

Cover Story



The Foreign Corrupt Practices Act and Pharma in the Chinese Market:

United States Law Enforcement Pursues Corruption Crackdown Across Entire Industry

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Introduction

In recent months, United States law enforcement agencies have announced investigations into numerous pharmaceutical and medical-device companies for payments to doctors and health officials, in possible violation of the Foreign Corrupt Practices Act (FCPA).¹ These investigations appear to make good on the U.S. Department of Justice (DOJ)'s announcement late last year that federal law enforcement planned to initiate an industry-wide probe into pharma companies' compliance with FCPA.

While these recent developments have sent shock waves through the industry and among legal practitioners, in retrospect, the news should not be surprising. Currently, an estimated one third—or approximately USD 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 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. China, in particular, has been a robust nexus of growth and enforcement scrutiny.

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.

China possesses certain cultural and governmental particularities that pose specific problems to Western companies considering investment or opening operations there. The vast majority of the healthcare system in China is run by the Chinese government, putting many doctors firmly under the purview of the FCPA as "foreign officials." In addition, cultural traditions

such as "red envelopes," as well as long-established business practices such as paying commissions to doctors, increase the potential likelihood of FCPA violations.

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 cause much alarm and that China's incredible growth prospects can still be a valuable upside for interested Western investors.

Targeting Pharma and China

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 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 last November.

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 healthcare expertise of the healthcare fraud unit with the international bribery expertise of the FCPA unit. As Breuer noted, "[O]ur FCPA unit and our healthcare

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.

In addition to targeting pharma as an industry, the SEC and DOJ have been focused on China as a country in particular. In 2010 alone, two high-profile cases have surfaced concerning FCPA violations in China. In April 2010, Avon Products suspended five employees following an internal investigation of bribery allegations in China. In June 2010, the SEC filed an FCPA enforcement action against Veraz Networks, alleging that Veraz made improper payments to foreign officials in Vietnam and China. These recent enforcement cases indicate that there appear to be systemic potential FCPA issues in China and that Western companies engaging with the Chinese government are under strict scrutiny by the agencies that enforce the FCPA.

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. 15 U.S.C. §§ 78dd-1(a), 78dd-2(a). The FCPA also proscribes failure to meet specified record-keeping and internal control requirements. *Id.* § 78m (b)(2) and (b)(5). 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 USD 17.8 million settlement with a company whose only connection to the U.S. was the American Depositary Receipts traded on the New York Stock Exchange and, therefore, was subject to the FCPA's accounting and internal control provisions.²

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. 15 U.S.C. §§ 78dd-3. 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." *Id.*

The FCPA also contains two affirmative defenses to an alleged anti-bribery violation, which the defendant has the burden of establishing. *See id.* 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." *Id.*

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.³ 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 (OECD)'s Anti-Bribery Convention, which sets forth standards for anti-corruption legislation and enforcement in 38 signatory nations.⁴ Recently, the United Kingdom passed its own version of the FCPA, the UK Bribery Act, which is stricter and more punitive than the FCPA. The global focus on anti-bribery measures can also be attributed to the increased resources the U.S. government has provided for anti-corruption investigations worldwide. Not only has the United States bolstered the FBI and other agencies tasked with investigating FCPA violations but also 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.⁵

Not surprisingly given the increasing focus on FCPA prosecutions, financial penalties for FCPA violations are reaching astronomical heights. In December 2008, the German corporation Siemens AG and three of its subsidiaries pleaded guilty to FCPA violations resulting from approximately USD 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 USD 450 million, as well as disgorgement of profits totaling USD 350 million (on top of approximately USD

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.⁶ 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,⁷ Breuer warned of the "depth of government involvement in foreign health systems." Breuer explained that "[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 pharmaceutical regulators. To manufacture the drugs, companies must obtain approvals and certificates, such as a good manufacturing practice (GMP) 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 con-

tributions, 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. China has been an especially important market for many pharma companies. 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.⁸ 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.⁹

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 in-

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1. See, e.g., Gardiner Harris & Natasha Singer, *U.S. Inquiry of Drug Makers Is Widened*, N.Y. TIMES (August 13, 2010).
2. Fiat, December 2008.
3. 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.
4. OECD's Convention on Combating Bribery of Foreign Officials in International Business Transactions, art. 1, Dec. 17, 1997 (OECD Convention).
5. FCPA Enforcement Webcast, sponsored by KPMG Forensic (Jan. 28, 2009).
6. *United States v. Jumet*, E.D. Va., No. 3:09-CR-00397-HEH.
7. See Syncor Taiwan (December 10, 2002) and Schering-Plough (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.
8. H.R. Conf. Rep. No. 100-576 at 919-20 (1988).
9. 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.

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