

A Review of the Federal Guidelines That Inform and Influence Relationships Between Physicians and Industry

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Abstract

The effective delivery and continued advancement of health care is critically dependent on the relationship between physicians and industry. The private sector accounts for 60% of the funding for clinical research and more than 50% of the funding sources for physician education. The nature of the physician–industry relationship and the role of the physician as a gatekeeper for health care make this association vulnerable to abuse if certain safeguards are not observed. This article will review the current federal guidelines that affect the physician–industry relationship and highlight several illustrative cases to show how the potential for abuse can subvert this relationship. The recommendations and “safe harbors” that have been designed to guide business relationships in health care are discussed.

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The nature of physician–industry interactions has come under increasing scrutiny in recent years. There is no doubt that the partnership between physicians and industry has been mutually synergistic, fostering scientific breakthroughs and enhancing the educational experience of all physicians. However, this partnership developed during a period in which the biotechnology and pharmaceutical sectors reported record profits. The increasing reliance of an aging population on the federal government for health care, coupled with a new prescription benefit program, has brought the judicial arm of government regulation to the forefront of the health care arena. In addition, some well-publicized and dubious arrangements between physicians and

industry have called into question long-standing practices in the business of medicine.

The very existence of a financial relationship between physicians and industry frames a duality that is not unfamiliar in the field of medicine, but could easily be viewed as harmful by an outside observer. Physicians have a fiduciary responsibility to patients, yet medicine itself is a business. Often a physician’s income is tied to the level and amount of service provided. More importantly, while physicians have a responsibility to an individual patient, they also practice within a larger health care system that has increasing levels of complexity and arguably just as many needs as an individual patient. In ethics this could be termed a dual moral agency, because the needs of the system and the needs of the patient (as well as the needs of the physician) can at times come into direct conflict. While it can be uncomfortable to mention the possibility that health care provision is guided by anything other than the patients’ best interests, the reality is that decisions in medicine are guided by a complex array of variables—of which patient interest and autonomy may be the most important, but not the only, consideration. While physicians often consciously minimize this duality, it is important to recognize that perception is often more important than reality. The mere appearance of impropriety can be sufficient to undermine public trust even in the absence of misconduct, making professionalism just as important as legal regulation.

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This review will discuss the federal regulations that govern the relationship of the physician with the private sector and highlight certain high-risk relationships that have been targeted for review by the Office of the Inspector General (OIG). The resources available to and recommendations provided by this investigative branch of government will be reviewed for several common business arrangements that physicians may enter into with industry.

FEDERAL GUIDELINES

The review and enforcement of statutes that regulate physician–industry interactions falls primarily to the Department of Health and Human Services (HHS). Within HHS, the OIG is mandated to protect both the integrity of HHS programs and the health and welfare of the beneficiaries of those programs. This broad mandate is carried out through a nationwide network of audits, investigations, inspections, and other mission-related functions performed by OIG components.

The OIG has taken a specific interest in the interactions between physicians and industry since at least 1990, when the American Medical Association (AMA) filed its report before the House of Delegates regarding its opinion on gifts to physicians from industry.¹ Since then the OIG has shown increased interest in physician–industry interactions, as evidenced by its communications, published opinions, congressional testimony, and the federal Compliance Program Guidelines for Pharmaceutical Manufacturers published in 2003.^{2–9} These communications demonstrate an evolving interpretation of, rather than a change in, existing statutes.

The OIG has at its disposal three primary means of influencing the physician–industry relationship: the False Claims Act (FCA), the Federal Anti-Kickback Statute, and the Civil Monetary Penalties Law. The FCA is the primary tool used by the OIG in enforcement and, when linked with the Anti-Kickback Statute, has broad implications for the health care industry. Certain customs and practices commonplace in other industries can be highly suspect in the eyes of the federal government when used in the health care sector.

