing charges in connection with its pain reliever Bextra. The Pfizer settlement is the largest health care fraud settlement and the largest criminal fine of any kind. In 2010, this trend continued, as Allergan pled guilty to criminal and civil allegations of illegal, off-label promotion of Botox and paid $600 million in fines. In addition, Novartis agreed to pay $422 million to settle criminal and civil claims in connection with alleged off-label promotion of Trileptal and five other drugs. In what U.S. Attorney General Eric Holder called a "historic settlement," AstraZeneca agreed to pay $520 million to settle claims that the company illegally marketed Seroquel, a popular antipsychotic drug. This is the largest amount paid by a pharmaceutical company to settle civil-only charges involving off-label promotion.

It is estimated that that approximately 20 percent of all prescriptions that doctors write are for off-label use. As a result, federal health and legal officials are increasingly interested in how financial relationships between drug makers and physicians may impact physician off-label prescribing practices.

Actions Against Individual Doctors

More recently, the federal government has shown a greater willingness to target doctors in fraud cases. As Michael J. Sullivan, former United States Attorney for Massachusetts, observed, "The strategy of looking at the companies alone was not completely successful in terms of our objective to deter health care fraud." The steep $2.3 billion fine paid by Pfizer represents less than three weeks of that company's sales. As a result, federal prosecutors and health officials have started to focus on the "demand" side, stepping up investigations of doctors, especially surgeons.

For a doctor, the repercussions of a criminal conviction and a civil judgment could be severe, including prison time, hefty fines, a lost medical license, and exclusion from health care programs. As Lewis Morris, the chief counsel to the inspector general of the U.S. Department of Health and Human Services, recently stated, "What we need to do is make examples of a couple of doctors so that their colleagues see that this isn't worth it."

A total of five physicians received convictions and sentences in connection with the TAP Pharmaceutical investigation. The government charged four of the five doctors early in the investigation, and they pleaded guilty soon afterward. They were sentenced to probation in exchange for cooperating and assisting with the investigation. The fifth physician was indicted on the day that the company announced its settlement agreement with the government. He pleaded guilty three years later and was sentenced to two years probation, the first six months of which he would serve in home confinement with electronic monitoring. The doctor was also ordered to pay fines and restitution.

In 2010, Dr. Scott Reuben, a once well-respected anesthesiologist from Massachusetts, was sentenced to six months in jail followed by three years of supervised

release, along with fines and restitution, after pleading guilty to health care fraud. An investigation had revealed that more than 20 of Reuben's research studies had been falsified in favor of the use of drugs such as Pfizer's Celebrex and Merck's Vioxx in postoperative pain management. Reuben was a member of Pfizer's speaker's bureau and had received five research grants from the company. Pfizer adamantly denies any involvement in Reuben's falsified studies, and while nothing indicated that any patients whose doctors relied on Reuben's findings were significantly harmed by the use of the drugs, Reuben's proposed therapies may have prolonged their recovery periods.

Actions Against Drug and Medical Device Company Employees and Executives

Federal prosecutors have not enjoyed similar successes in their efforts to prosecute individual corporate employees. Despite the $875 million paid by TAP Pharmaceuticals in civil and criminal penalties, a jury acquitted eight allegedly culpable employees, while a federal judge directed "not guilty" verdicts for two others. Similarly, a federal jury acquitted four Serono executives of offering kickbacks to physicians to boost sales of an AIDS drug, despite the fact that Serono had previously agreed to pay $705 million in civil and criminal penalties.

Within the last year, the federal government has clearly stated that it intends to prosecute pharmaceutical and medical device corporate executives more frequently under the *Park* doctrine, also known as the "responsible corporate officer" (RCO) doctrine, which allows the federal government to criminally charge corporate officers with misdemeanors even if those officers lacked involvement in or knowledge of wrongdoing. *See United States v. Park*, 421 U.S. 658 (1975) (establishing the responsible corporate officer doctrine). Rather, the government need only prove that an executive was in a position to prevent wrongdoing and failed to do so. In January 2011, the U.S. Food and Drug Administration (FDA) issued nonbinding guidance regarding RCO doctrine prosecutions and stated that they "can have a strong deterrent effect on the defendants and other regulated entities." Individuals convicted can face jail time, fines, and potential exclusion from Medicare, Medicaid, and all other federal health programs.

