

The Foreign Corrupt Practices Act and Pharma: Is DOJ Following Through on its Tough Talk Towards the Industry?

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Introduction

Late last year, the U.S. Department of Justice ("DOJ") fired a shot across the bow of the pharmaceutical industry, warning that federal law enforcement would be beefing up efforts to monitor pharma companies for compliance with the Foreign Corrupt Practices Act ("FCPA"). While the announcement sent shock waves through the industry and among legal practitioners, it is more surprising that the announcement had not come sooner. Currently, an estimated one third — or approximately \$100 billion — of all pharmaceutical sales occur in overseas markets, and recent years have witnessed an explosive growth in overseas product development and clinical trials. On this basis alone, the pharmaceutical industry ("Pharma") provides fertile ground for FCPA enforcement. Indeed, it is difficult to imagine a more likely target for an increasingly active DOJ seeking to enforce anti-corruption statutes on an international scale.

Pharma's unique structure and operations also present unique FCPA compliance obstacles. For one thing, the FCPA's definition of "foreign official" is expansive, and the prohibition against bribing foreign officials extends well beyond government ministers and other obvious political administrators. Another challenge stems from the Pharma model of engaging subsidiaries, agents, consultants and distributors, many of whom either qualify as foreign officials or may have connections to foreign officials.

As this article will illuminate, Pharma faces particular challenges in complying with the FCPA, the violation of which could have reputational, business, and criminal consequences. Nonetheless, if Pharma companies attend to the potential FCPA vulnerabilities and implement the best practices discussed in this article, the DOJ's announcement that it is watching should not be cause for much alarm.

Targeting Pharma

The warning to the pharmaceutical industry was loud and clear: "Our focus and resolve in the FCPA area will not abate, and we will be intensely focused on rooting

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out foreign bribery in your industry," said Lanny A. Breuer, the DOJ's Assistant Attorney General for the Criminal Division, in his address at the Tenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum in November 2009.

Among the reasons Breuer cited for targeting Pharma were the significant overseas sales generated outside the U.S., where health systems are regulated and operated by government entities to a greater degree, as well as the natural extension of the domestic Stark Anti-Kickback laws to the international arena. Indeed, as Breuer noted during his address, "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." The extension is logical not just in rationale, but in resources. The DOJ is assembling special teams to support this FCPA focus on Pharma by combining the health-care expertise of the health care fraud unit with the international bribery expertise of the FCPA unit. As Breuer noted, "[O]ur 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." For Pharma, now is the time to learn the anti-corruption rules and start playing by them.

What Are the Key FCPA Provisions?

The FCPA makes it a federal crime for a business or individual "corruptly" to offer, pay, promise to pay, or authorize payment of anything of value to a "foreign official" for the purpose of obtaining or retaining business or securing any improper business advantage.¹ The FCPA also proscribes failure to meet specified record-keeping and internal control requirements.² The FCPA's accounting provisions apply to both domestic and foreign companies whose stock is traded on U.S. exchanges, and to domestic and foreign companies required to file reports with the Securities and Exchange Commission ("SEC"). The FCPA's provisions also broadly apply to "any person" (a natural person or a corporate entity) who engages in such conduct, regardless of whether the person is a U.S. citizen or resident or does business in the United States.

Today, any company with a nexus to the United States is potentially subject to FCPA enforcement, even if the company and the illegal activity were located outside the U.S. In late 2008, for example, the DOJ reached a \$17.8 million settlement with a company whose only connection to the U.S. was the American Depositary Receipts it traded on the New York Stock Exchange which, therefore, subjected the company to the FCPA's accounting and internal control provisions.³

The FCPA exempts from its prohibitions the payment of "facilitation" or "grease" payments to "expedite or to secure the performance of a routine governmental action," provided that such action does not include a decision by a foreign official to award new business or continue an existing business relationship.⁴ The statute specifies that "routine governmental action" refers to "an action which is ordinarily and commonly performed by a foreign official," such as issuing permits or licenses to

enable a company to do business in a foreign country, processing official documents such as visas and work orders, scheduling inspections, loading or unloading cargo, providing certain utility services, "or actions of a similar nature."⁵

The FCPA also contains two affirmative defenses to an alleged antibribery violation, which the defendant has the burden of establishing.⁶ First, a defendant may assert that the payment in question was lawful under the written laws of the foreign country in which the payment was made. Second, a defendant may assert that the payment (or gift) was a "reasonable and bona fide expenditure, such as travel and lodging expenses," and was "directly related to" either "the promotion, demonstration, or explanation of products or services" or to "the execution or performance of a contract with a foreign government or agency thereof."⁷

FCPA Prosecutions on the Rise

The focus of FCPA enforcement on the pharmaceutical industry reflects another step in a steady expansion of the scope of FCPA prosecutions, which seem to be coming more quickly and in industry-specific waves. FCPA enforcement has proliferated and now trails only terrorism as a DOJ enforcement priority.⁸ Whereas, between 1977 and 1997, the government prosecuted only 17 companies (on average, less than one company each year), between 1998 and 2008, the government prosecuted more than 50 companies. According to the DOJ, there were approximately 120 active FCPA investigations in 2009.

