

OIG's Morris: An enforcer's perspective

By Lewis Morris, JD

Relationships between physicians and the healthcare industry, including pharmaceutical and device manufacturers and suppliers, are under intense scrutiny. The popular press and professional journals are raising questions about the ability of physicians to maintain their professional integrity in an environment where lucrative physician-industry deals flourish.

The Office of Inspector General (OIG) for the Department of Health and Human Services (HHS) and the Department of Justice are committing substantial resources to the investigation and prosecution of companies and individuals who engage in illegal schemes disguised as consulting arrangements. In September 2007, four major medical device manufacturers entered into civil settlement agreements with the government, collectively paying \$311 million in fines to resolve allegations that they provided illegal financial incentives to induce physicians to use a particular company's artificial hip and knee reconstruction and replacement products.

These relationships have also caught the attention of Congress. In February 2008, the U.S. Senate Special Committee on Aging held a hearing on the relationship between the medical device industry and physicians. Concerns about the impact of these arrangements on the physician-patient relationship also triggered proposed legislation that would require public disclosure of most industry-physician financial arrangements.

Concern and collaboration

Although there is concern about these financial relationships, the collaboration between industry and healthcare providers can advance medical science and benefit patients. In the development of new technologies and products, the interaction between device manufacturers and orthopaedic surgeons can be especially valuable. Physicians play an essential role in the development, testing, and extensive training involved in producing effective and safe medical devices.

In an environment where physicians routinely receive substantial compensation from medical device companies through stock options, royalty agreements, consulting agreements, and research grants, however, a significant risk that such payments will improperly influence medical decision-making exists.

To appreciate better the current enforcement environment and its implications for orthopaedic

surgeons, it is necessary first to understand the anti-fraud laws that govern Federal healthcare programs (See "Relevant anti-fraud statutes," below). Financial relationships between device manufacturers and physicians raise the types of risks that these statutes are designed to address. With an understanding of the anti-fraud laws, orthopaedic surgeons can devise a strategy for managing potential conflicts of interest and minimizing the risks presented by these arrangements.



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One of the objectives of these anti-fraud statutes is to protect patients and healthcare programs from the consequences of industry-induced bias. When a physician's self-interest compromises independent judgment, the patient faces the risk that the physician is making decisions that are not in the patient's best interest.

Excessive payments to physicians can also increase healthcare costs. When a device manufacturer pays a physician to influence the physician's use or recommendation of its products, rather than to advance a legitimate medical interest, the additional costs are passed on to the patients, Federal healthcare programs, and private insurers. Such payments can also distort the marketplace by providing an unfair competitive edge to the company making the payments, regardless of the relative therapeutic value of the company's products. Finally, corrupt payments can compromise medical research independence and the standards of scientific integrity.

Kickbacks and kindness

Sometimes industry payments to physicians are not related to the actual contributions of the physicians, but instead are kickbacks designed to influence the physicians' medical decision-making. Kickbacks offered to physicians by medical device manufacturers take a variety of forms, including the following:

- consulting and royalty agreements for which little or no work was performed
- trips for doctors, their spouses, and families
- consultant meetings held at lavish venues

We have also seen instances in which physicians have signaled to industry that their loyalty and business are for sale to the highest bidder.

Although most physicians believe that free lunches, subsidized trips, or gifts have no effect on their medical judgment, research has shown that these types of perquisites can affect, often unconsciously, how humans act. Researchers reporting in medical journals, such as the *Journal of the American Medical Association* and the *New England Journal of Medicine*, have found that such financial industry-physician relationships are pervasive and that the impulse to reciprocate for even small gifts has a powerful influence on behavior.

Physicians who request additions to hospital drug formularies, for example, are far more likely to have accepted free meals or travel funds from drug manufacturers. Similarly, a device company's largess may influence a physician to favor the company's products. Because an orthopaedic surgeon may decide or influence decisions regarding the selection of medical devices, a device manufacturer has a strong financial incentive to use consulting contracts and gifts to persuade the surgeon to use or recommend the manufacturer's devices.

