

# Blowing the Whistle on Healthcare Fraud

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Medical technology is crucial to the health and welfare of our citizens. The industry provides us with early detection of diseases, safe and effective treatment options for the diseases that are detected and so on. It goes without saying that the marketing and sales of such devices and products should be based on their benefits to the patients, not on inappropriate incentives to the healthcare providers that utilize or prescribe the technology.

## Buyers of the business—beware!

Speaking or attendance honoraria, consulting and advisory payments, lavish entertainment, grants and gifts are all ways for medical technology manufacturers and distributors to “buy the business” of healthcare providers. If these payments are made to induce the prescribing or purchasing patterns of products or services paid for by government healthcare programs, they are against the law!

The federal Anti-kickback Statute prohibits giving or accepting anything of value in exchange for a referral of federally subsidized service or item, such as the purchase of a device, or use of a test or product, paid for by a federal (or state) healthcare program. This statute exists today because of concerns that such payments to physicians and other healthcare providers will result in medically unnecessary, poor quality or even harmful treatment to vulnerable patients. No doubt, hundreds of millions of dollars have been used over the past decade for this very purpose, and the industry will begin to see the uncovering of these practices very shortly, due to the increased application of the federal False Claims Act and its [qui tam](#) provisions.

Qui tam is a unique mechanism in the False Claims Act that allows persons and entities with evidence of fraud against federal programs or contracts to sue the wrongdoer on behalf of the United States. This Act and its qui tam provisions have returned more than \$10 billion to the United States Treasury over the past 17 years.

## Lessons from Pharma

In April, 2003 the Department of Health and Human Services released a Compliance Program Guidance for Pharmaceutical Manufacturers (“CPG”) in an effort to, as then Inspector General Janet Rehnquist said, “... help companies prevent [healthcare fraud](#) and abuse by promoting a high level of ethical and lawful corporate conduct.” The CPG hammered home the fact that it is illegal to pay off doctors to prescribe drugs. The Pharma industry CPG also applies to device manufacturers’ products that are reimbursed by federal healthcare programs.

The guidance came too late for many drug companies, including AstraZeneca, Bayer, Dey, GlaxoSmithKline and Pfizer and TAP Pharmaceuticals, all of whom settled cases involving allegations of Medicare and/or Medicaid fraud for tens, if not hundreds-of-millions of dollars. The price of defrauding the government can be enormous. To-date, total payouts by these pharmaceutical manufacturers to settle qui tam cases and related civil and criminal penalties, has amounted to over \$1.6 billion.

## **Technology's response**

In order to avoid a repeat of the Pharma fallout, the medical technology industry has actively been involved in implementing voluntary codes of conduct. The AdvaMed Code of Ethics on Interactions with Healthcare Professionals went into voluntary effect January 1. The purpose of the AdvaMed Code is to “facilitate members’ ethical interactions with those individuals or entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe members’ medical technology products in the United States.” The Code has obviously been designed as a guide for medical technology companies to steer clear of violation of the federal Anti-kickback statute, 42 U.S.C. [section] 1320a-7b(b)(2)(A). The statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally-funded medical services, including services provided under the Medicare, Medicaid and TRICARE programs.

Medical device and diagnostic companies should take heed of the AdvaMed Code, and go further in increasing their compliance oversight in order to reduce liability risks. Maintaining compliance and staying competitive do not need to be mutually exclusive—and in fact, can be complimentary. Companies are bound by the actions of their sales forces when they interface with physicians—adhering to the AdvaMed Code, at minimum, and enforcing compliance with it, is a must in today’s climate. Even with such Codes, monetary incentives that are disguised as legitimate payments (such as payments to physicians for consulting, advisory boards, feedback, medical education attendance, educational research grants, and so on), are still wrong. The healthcare providers who receive these payments are typically selected by sales departments based on their ability to prescribe, their past prescribing practices, or even their willingness to influence other doctors to do so—as opposed to any reason on the merits.

**Here are several examples of practices that may be unlawful and are followed by the AdvaMed Code suggested course of conduct:**

### **\* Consultants’ Meetings**

The practice: Under this guise, the companies recruit physicians to dinners or conferences and pay them to hear presentations about their products. Under the fiction that these doctors are acting as consultants, the companies usually have the doctors sign sham consulting agreements.

A typical consultants’ meeting is held at a resort location. The “consultants” selected for this meeting are not chosen on the basis of their expertise, but because of the potential to write prescriptions, purchase or use the product, test or device. Qualifying physicians are typically given round-trip airfare to the resort (worth \$500.00-\$1,000.00), a night’s accommodations (worth \$250.00-\$500.00), free meals, substantial entertainment, ground transportation and a “consultant’s fee” (\$250.00-\$2,500.00). The value of the trip usually approximates \$1,000.00-\$3,000.00 per physician consultant.

