

Top 10 Things Life Sciences Companies Need to Know About the FCPA

1. The Foreign Corrupt Practices Act (FCPA) is a federal criminal law that prohibits foreign bribery.
2. FCPA enforcement has been very aggressive in the life sciences industry. By way of example, the following companies have announced the following FCPA resolutions with the U.S. regulators: Biomet (>\$22 million); Eli Lilly (>\$29 million); Johnson & Johnson (>\$60 million); Stryker (>\$13 million).
3. The FCPA applies to any U.S. citizen, U.S. company, any company listed on a U.S. exchange or otherwise classified as a U.S. "issuer," as well as to anyone who takes steps in furtherance of a foreign bribery scheme in the United States.
4. U.S. companies and individuals can be held liable under the FCPA for bribery that occurs anywhere in the world, even by a foreign subsidiary.
5. The FCPA applies to bribes paid directly or indirectly – *improper payments made by agents, consultants, brokers and distributors can subject companies to FCPA liability.*
6. Individual executives have been and continue to be criminally prosecuted and imprisoned for participating in or knowing about foreign bribery schemes. The U.S. Department of Justice has indicated that it intends to pursue individual prosecutions even more aggressively in the future.
7. Any payment or provision of something of value to a "foreign official" implicates the FCPA. "Foreign official" is interpreted broadly to include many non-U.S. persons with whom life sciences companies routinely interact—including, in many cases, hospital administrators, doctors, nurses, and pharmacists.
8. The FCPA does not just prohibit payments to foreign officials. Providing "anything of value" to a foreign official—including providing excessive or lavish gifts, meals, entertainment, hiring friends and relatives, and even charitable donations—implicates the FCPA.
9. There is an important exception to the FCPA that permits reasonable and bona fide payments that are *directly related to* (1) the promotion or demonstration of the company's products or services or (2) the negotiation, execution, or performance of a contract.
10. U.S. enforcement agencies have identified three common fact patterns that have led to FCPA liability for life sciences companies: (1) pay-to-prescribe schemes involving payments to doctors or other health care providers designed to influence their choice of pharmaceutical or medical device; (2) payments to get drugs or medical devices on an approved government insurance reimbursement list or formulary; and (3) bribes disguised as charitable contributions.

CONTACT:

David W. Simon
Partner
Foley & Lardner LLP
414.297.5519
dsimon@foley.com

