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The Government's Continued Targeting of the Pharmaceutical and Medical-Device Industries

By Eric Kraeutler and Alison Tanchyk

The pharmaceutical and medical device industries long have been target of the Department of Justice (DOJ), state attorneys general, and whistleblowers, all of whom have had repeated success in securing billions of dollars in criminal and civil actions. Those industries will remain targets because many long-standing practices—including gifts, honoraria, consulting arrangements, education grants, advisory councils, speaker programs, and product samples—present as great a risk under the Foreign Corrupt Practices Act (FCPA) as they do under fraud-and-abuse laws.

Even companies that have achieved a high level of compliance internally need to be concerned that their foreign business partners are a step behind. As assistant attorney general for the DOJ's Criminal Division, Lanny Breuer stated in November 2009:

[T]he types of corrupt payments that violate the FCPA because they are given to obtain or retain business in other countries are not any different than the items of value that would violate the Anti-Kickback Statute if given within the United States—cash, gifts, charitable donations, travel, meals, entertainment, grants, speaking fees, honoraria, and consultant arrangements, to name a few.

In theory, the pharmaceutical and medical-device industries' long history of fraud-and-abuse enforcement renders such companies better prepared to manage and mitigate FCPA risks. Both the pharmaceutical and medical-device industries have substantially strengthened their compliance programs over the past decade and have adopted codes of conduct aimed at avoiding unlawful inducement and ensuring appropriate marketing of medication and devices to healthcare professionals. The Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals, effective January 2009, by which 52 pharmaceutical manufacturers have announced they intend to abide, addresses the provision of meals in connection with information presentations, adopts a prohibition on the provision of entertainment and recreation, and sets forth guidelines with respect to the engagement of healthcare professionals as consultants.

Still, the FCPA enforcement risk in the pharmaceutical and medical-device industries has never been higher. There are six primary factors driving the risk:

1. The pharmaceutical and medical-device industries have long been the target of enforcement activities and remain squarely within the government's sights.
2. The DOJ has announced that the pharmaceutical and medical-device industries are FCPA enforcement priorities.
3. The Financial Reform Act signed into law in July 2010 creates powerful monetary incentives for whistleblowers.
4. The pharmaceutical and medical-device industries have regular and frequent interactions with foreign officials.
5. The pharmaceutical and medical-device industries heavily rely on third-party representatives to do business overseas.
6. The pharmaceutical and medical-device industries are operating and seeking to expand in some of the world's highest public-corruption-risk nations.

The Government's Call to Arms

At the conclusion of a year resulting in an unprecedented number of FCPA prosecutions and enforcement actions, Lanny Breuer gave two major speeches in November 2009 in which he discussed FCPA enforcement and the pharmaceutical industry. Breuer stated that the DOJ intends to focus its efforts on investigating FCPA violations by pharmaceutical companies, and the DOJ's healthcare-fraud and FCPA units are teaming up to investigate and prosecute bribery in the pharmaceutical industry's foreign operations. Breuer's announcements reinforced statements made in 2008 by the now former deputy chief of the Fraud Section, Mark Mendelsohn, in which he identified the pharmaceutical and medical-device industries among those upon which the DOJ intends to focus its FCPA investigative resources.

The DOJ's focus on the pharmaceutical and medical-device industries is undoubtedly driven, at least in part, by the industries' rapid and lucrative growth on foreign soil, where most health systems are government-run. During his keynote address to the Tenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum, Breuer cited the PhRMA 2009 Membership Survey, reflecting that approximately \$100 billion, or one-third of total sales of PhRMA members, was generated outside of the United States where, according to Breuer:

[H]ealth systems are regulated, operated and financed by government entities to a significantly greater degree than in the United States. As a result, a typical U.S. pharmaceutical company that sells its products overseas will likely interact with foreign government officials on a fairly frequent and consistent basis.

He added that:

The depth of government involvement in foreign health systems, combined with fierce industry competition and the closed nature of many public formularies, creates a significant risk that corrupt payments will infect the process. The Criminal Division stands ready to ferret out this illegal conduct and we are uniquely situated to do so.

Breuer's statements came in the midst of an aggressive increase in the DOJ's and the Securities and Exchange Commission's (SEC) FCPA enforcement against both companies and individuals, including the SEC's creation of a specialized "FCPA unit" armed with new cooperation and intelligence tools. The number of FCPA prosecutions has exponentially risen since the DOJ began actively enforcing the statute earlier in the decade. The DOJ currently has a record number of open FCPA investigations, estimated at 130. This represents a huge spike in the number of open investigations over just the past two years when, in mid-2008, there were an estimated 20 open investigations, to 18 in 2007, and to 50 in 2009.

In addition, the DOJ has begun to use traditional criminal-law-enforcement techniques to investigate FCPA violations. On January 19, 2010, the DOJ unsealed 16 indictments and arrested 22 executives and employees of law-enforcement-products companies. The action involved 150 agents and 14 search warrants, and was the result of an undercover sting operation. A Federal Bureau of Investigation agent posed as a sales agent acting on behalf of an African minister of defense. The individuals agreed to pay the undercover agent a 20 percent commission to win part of a \$15 million deal to provide military products to the African country's presidential guard. Twenty-one of the January 2010 arrests were made at a firearms-industry trade show in Las Vegas.

