

Overview of healthcare fraud investigations in the US

Kathleen M Sanzo, Stephen Paul Mahinka and Patrick L Gilmore,
Morgan, Lewis & Bockius LLP

www.practicallaw.com/8-205-5261

Over the last decade, the number and significance of healthcare fraud and abuse investigations brought by US federal and state governments regarding the marketing activities of pharmaceutical and medical device companies has grown steadily. These investigations have resulted in the negotiation of civil and criminal settlements, usually involving payments of millions of dollars in fines and penalties, and commitments to mandatory compliance programmes that have caused significant changes to how these companies market and sell their products (*see box, Recent significant healthcare investigations and settlements*).

This chapter reviews this rising trend and focuses on:

- The reasons behind the increasing importance of healthcare fraud.
- Enforcement tools used against healthcare fraud.
- Who investigates healthcare fraud.
- What activities lead to healthcare fraud investigations.
- Settlement of a healthcare fraud investigation.
- Using compliance programmes to prevent fraud.
- Lessons learned from recent pharmaceutical and device investigations.

THE INCREASING IMPORTANCE OF HEALTHCARE FRAUD

There are two primary reasons for the increased focus being placed on healthcare fraud:

- As the US government has become the largest single purchaser of prescription drugs and devices in the US (due to new programmes such as the Medicare (the federal healthcare programme for the aged and disabled) Part D programme for prescription drug coverage begun in 2006), the government has become more concerned about marketing practices that may improperly inflate the price or increase the medically unnecessary use of drugs and medical devices.
- The changing demographics of the US population (that is, increasingly senior) require continued increases in public healthcare spending.

As with the federal government, the budgetary pressures faced by states, which are responsible for the Medicaid programme (the joint federal and state funded programme to provide healthcare

services to the financially needy), have encouraged states to pursue healthcare fraud investigations under their own independent legal authorities.

Recent examples of healthcare fraud investigations at the state level include:

- The Attorneys General for Hawaii and Arizona filed lawsuits against multiple pharmaceutical companies alleging that they manipulated or misstated the average wholesale price of prescription drugs, resulting in the overpayment of millions of dollars in drug reimbursements under the Medicaid programme.
- The Attorney General for Texas sued Merck alleging that it violated the Texas Medicaid Fraud Prevention Act by "pushing" to have Vioxx placed on the state's Medicaid formulary, knowing that the drug had a higher risk of causing heart attacks and other cardiovascular problems.
- New York and Connecticut issued subpoenas to Pfizer to investigate possible off-label marketing of drugs.

ENFORCEMENT TOOLS AGAINST HEALTHCARE FRAUD

The following means can be used to combat healthcare fraud:

- Criminal statutes, including the Anti-kickback Statute (*42 U.S.C. §1320a-7b(b)*) (*see below, Anti-kickback Statute*).
- Civil statutes, including the federal civil False Claims Act (*31 U.S.C. §3729*).
- Administrative authorities.
- State enforcement authorities.

Criminal statutes

The federal government, through the Department of Justice (DOJ), has many legal authorities at its disposal to pursue healthcare fraud. For example, the DOJ can argue that pharmaceutical and device companies violated the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA) by:

- Introducing into interstate commerce adulterated or misbranded drugs or devices, which includes marketing drugs or devices for off-label or unapproved uses (*21 U.S.C. §331(a)*).
- Selling free samples (*21 U.S.C. §§331(t) and 353(c)*).

RECENT SIGNIFICANT HEALTHCARE INVESTIGATIONS AND SETTLEMENTS

The following are the most significant healthcare investigations and settlements of the last few years:

