LATHAM & WATKINS

Number 960 November 24, 2009

Client Alert

Latham & Watkins
Litigation Department

US Department of Justice Announces Stepped-Up Criminal Enforcement of Foreign Corrupt Practices Act Against Pharmaceutical Industry

"Companies that assess their risks, implement comprehensive compliance programs and respond proactively when potential violations are discovered, will certainly find themselves in a stronger position to prevent violations before they occur and respond proactively when problems are found."

Describing corruption and bribery as "a scourge on civil society" and a "global blight," the head of the Criminal Division of the United States Department of Justice (DOJ), Assistant Attorney General Lanny A. Breuer, announced in two recent speeches that the DOJ intends to step-up enforcement of the Foreign Corrupt Practices Act (FCPA) against individuals and companies in the pharmaceutical industry.[1]

In the past five years, FCPA enforcement has been one of the criminal division's "top priorities," and the DOJ has brought 58 cases since 2005 alone, which is more than the number of prosecutions brought by the DOJ from 1977, when the FCPA was enacted, through 2004. Two recent cases that were highlighted during the speeches were the US government's record-breaking settlement with Siemens, where the company agreed to pay $1.6 billion in fines, penalties and disgorgement of profits as a result of numerous FCPA violations and related charges, and the agreement with Kellogg, Brown and Root (KBR), which led to a corporate guilty plea, a guilty plea from KBR's former Chairman and CEO (and a seven-year prison sentence), and combined DOJ and Securities and Exchange Commission (SEC) penalties of $579 million.

The DOJ is currently pursuing 120-130 FCPA investigations, and now it has set its sights on enforcement in the pharmaceutical industry where on an annual basis "close to $100 billion dollars, or roughly one-third, of total sales … [are] generated outside of the United States." The DOJ's new focus stems in part from the fact that many foreign health systems are regulated, operated and financed by government entities, and competition is intense, which creates more opportunities to "pay off foreign officials for the sake of profit," and a perceived need for greater supervision from law enforcement.

Breuer emphasized that the range of "foreign officials" that pharmaceutical companies interact with is broad, and it may not always be obvious to which government employees this term applies. Obvious "foreign officials" include "health ministry or customs officials," but "doctors, pharmacists, lab technicians and other health professionals who are employed by state-owned facilities," may also be foreign officials under the FCPA. Because the FCPA's broad definition of a "foreign official" includes virtually

any employee of any such facility, the ordinary commercial activities of many companies in the medical industry bring them into virtual constant contact with such officials. As Breuer stated: "[I]t 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."

The DOJ's focus on pharmaceutical companies will necessarily mean investigation and possible prosecution of corporations. But Breuer also made clear that the "prosecution of individuals is a cornerstone of our enforcement strategy," and that the DOJ will focus on the "investigation and prosecution of senior executives" in the pharmaceutical and other industries, because "culpable individuals must be prosecuted and go to jail where the facts and the law warrant."

The most obvious and essential first step for a company to avoid FCPA problems is to implement a robust FCPA compliance program and ensure that those policies and procedures are incorporated into the business practices of the corporation—in DOJ's words, "a rigorous FCPA compliance policy that is faithfully enforced." Every company should develop its own policies and procedures tailored to its specific business and risk profile. The existence of an extensive—and properly implemented—compliance program can pay off not only in helping to prevent violations before they occur, but also in reducing the severity of any sanction for a violation, or even avoiding criminal or civil liability altogether.

The Federal Sentencing Guidelines themselves, which are relevant to determining punishment in corporate prosecutions, make clear that "the existence of an effective compliance and ethics program" can "mitigate the ultimate punishment of an organization."[2] In the *Siemens* case, for example, the Guidelines suggested a fine between $1.35 billion and $2.7 billion, but a determinative factor in DOJ's decision not to seek the highest fine possible was Siemens' cooperation with the investigation, "substantial compliance and remediation efforts," and Siemens' "extensive commitment to restructure and remediate its operations to make it a worldwide leader in transparent and responsible corporate practices going forward."[3]

Conversely, the government has been particularly unsympathetic to companies that seek leniency for FCPA violations when those companies did not have in place any mechanisms, controls or procedures to prevent and detect FCPA violations—or failed to comply with their own compliance policies and procedures. While acknowledging the potentially high costs of compliance, Breuer warned 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." In most major cases, moreover, the government insists that the company implement substantial remedial measures and requires a compliance monitor (an outside party with access to the company's operations) to ensure that the company is actually living up to the agreement. The DOJ believes that "corporate monitors continue to play a crucial role and responsibility in ensuring the proper implementation of effective compliance measures and in deterring and detecting future violations." These third-party monitors can present numerous problems for companies because they can be invasive and often very expensive.

