CLIENT ALERT

Pharmaceutical and Medical Device Industries are The Top Targets for Foreign Corrupt Practices Act ("FCPA") Enforcement

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According to nearly simultaneous statements made by three senior Justice Department officials on November 12, 2009, the Justice Department is planning to focus more criminal enforcement against the pharmaceutical and medical device industry's interaction with foreign officials.

First, Assistant Attorney General Lanny Breuer, addressing the 10th Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum in Washington, D.C., said "I would like to share with you this morning one area of criminal enforcement that will be a focus for the Criminal Division in the months and years ahead - and that's the application of the Foreign Corrupt Practices Act (or "FCPA") to the pharmaceutical industry." He noted the depth of government involvement in foreign health care systems and said it creates a "significant risk that corrupt payments will infect the process." Breuer also noted that enforcement will not stop at corporations—but that senior executives would also find themselves in DOJ's sights. Justice prosecutors, Breuer said, "will be intensely focused on rooting out foreign bribery in your industry. That will mean investigation and, if warranted, prosecution of corporations, to be sure, but also it will involve investigation and prosecution of senior executives." Overall, he said that the Justice Department is pursuing more than 120 FCPA investigations in cooperation with the FBI and the Securities and Exchange Commission. This is a ten-fold increase in FCPA investigations over past years.

Second, Assistant Attorney General Tony West, Chief of Justice's Civil Division, called health care fraud "a multibillion-dollar problem. And it's simply unacceptable." West, who also addressed last Thursday's Pharmaceutical Compliance Conference, said that he recently testified before the Senate Judiciary Committee that enforcement will not be limited to corporate actors. "In those cases where the facts and law allow us to pursue criminal cases against individuals responsible for illegal conduct, we will do so," West said.

Third, Charles McKenna, Chief, Criminal Division, U.S. Attorney's Office for the District of New Jersey, echoed that the pharmaceutical and medical device industries were DOJ's top new FCPA enforcement priority last Thursday as a panelist in the American Bar Association's Program, "Current Issues in Medical Device and Pharmaceutical Litigation," held at the Schering-Plough Corporation in Kenilworth, New Jersey. Importantly, Mr. McKenna noted that FCPA enforcement trailed only terrorism as a DOJ enforcement priority.

The FCPA as the International Application of the Healthcare Anti-Kickback Statute

The Justice Department views the FCPA as the natural extension of the Healthcare Anti-Kickback Statutes to international markets. Many prosecutors view the application of the FCPA in the pharmaceutical and medical device industries as essentially extra-territorial enforcement of the Stark Anti-Kickback laws. Indeed, Assistant Attorney General Breuer noted during his speech that, "I can tell you that the types of corrupt payments that violate the FCPA because they are given to obtain or retain business in other countries are not any different than the items of value that would violate the Anti-Kickback Statute if given within the United States - cash, gifts, charitable donations, travel, meals, entertainment, grants, speaking fees, honoraria, and consultant

arrangements, to name a few." Moreover, DOJ is assembling special teams to support this new FCPA focus on pharmaceutical and medical device companies by combining the healthcare expertise of the healthcare fraud unit with the international bribery expertise of the FCPA unit. As Breuer noted "These two groups - our FCPA unit and our 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 Assistant Attorney General Breuer.

The take away from the recent DOJ pronouncements is that pharmaceutical and medical devise companies must take proactive steps to avoid FCPA enforcement. As Assistant Attorney General Breuer said, "We are fully aware that internal investigations and remedial measures may be costly. But 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….In this, as in so many areas, doing the right thing, in my view, also makes good business sense."

What Should Pharmaceutical and Medical Device Companies Do To Avoid FCPA Enforcement?

Faced with the rising tide of FCPA enforcement aimed squarely at pharmaceutical and medical device companies, what steps can they take to avoid enforcement actions? In short—be Proactive. Particularly in high-risk countries such as Mexico, China, Russia, Africa and the former Soviet republics, every juncture of interaction with foreign officials may entail a risk of potentially improper payments, particularly when agents or consultants are involved in a transaction. Consider the possible range of "foreign officials" who are covered by the FCPA in the context of international pharmaceutical and medical device transactions: Some are obvious, like health ministry and customs officials of other countries. But some others 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 or medical device product in a foreign country will involve a "foreign official" within the meaning of the FCPA.