- In 2006, Medco, a pharmacy benefits management company, agreed to pay US\$155 million (about EUR120.8 million) to settle allegations that it submitted false claims to the government under the Federal Employees Health Benefits Program and violated the Anti-Kickback Statute by accepting payments from pharmaceutical companies to favour their products, and paid kickbacks to health plans to obtain their business.
- In 2006, Schering-Plough agreed to pay US\$435 million (about EUR339 million) to settle charges of Medicaid fraud and improper marketing of several drugs.
- In 2006, Medtronic agreed to pay US\$40 million (about EUR31 million) to settle charges that its Sofamor Danek division paid kickbacks to doctors in the form of sham consulting and royalty agreements, and luxury trips in exchange for using the company's spinal products.
- In 2006, Eli Lilly pleaded guilty to misbranding and paid US\$36 million (about EUR28 million) to settle claims that it illegally marketed its osteoporosis drug for unapproved indications.
- In 2005, GlaxoSmithKline paid in excess of US\$150 million (about EUR117 million) to settle charges that it inflated the average wholesale prices of Zofran and Kytril and used the "spread" between reimbursement and actual cost to market and promote the drugs.
- In 2005, Serono pled guilty to two counts of criminal conspiracy and agreed to pay US\$704 million (about EUR549 million) to settle charges that it used illegal schemes to market its HIV drug Serostim.
- In 2005, the US Attorney's Office for the District of New Jersey issued subpoenas to manufacturers of orthopaedic medical devices seeking documents relating to allegedly improper consulting contracts, professional service agreements and remuneration agreements with orthopaedic surgeons.
- In 2004, Schering-Plough pleaded guilty and paid US\$345.5 million (about EUR269 million) to settle charges it had defrauded Medicare by overcharging the agency for its allergy drug Claritin.
- In 2004, Cephalon received a subpoena from the US Attorney's Office for the Eastern District of Pennsylvania requesting documents regarding alleged abusive off-label sales and promotional practices for the company's products.
- In 2004, Pfizer pleaded guilty to a false claims action and agreed to pay US\$430 million (about EUR335 million) to state and federal governments to resolve criminal and civil charges involving alleged off-label marketing of Neurontin to physicians in violation of the FFDCA.
- In 2003, Abbott Laboratories paid US\$600 million (about EUR468 million) for counselling its medical equipment supply customers to submit improperly bundled Medicare claims, causing the payment of improper reimbursement for enteral feeding pumps and tubing.
- In 2003, Endovascular Technologies (a Guidant subsidiary) paid US\$92.4 million (about EUR72 million) to settle criminal and civil charges that it failed to report thousands of malfunctions of its Ancure Endograft System to the FDA.
- In 2003, AstraZeneca Pharmaceuticals agreed to pay US\$355 million (about EUR277 million) to resolve allegations that it provided physicians with free samples of its prostate cancer drug Zoladex, knowing that the doctors would bill Medicare for the drug in violation of the Prescription Drug Marketing Act (PDMA).
- In 2001, TAP Pharmaceutical Products paid US\$875 million (about EUR682 million) to resolve criminal and civil claims arising from allegations of fraudulently manipulating the average wholesale price of its prostate cancer drug Lupron, improperly providing grants and other free services and entertainment to physicians, and providing free samples in violation of the PDMA.

In addition, there are a variety of general criminal statutes that are often used to pursue healthcare fraud, including prohibitions on:

- Using the mail to commit a scheme or artifice to defraud (*18 U.S.C. §1341*).
- Using wire, radio or television to transmit information to execute a scheme or artifice to defraud (*18. U.S.C. §1343*).
- Presenting false claims to the government (*18 U.S.C. §287*).
- Conspiring to defraud the government by obtaining payment of a false or fictitious claim (*18 U.S.C. §286*).
- Making false statements (*18 U.S.C. §1001*).
- Supplementing the general fraud statutes are an entire class of criminal statutes focused on specifically preventing healthcare fraud. Such statutes include prohibitions on:
 - Healthcare fraud (*18 U.S.C. §1347*).
 - Obstructing criminal investigations into a healthcare offence (*18 U.S.C. §1518*).
 - False statements relating to healthcare matters (*18 U.S.C. §1035*).

However, the principal criminal authority for pursuing healthcare fraud remains the Anti-kickback Statute.

Anti-kickback Statute

The Anti-kickback Statute prohibits offering or receiving any remuneration in return for (42 U.S.C. §1320a-7b(b)(1) and (2)):

- Referring, or inducing a person to refer, an individual for the furnishing of healthcare items or services for which payment may be made under a federal healthcare programme.
- Purchasing, leasing, or ordering any goods or services for which payment can be made under a federal healthcare programme.