The remedy: The AdvaMed Code acknowledges reasonable compensation for arrangements with consultants, for “valuable bona fide consulting services, including research, participation on advisory boards, presentations at Member-sponsored training, and product collaboration.” The requirements

include a written, signed contract by the parties, consistent with fair market value, and entered into only where there is a legitimate need and purpose for such consultant's purpose.

Probably most important is the obvious restriction that selection of consultants should be on the merits, and "should not be on the basis of volume or value of business generated by the consultant." The best practice would be for the sales force to have no involvement with consultant selection or meetings, period.

### **\* Third-Party "Sponsored" Educational Conferences**

The practice: Although technically the presentations at (inappropriate) educational meetings are set up so that they appear to be provided by an independent company, all aspects of the presentation are designed, monitored, and approved by the sponsoring company. Typically, it selects the speakers, picks the presentation topics and previews the content of the presentation to make sure they are acceptable. Such companies pay all expenses relating to the "consultants'" meeting, including all payments to the attendees and the presenters, all travel, accommodation, meals and entertainment, all presentation expenses, all expenses and fees incurred by the "independent company," honoraria for spouses, and of course the substantial fees paid to the presenting physicians.

Although the "independent" seminar companies act as the conduit for the payments and gratuities given to the physician attendees, the sponsoring company controls every aspect of the Continuing Medical Education ("CME") programs. It designs and approves the programs, hand-picks the speakers for the seminars, approves the presentations of the seminar, previews (in most cases) the contents of the seminars prior to delivery, selects the attendees based on their ability and willingness to prescribe or purchase high quantities of the product or service, and monitors the prescribing patterns of the physicians who attend these conferences. The actions are designed to insure the purpose of the conference—increase use or prescribing or purchasing (as opposed to educating physicians on their products, tests or services.)

A "Speakers' Bureau" or other similarly rifled program is another method to make large and numerous payments to physicians who recommend the company's products, regardless of the merits, at teleconferences, dinner meetings, consultant meetings, educational seminars, and other events. These speakers repeatedly give short presentations relating to the company's products or services, for which they are paid anywhere from \$250.00-\$5,000.00 per event. The payments that these doctors receive are far in excess of the fair market value of the work they perform. Speakers who most zealously advocate are hired most frequently for speaking events, not-withstanding the fact that many of these events purported to be independent medical education seminars where independent information is supposed to be delivered.

The remedy: The AdvaMed Code allows support of these conferences in various ways, including the provision of educational grants to "the conference sponsor to receive conference costs, or to a training institution or other conference sponsor to allow attendance by medical students, residents, fellows, and others who are Health Care Professionals in training." However, "The conference sponsor should be

responsible for and control the selection of program content, faculty, educational methods, and materials.”

Consistent with a company-direct sponsorship of programs, meals may be paid for, but “should be modest in value and should be subordinate in time and focus to the purpose of the conference,” grants may be for travel, and meal expenses may be paid for but only “for Health Care Professionals who are bona fide conference faculty members.” Additionally the Code recognizes member-sponsored product training and education, and even acknowledges that payment may be made for “out-of-town travel for some participants, and may extend more than one day.”

However, the Code limits hospitality to meals and receptions that are “modest in value and subordinate in time and focus to the educational or training purpose of the meeting.” The Code has similar restrictions for member-sponsored sales and promotional meetings, and agreements with consultants. The best practice would be for the sales force to have no involvement with educational meetings—ever. Educating physicians on a device or product can certainly be achieved by another department.

#### **\* Grants**

The practice: Companies make outright payments in the form of grants to reward physicians. Once a sales representative or sales manager identifies key doctors who actively prescribe or purchase products or services, they encourage (or facilitate) such persons or programs to obtain “educational grants” from the company. Charged to the company’s marketing budget, not scientific budget, such grants are made solely because a physician who would receive the money is a large prescriber or otherwise big supporter.

The remedy: The AdvaMed Code allows for grants and other charitable donations, for the “Advancement of Medical Education,” the “Support of Research with Scientific Merit,” and for “Public Education.”

The Code allows for too much leeway. It even allows for grants “in rare instances, to individuals engaged in genuine charitable missions for the support of that mission.” The best practice would be for the sales force to have no involvement with grants—ever.

Medical technology will follow Pharma down the qui tam path

In the next several years, industry observers will see a repeat of the pharmaceutical industry False Claims Act settlements, albeit on a smaller scale. The settlements, as with Pharma so far, will be a result of qui tam lawsuits brought by industry employees who relate their knowledge of unlawful kickbacks and other inappropriate practices that their company has engaged in.

