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Government FCPA Enforcement "Intensely Focused" on Life Sciences Companies

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On November 12, 2009, Lanny Breuer, Assistant Attorney General for the Criminal Division of the Department of Justice, warned that in the "months and years ahead," the Department of Justice will focus on "the application of the Foreign Corrupt Practices Act (or 'FCPA') to the pharmaceutical industry." Previous FCPA enforcement actions also have focused on medical device companies. Given this DOJ initiative, life sciences companies should actively review and reinvigorate their FCPA compliance efforts.

The FCPA Prohibits Foreign Bribery.
Put simply, the FCPA prohibits, among other things, the actual or attempted bribery of foreign government officials in order to assist in obtaining or retaining business. Potentially violative payments include cash, gifts, charitable donations, travel, meals, entertainment, grants, speaking fees, honoraria, and consultant arrangements. The FCPA does not contain a materiality threshold as to the size of the payment to the government official or the amount of business obtained. While there are some safe harbors for payments to foreign officials, these exceptions are narrowly construed and apply only rarely. The DOJ and Securities and Exchange Commission share FCPA enforcement responsibility.

FCPA Enforcement Efforts Will Focus on the Pharmaceutical Industry.
Mr. Breuer said that the government's "focus and resolve in the FCPA area will not abate, and we will be intensely focused on rooting out foreign bribery" in the pharmaceutical industry. Several attributes of this industry contribute to an increased risk for FCPA violations.

First, pharmaceutical sales outside the U.S. are significant and involve frequent contact with foreign government officials. Mr. Breuer noted that "close to $100 billion dollars, or roughly one-third, of total sales for [the U.S. industry] were generated outside of the United States, where health systems are regulated, operated, and financed by government entities to a significantly greater degree than in the United States."

Second, it is often difficult to identify foreign government officials in the health care industry. As well as

the obvious officials – e.g., health ministry and customs officials – foreign government officials may include the less obvious – e.g., doctors, pharmacists, lab technicians, and other professions employed by state-owned facilities. In December 2002, for example, Syncor Taiwan, Inc., settled criminal charges that it paid physicians employed by state-owned hospitals in Taiwan to induce the sale of radiopharmaceuticals. And in June 2008, AGA Medical Corporation settled criminal charges for payments it made to physicians employed by Chinese state-owned hospitals to induce the purchase of products to treat congenital heart defects.

Third, "fierce industry competition and the close nature of many public formularies" heightens the risk of illegal "short-cuts." Persuading foreign health care officials to purchase specific products may quickly turn to improper inducement, particularly in countries or cultures where a *quid pro quo* is commonplace or expected. For example, in June 2004, a large pharmaceutical company settled an SEC enforcement action alleging payments to the favorite charity of a Polish governmental official responsible for purchasing pharmaceutical products for the country's hospitals.

Fourth, some companies employ overseas intermediaries. These might take the form of joint ventures, distributors, agents, consultants, or other facilitators. Absent sufficient due diligence and controls, intermediaries can heighten FCPA risks. For example, a U.S. company settled civil FCPA charges resulting from payments of bribes to Iraqi officials by "consultants" based in Jordan and Lebanon. Companies may also be liable for the actions of their foreign subsidiaries. In May 2005, for example, a U.S. company and its Chinese subsidiary settled civil and criminal FCPA actions alleging that the subsidiary paid illegal "commissions" to employees of Chinese state-owned hospitals to induce the sale of diagnostic testing systems and kits.

FCPA Enforcement Also Focused on Medical Device Companies.
The DOJ's announcement that it intends to focus on pharmaceutical companies is not the government's first foray into FCPA enforcement in the life sciences area. Previous enforcement efforts also have involved medical device companies, as noted in several of the examples cited above. Additionally, in 2007 and 2008 both the DOJ and SEC investigated orthopedic implant manufacturers and payments to government-employed physicians in several countries, including Germany, Greece, and Poland. And in September 2007, the president and COO of Immucor, Inc., settled an SEC action alleging improper payments to the director of a public hospital in Italy in exchange for favorable consideration of a contract to provide blood analysis products and services.