The FCA originated in 1863 when President Lincoln enacted legislation to pursue unscrupulous defense contractors during the Civil War. The FCA provides for substantial monetary penalties for anyone who submits false or fraudulent claims to the government. This is the primary tool the OIG uses to investigate and prosecute health care fraud, with penalties of \$5,000 to \$11,000 per claim plus three times the damages incurred by the government, as well as exclusion from federal health care programs. Since its amendment in 1986, the government has used the FCA to recover in excess of \$21 billion for the Treasury Department.¹⁰ Of specific note is that the FCA has within it a whistleblower (or *qui tam*) provision that empowers lay people to pursue litigation under the statute with a reward of 15% to 30% of the amount recovered in the action. Since 2000, 78% of all fraud settlements or judgments have been initiated by *qui tam* actions, and 80% of those *qui tam* actions have involved health care fraud, often initiated

by former employees or customers of the company in question.¹⁰

The Anti-Kickback Statute was introduced in 1972 to protect Medicare and Medicaid programs from inappropriate utilization and expense, although it was not successfully linked to the FCA until the 1990s. The federal Anti-Kickback Statute makes it illegal to knowingly and willfully offer, solicit, or receive remuneration to induce the referral of federal health care program business. Remuneration has been taken by the courts to mean anything of value, whether or not the item is used for patient care or personal gain. It is also important to note that an arrangement undertaken for lawful and legitimate purposes is still implicated under the Anti-Kickback Statute if at least one of its goals is to increase or induce federal health care program utilization.² This statement is far-reaching because common practices, such as sales incentives, volume pricing and discounts, physician ownership of companies or patents, and even medical specialty referrals may be implicated under the Anti-Kickback Statute.

Although fraud is not normally a concept tied to the interactions between physicians and industry, the linkage of the Anti-Kickback Statute to the FCA made these two statutes the most important to consider when analyzing any financial or business relationship in health care. The legal argument that has been upheld in certain cases is that a request for reimbursement from Medicare or Medicaid for a service or product obtained through a kickback scheme constitutes a false claim and exposes both the giver and the recipient to liability under the FCA.

To address the concerns that many in the health care industry have regarding the application of this statute, the government established, and continues to adapt, a list of “safe harbors” in common business arrangements which, when followed, limit the risk of prosecution under the antifraud statutes.¹¹ Among the topics most relevant to the physician–industry relationship, these safe harbors cover personal service and management contracts, investment or ownership in industry, employee relationships, and physician referrals. The OIG strongly recommends that whenever possible, business arrangements should be constructed to fit within one of these safe harbors. Failure to do so does not mean that an arrangement or practice is prohibited, but the OIG recommends that the following four questions be asked when considering the potential for prosecution.² First, does the arrangement or practice have a potential to interfere with or skew clinical decision-making? Second, does the arrangement or practice have a potential to increase the costs to federal health care programs, beneficiaries, or enrollees? Third, does the arrangement or practice have a potential to increase the risk of overutilization or inappropriate utilization? Finally, does the arrangement or practice raise safety or quality of care concerns?

The combination of the Anti-Kickback Statute and the FCA has resulted in a number of recent enforcements that have exposed the darker side of the physician–industry relationship. The most illustrative is the 1997 investigation of TAP pharmaceuticals, the maker of Lupron (leuprolide) and a joint venture between Takeda

Chemical Industries and Abbott Laboratories.¹² In a *qui tam* action brought by a former TAP employee and health plan administrator, the OIG discovered that TAP encouraged urologists to bill Medicare the average wholesale price of Lupron for samples that were provided free or at a steeply discounted price by the company. The company also engaged the urologists as consultants without specific deliverables, provided all-expense paid trips, and awarded unrestricted educational grants. These items were found by the court to be tantamount to gifts provided by TAP to urologists in exchange for Lupron prescriptions, which were then billed to Medicare. In the resultant settlement TAP agreed to pay the government \$875 million in criminal and civil liabilities, of which the whistleblowers were awarded almost \$100 million.

In 2003, a nearly identical investigation to the Lupron case charged AstraZeneca with fraud in the marketing of its cancer drug Zoladex (goserelin). The drug company provided free or discounted drug to physicians between 1993 and 1996, which was then billed back to Medicare at a substantially inflated rate. The government also charged that AstraZeneca provided illegal remuneration to doctors who agreed to purchase Zolodex, offering enticements in the form of educational grants, business assistance grants and services, travel, entertainment, and consulting services. In the resulting settlement, AstraZeneca agreed to pay \$355 million in civil and criminal liability for providing illegal kickbacks to physicians.