Just days before, on January 13, 2010, Robert Khuzami, the director of the SEC's Division of Enforcement, announced a series of enforcement initiatives and the streamlining of management and internal processes. Included among the new initiatives is what Khuzami described as a "game changer" for the Enforcement Division—the "Cooperation Initiative," which includes the use of cooperation agreements, deferred-prosecution agreements, and non-prosecution agreements to encourage individuals to assist the SEC in investigations.

The Whistleblowers' Bounty

Perhaps the most significant weapon in the SEC's arsenal is the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Financial Reform Act), signed into law by President Obama on July 21, 2010. Section 922 of the Financial Reform Act amends the Securities Exchange Act, of which the FCPA is a part, to provide for monetary awards and protection against retaliation for whistleblowers who provide "original information" to the SEC relating to a violation of securities laws. It has been reported that the SEC is receiving an average of one whistleblower report per day. The SEC is planning to establish a Whistleblower Office and has advertised for a "coordinator" position. The SEC already confirmed in its Annual Report on Whistleblower Program issued on October 29, 2010, that it has received tips and complaints from potential whistleblowers, following the passage of the Financial Reform Act.

The False Claims Act's (FCA) whistleblower provisions have played a significant role over the last decade in the government's investigations and enforcement of fraud-and-abuse laws, incentivizing employees to report suspected violations. In 2009 alone, the DOJ recovered \$2.4 billion in False Claims Act cases.

According to the report, over \$451 million is available to potential whistleblowers for fiscal year 2010. However, unlike the FCA, the Financial Reform Act does not authorize *qui tam* actions. Thus, would-be whistleblowers need not carry the burden of setting forth a *prima facie* violation of the FCPA. Rather, if the whistleblower's reported information leads to the enforcement of a covered judicial or administrative action by the SEC resulting in sanctions of over \$1 million, the whistleblower is entitled to between 10 and 30 percent of the imposed sanctions. Recoveries by foreign authorities are included in determining the amount of the award. This is particularly significant in light of the increase in antibribery enforcement by foreign authorities, the recent passage of the U.K. Anti-Bribery Act, and the act's authorization to the SEC to share, on a confidential basis, information obtained from whistleblowers with foreign law-enforcement authorities.

It remains unclear what role plaintiffs' counsel will have in facilitating whistleblower complaints to the SEC, particularly in the absence of a private right of action. However, the Financial Reform Act permits whistleblowers making a claim under the act to be represented by counsel, and requires that a whistleblower be represented by counsel if the whistleblower anonymously submits information upon which the claim is based. At the very least, with over \$451 million available to whistleblowers for fiscal year 2010, one can expect to see an increase in the number of SEC investigations originating from whistleblower tips.

Interactions with Foreign Government Officials

The pharmaceutical and medical-device industries stand on different footing from many companies with foreign operations that, for example, may encounter government officials seeking corrupt payments at a foreign border in clearing customs or at a ministry in seeking various business permits. While the pharmaceutical and medical-device industries interact with these same government officials, state-employed healthcare professionals are also industry customers, business partners, and an essential part of the industries' overseas businesses.

As Breuer pointed out, "foreign officials" include:

[D]octors, pharmacists, lab technicians and other health professionals who are employed by state-owned facilities.

Indeed, it is entirely possible, under certain circumstances and in certain countries, that nearly every aspect of the approval, manufacture, import, export, pricing, sale and marketing of a drug product in a foreign country will involve a 'foreign official' within the meaning of the FCPA.

When a customs agent demands a bribe to clear a container of product, the FCPA risk is readily apparent. When a pharmaceutical or medical-device company retains a state-employed physician as a consultant,

however, the FCPA risk is less obvious. The pharmaceutical and medical-device industries thus face greater and in many ways less apparent FCPA risk than other industries.

The industries are in constant contact with a large number of government officials—besides government-employed physicians—that are not easily identifiable. Thus, for example, hospital administrators, nurses, and pharmacists are all considered “foreign officials” under the FCPA if they are government-employed. Pharmaceutical and medical-device manufacturers must therefore know their customers—who they treat, what products they like, and who pays their salaries.

While the pharmaceutical and medical-device industries’ history with fraud-and-abuse enforcement arguably renders them better prepared to identify, manage, and mitigate FCPA risk, substantial vulnerabilities exist that must be addressed to avoid violations and enforcement actions. In particular, the pharmaceutical and medical device industries rely heavily on third-party representatives, and many of the countries and regions where the industries are expanding are among the most at risk from a corruption perspective.