FCPA Enforcement Matters Are Increasingly Numerous and Aggressive.
In the last five years, the SEC and DOJ brought an increasing number of FCPA cases. From 2005 to the present, the DOJ brought 57 cases, which Mr. Breuer explained is "more than the number of prosecutions brought in the almost 30 years between the enactment of the FCPA in 1977 and 2005." The SEC also brought more cases between 2005 and the present than it did in its prior history. According to Mr. Breuer, the government is currently pursuing more than 120 additional investigations. Both agencies, as well as the FBI, have developed specialized FCPA teams, and the DOJ will use the expertise of its health care fraud group to "significantly enhance[] [its] ability to proactively investigate and prosecute these often complex cases."

Resolving FCPA enforcement matters is increasingly expensive. Well-publicized recent FCPA settlements with the SEC and DOJ demonstrate that disgorgement of profits earned from business obtained through illegal bribery of foreign government officials, when added to civil and criminal sanctions, can cost hundreds of millions of dollars.

The SEC and DOJ are increasingly investigating and prosecuting individuals for FCPA violations. According to Mr. Breuer, "[e]ffective deterrence requires no less." The DOJ publicized several FCPA actions against individuals this year. SEC officials' public comments likewise stressed a willingness to pursue culpable individuals. In 2007, for example, the SEC settled with Monty Fu, the founding chairman of Syncor International Corp., nearly five years after, as described above, the company and its foreign subsidiary settled FCPA claims alleging improper commissions paid to physicians of state-owned hospitals. Likewise, in July 2009, the SEC filed a settled action that claimed that two officers were liable for their company's alleged FCPA violations solely because the officers were "control persons" over the company's internal controls and its books and records.

Life Sciences Companies Should Seek to Minimize Their FCPA Risks and Costs.
First and foremost, as Mr. Breuer noted, "every company should have a rigorous FCPA policy that is faithfully enforced." The policy must be more than mere paper. Companies must implement their policies globally and accompany them with frequent training, oversight, and testing. Companies should also support their policies with a compliance-oriented tone at the top. Failing to implement sufficient controls could result in greater FCPA liability. In May 2009, for example, a Maryland-based parent company was charged with violations of the FCPA in part because the company did not have sufficient controls to detect alleged illegal bribes approved and paid by its California-based subsidiary to Egyptian government officials.

Second, companies should seek to be as informed as possible about their overseas business. Companies should identify any government connections of individuals with whom they are dealing. And before hiring third parties, companies should gather as much intelligence as possible through background checks, interviews, and references. Specific contractual provisions prohibiting FCPA violations and allowing audits of the third parties may also help reduce risks.

Third, life sciences companies that discover potential FCPA issues should fully investigate and address the issues. Waiting for the government to discover issues on its own may compound the harm. Mr. Breuer recommended that companies "should seriously consider voluntarily disclosing the violation." Mr. Breuer and the SEC have both promised "meaningful credit" for self-disclosure of FCPA issues. Indeed, Mr. Breuer said that "a voluntary disclosure may result in no action being taken against a company, or the company may secure other preferred dispositions." Companies should also "seriously consider" cooperating with DOJ and SEC investigations. Again, both agencies repeatedly promised companies a "meaningful benefit" for their cooperation. Further, companies discovering FCPA issues should consider self-remediation. Both Mr. Breuer and the SEC promised that companies will "benefit" if they "remediate the problem and take steps to ensure that it does not recur."

Morrison & Foerster Provides Experienced Counsel in These Areas.
In today's environment, life sciences companies cannot afford to ignore potential FCPA matters. Morrison & Foerster can help life sciences companies craft, review, and implement a comprehensive global FCPA compliance program. And in the unfortunate event that a potential FCPA problem arises, Morrison & Foerster is well positioned to help life sciences companies work through the complex issues.
