

Managing Risk and Compliance Under the Foreign Corrupt Practices Act

David H. Laufman

White Collar Compliance and Litigation Partner
Kelley Drye & Warren LLP

The projected growth of the pharmaceutical industries in emerging markets such as China, Russia, India, and Brazil presents lucrative business opportunities for multinational pharmaceutical companies operating there. China's pharmaceutical market, for example, is growing annually by approximately 20 percent and – now valued at more than \$37 billion -- is predicted to become the world's fifth-largest pharmaceutical market by 2010. With those opportunities, however, come heightened risks. The pharmaceutical industry is under increased scrutiny by the Department of Justice ("DOJ") and the Securities and Exchange Commission ("SEC") for potential violations of the Foreign Corrupt Practices Act ("FCPA" or "Act"), and the business environment in many emerging markets is marred by a high incidence of official corruption. Given the severity of penalties for FCPA violations and the increasing internationalization of anti-corruption efforts, it is therefore critical for pharmaceutical companies to ensure that robust anti-bribery compliance and internal control systems are in effect to prevent and detect corrupt business practices.

The FCPA in a Nutshell

Anti-Bribery Provisions. Under the FCPA, it is a criminal offense to make a "corrupt" payment to a foreign official (or agree to make such a payment), regardless of the official's rank or position, for the purpose of obtaining or retaining business. The Act's anti-bribery provisions broadly apply to any individual, firm, director, employee, agent, or stockholder acting on behalf of the firm, including foreign nationals. U.S. parent corporations may be held liable for the acts of foreign subsidiaries if the parent authorized, directed, or controlled the activity in question; so, too, U.S. citizens or residents employed by a foreign subsidiary are subject to liability. Foreign companies that are "issuers" under the Securities Exchange Act of 1934 are covered by the FCPA and are also subject to liability if they cause, directly or through agents or other third parties, an act in furtherance of a corrupt payment to take place within the territory of the United States.

The FCPA prohibits payments through intermediaries in addition to direct payments to foreign officials. It is unlawful to make a payment to a third party – such as an agent, consultant, broker, or distributor – while knowing that all or a portion of the payment will be transmitted directly or indirectly to a foreign official. Moreover, conscious disregard and deliberate ignorance regarding payments by third parties may constitute actionable "knowledge" sufficient to impose criminal liability. Thus, it is essential for companies operating overseas to exercise due diligence and vetting of third parties, particularly in countries with a high incidence of corruption.

Only payments made with "corrupt" intent are prohibited by the FCPA, but any direct or indirect offer, payment, promise, or authorization intended to induce a foreign official to misuse the official's position may be deemed corrupt for FCPA purposes. The payment, offer, or promise of anything of value – including but not limited to money – triggers the FCPA's prohibitions if it is made with corrupt intent and for the purpose of obtaining or retaining business or "securing any improper business advantage." Payments to private parties unrelated to potential business with a foreign government are not unlawful under the FCPA. "Foreign officials," however, are broadly defined to include employees of state-owned enterprises as well as executive-branch officials, members of legislatures, political parties or their members, government employees, candidates for political office, and employees of international organizations.

Accounting Provisions. In addition to the FCPA's antibribery provisions, the Act requires publicly-held companies that are "issuers" under the Securities Exchange Act of 1934, as well as companies that hold American Depository Receipts, to adhere to specified accounting procedures to preclude the concealment of bribes. Specifically, covered entities must make and keep books and records "which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the issuer." Records must be kept in "such level of detail and degree of assurance as would satisfy prudent officials in the conduct of their own affairs." Examples of accounting practices that would violate the FCPA include purposefully recording payments to a foreign official

improperly, mislabeling bribes as “commissions” or other expenses, omissions of payment entries, or other misclassifications or mis-recordings of expenses.

Exceptions to Anti-Bribery Prohibitions. Actions to facilitate or expedite a “routine governmental action” – sometimes referred to as “grease payments” -- are not prohibited by the FCPA. Examples of such actions include obtaining permits, licenses, or other official documents; processing governmental papers such as visas and work orders; providing police protection, mail pick-up and delivery; providing telephone service, power, and water supply; loading and unloading cargo, and protecting perishable products; and scheduling inspections associated with contract performance or transit of goods across a country. However, any decision by a foreign official to award new business or continue business with a particular party, in connection with such a payment, would not constitute “routine governmental action.”

Affirmative Defenses to Anti-Bribery Violations. The FCPA contains two affirmative defenses to an alleged violation of the Act’s anti-bribery provisions. First, a person charged with a violation may assert as a defense that the payment was lawful under the written laws of the foreign country. Second, the person charged may assert that the payment, gift, offer, or promise of anything of value was a “reasonable and bona fide expenditure, such as travel and lodging expenses,” and was directly related to “the promotion, demonstration, or explanation of products or services.” The fact that it may be common in the culture of a particular foreign country to pay bribes to government officials is not an affirmative defense to an FCPA violation.

