

The Foreign Corrupt Practices Act and Clinical Research

By Darshan Kulkarni

Companies expanding into emerging markets like Russia, India and Thailand are often asked for payments called commissions, tips, facilitation fees, finder's fees, baksheesh or palm-greasing. While such payments are considered unethical bribes in the U.S. and many other developed countries, they are accepted business practices in many developing countries. Refusing to make such payments can interfere with business objectives and mystify people who are only operating according to their local customs. Nevertheless, the U.S. Foreign Corrupt Practices Act (FCPA) (and its United Kingdom counterpart, the Bribery Act) make it unlawful to engage in such behavior anywhere in the world.

In 2010, at the Pharmaceutical Regulatory and Compliance Congress's annual forum, Assistant Attorney General Lanny Breuer stated that the Department of Justice (DOJ) "will be intensely focused on rooting out foreign bribery in [the pharmaceutical and biotech industry]... That will mean investigation and, if warranted, prosecution of corporations to be sure, but also investigation and prosecution of senior executives."¹ In line with his comments, there are several ongoing investigations of life science companies. Until recently, there have been no enforcement actions; however, on March 26, 2012, the DOJ entered into FCPA deferred prosecution agreements with Biomet, Inc.², and Johnson & Johnson.³

The FCPA

The FCPA makes it unlawful for a broad range of companies and their representatives to make "corrupt payments" to foreign government officials in connection with obtaining or retaining business. The anti-bribery provisions of the FCPA typically apply to all U.S. companies and persons, and to foreign companies and individuals who work on behalf of U.S. individuals and companies. In other words, delegating bribery to a foreign intermediary does not shield anyone from the FCPA, even if the U.S. individual entity did not authorize or have knowledge of the payments. The only protections are to not make such payments and to take proper actions to prevent them from being made by third parties.

Impact of the FCPA

Corporations and other business entities are subject to a fine of up to \$2 million per violation. Officers, directors, stockholders, employees and agents are subject to a fine of up to \$100,000 and imprisonment for up to five years. Moreover, under the Alternative Fines Act of 1987 (18 USC 3571(d)), these fines may be much higher, possibly up to twice the benefit the defendant sought to obtain by making the corrupt payment. In addition, fines imposed on individuals may not be paid by their employer or principal.⁴

Impact on Life Sciences Companies

Potential FCPA violations should be a concern for all companies with global operations in the pharmaceutical, biopharmaceutical and medical device industries (collectively, "the Life Sciences Industry" in this article).

In November 2009, Assistant Attorney General Lanny Breuer predicted that U.S. companies, including those in the Life Sciences Industry, will have an increased risk of "paying to play." He then charged that government prosecutors would impress the seriousness of such payments by prosecuting not only the corporations but also senior executives, and would work to have the individuals sent to prison.⁵ Since then, the DOJ has stepped up

enforcement, with several life sciences companies under examination. The DOJ has also recently stepped up use of the Park doctrine, and it is certainly applicable in FCPA enforcement.⁶

The risk of an FCPA violation increases when Life Sciences Industry personnel do not recognize their exposure to agencies other than the Food & Drug Administration (FDA). The FCPA is primarily administered by the U.S. Department of Justice (DOJ), which works in conjunction with the U.S. Attorney General's Office, the U.S. Securities and Exchange Commission (SEC) and the FDA on these matters. Potential violations typically come to the attention of these agencies through whistleblowers, including competitors and disgruntled current and former employees who might have been personally involved in the illegal activities.

Most individuals aware of the FCPA recognize that providing a bag of cash to a high-ranking politician to curry favor would likely fall afoul of the law. However, under the FCPA, the term "foreign official" is expansively read to include essentially any government employee. In clinical research, they may also include physicians, lab technicians, procurement officers, pharmacists, nurses and other healthcare workers at state-owned or controlled hospitals and healthcare systems. In the context of a clinical trial, this broad definition of "officials" means that many kinds of payments could violate FCPA. For example, the DOJ's recent deferred prosecution agreement with Biomet cited emails from 2005 indicating that payments made to physicians conducting clinical trials were inappropriately recorded as "entertainment" in the company books, and the doctors were also paid a 10-15% "consulting fee."⁷

The following are potential areas of exposure of life sciences companies to FCPA violations:

Regulatory Submissions

Obtaining the required governmental approvals for a clinical study can be a bureaucratic nightmare, so it can be tempting to speed the process by paying government officials. Local contract research organizations (CROs) and consultants tasked with obtaining the approvals may take it upon themselves to do so. It is critical to recognize that such payments, whether directly by study sponsors or indirectly via intermediaries, may violate the FCPA.

Seeding Trials

Seeding trials are "marketing in the guise of science." The main goal of a seeding trial is not to get high-quality scientific information but to change the prescribing habits of physicians. A secondary purpose is to convert physicians into advocates for the sponsor's drug. The company flatters physicians by selecting them as "opinion leaders" and incorporating them into the research team with the title of "investigator." It then pays them well with study and, perhaps, consulting fees. Unwittingly, the physician joins the sponsor's marketing team.⁷ While such payments to influence physicians may not, *per se*, be illegal, they expose sponsors to the risk of violating the FCPA if the physicians are governmental employees, similar to violations of the Anti-Kickback Statute.

Authorship

Clinical trials are often the first experiences healthcare providers have with novel pharmaceuticals. Having fellow physicians or healthcare providers discuss their experiences with a drug can often provide evidence of the appropriate use of the drug, and experiences by influential healthcare providers often carry more weight. Journal articles are thus useful to convince a physician to prescribe the new drug. As a result, journal articles not only help facilitate an appropriate scientific discussion, but also may be used by some sponsors for marketing purposes.

Some sponsors ask influential physicians to become authors on journal articles merely to influence the author and use the author's reputation to generate greater sales. Under the FCPA, a bribe includes "anything of value." Since authorship can be prestigious and may lead to pay raises for faculty members, such actions may constitute bribery.

Steps to Ensure Compliance

To avoid possible multimillion-dollar fines, civil and administrative penalties, and significant compliance burdens, companies must ensure that they comply with FCPA regulations. Assistant Attorney General Breuer pointed out that it is critical to have an appropriate and adequate compliance program in place, including an ongoing system of reviewing existing policies and procedures, auditing the results of these procedures, and conducting appropriate training.⁵ In addition, contracts with intermediaries should include explicit prohibitions with severe penalties for any violation. Regular audits should cover not only appropriate contractors but also subcontractors. For study sponsors, this group includes global CROs, subcontracted CROs, and "facilitators." Sponsors should not only review financial documents, but also conduct gap analyses and risk assessments. Some potential "red flags" include the following:

- Requests for payments to be paid to an account in a third-party country, to a third-party individual or entity, or in cash or untraceable funds
- Claims of influence with political or government contacts as opposed to knowledgeable staff and investment of time to promote the company's interests
- Requests to keep third-party representation secret
- Invoices for large entertainment, consulting or other suspicious expenses
- News reports or rumors of illicit payments

These red flags may have innocent explanations, especially if the foreign party is unfamiliar with U.S. business practices.

Conclusion

The FCPA, until recently, was a theoretical risk for Life Sciences Companies. It was thought that the DOJ would initially focus on large pharma, but the recent deferred prosecution agreements against J&J and Biomet and current ongoing investigations indicate that both drug and device companies of various sizes may be targeted. Further, as the Biomet example above illustrates, FCPA investigations can look back several years. In addition, even FCPA investigations that focus on product sales to foreign governments can extend to clinical trial activities. Life sciences companies should recognize these risks and proactively address these concerns with strong compliance programs.

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