The government has also clearly stated it intends increasingly to use its permissive exclusion authority to exclude owners, officers, and managers of sanctioned entities from participating in federal health programs. Exclusion is potentially the most devastating penalty of all. The exclusion statute, 42 U.S.C. §1320a-7, mandates exclusion from the Medicare, Medicaid and all other federal health programs, and access to the millions of Americans covered by these programs, for companies and individuals convicted of health care fraud felonies. It will likely end the career of any health care executive, as it bars him or her from working for any company, hospital, or nonprofit that receives Medicare or Medicaid reimbursement.

In October 2010, the U.S. Department of Health and Human Services Office of the Inspector General (OIG) issued a new guidance document, "Guidance for Implementing Permissive Exclusion Authority," which discusses nonbinding factors that the OIG will consider in assessing whether to impose permissive exclusion against an officer or managing employee of a sanctioned entity. The document is available at http://oig.hhs.gov/exclusions/files/permissive_excl_under_1128b15_10192010.pdf.

If the evidence supports a finding that an owner knew or should have known of conduct for which the government sanctioned the entity, the OIG will operate with a presumption in favor of exclusion, but an officer or managing employee can face exclusion "based solely on their position within the entity." *Id.* at 1. In any event, when the OIG finds that significant factors weigh against exclusion, it may overcome the presumption. Such factors include the circumstances of the misconduct and seriousness of the offense, the individual's role in the sanctioned entity, the individual's actions in response to the misconduct, and other information about the entity.

Given the OIG's broad discretion and recent FDA commentary, it is likely that the OIG will continue to impose lengthy exclusions on corporate executives.

In December 2010, a federal district court upheld a 12-year exclusion for the three senior executives of Purdue Frederick Co. after they pleaded guilty to RCO charges relating to allegations that Purdue employees illegally promoted OxyContin. In early 2011, Forest Labs CEO Howard Soloman received notice that the U.S. Department of Health and Human Services (HHS) intended to exclude him from involvement with all federal health programs. In September 2010, Forest Labs agreed to pay $313 million in civil and criminal penalties over illegal marketing and misbranding of the antidepressant drugs Celexa and Lexapro. The deal was finalized in March 2011, just weeks before Soloman received notice from the HHS. Soloman had never been accused of misconduct throughout the investigation. If the HHS moves forward with the exclusion, Soloman, who is 83 years old, will be forced to leave Forest Labs.

State Government Enforcement

In addition to federal action, a number of states have entered the fray. States traditionally have regulated issues of ethical integrity involving physicians through their boards of registration and their power to issue and suspend medical licenses. This authority has generally not been exercised in overseeing potential conflicts of interest stemming from physician relationships with the drug and medical device industries.

Acting from a sense of frustration with federal law and legal authorities, some states have employed their own legislative tools to address conflicts of interest between physicians and drug and medical device companies. Under the authority of the New Jersey Consumer Fraud Act, in 2008 former state Attorney General Anne Milgram launched an investigation into a medical device manufacturer, Synthes, Inc., over alleged conflicts of interests of physicians participating in clinical trials of the firm's artificial spinal discs.

Upon determining that a majority of surgeons participating in the clinical trials had "significant investments in the products—investments that would have been worthless had the product failed to obtain regulatory approval from the FDA," and that Synthes had not disclosed these conflicts in its applications for premarket approval, New Jersey reached a landmark settlement with Synthes under which the company agreed to

1. Monitor, collect and disclose any and all payments to clinical investigators;

2. Prohibit compensation of clinical investigators tied to the outcome of a clinical trial; and
3. Pay clinical investigators "fair market value compensation" for their clinical trial work, as well as any other consulting services.

Furthermore, Synthes became the first company to agree to ban compensating clinical researchers with company stock or stock options.

The federal government has clearly stated that it intends to prosecute pharmaceutical and medical device corporate executives more frequently.

In a letter dated May 5, 2009, to the acting commissioner of the FDA, Milgram pointed out that her investigation revealed that the company "failed to disclose these financial conflicts of interest to the FDA. Despite the fact that Synthes' failure to adequately disclose these interests should have been obvious from even a cursory review of its FDA submissions… the FDA approved Synthes' applications for premarket approval without any delay or further inquiry into this issue." She admonished the FDA for its lax oversight in the area of conflict of interest, suggesting that the agency adopt the provisions in the Synthes settlement as "best practices."

Regulation

Several regulatory fronts are converging, creating a perfect storm that almost certainly will entail far greater levels of disclosure by drug and medical device companies and physicians of their financial relationships. These fronts are emerging from various, albeit interrelated, sources: government, at both the federal and state levels; medical and health care policy institutions, associations, and journals; and the pharmaceutical and medical device industries themselves.