Penalties for Violations. Violations of the FCPA can result in substantial criminal and civil penalties. Companies convicted under the Act’s antibribery provisions are subject to a criminal fine of up to \$2 million per violation, while individuals face up to five years’ imprisonment and criminal fines of up to \$100,000 per violation. Criminal violations of the FCPA’s accounting provisions are subject to a fine of up to \$25 million, while individuals face up to a \$5 million fine and 20 years’ imprisonment. In addition, the SEC has authority to impose civil penalties of up to \$10,000 per violation.

Risks for Pharmaceutical Companies

According to the Department of Justice, approximately one-third of total sales of U.S. pharmaceutical companies (an estimated \$100 billion) is now generated outside the United States. Pharmaceutical companies operating overseas are particularly vulnerable to FCPA violations because of the nature of public health systems in many foreign countries and companies’ frequent reliance on intermediaries to market and distribute their products. As in the United States, pharmaceutical companies operating overseas target doctors, clinics, and hospitals for the sale of their products. In many countries, the health care system is owned or operated by the government, and doctors, hospital officials, laboratory technicians, and pharmacists are consequently viewed by DOJ and the SEC as government employees (and therefore “foreign officials”) for FCPA purposes. For example, in 2005, the Chinese subsidiary of Diagnostic Products Corporation pleaded guilty to FCPA violations for paying \$1.6 million to Chinese physicians and laboratory workers (in payments internally characterized as “commissions”) at government-owned hospitals in exchange for agreements that the hospitals would purchase the company’s products and services. Particularly in high-risk countries such as China, Russia, and the former Soviet republics, every juncture of interaction with medical personnel therefore entails a risk of improper payments – a risk compounded when intermediaries are involved in a transaction. Intense industry competition overseas adds to the possibility of improper transactions to win or retain business.

While monetary payments to foreign doctors or hospital officials in exchange for business clearly raise FCPA problems in government-run health care systems, non-monetary marketing is also problematic.

For example, gifts of free pharmaceutical samples and the payment of travel to conferences and educational seminars also can violate the FCPA when they involve foreign medical personnel and facilities. Even charitable donations can run afoul of the FCPA: In 2004, Schering-Plough Corporation settled an SEC enforcement action for a violation of the FCPA’s accounting provisions after the company’s subsidiary in Poland made a series of payments to a local Polish charitable foundation to induce the foundation’s president, who was a Polish government official, to influence the purchase of Schering-Plough’s pharmaceutical products.

Enforcement Trends

The last few years have seen the emergence of several trends in anti-bribery enforcement with implications for pharmaceutical companies.

Surge in Enforcement Actions. FCPA enforcement has become a top priority for the DOJ and the SEC, which jointly enforce the Act. In the first 20 years after the FCPA’s enactment in 1977, the government prosecuted only 17 companies, whereas, between 1998 and 2008, more than 50 companies were prosecuted. Approximately 120 FCPA investigations are currently open, and the DOJ and the FBI have augmented prosecutorial and agent resources to pursue FCPA cases.

The Department of Justice has publicly warned the U.S. pharmaceutical industry that it is now under enhanced FCPA scrutiny. In a speech on November 12, 2009, Assistant Attorney General Lanny Breuer, who is in charge of the Criminal Division responsible for FCPA enforcement, advised an audience of pharmaceutical officials of the particular FCPA risks confronting the industry and bluntly warned that “[o]ur focus and resolve in the FCPA will not abate, and we will be intensely focused on rooting out foreign bribery in your industry.

Recent SEC filings indicate that pharmaceutical companies Eli Lilly, AstraZeneca, and Bristol-Myers Squibb are currently the subject of FCPA investigation. AstraZeneca’s filing specifically disclosed that the SEC has requested documents concerning payments to doctors or government officials in Croatia, Russia, and Slovakia. In May 2009, Danish pharmaceutical giant Novo Nordisk agreed to pay the United States a \$9 million penalty, and to enter into a three-year DPA, in connection with illegal payments by its agents to the former Iraqi government to obtain contracts to provide insulin and other medicines.

Increased Prosecution of Individuals. Between 1977 and 1997, only 33 individuals were prosecuted. In contrast, between 1998 and 2008, the government charged more than 70 individuals with FCPA violations, including senior company officials.

Larger Financial Penalties. In December 2008, the German corporation Siemens AG and three of its subsidiaries (“Siemens”) pleaded guilty to FCPA violations resulting from approximately \$1.4 billion in payments to government officials and intermediaries in Asia, Africa, Europe, the Middle East, and South America. Siemens shattered all previous records by paying a criminal fine of \$450 million as well as disgorgement of profits totaling \$350 million (on top of approximately \$856 million in fines and disgorgement of profits imposed by the German government). Nor was the Siemens case an outlier: In February 2009, Halliburton subsidiary KBR agreed to pay a \$402 million criminal fine as part of a guilty plea to charges that it conducted a decade-long operation to bribe Nigerian government officials.

