Foreign Corrupt Practices Act (FCPA) Alert: The DOJ's FCPA Crackdown on the Pharmaceutical and Medical Devices Industry

9/23/2010

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The Foreign Corrupt Practices Act (FCPA), first enacted in 1977, prohibits issuers, domestic concerns, and foreign persons acting within the U.S. from corruptly making payments to foreign government officials in exchange for assistance in obtaining or enhancing business.[1] Additionally, the FCPA requires all U.S. companies to maintain internal accounting controls and precise records of its transactions.[2]

In the last few years, companies have increasingly come under fire for FCPA violations. On November 12, 2009, Lanny A. Breuer, Assistant U.S. Attorney General in charge of the Criminal Division for the United States Department of Justice (DOJ), was the keynote speaker at the 10th Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum. At the forum, Breuer stated that "one area of criminal enforcement that will be a focus for the Criminal Division in the months and years ahead [is] the application of the Foreign Corrupt Practices Act…to the pharmaceutical industry." Breuer added that not only corporations but also individual executives would be subject to enforcement efforts under the FCPA.

Additionally, on the same day that Assistant U.S. Attorney General Breuer made his speech, the Chief of the U.S. Attorney's Office for the District of New Jersey for the Criminal Division, Charles McKenna, spoke as a panelist at the American Bar Association's presentation "Current Issues in Medical Device and Pharmaceutical Litigation." At the event, McKenna stated that the FCPA had become the DOJ's main priority, second only to terrorism, and he added that the medical device industry, in addition to the pharmaceutical industry, would be subject to DOJ scrutiny. (http://www.mddionline.com/article/no-doctoring-books).

The following is a summary of the ways in which the FCPA has been, and will likely continue to be, directed against the pharmaceutical and medical device industries.

Recent Events Involving the FCPA and Health Care

By the end of April 2010, a number of pharmaceutical companies had been issued letters of inquiry by the DOJ and the Securities and Exchange Commission (SEC). These letters demonstrate the increased FCPA scrutiny being applied to prominent U.S. pharmaceutical companies.

Additionally, pharmaceutical companies have disclosed DOJ and SEC investigations in regulatory filings. For example, on August 5 and 6, 2010, SciClone Pharmaceuticals Inc.

disclosed in their 10-Q filing for the quarterly period ended June 30, 2010 that the company is under investigation by the DOJ and SEC regarding "the Company's sale, licensing, and marketing of its products in foreign countries, including China." The filing adds that the Company intends to cooperate with the investigation and has appointed a special committee of independent directors to supervise the Company's efforts. (http://sec.gov/Archives/edgar/data/880771/000119312510183318/d10q.htm#tx36842_11 – pages 13, 21, and 28).

More Investigations and Prosecutions to Come

The DOJ and SEC have been marshalling and coordinating resources to advance their FCPA investigations. In an August 6, 2009 speech delivered to the Bar Association of the City of New York, SEC Enforcement Director Rob Khuzami announced the creation of a new specialized FCPA unit at the SEC. The SEC's new FCPA unit will help the DOJ Fraud Section's experienced prosecutors ferret out violations of the FCPA. Moreover, within DOJ, the health care fraud unit is working in tandem with the FBI's FCPA unit to provide the necessary industry knowledge to identify corrupt practices in the pharmaceutical industry, according to Assistant U.S. Attorney General Breuer in his November speech.

The FBI is supporting these efforts. In 2008, the FBI created the International Corruption Unit (ICU) to "oversee the increasing number of corruption and fraud investigations with an international nexus requiring extensive coordination with FBI field offices, legal attaché offices, U.S. federal agencies, and the law enforcement agencies of host countries. Specifically, the ICU oversees International Contract Corruption Task Force matters, FCPA investigations, and antitrust investigations." (http://www.fbi.gov/congress/congress10/perkins052410.htm).

In sum, three prominent, powerful federal enforcement agencies have dedicated resources and are coordinating for maximum impact, foreshadowing prosecutions in this area.

Reasons Behind the Government DOJ Initiative Regarding the FCPA and Health Care

In his November 12th speech, Breuer explained that FCPA enforcement, specifically with respect to the pharmaceutical and medical device industries, has grown tremendously over the past two years. This is because most pharmaceutical companies that sell products overseas will interact with foreign officials on a regular basis. Breuer cited PhRMA's 2009 Membership survey, which revealed that almost $100 billion, close to one-third of PhRMA members' total sales, has been generated outside of the United States. Moreover, the DOJ is taking an expansive view of who is considered a foreign official. Breuer noted that "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."

An additional reason for this FCPA focus on the health care industries is undoubtedly the number of clinical trials conducted abroad. The Department of Health and Human Services'

Office of Inspector General released a June 2010 report noting that "between 40 percent and 65 percent of clinical trials investigating FDA-regulated products are conducted outside the United States…The 20 largest United States-based pharmaceutical companies were conducting one-third of their clinical trials exclusively at foreign sites." The report went on to note that "80 percent of approved marketing applications for drugs and biologics contained data from foreign clinical trials." Moreover, 78% of all participants in clinical trials were enrolled at foreign sites with 54% of all trial sites located outside the U.S. (http://oig.hhs.gov/oei/reports/oei-01-08-00510.pdf -page i, ii, 1, and 10).

Consistent with these findings, numerous government agencies have been concentrating their efforts on finding and eradicating fraudulent or otherwise illegal activity by the pharmaceutical and medical device industries whose main business is often done on foreign soil, and we can assume this focus will continue.

What Your Pharmaceutical or Medical Device Company Should Do

In light of the increased FCPA focus on the pharmaceutical and medical device industries, companies need to utilize all available measures to ensure that they are compliant with all applicable rules and regulations. That means:

- For publicly traded health care companies, ensuring sufficient integration of Sarbanes-Oxley and FCPA compliance
- Creating for, distributing to, and ensuring receipt of FCPA guidelines by all employees (including those overseas) regarding all aspects of the FCPA
- Analyzing the extent to which FCPA compliance needs to be implemented for foreign subsidiaries and affiliates under theories of extended U.S. jurisdiction articulated in recent settlements with DOJ
- Having and utilizing standardized documentation and contractual terms for all foreign entities and personnel working with the company wherein they agree to comply with FCPA regulations
- Training new employees regarding the FCPA at the time of hiring and yearly training of all employees
- Performing due diligence and oversight of third parties, including consultants, distributors, and clinical research organizations, both before establishing a relationship and on an ongoing basis thereafter
- Identifying and thoroughly investigating any FCPA-related issues relating to a target of any merger, acquisition, or joint venture
- Encouraging employees to come forward with any information they come across regarding abuse, fraud or other efforts to hide the nature or purpose of any transaction
- Instituting effective mechanisms to address any suspicious or fraudulent activity
- Developing and acting on compliance risk assessments
- Auditing and ensuring adherence to internal controls
- Evaluating whether it is prudent to report to DOJ and/or SEC any issues arising from due diligence or a transaction

Conclusion

Since Assistant U.S. Attorney General Breuer's November 12th speech, we have seen time, money, resources, and manpower devoted to uncovering and prosecuting FCPA violations, especially those occurring in the health care industry. There is no sign that the government's focus on FCPA violations will diminish; therefore, companies need to focus on their compliance efforts. Breuer acknowledged that "internal investigations and remedial measures may be costly. But the costs of not doing the responsible thing can be much higher."

Endnotes

[1] 15 U.S.C. §§ 78dd-1, 78dd-2, 78dd-3.

[2] 15 U.S.C. § 78m(b).

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