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DoJ Tells Pharma to Brace for FCPA

By Jaclyn Jaeger — March 2, 2010

The Department of Justice has issued a strong warning in recent months to those in the pharmaceutical and healthcare industries: find a way to deter fraud and other corporate corruption, or face hefty consequences.

The opening declaration came from Assistant Attorney General Lanny Breuer in a speech last November, when he pointedly said: “Pharmaceutical companies must ensure that they are dealing honestly and fairly with patients, healthcare providers, private insurers, and government programs.” If they don’t, he advised, the Justice Department will be “vigilant” in holding companies and individuals who break the law accountable, particularly for violations under the Foreign Corrupt Practices Act.

To prove the point, just eight weeks later the Justice Department arrested 22 executives and employees of companies in the security industry on FCPA charges. While the targets of that investigation weren’t in the pharma or healthcare industries, the nature of the bust—an elaborate sting operation complete with undercover agents and high-profile arrests in Las Vegas and London—made corporate legal officers everywhere sit up and take notice.

Historically, federal prosecutors have relied on self-reporting or tips from outsiders to bring an FCPA action, says Will Barry, a partner at the law firm Richards, Kibbe & Orbe. Actually posing as a foreign official (which an undercover FBI agent did) and approaching companies subject to the law are “more aggressive tactics” that should be a warning to other highly regulated industries, he says.

“It’s a clear message to the compliance and legal departments in the pharmaceutical industry that they need to be really careful, and they need to make sure their people in the field understand where the landmines are,” Barry says.

But identifying one of those landmines without actually stepping on it is not so easy in the healthcare sector. The FCPA clearly forbids bribing “a foreign official” to win business, but in many countries with government-run healthcare systems, knowing exactly who qualifies as a foreign official can be difficult. Even Breuer admitted in his November speech that constitutes a corrupt payment in that context “will depend on the facts and circumstances of every case.”

Some foreign officials will be obvious: healthcare ministers, drug regulators, or customs officials, for examples. Others—doctors, pharmacists, lab technicians, or others employed in state-run healthcare businesses—will not, Breuer said.

The types of corrupt payments that violate the FCPA are also "extraordinarily broad," Barry says. They could include cash, gifts, charitable donations, meals, entertainment, speaking fees, or research grants. Indeed, many payments that might violate the FCPA overseas are even the same items a pharmaceutical sales rep wouldn't hesitate to offer a doctor here in the United States.

"The travel and entertainment budgets for marketing professionals are an area that compliance and legal really need to be focusing on, because that's an area where the abuses can occur," Barry says. The abuses themselves might not be large, but they could indicate larger-scale problems at the company and turn into a compliance nightmare, he says.

When to Disclose

When a problem does arise, the company has an obligation to investigate and determine whether it is a single incident or part of a pattern of activity, says Howard W. Goldstein, a partner in the white-collar defense practice of law firm Fried Frank. Usually—and especially if the problem is part of an ongoing pattern—the company's best path is to confess the incident to regulators, rather than resolve the matter internally and hope nobody at the Justice Department notices.

"You have to evaluate voluntary disclosure carefully," Barry says. "It is often in the best interest of the enterprise to make that voluntary disclosure, so that the company can show that it has taken this seriously, that it has dealt with the underlying issues both from a compliance and infrastructure perspective and from a personnel perspective."

Breuer said he and his prosecutors "are fully aware that internal investigations and remedial measures may be costly," but he cautioned companies to consider the alternative of hushing up problems, getting caught, and then paying the price of regulatory fines, bad publicity, and any settlements that might require outside compliance monitors or new training programs for employees.

In addition, companies that run afoul of the Justice Department once will probably then need to step up their due diligence to vet overseas partners, "because once you're on the radar screen, you need to understand that everything you do is going to be scrutinized from an even greater extent," he said.

Speaking of Due Diligence

Due diligence can be a tough job; companies can't chaperone every single sales agent in their global operations, after all. Still, they can implement some basic structures for a simple, effective due diligence process. The goal, Barry says, is "to make sure that every

one of your agents understands what's expected, has the tools to react to it, and has somebody they can go to when they have a question as to whether a particular step is appropriate."