A conviction for violating the Anti-kickback Statute can lead to substantial criminal fines (up to US\$25,000 (about EUR19,485) per incident) and imprisonment.

Courts interpreting the Anti-kickback Statute have supported the "one purpose" test for determining whether the requisite criminal intent to violate the statute is present (*US v McClatchey*, 217 F.3d 823 (10th Cir. 2000)). Under the "one purpose" test, the intent to induce referrals does not need to be the primary or sole reason for the remuneration, but need only be one among many, otherwise legitimate, reasons (see *US v Greber*, 760 F.2d 68 (3d Cir. Pa. 1985)).

The scope of the Anti-kickback Statute is so broad that it renders otherwise beneficial business arrangements illegal. Therefore, Congress statutorily exempted certain business activities from prosecution and authorised the Office of Inspector General (OIG) of the Department of Health and Human Services to promulgate regulatory "safe harbours" to protect certain transactions where the risk of illegal remuneration was minimal (see 42 C.F.R. §1001.952). Transactions given safe harbour status include, but are not limited to:

- Warranty programmes.
- Leasing programmes.
- Consulting and other service arrangements.
- Referral services.
- Discounts.

Pharmaceutical and medical device companies expend substantial time, effort and financial resources into trying to structure their promotional activities to be within a safe harbour.

Civil statutes

The OIG, which monitors and investigates fraud, abuse and waste in the Medicare and Medicaid programmes, has an array of civil enforcement tools. These include the authority to impose monetary penalties and assessments against individuals and entities for activities to defraud the healthcare system, including submitting claims for medical items or services that (42 U.S.C. §1320a-7a):

- Were not provided.
- Are false.

- Represent a pattern of providing medical items or services that are not medically necessary.

Most importantly, the DOJ can bring a claim under the federal civil False Claims Act (see below, *Federal civil False Claims Act*).

Federal civil False Claims Act

The federal civil False Claims Act (31 U.S.C. §3729) prohibits knowingly presenting, or causing to be presented, to the government a false or fraudulent claim for payment. The term "knowingly" refers to any of the following situations where a person, with respect to the false or fraudulent information:

- Has actual knowledge of the information.
- Acts in deliberate ignorance of the truth or falsity of the information.
- Acts in reckless disregard of the truth or falsity of the information.

No proof of specific intent to defraud is required (31 U.S.C. §3729(b)). An actionable claim under the Act can be either:

- A facially false claim.
- A claim that has been tainted by having been procured through the payment of kickbacks or through a fraudulent course of conduct.

Under the False Claims Act, a person who has knowledge of non-publicly disclosed information (unless that person is the original source for the publicly disclosed information) is authorised to bring a civil action in the name of the government against an entity for violating the Act. This is known as a *qui tam* action and the person bringing the action is known as a *qui tam* relator. The government has the option to intervene in the case and proceed with the action or it may decline to do so, in which case the *qui tam* relator can conduct the action. Whether the government intervenes in the case or not, the *qui tam* relator is entitled to share in any judgment for the government or in any settlement of the case. For a multi-million dollar settlement, this can be a huge payoff for the *qui tam* relator. For example, in the TAP and AstraZeneca cases, the *qui tam* relator recovered a combined amount of about US\$143 million (about EUR111 million) (see *US v TAP Pharmaceutical Products, Inc.*, D. Mass. No. 01-CR-10354 (2001); *US ex. rel. Durand v AstraZeneca Pharmaceuticals LP*, D. Del. No. 03-122-JJF (2003)).

Administrative authorities

The OIG also has the authority to exclude an individual or entity from participation in any federal healthcare programme, which is the most effective administrative enforcement tool at its disposal (42 U.S.C. §1320a-7). Reasons for exclusion include, but are not limited to, the following:

- The person or entity has been convicted of one of the following:
 - committing fraud against the Medicare or Medicaid programme;

- a felony relating to healthcare fraud;
- obstructing a healthcare investigation.
- The OIG determines that the person or entity has committed fraud or paid kickbacks as described under 42 U.S.C. §1320a-7b(b).