To the extent a company already has an FCPA policy, it should review that policy

to ensure that the definition of "foreign official" comports with the DOJ's recent pronouncement. The DOJ emphasized its view that the FCPA's broad definition of "foreign official" includes "doctors, pharmacists, lab technicians and other health professionals who are employed by state-owned facilities." Companies in the pharmaceutical industry operating abroad are highly likely to encounter these individuals frequently, and will want to ensure that a compliance policy appropriately recognizes the risks of these interactions. Companies should also consider whether additional training for executives and employees is necessary to ensure that those who interact with potential foreign officials are aware of the potential pitfalls under the DOJ's broad definition.

The DOJ also encourages, as part of "corporate self-policing," the voluntary disclosure to the government of any FCPA problems the corporation discovers on its own.[4] In his remarks, Breuer reinforced the promise that voluntary disclosure will result in a meaningful benefit for the company, stating, "any pharmaceutical company that discovers an FCPA violation should seriously consider voluntarily disclosing the violation and cooperating with the Department's investigation." A company that self-reports violations will "receive meaningful credit" for that disclosure, and a company that continues to cooperate in an investigation will also "receive a meaningful benefit for that cooperation—without any request that [it] disclose privileged material."

This principle is also reflected in the Federal Sentencing Guidelines, which state that self reporting can "mitigate the ultimate punishment of an organization."[5] A review of the DOJ's recent prosecutions and public statements makes this evident. Helmerich & Payne, for example, self-disclosed improper or questionable payments and the matter was resolved through a non-prosecution agreement, a penalty of $1 million—approximately 30 percent below the bottom of the suggested guidelines range—and the DOJ agreed to compliance self-reporting for two years instead of mandating an independent compliance monitor.[6] Given similar conduct, companies that self report their own potential violations, conduct a rigorous internal investigation and share the results with the government have generally fared better than companies that do not take these steps.[7]

Public companies should also remember that the SEC enforces the FCPA,[8] and the SEC has similarly made FCPA enforcement a priority. SEC Director of Enforcement Robert Khuzami recently announced the formation of a specialized unit solely focused on FCPA violations.[9] The DOJ has also begun discussions with the Internal Revenue Service's Criminal Investigations Division about partnering on cases around the country, and countries other than the United States have increasingly focused upon anti-corruption enforcement efforts, and have worked in cooperation with United States authorities.

Breuer's speeches make clear for all companies and executives—not just those in the pharmaceutical industry—that the change in presidential administrations has not altered the DOJ's focus on ferreting out and prosecuting FCPA violations. Indeed, while DOJ has recently set its sights on pharmaceutical companies, Breuer announced that the government "will be looking at other areas and industries for stepped-up enforcement where we deem appropriate." Companies that assess their risks, implement comprehensive compliance programs and respond proactively when potential violations are discovered, will certainly find themselves in a stronger position to prevent violations before they occur and respond proactively when problems are found.

Endnotes

1 Breuer spoke on November 12th at the 10th Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum (text of the speech available at http://www.mainjustice.com/2009/11/12/criminal-division-chief-breuers-fcpa-pharma-speech/), and on November 17th at the 22nd National Forum on the Foreign Corrupt Practices Act (text available at http://blogs.wsj.com/law/2009/11/17/breuer-beware-execs-the-doj-wants-your-fancy-cars/). The FCPA, which prohibits paying bribes to a "foreign official" to "obtain[ ] or retain[ ] business," 15 U.S.C. §78dd-1(a)(1)(B), has been broadly interpreted by DOJ and the SEC to prohibit any corrupt payments to foreign officials to gain any business advantage.

2 UNITED STATES SENTENCING GUIDELINES MANUAL § 8a1.1. *See also* § 8B2.1 (articulating standards for what counts as an "effective compliance and ethics program" under Sections 8C2.5(f) (Culpability Score) and 8D1.4 (Recommended Conditions of Probation)). While a compliance plan is relevant to the severity of punishment for a violation, a federal court of appeals recently held that it is not relevant to liability, and the government does not need to prove in its case in chief that a company lacked effective policies and procedures. *See United States v. Ionia Mgmt., S.A.*, 555 F.3d 303, 310 (2d Cir. 2009). *See also* UNITED STATES ATTORNEYS' MANUAL § 9-28.800 ("The existence of a corporate compliance program, even one that specifically prohibited the very conduct in question, does not absolve the corporation from criminal liability under the doctrine of respondeat superior."), *available at* http://www.justice.gov/usao/eousa/foia_reading_room/usam/title9/28mcrm.htm#9-28.800