Federal Statutes

National health care reform is the most important driver of federal efforts to strengthen the regime for regulating financial relationships and potential conflicts of interest between physicians and pharmaceutical and medical device companies. On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act, which included "sunshine provisions" requiring pharmaceutical, medical device, and biotechnology companies to publicly disclose payments of $10 or more made to physicians and teaching hospitals. Payments requiring disclosure include compensation, food, entertainment, gifts, travel, consulting fees, honoraria, research funding and grants, education or conference funding, stocks or stock options, ownership or investment interests, royalties or licenses, and charitable contributions.

Reporting entities must begin recording all transfers of value as of January 1, 2012. They must submit their first reports to the HHS by March 31, 2013, and then annually. On September 30, 2013, the HHS will post the information in a publicly available and searchable online database. The HHS will then post the information annually on June 30 of each subsequent year.

State Statutes

The federal law does not contain a strong preemption provision sought by industry. In fact, it explicitly does not prevent states from adopting more stringent reporting requirements or other restrictions on physician-industry financial relationships than those imposed by federal law. In the past decade, six states, Massachusetts, Maine, Minnesota, Nevada, Vermont, and West Virginia, and the District of Columbia have adopted such laws.

The Massachusetts "Pharmaceutical and Medical Device Manufacturer Conduct" law, Mass. Gen. Laws ch. 111N, is currently the strictest in the nation. It requires companies to report any payments of at least $50 made to any physician, hospital, any other person authorized to prescribe, dispense, or purchase prescription drugs or medical devices. These payments are to be posted in an easily searchable manner on the Commonwealth's Department of Public Health website.

The Massachusetts law also prohibits companies from providing meals, entertainment, and recreational events, or from making any payments in cash, cash equivalents, equity, or tangible items—including things such as pens and mugs—to any health care providers except for "bona fide services." These services include consulting and participation in research and clinical trials, for which a company can pay "reasonable compensation."

As a national leader in health care policy, Massachusetts believes that its law may serve as a model for regulating physician-industry financial relationships for other states to emulate, much in the way that Congress had patterned its health reform bills on the 2006 Massachusetts health care reform law. With Congress opening the gates to stricter state regulation, we can anticipate continued ferment at the state level and the development of a myriad of standards and restrictions with which companies and physicians will need to comply.

Industry Codes of Conduct

Passage of the sunshine provisions in national health care reform legislation does not mark the end of Congress' efforts to force physicians and the drug and medical device industries to disclose conflicts of interest. Senators Charles Grassley (R-Iowa) and Herb Kohl (D-Wisconsin) show no signs of abating in their efforts to restrict what Senator Kohl has described as "frequently unethical payments" that have been "pervasive and industry-wide for far too long."

Senator Grassley has taken particular aim at the practice of industry ghostwriting of medical journal articles for physicians. Senator Grassley has stated that such articles, which are "widely read by practitioners and are relied upon as being objective and scientific in nature," may be "little more than subtle advertisements rather than independent research." Congress may target the National Institutes of Health to exert leverage with teaching hospitals and universities so that they adopt more stringent limitations on the practice.

The International Committee of Medical Journal Editors (ICMJE) has implemented a uniform disclosure form, which all authors must submit with all manuscripts, which requires disclosure of all financial and per-

sonal relationships that might bias their work. To prevent ambiguity, authors must state explicitly whether potential conflicts do or do not exist. The ICMJE policy states that authors should identify individuals who provide writing or other assistance and disclose the funding source for this assistance. In addition, investigators must disclose potential conflicts to study participants and should state in their manuscripts whether they have done so.

Drug and medical device companies have been scrambling to jump ahead of the regulatory curve to preempt potentially more onerous and disruptive government and professional regulation. The Pharmaceutical Research and Manufacturers of America (PhRMA) has adopted several voluntary codes of conduct. Among these is a Code on Interactions with Healthcare Professionals, which, among other provisions, calls on member companies to cease providing meals, entertainment, or recreational benefits to health care professionals.

The PhRMA and other industry efforts, however laudatory, seem unlikely to stem the tide of tougher federal and state government regulation, or to stem expanded efforts to enhance disclosure of and impose further restrictions on physician-industry relationships. These pressures will only likely build as the shift toward more evidence-based medicine intensifies as a result of concerns over the utilization, quality, and cost of medical care. Evidence-based medicine will demand greater confidence that research evaluating the effectiveness of certain procedures, diagnostics, drugs, and devices is free of industry bias.

Civil Litigation

Pressures for enhanced disclosure of and further restrictions on relationships between physicians and drug and medical device companies have also emanated indirectly from civil litigation. Unlike the government enforcement and regulatory realms, here rulings and themes presented in product liability lawsuits shape the legal landscape.