If the government intervenes in a healthcare fraud case, the whistleblower can be awarded 15-25% of the final recovery. Without government intervention the whistleblower can receive 25-30% of the final recovery.

Any company that has given cash, services, or items of value to physicians, managed care companies, or other healthcare providers, with the end result being a reimbursement paid for by a government healthcare program—beware. Whistleblowers who have knowledge of these activities can still, and will be rewarded by the process of filing and pursuing a qui tam lawsuit.

### **Whistleblowing—the process**

The government takes one in every five false claims cases that are ever filed. However, many lawyers take the cases the government does not, because they feel that they have enough information to move forward without the fruits of a government investigation.

#### **\* Document the facts**

If employees believe that they have witnessed false claims or kickback behavior, and desire to report their employer, their first step should be (or should have been) to legally and ethically document proof and gather evidence. They should keep copies of all paperwork that they feel documents inappropriate activity. If still employed, they should not violate company policy to do this, nor should they seek out records that would not cross their desk in a normal work day.

#### **\* Work up the case**

The whistleblower cannot simply report violations of the False Claims Act or kickbacks, to the government. They need to actually file a qui tam lawsuit, and often do so by finding a qui tam lawyer, with experience in the False Claims Act arena, to prepare a case. The case must be worked up in detail in order to increase the chances of the government review of the case.

Assuming the whistleblower has sufficient content, cases take anywhere from three weeks to many months to work up. The attorney, along with the whistleblower, will prepare a book of facts called a “disclosure memorandum” which includes witness briefs and documents that will serve as background information for filing the case. This step in the process usually involves hiring consultants in order to assure that the inappropriate activity giving rise to violations of the False Claims Act can be substantiated.

#### **File the case**

Then the case is filed “under seal” with the government. This means that the company the case is being filed against is not informed. Because qui tam cases, based on the same or similar allegations, cannot be filed more than once, it is critical to file the case first. The team that is first to file the case will be the only team that can pursue the qui tam case.

#### **\* Government intervention**

The case is then provided to the Department of Justice and the local United States Attorney’s office. They then have a period of time in which they, and other offices such as the inspector general of the

Department of Health and Human Services, can investigate the alleged fraud. The FBI also investigates False Claims Act cases, as well as the Defense Criminal Investigative Service.

Prior to making the decision of whether or not to intervene, the government typically chooses to discuss the circumstances with the whistleblower. It also conducts a broad investigation. Accordingly, the entire seal typically takes one to three years, or more. If the case is investigated correctly, and the information provided to the government is comprehensive enough, there is generally nothing more for the whistleblower to do once the case gets to this point, outside of answering additional questions or reviewing documents. However, in rare cases, the whistleblower may be asked to wear a wire (if they still work for the healthcare company on which they have blown the whistle).

Then, once the government decides to intervene or not, the seal is lifted, the company is informed of the allegations against it and a lawsuit proceeds like any other criminal or civil lawsuit.

Many cases are resolved with a Settlement Agreement. Typically the government is looking for repayment of damages, meaning repayment of the money that the government overpaid due to the fraudulent actions of the healthcare provider. If the healthcare provider does not settle, then the case proceeds just like any other civil lawsuit.

### **It's Not Too Late**

Bottom line, thanks to whistleblowers who were justly awarded nearly \$188 million for bringing qui tam lawsuits against pharmaceutical manufacturers alone, the majority of today's healthcare organizations and employees are broadly aware of the implications of False Claims Act violations and kickback behavior. But for those companies, doctors, sales professionals and marketers who have engaged in false claims or "buying the business" behavior over the past six years—beware! Medical technology and other healthcare companies can still be the subject of qui tam lawsuits.

### **Facing the facts**

Future qui tam lawsuits will only involve a small portion of medical technology companies, but even this small portion has cost taxpayers hundred of millions of dollars. Had such companies not egregiously violated the Anti-kickback statute, hundreds of millions of dollars in costs would have been paid by government and private healthcare programs. And, an untold amount would not have been incurred for physician visits and side-effect management for prescribing the devices or tests, for unnecessary purposes. Moreover, competitor companies that were abiding by federal and state law, and did not engage in kickbacks, would have had a more level playing field to market their devices and tests.

Nolan & Auerbach has significant experience in qui tam/False Claims Act cases and recoveries. Mr. Nolan has recently been selected for the Bar Register of Preeminent Lawyers. According to Martindale-Hubbel, it is the only directory of its kind to feature the nation's most esteemed legal practices. He has also been selected as a "Leading American Attorney" by his peers. [Click Here](#) to read more about Kenneth J. Nolan's recent cases.

If you are aware of false claims behavior that has taken place over the past six years  
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