The arrangements in the Zoladex and Lupron cases occurred prior to the self-regulation promoted by both industry and physician groups. The Lupron case provided the impetus for The Pharmaceutical Research Manufacturers of America (PhRMA) Code of Conduct in 2002, and in 2002/2003 the reformulation of standards put forth by the AMA and the Accreditation Council for Continuing Medical Education (ACCME) changed the way medical societies viewed the physician-industry interaction.¹³⁻¹⁵ While these standards and their presentation before Congress forestalled further legislation, they were only able to curtail the most abusive practices. Recent moves by some state legislatures to make payments to physicians by industry more transparent by creating a public register have thus far yielded limited results.¹⁶⁻¹⁸

A more recent 2007 settlement totaling \$311 million against four medical device companies that offered illegal kickbacks to physicians to promote the use of orthopedic devices did little to reassure the public that physicians and industry are capable of self-regulation.⁹ In this investigation, it came to light that the four device manufacturers (who controlled 75% of the hip and knee replacement market) had offered lucrative consulting arrangements, lavish trips, and other perks to induce the surgeons to use their prosthetic devices between 2002 and 2006. The consulting agreements were suspect because they were often drafted by sales representatives and failed to require specific deliverables. In some arrangements, physicians would receive \$5,000 payments to provide quarterly market reports, operating room activity reports, and reports on product issues, many of which were of little or no value to the company. The companies arranged panel meetings at resort

locations and reimbursed physicians for travel expenses and compensated them with an additional \$5,000 in consultant fees for their attendance at the conference. The OIG reported that over the 4-year period, the four device companies paid \$800 million to orthopedic surgeons in royalties and fees. The OIG has an ongoing investigation into the details behind these payments using information provided by the companies as part of the settlement agreement.¹⁹

The final tool at the disposal of the OIG is the Civil Monetary Penalties Law (CMP). This law can be used to enforce the Anti-Kickback Statute and provides for 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 health care programs. The CMP can be an attractive alternative to the FCA since it is tried before an HHS administrative law judge and the rules of evidence are more relaxed. As an example of the law's use, in July 2007 the OIG entered into a \$2.95 million CMP settlement with Advanced Neuromodulation Systems, Inc. (ANS), over their payment of \$5,000 to neurosurgeons as a "data collection fee" for every five new patients tested with the device.⁹ The OIG alleged that the program provided no significant clinical value but was merely a marketing tool to increase sales, that the program was developed by ANS's Vice President of Sales and Marketing, that the fee was not set through fair market value, and that the clinical research department of ANS did not use the data.

The limited resources of the OIG are typically targeted against major device and pharmaceutical companies rather than individual physicians, although the statutes specifically provide for criminal and civil penalties against persons who accept kickbacks from industry. The OIG has specifically stated that enforcement targeting manufacturers has not been sufficient in limiting fraud and that medical professionals (surgeons in particular) need to be directly targeted to enhance enforcement of the existing statutes. As part of this strategy, in 2008 the OIG entered into a \$1.5 million settlement with an Arkansas neurosurgeon who had agreed to split the commissions with sales representatives for products used both during and after surgery on his patients.⁹ Using information obtained from the settlement with the four orthopedic device companies in 2007, the OIG has issued subpoenas to unnamed surgeons to further their fraud investigations.¹⁹

One other activity that physicians commonly participate in at the request of industry is product endorsement. Product endorsement may come in the form of direct advertising or more often in the form of continuing education sponsored by a device or drug company. In either event, such physician presentations are viewed as marketing activities and as such fall under regulation by the Food, Drug, and Cosmetics Act that prohibits unapproved (or off-label) marketing. Although a physician may prescribe a drug or device for any indication he or she sees fit, to promote a drug or device without the blessing of the Food and Drug Administration (FDA) exposes the sponsoring company to liability under the FCA. It is important to recognize that physicians paid by industry in this capacity are employees of

the company (whether contractual or statutory) and are therefore restricted as agents of the company when discussing off-label uses and are bound to adhere to company policy when it comes to the topic of off-label marketing.