The relationship between civil litigation involving drugs and medical devices and conflict of interest law is unclear because the relationship between drug and medical device companies and patients typically is mediated by two other agents: the FDA, which approves the drugs and medical devices, and the doctors who prescribe them. The relationships between physicians and drug and medical device companies potentially impact the judgments rendered by the FDA in approving new drugs and devices, as well as those by doctors in treating patients. As a result, these relationships can compromise two doctrines often relied upon in product liability defense—preemption and the learned intermediary defense. If a physician has a significant financial interest in the success of a product, bias can taint the results of clinical studies presented to the FDA, possibly affecting preemption arguments, and the choices presented by doctors to patient plaintiffs, possibly affecting the learned intermediary defense.

Preemption

Initially some commentators thought that the Supreme Court's ruling in *Riegel v. Medtronic*, 552 U.S. 312 (2008), might signal a strong movement in the direction of "preempting" all state tort lawsuits against manufacturers. Rooted in the supremacy clause of the U.S. Constitution, preemption holds that when federal and state law or regulation are in conflict, federal law or regulation takes precedence. In an 8–1 decision, the Court blocked state courts from allowing plaintiffs to pursue lawsuits challenging a medical device's specific design and labeling that have received premarket approval by the FDA. In the aftermath of *Riegel*, judges in many state courts nationwide dismissed lawsuits against medical device manufacturers on the basis of preemption. *See*, *e.g.*, *Sanders v. Advanced Neuromodulation Sys., Inc.*, 44 So. 3d 960 (Miss. 2010); *Robinson v. Endovascular Tech., Inc.*, 190 Cal. App. 4th 1490, 119 Cal. Rptr. 3d 158 (Cal. Ct. App. 2010); *Raleigh v. Alcon Labs, Inc.*, 934 N.E.2d 530 (Ill. App. Ct. 2010); *Mullin v. Guidant Corp.*, 970 A.2d 733 (Conn. App. Ct. 2010); *McGookin v. Guidant Corp.*, 942 N.E.2d 831 (Ind. Ct. App. 2011).

Note that the Court's decision in *Riegel* applies only to a limited number of medical devices that have gone through the rigorous premarket approval (PMA) process, roughly one percent of all new medical devices entering the market. Moreover, *Riegel* is based on the doctrine of "express preemption" because it rests on an explicit preemption clause in the Medical Device Amendments to the Federal Food, Drug, and Cosmetics Act (FDCA) that is not contained in the section of the FDCA that regulates pharmaceuticals. *See also Bruesewitz v. Wyeth*, 131 S. Ct. 1068 (2011) (holding that the structure of the National Childhood Vaccine Injury Act of 1986 (Vaccine Act), 42 U.S.C. §§300aa-1 *et seq.*, and Congress's intent in creating it supported the Court's finding that all design defect claims were preempted).

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Manufacturers have enjoyed little success in employing an "implied preemption" defense. One year after *Riegel*, the Supreme Court examined the doctrine of implied preemption in *Wyeth v. Levine*, 555 U.S. 555 (2009), a tort lawsuit involving a drug. Wyeth contended that even absent an explicit preemption clause in the FDCA, permitting state tort lawsuits challenging the standards approved by the FDA for the design, manufacture, and labeling of drugs was tantamount to condoning an alternative and competing regulatory system. The Court rejected Wyeth's argument, holding that the doctrine of implied preemption does not automatically protect drug manufacturers from lawsuits challenging FDA-approved drug warnings and standards. Instead, a drug manufacturer faces the burden of demonstrating that the FDA had access to complete and credible data in approving a drug as safe and efficacious.

Because *Wyeth* requires marshalling of clinical evidence, it raises important

questions about the nature and extent of relationships between a pharmaceutical company and the outside physicians who participate in clinical trials. Questions about the validity of an FDA approval and clinical monitoring touch the heart of a preemption rationale. Was the information submitted to the FDA compromised in any way? For instance, did a physician have a financial stake in a positive clinical trial outcome? Did the physician, pharmaceutical company, or both fully disclose to the FDA the existence and extent of the relationship? Does the relationship between the physician and pharmaceutical company taint the FDA approval and support arguments against deferring to the FDA's judgment? How we and our opponents present these issues during trials around the country will undoubtedly shape the debate about the fundamental fairness of preemption, and perhaps drive legislation to curb its application.

