DOJ Criminal Chief's Recent Speech Foreshadows Increased FCPA Prosecutions and Reminds Companies to Implement and Follow Best Practices

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On November 12, 2009, Lanny A. Breuer, the Assistant Attorney General in charge of the Criminal Division for the United States Department of Justice (DOJ), gave the Keynote Address at the Tenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum. His message was loud and clear: DOJ enforcement of the Foreign Corrupt Practices Act (FCPA) is going to become even more aggressive, and the health care industry is the next target.

What follows is a summary of the warning issued by Mr. Breuer, and our perspectives on how pharmaceutical and medical device companies must proceed if they are to avoid being ensnared in one of these expensive prosecutions.

DOJ's Increased Focus on FCPA Prosecutions

Mr. Breuer is very direct about the reason for the push on FCPA against pharmaceutical and medical device companies, the great breadth and scope of the FCPA, and the teamwork and expertise that will be brought to bear.

According to the organization's 2009 survey, $100 billion or approximately 1/3 of total sales for members of The Pharmaceutical Research and Manufacturers of America (PhRMA) was generated outside the United States. Moreover, to date, there has been a higher level of official involvement in the health care industry overseas. As Mr. Breuer put it, there may be a temptation or invitation to pay off foreign officials for profit.

The FCPA is very broad in its reach. First, let's quickly review the basics. The anti-bribery provisions of the FCPA prohibit issuers, domestic concerns and foreign persons acting within the U.S. from: corruptly using the mails or any means or instrumentality of interstate commerce in furtherance of a payment, agreement to pay, or offer to pay money or anything of value to any foreign official, foreign political party, political party official, candidate for political office or any known conduit for the purpose of influencing any act or decision of such foreign official in his official capacity, inducing any act or omission to act by such person in violation of his lawful duty or securing an improper advantage to assist in obtaining or retaining business. 15 U.S.C. §§ 78dd-1(a), 78dd-2(a) and 78dd-3a.

What does this mean in terms of FCPA enforcement with respect to pharmaceutical and medical

device companies? If your company has a class or securities subject to the registration and reporting requirements of the SEC, or has its principal place of business in the U.S., it is covered by the FCPA. Moreover, directors, officers, employees, or agents of the issuer or domestic concern fall within the statutory ambit.

The object of the bribery—i.e., the foreign official, or any officer or employee of a foreign government, department, agency or instrumentality—is similarly broadly defined. As Mr. Breuer stated, "Some are obvious, like the health ministry and customs officials of other countries. But some may not be, such as the doctors, pharmacists, lab technicians and other health professionals who are employed by state-owned facilities. Indeed 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." (Emphasis added).

The form of the FCPA-violative payment may include "cash, gifts, charitable donations, travel, meals, entertainment, grants, speaking fees, honoraria, and consultant arrangements, to name a few."

DOJ Strike Force Approach

Mr. Breuer was also direct about DOJ's approach: It has already dramatically increased its prosecution of FCPA cases in the last few years. The Criminal Division's Fraud Section has a specialized FCPA unit, and the FBI has a dedicated FCPA Squad. DOJ and the FBI are already working together with the Securities and Exchange Commission (SEC). (In an August 6, 2009 speech to the Bar Association of the City of New York, SEC Enforcement Director Rob Khuzami announced a new specialized FCPA unit at the SEC.). DOJ is also working with its international counterparts, such as in the Siemens investigation.

Additionally, DOJ's FCPA unit and its health care fraud unit "are already beginning to work together to investigate FCPA violations in the pharmaceutical and device industries in an effort to maximize our ability to effectively enforce the law in this area," according to Mr. Breuer.

What Your Pharmaceutical or Medical Device Company Must Do

Mr. Breuer articulated three protective steps that your company can take to best position itself in this era of increased FCPA enforcement:

- "a rigorous FCPA compliance program that is faithfully enforced"
- serious consideration of voluntarily disclosing any FCPA violation it discovers and cooperating with DOJ in an investigation
- remediation of any problem and implementation of steps to prevent its recurrence.

We would add that part and parcel of the first bullet point is that the tone from the top must be one of a global culture of integrity, there must be meaningful training on the compliance program, and there must also be monitoring of employees' adherence to compliance dictates and zero tolerance for violations.

The Cost

Mr. Breuer acknowledges that the cost of internal investigations and remedial measures may be high, but cautions that "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 prices, and possible exclusion from Medicare and Medicaid." He states that, on the other hand, voluntary disclosure can result in no action being taken against the corporation, a non-prosecution or deferred prosecution agreement, or a reduced fine under the Sentencing Guidelines. Engagement of a compliance monitor may also be part of the deal. But Mr. Breuer's point is that it makes good business sense to take the steps noted above because the costs will otherwise be greater.