Merger and acquisition activity is occurring at high levels across the pharmaceutical industry, and analysts expect the shopping spree to continue, with deals increasingly taking on an international flavor. Globalization opens the door to tremendous opportunities, but it also comes with additional risks. A notable one is the increased scrutiny of international activities by US Department of Justice (DOJ) and the Securities and Exchange Commission. It is important that pharmaceutical companies and their representatives have a solid grasp of the dangers and pitfalls in this area and that they take steps to avoid them.

DOJ officials have been clear about their intentions to closely scrutinize overseas business dealings of US pharmaceutical companies with an eye toward violations of the Foreign Corrupt Practices Act (FCPA). Speaking at the annual Pharmaceutical Regulatory and Compliance Congress last November 2009, US Assistant Attorney General Lanny Breuer pulled no punches, promising that DOJ "will be vigilant in holding companies and individuals who break the law accountable," and that application of FCPA to the pharmaceutical industry is going to be "a focus for the Criminal Division in the months and years ahead."

FCPA includes an antibribery provision enforced by DOJ and recordkeeping provisions enforced by the SEC. The antibribery provision outlaws the offer, payment, authorization, or promise by a US-based company or issuer of "anything of value" to "foreign officials" in an effort to secure business. Such payments made to foreign officials through subsidiaries, intermediaries, or third-party agents are as illegal as direct payments if made knowingly or with conscious disregard for the law. US issuers, including foreign companies on US exchanges, are required to maintain a sufficient set of FCPA-related internal controls pursuant to relevant federal securities laws under the SEC-enforced provisions. Violations include purposely recording payments to foreign officials improperly, mislabeling bribes as "commissions," or other expenses, omissions of payment entries, and similar actions.

FCPA was enacted in 1977 but was used sparingly for a long time. During its first 20 years of existence, it was used to prosecute just 17 companies. Over the last five years, however, DOJ has prosecuted 57 companies for FCPA violations — more than the total number of prosecutions brought between 1977 and 2005 — and during the past two years, it has launched approximately 260 related investigations. Historically, healthcare and pharmaceutical companies have accounted for about 11% of FCPA enforcement activity, but it's no mystery why DOJ is focusing its scrutiny in those industries. Nearly one third of pharmaceutical companies' total sales are now generated outside US borders, where health systems are regulated, operated, and financed by government entities to a significantly greater degree than in the United States. As a result, companies doing business overseas are likely to interact with foreign officials on a fairly frequent and consistent basis.

The bottom line for the pharmaceutical industry is increased exposure to risks of FCPA-related infraction. Many clinical trials and research now take place abroad, often in a decentralized manner involving third parties. These...
actions raise significant monitoring and compliance problems for pharmaceutical firms, including the expansive definition of "foreign official." Companies may be working for government healthcare programs or institutions or for state-owned organizations which, in turn, may be considered "foreign officials" for purposes of the FCPA. For example, because Chinese regulators are involved in most business enterprises, most hospitals and employees of hospitals— including doctors and technicians—are considered "foreign government officials."

DOJ is working with the Health Care Fraud Unit, FBI, US Attorneys' Offices, and IRS's Criminal Investigation Division to examine all international business transactions of pharmaceutical companies, and its efforts extend to investigation and prosecution of senior executives. "[For] enforcement efforts to have a real deterrent effect, culpable individuals must be prosecuted and go to jail," Breuer insisted.

Violations by pharmaceutical and healthcare companies that are currently under investigation include bribing doctors to purchase drugs, paying company sales agents commissions that are passed along to doctors, paying researchers to influence the reliability or integrity of data in clinical trials, and paying regulators to win drug approvals.

Other payments considered illegal may not be so apparently "corrupt," because the statute applies to "anything of value." If made in an effort to secure business, prohibited conduct may also include inviting officials to participate in overseas travel for purposes of attending conferences and educational seminars or to promote a particular product, funding postmarketing studies, and gifts of free pharmaceutical samples. Even payments to charitable foundations can be problematic. In 2004, a US-based pharmaceutical company settled with the SEC for a violation of the FCPA's accounting provisions after its Polish subsidiary made a series of payments to a local charity to induce the group's president (who was also a Polish government official) to influence the purchase of the company's pharmaceutical products.

