

Government's Industry Focus Puts Pharma Executives at Risk

DOJ Outlines Aggressive FCPA Agenda Focused on Pharmaceutical and Medical Device Companies

I. INTRODUCTION

Enforcement of the U.S. Foreign Corrupt Practices Act (FCPA) is at an all time high, targeting individual executives and board members as well as companies. Lanny A. Breuer, Assistant Attorney General of the Criminal Division, Department of Justice, made two separate speeches last month emphasizing the DOJ's focus on the pharmaceutical and medical device industries for potential FCPA violations. Mr. Breuer remarked that the DOJ, in collaboration with the FBI, IRS, FDA and other governmental agencies, is currently pursuing more than 130 active investigations. In the past year, four U.S. executives and a congressman have been convicted of FCPA violations and face substantial fines and prison sentences.

Mark Mendelsohn, the DOJ's top FCPA prosecutor, recently stated: "The number of individual prosecutions has risen – and that's not an accident. That is quite intentional on the part of the Department. It is our view that to have a credible deterrent effect, people have to go to jail. People have to be prosecuted where appropriate. This is a federal crime. This is not fun and games."

In the face of this increased scrutiny and rising individual liability, you need to consider how to help protect yourself and your organization from federal prosecution. How confident are you that your foreign subsidiaries and affiliates are not breaching FCPA protocols? What are your enterprise liabilities? What controls have been implemented governing the actions of your agents, distributors and other third parties acting on your behalf? What can you do to assure that your board members, executives and employees are not targeted for prosecution?

If you know the answers to these questions, you will not only be in a much better position to respond to any government inquiries but you will be seen as proactively trying to deal with FCPA issues. The procedures and controls you establish regarding FCPA compliance are critically important factors in influencing the government's decision as to whether to bring charges of FCPA violations.

II. FOCUS ON PHARMA

After warning that the DOJ will be vigilant in holding pharmaceutical and medical device companies and individuals who break the law accountable under civil and criminal statutes, Mr. Breuer began his November 12, 2009 remarks before the Tenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum by citing a 2009 industry survey revealing that pharmaceutical companies generate approximately one-third of their total revenue, about \$100 billion dollars, from sales outside the U.S. He asserted that because many health systems outside the

U.S. are regulated, operated and financed by foreign governments “...it is entirely possible...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..” Mr. Breuer warned that companies should carefully reconsider the range of individuals who could be deemed “foreign officials” under the FCPA—from the health minister to a lab technician at a government-owned hospital. “The depth of government involvement in foreign health systems, combined with fierce industry competition...creates a significant risk that corrupt payments will infect the process.”

The Administration’s response has been to team prosecutors from the DOJ’s Fraud Section and an elite FBI squad dedicated to investigating and prosecuting FCPA cases with prosecutors from the DOJ’s Healthcare Fraud Unit. The latter is comprised of people who have the pharmaceutical and medical industry knowledge necessary to identify potentially corrupt practices at all stages—discovery, development, approval, manufacturing, sales and surveillance of products. In Mr. Breuer’s words, this team “...stand[s] ready to ferret out...illegal conduct” in overseas pharmaceutical and medical device sales and clinical trials. Mr. Breuer emphasized that the DOJ’s “...focus and resolve in the FCPA area will not abate,” and he warned that “...culpable individuals must be prosecuted and go to jail.”

Five days later, in a speech on November 17, 2009, Mr. Breuer strongly reinforced the DOJ’s position that the prosecution of individuals (company employees, executives and board members), is a “cornerstone” of the DOJ’s enforcement policy, calling the prosecution of FCPA violations in the pharmaceutical industry “the road ahead.”

Recent prosecutions have been brought against individuals under the securities law concept of “control person liability” and the legal concept of “willful blindness.” “Control person liability” allows the government to hold senior executives responsible for the actions of employees and officers of foreign subsidiaries over which the executives have oversight; “willful blindness” pertains to whether a reasonable person knew or should have known of the illegal acts that took place. Both of these concepts give rise to the question of how confident you are that bribery isn’t taking place in your supply chain and whether you can be held accountable if it is.