3 *See United States v. Siemens Aktiengesellschaft*, No. 1:08-cr-00367-RJL (D.D.C. 2008) (Department's Sentencing Memorandum, Docket No. 3, at *14). Likewise, the SEC acknowledged that Siemens "cooperated fully with the ongoing investigation, and the SEC considered the remedial acts promptly undertaken by Siemens" in its decision to settle the case. *See* US Securities and Exchange Commission, *SEC Files Settled Foreign Corrupt Practices Act Charges Against Siemens AG for Engaging in Worldwide Bribery With Total Disgorgement and Criminal Fines of Over $1.6 Billion*, Litigation Release No. 20829 (Dec. 15, 2008). Another notable aspect of the *Siemens* case was the successful international cooperation in the investigation and prosecution. Both the DOJ and the SEC have publicly emphasized the importance of their working relationship with German authorities, and that cooperation between US and German authorities led not only to the DOJ and SEC settlements, but also settlements with German authorities. *See* Department of Justice Press Release, No. 08-1115, *Siemens AG and Three Subsidiaries Plead Guilty to Foreign Corrupt Practices Act Violations and Agree to Pay $450 Million in Combined Criminal Fines* (Dec. 15, 2008); US Securities and Exchange Commission, *SEC Charges Siemens AG for Engaging in Worldwide Bribery*, Release No. 2008-294 (Dec. 15, 2008).

4 UNITED STATES ATTORNEYS' MANUAL § 9-28.800, available at http://www.justice.gov/usao/eousa/foia_reading_room/usam/title9/28mcrm.htm

5 UNITED STATES SENTENCING GUIDELINES MANUAL § 8a1.1.

6 Breuer stated that "Helmerich & Payne benefited in several, very tangible ways from their efforts. The fine, type of disposition, length of disposition, and treatment of the monitor issue all reflect the forward leaning, pro-active, highly cooperative approach taken here."

7 *See, e.g.,* Department of Justice Press Release No. 09-741, *Helmerich & Payne Agrees to Pay $1 Million Penalty to Resolve Allegations of Foreign Bribery in South America* (July 30, 2009) ("The agreement recognizes H&P's voluntary disclosure and thorough self-investigation of the underlying conduct, the cooperation provided by the company to the Department, and the extensive remedial efforts undertaken by the company."); Department of Justice Press Release No. 08-1105, *Siemens AG and Three Subsidiaries Plead Guilty to Foreign Corrupt Practices Act Violations and Agree to Pay $450 Million in Combined Criminal Fines* (Dec. 15, 2008) (complimenting the "extraordinary steps" Siemens took to investigate and reveal its criminal conduct and the extent of its cooperation with investigators); Department of Justice Press Release No. 06-707, *Schnitzer Steel Industries Inc.'s Subsidiary Pleads Guilty to Foreign Bribes and Agrees to Pay a $7.5 Million Criminal Fine* (Oct. 16, 2006) ("This announcement also shows that when companies voluntarily disclose FCPA violations and cooperate with Justice Department investigations, they will get a real, tangible benefit. In fact, Schnitzer Steel's cooperation in this case was excellent, and I believe that the disposition announced today reflects that fact.").

8 In addition to its anti-bribery provisions, the FCPA's "accounting provisions" require US "issuers" to keep accurate books and records and maintain sufficient internal controls. *See* 15 U.S.C. §78m.

9 *See* Robert Khuzami, *Remarks Before the New York City Bar: My First 100 Days as Director of Enforcement* (Aug. 5, 2009), *available at* http://www.sec.gov/news/speech/2009/ spch080509rk.htm

If you have any questions about this *Client Alert*, please contact one of the authors listed below or the Latham attorney with whom you normally consult:

Alice S. Fisher
+1.202.637.2232 Phone
alice.fisher@lw.com
Washington, D.C.

Douglas N. Greenburg
+1.202.637.1093 Phone
douglas.greenburg@lw.com
Washington, D.C.

Barry M. Sabin
+1.202.637.2263 Phone
barry.sabin@lw.com
Washington, D.C.

Nathan H. Seltzer
+1.202.637.2206 Phone
nathan.seltzer@lw.com
Washington, D.C.

John Cooper*
+1.202.637.1022
john.cooper@lw.com
Washington, D.C.

*Not admitted to the D.C. bar, all work supervised by a member of the D.C. bar.