Goldstein contends that a centralized compliance function is the best way to achieve that. People who focus on compliance exclusively tend to develop a "sixth sense" about whether a situation requires further investigation, he says. Christopher Cook, a trial lawyer at the law firm Jones Day, further recommends that the individual charged with leading the compliance program be as close to the foreign operations as possible.

Companies must also ensure that their anti-corruption policies cite bribery as a forbidden practice and that their policies are drilled home to employees in concrete, practical ways. For example, Barry says, does the company use training methods that use real-life scenarios sales reps are likely to encounter overseas? Is the policy translated into local languages and modified to embrace local cultural norms? Any policy a company has must be understandable and relevant to the recipient of that particular country, Cook says.

More to Come

In addition to its more aggressive investigation tactics, the Justice Department is also expanding the size and expertise of its FCPA enforcement teams. In the pharma and healthcare sectors specifically, the department has created a healthcare fraud group dedicated to looking at bribery offenses, Breuer said. The Justice Department's standing FCPA unit and the healthcare fraud unit are "already beginning to work together to investigate FCPA violations in the pharmaceutical and device industries to maximize our ability to effectively enforce the law in this area," he said.

Barry warns that the Justice Department will now start to look at wrongdoing on a holistic level—that is, if prosecutors know a violation happened at one company in one region, they are more likely to explore whether other companies in that same region are committing similar offenses. That is the approach prosecutors took in their now-famous Las Vegas FCPA bust in January.

BREUER KEYNOTE

Below is an excerpt of the speech from Lanny Breuer on enforcement of the Foreign Corrupt Practices Act in the pharmaceutical industry:

Working together with the FBI, and often with our civil counterparts at the SEC, the Department currently is pursuing more than 120 FCPA investigations. In the pharmaceutical context, we have additional expertise that significantly enhances our ability to proactively investigate and prosecute these often complex cases. That additional expertise is located in our health care fraud group, where we have prosecutors and analysts with the industry knowledge necessary to quickly identify corrupt practices. 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.

Moreover, we will continue to work closely with our partners at the SEC to ensure that the full range of the federal government's enforcement tools and remedies are utilized. And we are seeing increasing international cooperation, coordination and information sharing. Last year's record-breaking resolution with Siemens in the United States and Germany, in which Siemens agreed to pay a combined total of more than $1.6 billion in fines, penalties and disgorgement of profits in connection with violations of and charges related to the FCPA, is but one example of this increase in coordination and cooperation with foreign law enforcement.

Our focus and resolve in the FCPA area will not abate, and we 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 investigation and prosecution of senior executives. Effective deterrence requires no less. Indeed, we firmly believe that for our enforcement efforts to have real deterrent effect, culpable individuals must be prosecuted and go to jail where the facts and the law warrant. To take just one example outside the pharmaceutical industry, and frankly, a case from which I am personally recused, earlier this year, the Department reported that Kellogg, Brown & Root pleaded guilty to FCPA violations and agreed to pay a $402 million fine. The Department did not, however, just stop at the prosecution of the corporation, but instead prosecuted a number of individuals for the same criminal conduct. Jack Stanley, KBR's former Chairman and CEO, pleaded guilty and agreed to a seven year prison sentence. In the past few months, we have the completed the trials of the Greens in California, of Mr. Bourke in New York and of former Congressman William Jefferson in Virginia. In each of these cases, individuals were found guilty of FCPA violations and face jail time.

So what can you do to protect your clients? First and foremost, every company should have a rigorous FCPA compliance policy that is faithfully enforced. Second, any pharmaceutical company that discovers an FCPA violation should seriously consider voluntarily disclosing the violation and cooperating with the Department's investigation. If you voluntarily disclose an FCPA violation, you will receive meaningful credit for that disclosure. And if you cooperate with the Department's investigation, you will receive a meaningful benefit for that cooperation—without any request or requirement that you disclose privileged material. Finally, if you remediate the problem and take steps to ensure that it does not recur, you will benefit from that as well.

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. Conversely, a voluntary disclosure may result in no action being taken against a company, or the company may secure other preferred dispositions, such as a deferred or non-prosecution agreement, or a reduced fine under the Sentencing Guidelines. In this, as in so many areas, doing the right thing, in my view, also makes good business sense.

Source: Assistant Attorney General Lanny Breuer's Keynote Address (Nov. 12, 2009).

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