The topic of off-label marketing remains at issue between the government and industry, with the guaranteed right of free speech on one side and the ability of the FDA to effectively regulate device and drug manufacturers on the other. Every case reviewed that involved an issue of off-label marketing and has been prosecuted under the FCA and has been decided on the basis of whether the information provided in the marketing campaign was itself fraudulent (and not simply because it was not approved by the FDA). Pfizer Inc. agreed in 2004 to a settlement because of "aggressive marketing" of off-label uses for Neurontin (gabapentin), including chronic pain, migraine headache, bipolar disorder, and attention deficit disorder.²⁰ Pfizer was charged by the government with manipulating the flow of scientific information, by delaying or suppressing studies that failed to demonstrate efficacy, generating ghost-written studies in support of off-label indications, and using sloppy science to gain marketing position. The settlement of \$430 million amounts to a fraction of the sales of Neurontin, which had risen to \$2.7 billion (94% for off-label uses) annually by 2003. Physicians were involved in all aspects of this marketing campaign whether or not they knew it was fraudulent.

Another notable case of fraud created by off-label marketing practices was brought against AbTox (decided in 2008) and had both the CEO and the compliance officer facing individual criminal prosecution. In this case the jury was specifically instructed by the court not to provide a guilty verdict on the basis of off-label product promotion and ultimately voted to convict because the individuals willfully, knowingly, and repeatedly lied to the FDA and then ignored repeated demands to desist, resulting in harm to patients that the company also failed to report to the FDA.²¹ A more recent case was brought in a *qui tam* action by former marketing managers against Scios and its parent company Johnson & Johnson for fraudulent off-label marketing of Natrecor (nesiritide). Specifically, Natrecor was approved in 2001 for use in acute decompensated congestive heart failure (CHF) over a 36-hour infusion, but Scios soon began an aggressive campaign marketing the outpatient use of Natrecor for CHF during serial scheduled visits over less than 6 hours, for which physicians billed a considerable amount to Medicaid and Medicare. In 2005, a panel of leading cardiologists advised Scios that it should stop promoting Natrecor for use in outpatient scheduled visits, which Scios did when they acknowledged in a letter to health care providers in 2005 that clinical evidence was lacking for both safety and efficacy in this off-label use. A Scios-sponsored study published in 2007 showed no benefit in using serial outpatient Natrecor infusions.²² The 2008 whistleblower lawsuits initiated under the FCA against Scios were joined in February 2009 by the Department of Justice after an investigation by HHS, OIG, FBI, FDA, and the Veterans Administration. The implications

for the physicians who participated in these marketing campaigns remain to be fully explored.

All of these civil and criminal actions are unlikely to stop or even slow the aggressive marketing practices that some drug and device manufacturers use and involve physicians in. Consider the recent settlement of \$1.42 billion that Eli Lilly Co. agreed to pay in 2009 for the illegal marketing of Zyprexa (olanzapine), which included the largest criminal fine in history in the amount of \$515 million. This staggering settlement of \$1.42 billion is approximately the amount Medicare and Medicaid programs pay for the use of Zyprexa annually, and the annual worldwide revenue for Zyprexa was \$3.5 billion through three quarters of 2008. Although fraud settlements arising from illegal marketing can amount to little more than the cost of doing business for a drug or device company, a physician might want to carefully consider the ramifications of assisting an industry sponsor with this type of marketing.

RECOMMENDATIONS FOR PHYSICIAN-INDUSTRY INTERACTIONS

The cases listed above are meant to be illustrative and not exhaustive of the types of abuses investigated by the OIG. The underlying tone is not meant to be anti-industry, as the collaboration between physicians and industry has been a largely successful one that has been marred over the years by a few cases of apparent fraud. The OIG acknowledges that the relationship between physicians and industry is necessary, but advocates that it should be conducted with greater transparency. To this end, it has authored guidelines in the form of a compliance program, endorsed safe harbors that limit liability for common business arrangements when followed, and established an advisory program whereby specific arrangements or practices can receive formal legal review and recommendations from the OIG. These formal reviews are posted on the OIG's Web site in the form of advisory opinions that are available as an additional source of guidance, although they confer specific immunity from prosecution only for the poster of the original question.