Greater International Cooperation. The FCPA is now part of a web of international anticorruption enforcement with which companies must contend. Nearly forty countries are signatories to the 1997 OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, and many have adopted domestic antibribery legislation. It was German authorities who initiated the Siemens investigation, and when Siemens pleaded guilty in the United States, the DOJ acknowledged that the unprecedented sharing of information and evidence between U.S. and German prosecutors was made possible by the use of mutual legal assistance provisions in the OECD Convention.

“Red Flags”

Information regarding any of the following circumstances should put companies on notice of a potential FCPA problem and prompt investigative action, especially in countries with a high incidence of bribery:

- Any gifts to foreign officials.
- Proposed agreements with individuals, companies, or organizations with ties to foreign officials.
- Unusual payment patterns or financial arrangements, such as payments to offshore accounts, accounts in the name of someone other than a vendor or business partner, or a bank or location not provided for in the agreement.
- Requests by intermediaries for unusually high commissions or payments.
- Inflated agent or vendor invoices.
- The refusal by a prospective foreign partner, agent, distributor, or representative to certify that it will not take any action in furtherance of an unlawful offer, promise, or payment to a foreign official.
- Sham agreements in which an agent, broker, vendor, or joint venture partner does not actually perform services, or performs services valued at substantially less than what the company is paying.
- Lack of transparency in expense and accounting records.
- Cash payments and payments drawn from accounts different from those appropriate for the type of payment at issue.
- Requests for payment for purposes not approved in an agreement.
- Proposed contributions to charities associated with foreign officials.
- Inadequate documentation for a payment request.

Best Practices

It is insufficient simply to have a written code of conduct that prohibits improper payments to foreign officials, particularly in the current enforcement environment. To prevent violations – and minimize the enforcement consequences if violations nonetheless occur – companies should implement the following prudential measures:

- Conduct risk assessments based on the incidence of corruption in the countries where they operate and the nature of interactions with foreign government officials by employees, agents, and distributors.
- Review sales and marketing operations in high-risk countries, particularly where there is dependence on third-party intermediaries.
- Translate the company code of conduct into the languages of each country where the company operates, and ensure that the translation is disseminated to employees, agents, and distributors there.
- Require company employees overseas – as well as foreign agents and distributors -- to receive interactive, Internet-based training in their native language, accompanied, where possible, by in-person training by company lawyers or ethics officials.

- Conduct rigorous vetting of foreign agents and distributors, including background checks with the U.S. embassy or consulate, and avoid hiring intermediaries with family or personal ties to foreign government officials.
- Require that foreign agents and distributors operate under written contracts that specify prohibited conduct under the FCPA, and obtain signed certifications that they understand and will comply with those provisions.
- Audit expenditures by agents and distributors more frequently and at random, particularly in high-risk countries.
- Eliminate compensation systems for agents and distributors that create potential incentives for corrupt payments to foreign officials, such as success fees.
- Require prior legal approval for anything that is, or could be construed as, a payment to a foreign official -- particularly gifts and entertainment expenses -- and ensure that such payments, if made, are fully and accurately documented in the company's books and records. Although permitted under the FCPA, “facilitating” payments to foreign officials to expedite “routine governmental functions” -- such as payments to obtain permits or license to do business in a foreign country, or to process visas and work orders -- should be prohibited to avoid even the appearance of impropriety.
- Examine the adequacy of confidential reporting mechanisms (such as a “hotline” or special website) for individuals to report allegations of corruption, and act upon credible allegations of wrongdoing in a timely manner [1].

Final Considerations

Company personnel should be encouraged to consult with in-house compliance counsel whenever they have questions about the propriety of an action under the FCPA. If timely and appropriate, companies may consider seeking a confidential opinion from the DOJ regarding proposed business conduct, as provided by regulation. Any conduct for which the DOJ issues an opinion finding the conduct lawful under current enforcement policy is entitled to a presumption of conformity with the FCPA in the event of a future enforcement action. Finally, in the event that a violation is discovered, it is essential to conduct a prompt and thorough investigation – ideally, by outside counsel -- to establish the relevant facts, institute remedial action, and assess whether to make a voluntary disclosure to the government.

References

1. *The “Best Practices” section originally appeared in an article by David H. Laufman in Life Science Leader, June 2009.*

David H. Laufman, a white-collar compliance and litigation partner in the Washington, D.C. office of Kelley Drye & Warren LLP, previously served as Assistant U.S. Attorney for the Eastern District of Virginia and as Chief of Staff to the Deputy Attorney General of the United States.

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