There are mandatory and permissive exclusions, depending on the severity of the infraction, which can result in exclusions for up to ten years, or permanent exclusion for repeat offenders. Exclusion is company-wide and not product specific, which means that no government funds can be spent on any of an excluded company's products, directly or indirectly. An excluded manufacturer cannot sell any products to hospitals, physicians, pharmacists or other healthcare providers who receive reimbursement from the government through any federal healthcare programme, including Medicare, Medicaid, the Department of Veterans Affairs or the Department of Defense. Exclusion from these programmes would prevent an individual from working in the healthcare industry and may cause financial ruin to a healthcare company, therefore representing one of the most devastating enforcement tools.

State enforcement authorities

Enforcement authorities' powers against healthcare fraud vary widely among states. Many states have their own version of the Anti-kickback Statute and the False Claims Act, along with consumer protection laws, general fraud statutes and criminal statutes specifically designed to protect the Medicaid programme. In addition, under the Deficit Reduction Act of 2005 (*P. L. 109-171*), which took effect on 1 January 2006, Congress created financial incentives for states (namely to receive 10% of the money recovered) to enact false claims laws similar to the federal False Claims Act. For a state to receive the incentives, the OIG must first determine that the state law meets certain minimum requirements. These requirements were published on 21 August 2006 at 71 *Fed. Reg.* 48552, and include:

- Liability to the state Medicaid Programme for:
 - knowingly presenting or causing to be presented a false claim for payment;
 - knowingly making or causing to be made a false record or statement to get a fraudulent claim paid;
 - conspiring to defraud the programme; and
 - knowingly making or causing to be made a false record to conceal an obligation to pay.
- The terms "knowing" and "knowingly" must include actual knowledge of the information, deliberate ignorance of the truth or falsity of the information or reckless disregard to the truth or falsity of the information.
- No proof of specific intent to defraud should be required.
- The law must contain provisions allowing private individuals to bring civil actions in the name of the state and permit the individuals to share in any reward or settlement.

These financial incentives will undoubtedly result in more states enacting false claims statutes. States can also pursue healthcare fraud through common law claims of fraud and misrepresentation.

For example, California has extensive statutory legal remedies, including:

- A false claims statute (*Cal. Government Code §§12650 - 12655*).
- A Medi-Cal fraud statute (*Cal. Welfare & Institutions Code §14107*).
- An anti-kickback law (*Cal. Welfare & Institutions Code §14107.2*).
- A requirement that drug and device manufacturers maintain a comprehensive compliance plan (*Cal. Health & Safety Code §§119400-119402*).
- A consumer protection statute that permits private citizens or the state Attorney General to take action against false and misleading practices (*Cal. Business & Professions Code §§17200-17210*).

Vermont requires that every pharmaceutical manufacturer annually disclose to the state Attorney General, with certain exceptions, the value, nature and purpose of any gift, fee, payment or other economic benefit provided in connection with promotional and other marketing activities by the company. Failure to properly report results in a civil penalty of up to US\$10,000 (about EUR7,794) for each violation (*33 V.S.A. §2005*).

In Maine, under 22 MRSA §2700-A, it is a violation of the Maine Fair Trade Practices Act if any of the following forms of advertisement violate state or federal law or regulations concerning prescription drug advertising:

- A broadcast over television or radio from a station in Maine.
- A broadcast over the internet from a location in Maine.
- Advertisements in magazines or newspapers printed, distributed or sold in Maine.

The law also requires manufacturers or labellers of prescription drugs dispensed in Maine that employ, direct or utilise marketing representatives in Maine to post clinical trial results on a publicly accessible website.

WHO INVESTIGATES HEALTHCARE FRAUD?

Healthcare fraud investigations can be undertaken by a variety of government entities. Most commonly, the US Attorney's Office and the Federal Bureau of Investigation (FBI) within the DOJ will initiate investigations of healthcare fraud. These investigations are frequently conducted in conjunction with the OIG, because the OIG:

- Is statutorily responsible for combating fraud, abuse and waste in federal healthcare programmes.

- Has enforcement tools not possessed by the DOJ.
- Has a great amount of expertise in the healthcare field.

Even if the DOJ is not involved, the OIG can independently:

- Conduct audits and investigations into healthcare matters.
- Impose civil monetary penalties.
- Exclude healthcare entities from participation in federal healthcare programmes.