U.S. regulators are also broadening the FCPA's geographic scope, with investigations now extending across five continents. Further, while the United States continues to lead the fight against foreign bribery around the world, other countries are increasing their own anticorruption enforcement. This change is due in part to the Organisation for Economic Co-operation and Development's Anti-Bribery Convention, which sets forth standards for anticorruption legislation and enforcement in 38 signatory nations.⁹ The global focus on anti-bribery measures can also be attributed to the increased resources the U.S. government has provided for anticorruption investigations worldwide. Not only has the United States bolstered the FBI and other agencies tasked with investigating FCPA violations, it has provided forensic training and technology to other countries. In many cases, FCPA-trained attorneys have been placed in foreign embassies to assist foreign governments with ongoing investigations.¹⁰

Recently, the United Kingdom passed its own version of the FCPA, the UK Bribery Act, which is on its face stricter and more punitive than the FCPA. Germany has, in the past several years, also tightened its reigns on corruption: Companies that were once allowed to deduct the cost of paying bribes as a business expense, are now being aggressively prosecuted for the payment of such bribes.¹¹

Enforcement actions against a multinational company in one country may also prompt regulators in other countries to act. The Siemens case is illustrative: after the German corporation was first prosecuted and fined in Germany for 77 different cases of bribery of foreign officials in Russia, Nigeria and Libya,¹² the U.S. DOJ and the SEC initiated their own investigation of Siemens for violations of the FCPA. A similar scenario occurred after the United Kingdom's 2006 investigation of BAE

Systems for alleged corruption violations in connection with defense contracts for Saudi Arabia. Just one year later, the U.S. DOJ and SEC initiated an FCPA investigation of BAE Systems.¹³ In the Pharma context, where many companies are multinational in scope, an increase in anticorruption enforcement globally means that all corporate activity is being carefully monitored and even rumored infractions will draw attention from regulators in multiple jurisdictions.

Not surprisingly given the increasing focus on FCPA prosecutions, financial penalties for FCPA violations are reaching astronomical heights. In December 2008, Siemens and three of its subsidiaries pleaded guilty to FCPA violations resulting from approximately \$1.4 billion in payments to government officials and intermediaries in Asia, Africa, Europe, the Middle East, and South America and paid a criminal fine of \$450 million, as well as disgorgement of profits totaling \$350 million (on top of approximately \$856 million in fines and disgorgement of profits imposed by the German government).

Prosecutions of individuals are also on the rise in the DOJ's continued efforts to enforce its anti-bribery mandate. Between 1977 and 1997, only 33 individuals were prosecuted. In contrast, between 1998 and 2008, the government charged more than 70 individuals with FCPA violations. The penalties imposed on individuals for FCPA violations can be severe, including lengthy prison sentences, legal fees, and steep financial penalties. In April 2010, a U.S. judge sentenced an individual defendant to 87 months in prison, the longest term of imprisonment ever imposed in the history of the FCPA, in connection with a scheme to bribe former Panamanian government officials in order to secure maritime contracts.¹⁴ As the DOJ increasingly looks to hold supervisors and managers responsible for failures to prevent FCPA violations, the prosecution of individuals is likely to escalate.

The Expansive Definition of 'Foreign Official'

As discussed above, the FCPA criminalizes making payments to foreign officials for the purpose of obtaining or retaining business or securing any improper business advantage. In the pharmaceutical industry context in particular, identifying a "foreign official" can be a challenge. In his remarks, Assistant Attorney General Breuer commented on the potential complexities involved in interpreting the term, which could encompass health ministry and customs officials, doctors, pharmacists, lab technicians, and other health professionals at state-owned facilities. While past enforcement actions focused on the sale of pharmaceutical products to state-owned entities,¹⁵ Breuer warned of the "depth of government involvement in foreign health systems." As Breuer explained: "[N]early 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." In other words, Pharma should be concerned with more than just overseas sales and must be attentive to FCPA vulnerabilities in nearly every facet of their business.

For example, prior to marketing and selling drugs in a foreign country, a company must secure licenses and approvals for those drugs from the country's pharmaceuticals regulator. To manufacture the drugs, companies must obtain approvals and certificates, such as a good manufacturing practices certificate. To keep the factories running, a company must pass factory inspections and meet

environmental regulations. These are just a few areas of pharmaceutical activity overseas that involve contact with foreign officials and, accordingly, create potential FCPA risks.

