

## **The Pharma-Physician Relationship: Physicians Now the Target of Enforcement Initiatives**

**L**ARGE pharmaceutical companies are a favorite target for government enforcement actions, particularly in kickback cases involving alleged inducements to physicians to prescribe certain drugs. The government has made this practice an enforcement priority because it believes that the kickbacks are likely to impair a physician's patient-care decisions and result in artificial inflation of health-care costs. To date, investigations and prosecutions have focused predominantly on pharmaceutical companies; individual physicians have seldom been prosecuted for their part in kickback schemes. However, this appears to be changing.

In recent weeks, a flurry of news articles have focused on physician culpability in allegedly corrupt pharmaceutical relationships. A *New York Times* article, titled, "Crackdown on Doctors Who Take Kickbacks," announced that pursuing doctors who accept illegal kickbacks from pharmaceutical companies is a new enforcement initiative for prosecutors.<sup>1</sup> The article quotes United States Attorney for Massachusetts, Michael J. Sullivan, stating: "Prosecutors—after winning record fines from a record number of companies—realized that they needed to expand the scope of their targets." Lewis Morris, chief counsel to the OIG, explained the deterrence objective of the enforcement initiative as follows: "officials hoped to send a strong message to doctors," and, "[w]hat we need to do is make examples of a couple of doctors so that their colleagues see that this isn't worth it. ... We want to send a message to the physician community ... that you can't do this."

Connecticut's Attorney General, Richard Blumenthal, similarly has called for an outright ban against drug company gifts to physicians and declared that, "[p]ervasive drug company payments or gifts to doctors—whether by money, scholarships or luxury trips to conferences—cannot be justified by any educational or instructional purpose. They are unconscionable and should be made unlawful." The Attorney General has proposed legislation prohibiting many types of gifts and payments to health-care providers, including "any gifts for the personal use of the health care provider."

### **Prosecution Under The AntiKickback Statute**

The federal antikickback statute prohibits kickbacks from pharmaceutical companies to physicians. The statute specifically prohibits payments or offers of payment

(cash or in-kind) in exchange for referrals for items or services reimbursable under Medicare, Medicaid or other federal or state health-care programs. Prosecution under the antikickback statute can result in imprisonment for up to five years and fines of up to \$25,000. Violation of the statute can also result in the imposition of civil penalties, including \$50,000 per violation, exclusion from participation in federal and state health-care programs, and treble damages.<sup>2</sup> Prosecution under the antikickback statute is also often accompanied by an allegation of a false claims act violation, under the theory that claims that were submitted as a result of the illegal kickbacks are false claims.

The prosecution of TAP Pharmaceutical Products, Inc. in 2001 was a well-publicized example of a case brought under the antikickback statute. In that case, TAP was alleged to have violated the antikickback statute in pricing and marketing the drug Lupron. The prosecution was ultimately resolved with TAP agreeing to pay \$875 million to settle both criminal and civil liability. Notably, the TAP investigation and prosecution also resulted in eight individual physicians settling criminal and civil liability for sums up to \$95,000 for receiving kickbacks from the company in exchange for prescribing Lupron to patients and for falsely billing Medicare and other insurers for free samples of Lupron received from TAP.

In 1994, the OIG issued a special fraud alert detailing the dangers of illegal kickback arrangements between physicians and pharmaceutical companies. The alert provides:

In recent years, prescription drug companies in the United States have increased their marketing activities among providers, patients and suppliers such as pharmacies. Many prescription drug marketing activities go far beyond traditional advertising and educational contacts. Physicians, suppliers and, increasingly, patients are being offered valuable, nonmedical benefits in exchange for selecting specific prescription drug brands. Traditionally, physicians and pharmacists have been trusted to provide treatments and recommend products in the best interest of the patient. In an era of aggressive drug marketing, however, patients may now be using prescription drug items, unaware that their physician or pharmacist is being compensated for promoting the selection of a specific product. ...<sup>3</sup>

A marketing program that is illegal under the antikickback statute may pose a danger to patients because the offering or payment of remuneration may interfere with a physician's judgment in determining the most appropriate treatment for a patient. Further, where the patient is a Medicaid beneficiary, these drug marketing practices may increase the Federal government's costs of reimbursing suppliers for the products.

The OIG's 2003 Compliance Program Guidance for Pharmaceutical Manufacturers also warns against relationships that constitute illegal kickback arrangements.<sup>4</sup> Although this guidance is intended for pharmaceutical manufacturers, providers are well-advised to read it, understand the OIG's concerns, and avoid practices that the OIG describes as suspect.

### Compliance

Enforcement under the antikickback statute is not novel, but the announced prospective emphasis on physician-focused enforcement underscores the need for providers to be keenly aware of the complex web of antikickback rules and regulations. For example, regulations promulgated under the antikickback statute contain a number of "safe-harbors." Illustrative is the personal services and management contracts safe harbor, that may protect certain pharma-physician relationships where the physician is being paid by the pharmaceutical company to perform personal services, such as conducting clinical trials.<sup>5</sup>

While it is prudent to ensure that all arrangements fit within a safe harbor, failure to fit within a safe harbor does not render the transaction per se illegal; the intent

of the parties, based on the totality of the facts and circumstances, is considered in determining whether the antikickback statute has been violated.

In addition, compliance and conflict of interest policies and procedures should be reviewed to ensure that they address all conduct that could be considered illegal. Furthermore, providers should consider conforming their practices to ethical guidelines, such as the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals and the American Medical Association, Ethical Guidelines for Gifts to Physicians from Industry.

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### REFERENCES

1. Crackdown on Doctors Who Take Kickbacks, *New York Times*, March 3, 2009, available at <http://www.nytimes.com/2009/03/04/health/policy/04doctors.html?partner=rss>.
2. 42 USC § 1320a-7b(b); 1320a-7a(a).
3. 59 Fed. Reg. 65372 (Dec. 19, 1994), available at <http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>.
4. 68 Federal Register 23731 (2003), available at <http://www.oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf>.
5. 42 CFR §1001.952(d).