III. IMPLICATIONS FOR EXECUTIVES AND BOARD MEMBERS OF PHARMACEUTICAL AND MEDICAL DEVICE COMPANIES

Pharmaceutical and medical device companies and their boards should immediately review their corporate compliance functions to ensure that their FCPA compliance program is sufficiently robust and provides employees, corporate executives and board members with adequate guidance on permitted or prohibited conduct at all stages of product development, manufacturing, and sales. In addition, senior management should take steps to ensure that the FCPA compliance program is faithfully enforced. Specifically, an effective FCPA compliance program should be risk-based and include the following:

- A. *Enterprise Level Bribery Risk Assessment* that uses technology to flag potential bribery risks associated with high risk third parties, such as agents, distributors, resellers,

consultants, suppliers, and joint venture partners and the geographic locations in which the company operates.

- B. *A System of Policies and Procedures* containing a clearly articulated policy against bribery and corruption and a code of conduct for all employees. The procedures should identify the responsibilities of the firm's senior compliance officer, clearly identify permitted and prohibited conduct at all product stages (discovery to sales) and require documented evidence that the procedures were followed.
- C. *An Internal Financial Controls System* to ensure that all payments, such as reimbursements, expenditures, gifts, promotional materials, samples and in-kind transactions are accurately recorded in the organization's books and records.
- D. *A Compliance Monitoring Program* that periodically audits the effectiveness of the compliance program.
- E. *Training* for all employees and board members and *Training Materials* clearly and concisely interpreting applicable legal, regulatory, policy and procedural requirements and the potential penalties of non-compliance.
- F. *A "Hotline" Program* for receiving allegations of bribery and corruption, as well as a system to thoroughly investigate such allegations and document actions taken with respect to complaints and investigations.

As Mr. Breuer noted, "the costs of not doing the responsible thing can be much higher—including significant criminal fines for the corporation, unwanted negative publicity, a potentially devastating impact on stock price and possible exclusion from Medicare and Medicaid."

The FDA is also a key participant in this compliance area and continues to warn firms that their people, up to and including board members, can be prosecuted for violations under the FD&C Act even if they were not aware of wrong doing. Since the FDA reviews discovery to post-marketing surveillance of drugs and devices, it frequently refers appearances of violations of the Act, FCPA, and federal healthcare programs to OIG (HHS) for further action.

IV. HOW DAYLIGHT AND LACHMAN CAN HELP

Daylight Forensic & Advisory and Lachman have teamed together to bring their own, deep subject matter expertise on the FCPA, international investigations, regulatory compliance and the pharmaceutical and medical device industries to help clients who are concerned about potential FCPA liability in the face of this new industry-wide prosecutive initiative.

The direct involvement of foreign governments in the healthcare industry and the government's newly announced industry focus amount to a perfect storm of FCPA risks for international pharmaceutical and medical device companies.

Adding to this risk is the importance of travel and entertainment in the marketing of products in the pharmaceutical and medical device sectors and the importance of China to both industries. Entertaining medical professionals or healthcare employees of government owned companies at events, seminars or dinners can lead to liability under the anti bribery provisions of the FCPA. China, a gift-giving culture in which most health care institutions are government owned, can be particularly challenging for those companies trying to comply with the FCPA. Companies are well advised to develop different practices for entertainment and gift exchange in dealing with employees and physicians of government owned entities.

Developing, procuring, manufacturing and/or selling pharmaceutical products and medical devices abroad often depends on interaction with and decisions made by a “foreign official,” whose status as such may not be readily apparent. Therefore, it is critical that any organization conducting business in a foreign country understand the provisions of the FCPA, implement an effective FCPA compliance program, conduct periodic and ongoing due diligence investigations of third party business partners (such as agents, distributors, and resellers), perform periodic FCPA risk assessments and conduct FCPA training to ensure compliance with applicable regulatory requirements.

Daylight Forensic & Advisory has unparalleled FCPA and anti-corruption expertise, Daylight has developed and implemented enterprise level, automated third party risk assessment and due diligence systems and programs, training programs, conducted investigations and assessed and enhanced compliance programs, including internal controls systems, for some of the world’s largest companies.

Lachman Consultant Services, Inc. has exceptional knowledge and experience in all aspects of pharmaceutical and device compliance, regulatory and science and technology matters, covering discovery, development, filing and approval, manufacturing, distribution and post- marketing surveillance. Lachman works with global pharmaceutical and device firms to develop, implement, audit and remediate systems and controls for corporate compliance programs.

If you would like further information on how Daylight and Lachman can better prepare your organization to address its FCPA compliance, please contact Joseph Spinelli, Chief Operating Officer, at (212) 554-2603, jspinelli@daylightforensic.com or Scott Moritz, Executive Director, at (212) 554-2626, smoritz@daylightforensic.com.