Though not an exhaustive list, pharmaceutical companies should be mindful that the activities of engaging the service of health care providers, sponsoring their attendance at meetings and events, providing gifts, entertainment, charitable contributions, sponsorships, grants or political contributions, and obtaining certificates and regulatory approvals are all potentially fraught with FCPA concerns. These activities should be embarked upon carefully and with proper approval and recordation at every stage.

The Decentralized Nature of Pharma's Operations and the FCPA's Knowledge Requirement

Pharmaceutical companies typically conduct a wide range of activities overseas, from the earliest stages of pre-clinical tests and product design to post-production marketing and sales. This activity is often undertaken in a decentralized fashion, involving any combination of subsidiaries, third-party contractors, distributors, and contract sales forces. This structure — in which managers may operate separately and autonomously without close supervision from a "central command"— poses massive monitoring and compliance difficulties. Even the best-intentioned company may find itself entangled in an FCPA investigation stemming from the actions of any of the numerous parties involved in the chain of operations. This stems, in large part, from the FCPA's watered-down knowledge standard, by which a company or executive may be held liable for the actions of others even without actual knowledge of the violation.

Under the "knowing" standard, corporate officials can be held culpable if they fail to take action when reasonable signs of an FCPA violation exist. The legislative history makes clear that the required state of mind for this type of offense includes a conscious purpose to avoid learning the truth.¹⁶ Thus, the knowing standard covers both the prohibitive action taken with "actual knowledge" of intended results as well as other actions that, while falling short of what the law terms actual knowledge, nevertheless demonstrate disregard or deliberate ignorance of circumstances that should reasonably alert an individual to violations of the Act. In other words, the standard covers actions that federal courts have previously characterized as "conscious disregard" and "willful blindness."

Accordingly, it is of utmost importance that pharmaceutical companies monitor the actions of every subsidiary, agent, consultant and employee of its company in order to mitigate potential liability that could be attributed to it. This can be no small feat, but extensive due diligence in the contracting process, insistence on familiarity and compliance with the FCPA's requirements, and ongoing certification and disclosure requirements are critical steps.¹⁷

What to Make of DOJ's Warning

As of this writing, there has been little publicly-reported FCPA enforcement in the pharmaceutical industry since Breuer's remarks last year. One of the only signs is

that Eli Lilly announced in February 2010 that the SEC and the DOJ had widened an investigation initiated in 2003 into activities of the company's subsidiaries in unspecified "other countries." Another development was the conviction of DePuy Director of Marketing Robert John Dougall in the United Kingdom. Acting upon the DOJ's referral, the UK's Serious Fraud Office investigated and prosecuted Mr. Dougall, who was recently sentenced to twelve months in prison for his role in making a total of £4.5 million in payments — disguised as "Professional Education" — to Greek medical professionals in order to purchase the company's products.

Pharma companies should not mistake this period of relative calm as cause for relief, and should instead take this opportunity to update and test their compliance policies as described in the next section. The SEC and DOJ are likely in the process of conducting numerous investigations, and the news about the latest targets of their enforcement is likely to come any day.

Compliance and Best Practices in the Pharma Context

The takeaway message from the recent DOJ pronouncement is that Pharma companies must be proactive. 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 [. . .] also makes good business sense."

As a practical matter, Pharma companies are well-advised to allocate time and resources now to evaluate past practices and procedures with respect to compliance matters. Specifically, every pharmaceutical company should, with the help of competent counsel, review its existing compliance program in light of current FCPA enforcement practices. An internal assessment identifying potential FCPA risk areas could also alert companies to deficiencies in their compliance practices.

If a company has not already done so, it would be well-advised to implement or update the following processes and resources, at minimum: (1) written uniform guidelines distributed to employees specifying the company's business ethics standards and its obligations under the FCPA (these documents should also be translated and distributed to employees in the company's overseas operations); (2) educational programs and ongoing attendance and certification requirements; (3) a confidential compliance hotline or other mechanism for the reporting of potential violations (this resource should also be broadly publicized and employees encouraged to utilize it should they suspect improprieties); (4) standardized documentation and contractual terms for foreign agents and representatives, including certifications that third-party contractors agree to comply with the FCPA's obligations; (5) sound accounting and monitoring practices; (6) due diligence procedures for the engagement of third parties; (7) a policy that requires prior written authorization by an identified compliance officer for any payment to a foreign official; and (8) any additional compliance measures necessary in light of the internal risk assessment mentioned above.