As a result, pharmaceutical and medical device manufacturers should take the following seven important, concrete steps to ensure that their current operations and policies do not create a risk of violating the FCPA:

Seven Steps To Getting The FCPA Bull's-eye Off of Your Company's Back

First, pharmaceutical and medical device companies should review their existing compliance policies and procedures to ensure that they adequately address the financial relationships that they or their foreign subsidiaries may enter with foreign physicians, hospital administrators, pharmacists and healthcare officials. Every company should have a rigorous FCPA compliance policy that is faithfully enforced.

Second, pharmaceutical and medical device companies should consider conducting an internal assessment audit to identify potential risk areas under the FCPA. This evaluation should include all of the company's foreign operations, including distributors, sales representatives, consultants, and others acting on their behalf, as well as the nature of the company's relationship with foreign business partners. Conduct risk assessments based on the incidence of corruption in the countries in which they operate and the nature of interaction with foreign government officials by employees, agents, consultants, and distributors. Make sure that your FCPA compliance program is specifically tailored to your company and the foreign jurisdictions

in which it operates. Remember --one program may not fit all countries. Target additional resources to those countries where the assessment indicates higher risks.

Third, pharmaceutical and medical device companies should conduct rigorous vetting of any foreign agents, distributors, or consultants, including in-person interviews by compliance lawyers and background checks with the U.S. embassy or consulate. Expenditures by agents and consultants should be subject to more frequent audits, particularly in high-risk countries. Compensation systems for agents and consultants that create potential incentives for corrupt payments to foreign officials, such as success fees, must be closely examined.

Fourth, pharmaceutical and medical device companies should require prior written approval for anything that is, or could be construed as, a payment to a foreign official, particularly gifts and entertainment expenses, in order to assess their reasonableness and connection to a bona fide business purpose. Ensure that such payments, if made, are fully and accurately documented in the company's books and records. Suspect payments may include donations made to a foreign official's favorite charity because such donations may violate the FCPA under certain circumstances. Moreover, although permitted under the FCPA, "facilitating" payments to foreign officials to expedite "routine governmental functions," such as payments to obtain permits or license to do business in a foreign country, or to process visas and work orders, should be carefully examined to determine if the benefit outweighs the FCPA risk.

Fifth, pharmaceutical and medical device companies should institute confidential reporting mechanisms, such as a "hotline" or special website, for individuals to report allegations of kick-backs and should act upon credible allegations of wrongdoing in a timely manner. But be sure that your "1-800 hotline" can be easily accessed from outside the United States. Simple as this may sound, many 1-800 numbers can not receive international calls. As you might imagine, it looks really bad to a prosecutor when you have a hotline for FCPA compliance that can't be called from overseas.

Sixth, pharmaceutical and medical device companies should carefully review the adequacy of ongoing FCPA training and monitoring procedures in its compliance program. Be sure to translate the company code of conduct and FCPA compliance policies into the languages of each country where the company operates. Ensure that the translation is disseminated from the CEO for emphasis. Make sure that officers, employees, consultants, and agents acknowledge receipt of the policies. Require company employees overseas, as well as foreign consultants, agents, and distributors, to receive interactive, Internet-based training in their native language, accompanied, where possible, by in-person training by company lawyers or ethics officials in higher risk locations.

Finally, pharmaceutical and medical device companies should conduct any internal investigations in a manner that provides maximum protection of the attorney client privilege, while being complete and effective. But from the outset, companies must understand that one potential result of any such investigation could be a self-disclosure of any FCPA violations to the Justice Department in return for leniency. In order to be efficient and effective, such investigations should be conducted by outside counsel that not only has expertise in FCPA investigations, but also the pharmaceutical and medical device industry.

Taking these proactive steps will help keep pharmaceutical and medical device companies stay off of DOJ's FCPA radar screen.

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