In the context of merger and acquisition activity, pharmaceutical companies must be wary not to "purchase" FCPA liability by failing to conduct due diligence on proposed transaction partners. Such "successor liability" generally attaches in stock transfers or mergers, but may also attach in an asset purchase. Prior to any merger, the acquiring company should assess corruption levels of the countries in which the target entity conducts business; search for government affiliations; review the target's existing FCPA compliance program and controls; test the adequacy of the target's books and records; and insert contract provisions in the merger agreement that would indemnify the acquirer against FCPA violations and include representations and warranties that the target has made no corrupt payments to foreign officials.

Penalties for running afoul of FCPA can be substantial. Companies convicted under the act's antibribery provisions are subject to criminal fines up to $2 million per violation, and individuals face up to five years' imprisonment, along with criminal fines of up to $100,000 per violation. Accounting provision violations can trigger fines as high as $25 million for companies while individuals face up to $5 million in fines and 20 years' imprisonment. In addition, the SEC can impose civil penalties up to $10,000 per violation. The cost of the investigation may also run into the hundreds of thousands of dollars. In December 2008, a German corporation and three of its subsidiaries pleaded guilty to criminal violations of FCPA's internal controls and account provisions. They paid criminal fines of $450 million, disgorged profits totaling $350 million, and paid approximately $856 million in additional fines and disgorgement of profits imposed by the German government.

Some of DOJ's "red flags" for pharmaceutical company FCPA violations include:

- Lack of transparency in expense and account records
- Transactions with a foreign third-party clinical research organization (CRO) that has ties to government officials or relies on government contracts
- Unusual payment patterns
- Collaborations with CROs based in countries or geographic regions with reputations for bribery (e.g., Russia, China, Middle East, Africa, Italy, Greece).
To avoid running afoul of FCPA and its enforcement agencies, pharmaceutical firms should:

- Develop an FCPA compliance policy, setting the right tone at the top of the organization and communicating it regularly to senior executives so that compliance is aligned with corporate policy.
- Translate the company code of conduct into the languages of each country where the company does business and ensure the translation is distributed to officers, employees, and agents in each office.
- Require interactive Internet-based training for both foreign-based employees and foreign agents. Training should be in the recipient's native language, accompanied, whenever possible, by personal training conducted by in-house counsel or ethics officers.
- Review sales and marketing operations in high-risk countries, particularly where there is dependence on third-party agents.
- Conduct documented due diligence on all CROs prior to engagement to identify any potential FCPA-related risks.
- Prohibit compensation packages for foreign agents that would incentivize corrupt payments, such as success fees, to foreign officials.
- Include a contractual right to audit CROs for compliance and subject all expenditures by foreign agents to frequent and random audits.
- Require foreign agents and distributors to operate under written contracts that specify prohibited conduct under the FCPA and obtain signed certifications that they understand and will comply with those provisions.
- Require written prior approval by an identified compliance officer for anything that could be construed as a payment to a foreign official.
- Make FCPA review part of merger-and-acquisition due diligence; insurance policies generally will not cover FCPA violations.
- Institute confidential reporting mechanisms.

Overall, the best approach for pharmaceutical companies dealing with third parties that are involved in the pharmaceutical industry abroad is to proceed under the assumption that the third parties are government officials in some shape, manner or form, and that for purposes of FCPA compliance, they are all "foreign officials." Consider any payment to these "foreign officials" as potentially creating a risk. Heightened scrutiny should be exercised to evaluate all expenditures made to these "foreign officials" to assess their reasonableness and connection to a legitimate business purpose, and to ensure that, if made, the payments are accurately documented in the company's books and records.

Carlos F. Ortiz* is a former federal prosecutor and current shareholder in LeClairRyan's Government Investigations and Criminal Defense, Taxation, Financial Services Litigation and Regulation, and Business Litigation Practice Area Teams, as well as its Healthcare Industry Team, based in Newark, NJ, and New York, NY, Carlos.Ortiz@leclairryan.com [carlos.ortiz@leclairryan.com]

. Michael Goldklang is an associate in LeClairRyan's Business Litigation Practice Area Team, based in Newark, NJ.

IMAGE: TIM LAMAN, GETTY IMAGES