As far as geographic regions where corrupt practices are likely to arise, companies should pay particular note to business activity in Russia, China, the Middle East, Africa and certain Latin American countries, and some European countries, such as Italy and Greece.¹⁸

Finally, Pharma companies should consider whether voluntarily to disclose past potential misconduct, should an internal investigation uncover possible violations. This decision should involve the assistance of counsel and consider a comprehensive risk analysis based on the advantages and disadvantages of voluntary disclosure to the DOJ or SEC. At the least, pharmaceutical companies should prepare themselves to respond quickly and effectively to any FCPA issues identified by an internal review.

Even a company with the most robust compliance program and the best of intentions may fail to prevent a foreign bribe. Having a demonstrably effective compliance program will weigh heavily in that company's favor in the event of a regulatory investigation. With increased government scrutiny on an industry laden with FCPA risk, Pharma must be on high alert and proactive in assuring its compliance with the FCPA.

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¹ 15 U.S.C. §§ 78dd-1(a), 78dd-2(a).

² *Id.* § 78m(b)(2) and (b)(5).

³ *See SEC v. Fiat S.p.A. and CNH Global N.V.*, No. 1:08-cv-02211 (D.D.C. 2008).

⁴ 15 U.S.C. §§ 78dd-3.

⁵ *Id.*

⁶ *See id.*

⁷ *Id.*

⁸ As noted by Charles McKenna, Chief, Criminal Division, U.S. Attorney's Office for the District of New Jersey, at 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.

⁹ OECD's Convention on Combating Bribery of Foreign Officials in International Business Transactions, art. 1, Dec. 17, 1997 (OECD Convention).

¹⁰ FCPA Enforcement Webcast, sponsored by KPMG Forensic (Jan. 28, 2009).

¹¹ *See* Nelson D. Schwarte & Lowell Bergman, Payload: Taking Aim at Corporate Bribery, N. Y. TIMES, Nov. 25, 2007, at C1.

¹² Siemens Aktiengesellschaft, Report of Foreign Private Issuer (Form 6-K), at 31 (Nov. 8, 2007).

¹³ James Boxell et al., BAE Faces Fines in US Bribery Probe, FIN. TIMES, June 26, 2007.

¹⁴ *United States v. Jumet*, E.D. Va., No. 3:09-cr-00397-HEH (Nov. 10, 2009).

¹⁵ *See SEC v. Syncor International Corp.*, C.A. No. 1:02CV02421 (EGS) (D.D.C.) (filed Dec. 10, 2002), Litigation Release No. 17887 (Dec. 10, 2002) and *SEC v. Schering-Plough Corp.*, Case No. 1:04-cv-00945 (D.D.C. June 9, 2004), Litigation Release No. 18740 (June 9, 2004); *In the Matter of Schering-Plough Corp.*, Administrative Proceeding File No. 3-11517, Rel. No. 49838, June 9, 2004. In 2002, Syncor Taiwan admitted to making improper payments to physicians employed by state-owned hospitals in Taiwan for the purpose of obtaining and retaining business for those hospitals in connection with the purchase and sale of radiopharmaceuticals. In 2004, Schering-Plough agreed to a \$500,000 settlement with the SEC because its Polish subsidiary had paid approximately \$75,000 to a Polish charitable

organization headed by a Polish government official. The official directed a Polish government agency that influenced pharmaceutical purchasing decisions of hospitals owned by the Polish government.

¹⁶ H.R. Conf. Rep. No. 100-576 at 919-20 (1988).

¹⁷ It is worth noting that some commentators believe that the federal courts are overstepping congressional intent as they interpret the knowing standard to include "conscious disregard" and "willful blindness" or evidence of "head in the sand" behavior. These commentators argue that, while failing to conduct sufficient due diligence or ignoring red flags can, in many circumstances, be foolish in the extreme, as noted in the FCPA's legislative history and cases cited therein, such "foolishness, in and of itself, cannot constitute a finding that knowledge is present." See Kenneth Winer and Gregory Husisian, "The 'Knowledge' Requirement of the FCPA Anti-Bribery Provisions: Effectuating or Frustrating Congressional Intent?" (2009); see also "The FCPA's Murky Knowledge Element" at <http://www.fcpaprofessor.blogspot.com>. These same commentators believe that the "net effect of this attitude is to bring the FCPA back to its original 'reason to know' standard" and the current enforcement approach utilizing this standard implements an approach that Congress specifically rejected. *Id.* While the debate remains heated and federal courts continue to find that a failure to conduct adequate due diligence or follow up on red flags is violative of the FCPA, Pharma companies should proceed conservatively.

¹⁸ Transparency International's 2009 Corruption Perceptions Index (CPI) compares the perceived level of public sector corruption of a country against 180 others. The CPI ranks Italy at 63, Greece at 71 and China at 79 (with 1 being the least corrupt and 180, the most). See http://www.transparency.org/policy_research/surveys_indices/cpi/2009/cpi_2009_table.