The Centers for Medicaid and Medicare Services (CMS) (the agency responsible for administering the Medicare and Medicaid programmes) contracts with entities known as Programme Safeguard Contractors (PSC) to monitor utilisation and to conduct claims review to ensure that medical services are provided in compliance with CMS requirements. If a PSC detects what may be fraudulent activity, the PSC is authorised to recommend payment suspensions and refer cases to law enforcement entities. The CMS also provides funding and guidance for state law enforcement entities, known as Medicaid Fraud Control Units, that investigate potential fraud in the state Medicaid programmes.

The Food and Drug Administration (FDA) also maintains its own independent criminal investigators to investigate possible violations of the FDCA, including possible violations of current good manufacturing practices, and whether drugs and devices are marketed for off-label uses.

WHAT ACTIVITIES LEAD TO HEALTHCARE FRAUD INVESTIGATIONS?

Promotion and marketing practices

Certain practices within the pharmaceutical and medical device industries are susceptible to governmental scrutiny. For example, the following violations of the FDCA may give rise to investigations by the FDA's OCI or the FBI:

- Not reporting adverse events.
- Promoting drugs or devices for off-label use.
- Product sample diversion, for example, selling samples.
- Misrepresenting the results of clinical studies.

In addition, pharmaceutical and device manufacturers are at risk of scrutiny under the Anti-kickback Statute for competitive marketing practices involving healthcare providers (HCPs). Companies have been challenged for:

- Paying physicians' excessive consulting fees to participate on advisory boards and in focus groups, and to be promotional speakers.
- Providing excessive free goods (for example, samples and loans of equipment) and entertainment (including golf, sporting events, cruises and skiing holidays).

- Providing excessive educational grants or grants for improper business assistance (for example, advertising for a physician group).

- Providing unreported discounts and rebates.

In addition, companies have been challenged for offering HCPs:

- Favourable business deals and investment opportunities.
- Overly generous financing for purchases of drugs.
- Favourable lease arrangements for device equipment.

All of these types of activities are potential kickbacks and may form the basis for allegations of causing the filing of false claims for reimbursement of drugs or devices.

Pricing practices

Because pharmaceutical manufacturers are required to report pricing data so that CMS can calculate reimbursement rates and mandatory rebates, pharmaceutical companies are vulnerable to allegations of manipulating pricing data or reporting false or inaccurate data.

Typically, the manufacturer is accused of manipulating reported prices to maximise the difference between the price at which a drug is reimbursed and the price at which it is purchased by an end user (HCP or hospital), and then marketing by providing the "spread" or potential increased profit to end-users to increase sales. If the increased profit to the end user increases the Medicare or Medicaid programme costs or improperly causes increases in use, the government can allege the discount scheme is a kickback and caused false claims submissions.

In addition, manufacturers have been accused of Medicaid fraud by not properly including certain discounts into the calculation of their best price (which is used to calculate Medicaid rebates), thereby arguably reducing the mandatory rebates required to be paid to states by manufacturers under the programme.

Many of the current state healthcare fraud investigations discussed in this chapter are based on these pricing allegations.

Medical device manufacturers also have potential exposure through pricing practices. As many medical devices are used during complex medical procedures, medical device manufacturers often provide detailed guidance on how to code and bill for their products in connection with those medical procedures. Because of this active involvement, device manufacturers are susceptible to False Claims Act violations for "causing" the filing of a false claim if the coding advice is incorrect. In addition, devices are often promoted and sold as bundled with other devices (for example, an insulin pump and tubing). These bundled product sales may lead to charges of manipulating the reimbursement (for example, charging for the Medicare reimbursed product but not the non-covered product) and the submission of false claims.

SETTLEMENT OF A HEALTHCARE FRAUD INVESTIGATION

Because programme exclusion may significantly injure a company, most drug and device manufacturers choose to settle

fraud allegations with the government rather than litigate the case and risk a fraud or felony conviction that will result in a mandatory exclusion.

Settlements include:

- Significant criminal and civil fines and penalties.
- A requirement for the company to enter into a "corporate integrity agreement" with the OIG, in which the company agrees to implement a comprehensive compliance programme that typically includes:
 - training employees on compliance issues;
 - hiring outside auditors to monitor corporate activities;
 - extensive government reporting requirements.
- In most circumstances, a requirement for the company to waive the attorney-client privilege as to all documents produced during the investigation.