Third-Party Representatives

All multinational companies work with third-party representatives in some fashion—whether it is with customs-clearing agents who help get product into a country, resellers, or even lawyers. There is no immunity under the FCPA by doing business through foreign affiliates or third parties. Rather, the FCPA’s anti-bribery provisions cover improper payments made to “any person, while *knowing* that all or a portion of such money or thing of value will be offered, given, or promised, directly or indirectly, to any foreign official.” Knowledge is established “if a person is aware of a high probability of the existence of such circumstance, unless the person believes that such circumstance does not exist.”

In other words, unless a company has a particular reason to believe that its third party representatives are not violating the FCPA, the company must do something affirmative whenever it and its third-party representatives are operating in risk areas. Therefore, in light of the government’s stated intent to ramp up enforcement efforts, due diligence and ongoing monitoring of third-party representatives are increasingly important.

Due diligence is a key component of an effective FCPA compliance program and an essential tool in limiting the risk of working with third-party representatives. The FCPA requires under its books-and-records provisions that companies will perform due diligence on prospective representatives. The importance of due diligence cannot be overstated in the healthcare world where, in many if not all countries, healthcare-industry third-party representatives are constantly interacting with, for example, government-employed hospital administrators who purchase medications and devices; government-employed physicians who recommend the purchase of medications and devices; and health-ministry officials who approve the sale of medications and devices and set their prices. Therefore, pharmaceutical and medical-device companies must be on the lookout for red flags from the outset of and throughout their relationships with third-party representatives.

In addition to promptly identifying and responding to red flags, companies must be proactive in working with third-party representatives. Step one is knowing your third-party representatives and understanding how they were identified or recommended. Many companies use checklists both internally and for distribution and completion by third-party representatives. Checklists and questionnaires are a means to gather information concerning third-party representatives that can identify risk areas. For example, questionnaires can elicit information concerning a third-party representative’s management-and-ownership interest. If the brother of a decision-maker at the Russian Ministry of Health is a manager of the consulting firm a pharmaceutical company uses to assist it in submitting drug applications, the company will need to carefully evaluate whether to retain that third-party representative, and if it does, carefully monitor that third-party representative.

Moreover, any information collected directly from the third-party representative should be verified through Internet searches and face-to-face interviews. Companies can also retain compliance consultants who provide on-the-ground due diligence investigations. The importance of verification is perhaps best exemplified by examples of problems companies have faced when they have relied on paper alone. In June, 2010, Technip, an engineering and project-management company that works with the oil-and-gas industry, agreed to pay a \$240 million criminal penalty to the DOJ and \$98 million in disgorgement to the SEC for its participation in a scheme to bribe through agents Nigerian government officials to obtain contracts to build LNG facilities in Nigeria. According to the SEC's press release, Technip performed due diligence on one of the agents by asking the agent to complete a questionnaire seeking basic background information. Technip did not interview the agent, do a background check, or verify the information the agent provided. The lesson is that papering the files is not enough.

Many companies are addressing the risks presented by their reliance on third-party representatives by including annual certifications from representatives that they will comply with the FCPA and local anti-corruption laws. In addition, companies require their third-party representatives to provide them with audit rights. Because the exercise of such audit rights for all third-party representative contracts is a Herculean task, many companies use a risk-based approach, performing regular audits for high-risk regions or for representatives that have presented red flags.

Recent Healthcare-Industry Investigations

In many ways, Breuer's 2009 announcements simply spell out the government's intent to prosecute *more* FCPA violations in the healthcare industry. Indeed, both the DOJ and the SEC long have targeted the overseas healthcare industry, which is expanding by leaps and bounds in some of the highest-risk regions in the world including Eastern Europe, Asia, and South America.

In 2004, for example, Schering-Plough agreed to pay \$500,000 to settle an SEC enforcement action arising from payments by the company's Polish subsidiary to the favorite charity of a Polish government official responsible for purchasing pharmaceutical products for hospitals. The payments were made without the knowledge of any U.S. employee. According to the SEC, the problem arose because of the company's inadequate internal controls, and the company was ordered to improve those controls with the assistance of an independent consultant.

In June 2008, medical-device manufacturer AGA Medical Corp. settled criminal charges alleging that a company official made illegal payments to doctors employed by government-owned hospitals in China and to Chinese patent officials in an attempt to influence them to buy AGA products and approve AGA patent applications. AGA agreed to pay a \$2 million criminal penalty and to retain an independent compliance monitor for three years. Payments to foreign doctors have also resulted in FCPA enforcement actions against DPC (Tianjin) Co. Ltd., a Chinese subsidiary of Diagnostic Products Corp., Micrus Corp., Syncor and Syncor Taiwan.

More recently, in April 2010, the DOJ and SEC each sent letters to at least four pharmaceutical companies and informed them that they are focusing on their practices in at least eight countries: Brazil, China, Poland, Russia, Saudi Arabia, Greece, Italy, and Germany. Since then, other healthcare-industry companies have disclosed that they have received FCPA-related inquiries. The government is reportedly investigating a number of potential FCPA violations, including paying government-employed doctors to purchase drugs, paying company sales agents commissions that are passed along to government doctors, paying hospital committees to approve drug purchases, and paying regulators to win drug approvals.

It appears that the government is making good on its word.

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