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Learned Intermediary

If the reliability of the FDA's judgment is central to a preemption argument, the integrity of a doctor's opinion is at the heart of a learned intermediary defense. Pharmaceutical and medical device companies have long relied upon this doctrine, which holds that the duty to warn extends from the manufacturer only to the prescribing physician, who then has the duty to inform patients of the relative risks and benefits of a drug or medical device.

Plaintiffs have challenged the viability of the learned intermediary doctrine in several courts, albeit with little success. While courts have recognized a number of exceptions to the learned intermediary defense for vaccines, oral contraceptives, contraceptive devices, direct-to-consumer advertised drugs, and drugs withdrawn from the market, to date West Virginia is the only state that has rejected the doctrine outright. *See State ex. rel Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 913 (W. Va. 2007). Despite broad-sweeping attacks on the learned intermediary doctrine, courts probably will not abandon it in the near future as they continue to justify its rationale. *See*, *e.g.*, *Tortorelli v. Mercy Health Ctr.*, 242 F.3d 549, 560 (Okla. Ct. Civ. App. 2010) ("[a] major underlying assumption of the learned intermediary doctrine is that a product has properties rendering it dangerous so as to require a doctor's prescription or order for its use.").

In February 2011, however, a bill was introduced in the U.S. House of Representatives seeking to eliminate the learned intermediary defense to tort claims based on product liability. If passed, H.R. 546 would have a potentially devastating impact on pharmaceutical and medical device companies, as they would no longer be able to rely on the fact that they provided all the necessary information to physicians to fulfill their duties to warn. Instead, companies would need to take on the extraordinary financial burden of establishing open communication with patients taking their medications.

In part, the issue turns on how physician-industry relationships can impact a learned intermediary defense: first, by calling into question whether advice given by a prescribing doctor was compromised; and second, by calling into question whether the information on which a doctor relied was compromised. If a patient's physician has a financial interest in the product that he or she has prescribed and failed to disclose that interest to a patient, does that negate or dilute the warning that a physician delivered to the patient? Such potential conflicts raise troubling questions about whether a physician acted in the best interest of a patient, and thus whether the learned intermediary defense is justified. *See*, *e.g.*, *Proctor v. Davis*, 682 N.E.2d 1203 (Ill. App. Ct. 1997) (holding that a drug company was not absolved of a duty to warn when it promoted off-label use of a drug by providing financial and technical assistance to physicians, but did not ensure that they were properly informed of the risks of use); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973) (explaining that an adequate warning to physicians may be voided by particular actions that may persuade the prescribing doctors to disregard warnings).

Full and complete disclosure of physician relationships with drug and medical device companies certainly can lessen charges that manufacturers or physicians failed in their duties to warn. But it is unclear whether disclosure is sufficient to convince jurors that a physicians or a patient could adequately assess risks and make truly informed judgments about the relative risks and benefits of a drug or medical device. Confronted with information that his or her physician has served as a paid consultant to the pharmaceutical company that manufactures a prescribed drug, is a patient in a position to make a truly informed decision?

Conclusion

The enterprises of medical research and medical innovation depend entirely on close collaboration with practicing physicians. Today this collaboration is threatened by the perception that a web of conflicts of interest has become interwoven into the very fabric of these relationships. Disclosure of the close connections between physicians and the drug and medical device industries is generating strong pressure for a new legal regime for managing these relationships. That regime is emerging in piecemeal fashion from many different sources: Congress, the U.S. Department of Justice, federal agencies and advisory bodies, state legislatures, state attorneys general, mass tort litigation and other civil lawsuits, and a growing number of medical researchers, medical journal editors, and research institutes.

The pressures from these sources will only intensify due to growing concerns over the costs and quality of health care. The shift toward more evidence-based medicine will expand as a result of concerns over the utilization, quality, and cost of medical care. The need to justify medical care as cost effective raises strong concerns about how the relationships between physicians and the drug and medical device industries may have affected approvals of certain drugs and devices.

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The drug and medical device industries and the medical community will need to do more to jump ahead of these trends. Complete and accurate disclosure of these relationships is a necessary first step, but it no longer seems sufficient to placate rising concerns. Physicians and companies can anticipate a range of restrictions of the kind recommended by PhRMA, as well as calls to find alternative sources of funding for continuing medical education.

In the end, physicians, companies, and consumers will be best served by a uniform, national set of rules rather than a maelstrom of overlapping, conflicting, and confusing federal and state legislative, regulatory, and enforcement actions, jury decisions, and unilateral research university and medical journal guidelines and restrictions, which promise to be much more costly, much less effective and needlessly disruptive of the powerful and beneficial collaborations that fuel medical research and innovation than a national set of rules.