The DOJ and some state governments also demand that the company co-operate in the prosecution of individuals, inside and outside of the company, who may have been involved in the alleged fraud.

USING COMPLIANCE PROGRAMMES TO PREVENT FRAUD

To assist pharmaceutical and medical device companies to avoid healthcare fraud investigations, the OIG has developed guidelines on implementing effective compliance programmes. The existence of an effective compliance programme is also considered under the US sentencing guidelines as a factor to reduce a corporate sentence, and can provide company directors and other officers with some level of protection against personal liability. Under the OIG's guidelines, an effective compliance programme contains:

- Written compliance policies and procedures.
- A compliance officer and committee responsible for overseeing the programme.
- Effective compliance training.
- Communication mechanisms for reporting potentially violative practices.
- Effective compliance monitoring and auditing programmes.
- Well-publicised disciplinary guidelines for non-compliance.
- Procedures for responding promptly to detected problems and undertaking corrective action.

The pharmaceutical and medical device trade associations, the Pharmaceutical Research and Manufacturers of America and the Advanced Medical Technology Association, have also adopted voluntary codes of conduct on interactions with healthcare providers to reduce potentially violative promotional and marketing practices. These codes provide guidance on gifts to HCPs, consulting arrangements, grants and other routine industry practices.

LESSONS LEARNED FROM RECENT PHARMACEUTICAL AND DEVICE INVESTIGATIONS

Companies in the life sciences industry can protect themselves by understanding and incorporating the following valuable lessons provided by previous investigations:

- **Don't make yourself vulnerable.** Do not engage in activities that make you an easy target for federal or state investigators. By actively monitoring operations and marketing practices, a company can avoid unnecessary scrutiny.
- **Following industry practice is no defence.** Just because your competitors use risky marketing practices, this does not provide any immunity if you do also. The federal government prefers to prosecute an entire segment of an industry to take advantage of resource and knowledge efficiencies which it develops throughout the case. The recent subpoenas to all large US orthopaedic device manufacturers concerning industry marketing practices with orthopaedic doctors is an example.
- **Be aware of your customers and suppliers.** The actions of physicians, hospitals and suppliers can be imputed back to the company. Because the False Claims Act only requires a company to have "caused" the filing of an improper claim, and the Anti-kickback Statute covers all parties in a kickback transaction, a company may be liable for damages resulting from its customers' or suppliers' behaviour.
- **E-mails.** E-mails provide the government with a lengthy paper trail of poorly-drafted messages, emotional outbursts, brainstorming and inappropriate humour, all of which may suggest guilt when taken out of context. E-mails should always be written with the expectation that they will be read by a government investigator.
- **Exclusion negates any settlement leverage.** Mandatory or permissive programme exclusion ordinarily constitutes a severe loss of sales and market share. Faced with this prospect, a company has very little leverage in negotiating a fair settlement. Unless the company is willing to take its chances in court, where a loss could ultimately destroy the company and potentially lead to derivative suits against its officers, the government is increasingly able to dictate the financial and other terms of settlements.
- **Settlement often requires a complete waiver of the legal privilege.** Depending on other activities engaged in by the company, this waiver can potentially lead to more or expanded investigations.
- **Compliance programmes must be user friendly.** Having an effective compliance programme requires that the plan be practical. Every person in the company, from the most senior directors and officers to the newest employees, must understand the aims of the compliance programme and their individual responsibilities.
- **A compliance programme is only as good as its annual audit plan.** Even with an uncomplicated, comprehensive and universally accepted compliance programme, the programme is useless if there is no mechanism to test its effectiveness. Active, regular compliance auditing is a necessity.



protecting the complete life cycle

Depth, quality and experience in all aspects of the product life cycle.

- Emerging Growth and Finance
- Intellectual Property Strategy
- Product Development
- Regulatory Approval
- Pricing and Reimbursement
- Global Marketing and Operations
- Collaborations, M&A and Outsourcing
- Litigation and Investigations

Morgan Lewis Life Sciences
www.morganlewis.com

Morgan Lewis