How much money device manufacturers pay to physicians to influence the selection of a medical device is not known. However, the government's recent investigations of manufacturers of hip and knee surgical implants offer some insight. During the years 2002 through 2006, the four manufacturers that controlled almost 75 percent of the hip and knee replacement market paid physician consultants more than \$800 million under the terms of roughly 6,500 consulting agreements. Although many of these payments were for legitimate services, others were not.

Mitigating the risks

Physician-industry interactions can provide tangible benefits to patients and advance medical science. These relationships also create conflicts of interest that, if not managed effectively, can pose significant challenges to medical professionalism and undermine the integrity of the U.S. healthcare system.

Enforcement of the anti-fraud laws is an important part of an overall strategy to discourage financial arrangements that distort physicians' professional judgment. However, it would be both inappropriate and impractical to rely solely on government enforcement to address an issue of this complexity. The healthcare industry and the medical community also must take steps to reduce the risks raised by these arrangements.

OIG commits substantial resources to encourage the healthcare industry to adopt voluntary anti-fraud and compliance measures. It promotes these efforts by providing a range of comprehensive guidance, including advisory opinions, compliance program guidance, and special fraud alerts and bulletins. All of these resources are available on the OIG Web site (www.oig.hhs.gov). In addition to taking advantage of this wealth of information, you may want to undertake the following steps to minimize your legal risk:

- Adhere to professional guidelines, such as the AAOS Standards of Professionalism on Orthopaedist-Industry Conflicts of Interest.
- Establish a compliance program for your practice.
- Demand that the companies with which you have financial arrangements have robust compliance programs and engage in ethical practices.
- Use the "Fair Market Value" test to judge whether payments you receive from a device manufacturer are excessive.
- Rely on the "local newspaper" test—if you would not want a story about your arrangement with a device company to appear on the front page of your local paper, don't get into the deal.

Remember, companies are in business to sell their products and make a profit. If a device manufacturer offers you a lucrative deal that is too good to be true, ask yourself what the

company expects in return for its “generosity.”

In conclusion

Financial relationships between the medical device industry and physicians are pervasive and can create both benefits and risks to patients and healthcare programs.

Effectively managing the risks associated with these financial relationships is a challenge that warrants a comprehensive strategy by government, the healthcare industry, and physicians. Efforts by industry and physicians to promote awareness of the anti-fraud laws and implement appropriate policies to manage these risks will help to safeguard the welfare of patients, healthcare programs, and the integrity of the medical profession.

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Relevant Federal anti-fraud statutes

The following Federal statutes are among those relevant to manufacturer-physician payment relationships.

False Claims Act

The False Claims Act is the federal government’s primary civil enforcement tool for addressing healthcare fraud. Under the False Claims Act, the government may obtain substantial penalties against any person who knowingly submits, or causes the submission of, false or fraudulent claims to the federal government.

For example, a claim submitted to the federal healthcare programs may be fraudulent if the physician’s decision to order the claimed item or service is corrupted by receipt of a kickback. The recent False Claims Act settlements with Zimmer, Inc.; DePuy Orthopaedics, Inc.; Biomet, Inc.; and Smith & Nephew, Inc., were based on allegations that the four companies had violated the False Claims Act by offering the surgeons illegal inducements, in the form of bogus consulting contracts and other arrangements, to order devices that were billed to Medicare.

Anti-kickback statutes

The federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer or pay remuneration to induce the referral of federal healthcare program business. The statute also criminalizes the knowing and willful solicitation or receipt of remuneration in exchange for such referrals. Thus, the prohibition applies to both a device manufacturer and the physician, and the statute is violated if one purpose of the arrangement is to induce referrals of Medicare or Medicaid program business. Whether a particular arrangement runs afoul of the statute depends on the facts and circumstances, including the intent of the parties.

Civil Monetary Penalties Law

OIG may also pursue violations of the anti-kickback statute under a provision of the Civil Monetary Penalties Law. Civil Monetary Penalty (CMP) cases can be attractive alternatives to criminal and civil enforcement for several reasons. Cases are tried before an HHS administrative law judge and the rules of evidence are relaxed to permit the admission of hearsay.

CMP remedies in kickback cases include monetary penalties of up to \$50,000 for each illegal act, assessments of up to three times the amount of the kickback, and exclusion from participation in federal healthcare programs. OIG is using the CMP authority to bring cases

against physicians who accepted kickbacks, including sham consulting agreements.

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