In the past 5 years the OIG has issued two advisory opinions that directly impact the physician-industry relationship.^{6,7} Both opinions dealt with market surveys conducted on behalf of pharmaceutical companies that targeted physicians directly. In one, the physician was compensated \$1 for answering a series of four to six questions, and in the other, the physician respondent chose a favorite charity to receive a donation. In both cases, the OIG was critical of the fact that such survey research was a thinly veiled marketing campaign and suggested that both forms of remuneration had inherent risks of liability under the Anti-Kickback Statute. However, the OIG concluded in both cases that the practices were not actionable, in the first case because the dollar amount (maximum of \$12/year/physician) was insignificant to invoke the statute and in the second case the use of bona fide charities over which the physicians had no personal control or interest provided

a sufficient safeguard to permit the practice. These opinions are perhaps most useful for illustrating the skepticism with which the OIG views "paid to listen" marketing arrangements, whether veiled as research or as education.

When evaluating potential or existing arrangements with industry, the OIG reminds physicians to be familiar with the safe harbor applicable to their activities. The published safe harbors include many activities that a physician can be involved with, such as investment interests, leasing of space, equipment rentals, personal services and management contracts, the sale of a medical practice, waiver of beneficiary coinsurance and deductible amounts, and practitioner recruitment in medically underserved areas. The OIG recommends that when working with an industry sponsor, the physician would be best protected if he or she created an arrangement whereby the physician is either a true employee of the company or a bona fide consultant who provides meaningful work at fair market value. The safe harbor that directly addresses the consultant contract has seven specific requirements that must be followed to reduce the risk of impropriety. Chief among these requirements is that the consultant hold a written contract that specifies exactly what the service being provided is, how often it is provided, at what rate, that this rate is set to reflect fair market value, and that the contract is for a term of not less than 1 year. The OIG further implies that consulting jobs originating from the sales and marketing division of a company deserve additional scrutiny and are best handled in the statutory employer-employee capacity. The underlying theme that runs through the OIG recommendations is that fee-for-service arrangements must be reasonable for the task performed and provide a legitimate value to the company (aside from merely generating business) and that the performance of this service must be governed by a written contract that is reviewed periodically to ensure completion.

Roughly 50% of continuing medical education (CME) is currently supported by the private sector, a reality that is unlikely to change in the current economy.²³ The OIG guidelines specifically acknowledge both the crucial role that a physician plays in conducting clinical research and the educational activities sponsored by industry sources. Physicians are advised to scrutinize the nature of educational or research grants to ensure that they are not based expressly or implicitly on referral of the manufacturer's product. Research grants arising from the sales and marketing divisions of industry (postmarketing) should be viewed with skepticism if the only discernible scientific objective is to increase the sales of the device or drug. It is incumbent upon organizers of educational activities to ensure that industry sponsors have no direct control over the content of the information provided at a CME event. The OIG guidelines specifically mention that industry funding for educational activities sponsored and organized by professional medical organizations raise little risk of fraud or abuse if the grant is unrestricted or not conditioned with respect to content or faculty.²

CONCLUSIONS

It is impossible for practicing physicians to insulate themselves from the private device and pharmaceutical sectors. The private sector is pervasive in the daily activities of a physician's practice, funding of clinical research, and physician education. The physician who enters into a more formal business arrangement with industry would be well counseled to become familiar with the regulations and recommendations set forth by the OIG that inform and influence the physician-industry relationship. Unfortunately, the recommendation that formal relationships between physicians and industry be governed by the guidelines outlined by the OIG, PhRMA, AMA, and ACCME did not prevent the recent associations that ended in civil and criminal liabilities. It remains to be seen if the even stricter guidelines recently endorsed by the Association of American Medical Colleges will have any more influence.²⁴ The fact remains that all of the causes of action investigated by the OIG were already prohibited by the code of conduct presented by PhRMA, the OIG, and all major medical organizations. Stricter self-regulatory guidelines may continue to be ineffective when no provision or recommendation for effective monitoring or enforcement accompanies the guidelines. To have any effect, these guidelines will at least require monitoring and enforcement at the institutional level or by professional medical societies. Prosecution of individual physicians has been rare to date, but will likely increase in an effort to curtail fraud and abuse.

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Appendix A. Industry relations committee, 2008–2009

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