



For any questions, please contact these or any Venable LLP attorneys in the FCPA Group.

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Is your company in the following industries?

- Vaccines
- Pharmaceuticals
- Life Sciences
- Medical Devices
- and
- Other Science-based Organizations and Associations.

If so, your company maybe a target of DOJ's new FCPA enforcement initiative.

## DOJ Targets Pharmaceutical & Life Sciences Companies for FCPA Enforcement

### Is Your FCPA Compliance House in Order for 2010?

The U.S. Department of Justice ("DOJ") has spoken, and U.S. pharmaceutical and life sciences industries should listen. DOJ has set its sights on "the application of the Foreign Corrupt Practices Act ("FCPA") to the pharmaceutical industry in the months and years ahead," said Lanny A. Breuer, Assistant Attorney General for DOJ's Criminal Division. In his November 2009 address to the "Pharmaceutical Regulatory and Compliance Congress and Best Practice Forum," Breuer made clear that DOJ will focus on the pharmaceutical and life sciences industries, where non-U.S. sales are "close to \$100 billion dollars, or roughly one-third," of the total industry revenue.

The FCPA prohibits the paying, offering, promising to pay (or authorizing to pay or offer) money or "anything of value" with corrupt intent, for the purpose of obtaining or retaining business. In addition, the FCPA requires publicly traded companies to accurately reflect all payments in their books and records, and to maintain adequate FCPA controls.

Over the last five years, there has been a dramatic increase in FCPA enforcement activity. Breuer points out that since 2005, DOJ has brought 57 new prosecutions -- more than the number of prosecutions brought between the FCPA's enactment in 1977 and 2005. Indeed, in 2009 DOJ is conducting more than 130 active FCPA investigations. Moreover, it will combine its FCPA attorneys and FBI agents with attorneys and agents from its "health care fraud unit" to undertake a focused inter-departmental initiative to "investigate FCPA violations in the pharmaceutical and device industries." Effective deterrence, said Breuer, will warrant investigation and prosecution of corporations, as well as their senior executives.

### Why pharmaceutical and medical device industries?

As Breuer points out, the \$100 billion spent in the international health care arena each year is typically spent in countries where health systems are regulated, operated and financed by government entities. As a result, DOJ has determined that a U.S. pharmaceutical company that sells its products overseas "will likely interact with *foreign government officials*, as that is defined in the FCPA context, on a fairly frequent and consistent basis."

### Who is a "foreign official" in the context of a public health care system?

DOJ's comprehensive "range" of who may be considered a "foreign official" covered by the FCPA are, according to Breuer, as follows:

Some are obvious, like health ministry and customs officials of other countries. But some others may not be, such as the doctors, pharmacists, lab technicians and other health professionals who are employed by state-owned facilities. Indeed, it 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.*

In June 2008, DOJ confirmed its broad application of these definitions in its settlement of criminal charges with AGA Medical Corporation ("AGA"). AGA, a privately-held medical device manufacturer, voluntarily disclosed certain payments to DOJ, including payments made to physicians employed by Chinese government-owned hospitals. DOJ held that these payments were made to induce and obtain contracts for AGA's medical devices from "instrumentalities" of the Chinese government, where physicians employed by the hospitals were "foreign officials." AGA settled for USD \$2,000,000 in criminal penalties, the imposition of an FCPA compliance program and independent corporate monitoring for a three-year period.

### What constitutes a "corrupt offer or payment" in violation of the FCPA to one of these officials?

Importantly, Breuer emphasized that the answers to these questions are fact-specific and will depend on the circumstances of an individual case. However, he also provides a number of examples of which the industry should take note. Corrupt payments, offered to "obtain or retain business," can include: "cash, gifts, charitable donations, travel, meals, entertainment, grants, speaking fees, honoraria, and consultant agreements," to name a few.

Even "charitable donations" can be considered an improper inducement. For example, in June 2004, Schering-Plough, a large publicly-traded company settled a Securities and Exchange Commission ("SEC") enforcement action for \$500,000 in civil penalties. There, the SEC alleged that Schering-Plough made

improper payments to the favorite charitable organization of a Polish government official who was head of a health fund that influenced and provided for the purchase of pharmaceutical products by Polish hospitals. The SEC also alleged that the “donations” were not accurately reflected in the company’s books and records.

### **How can U.S. pharmaceutical & device companies protect themselves from potential FCPA exposure?**

As the DOJ Deputy Chief for health care fraud enforcement said recently “[b]ottom line, don’t bribe anyone.” Thankfully, DOJ’s list of important corporate compliance steps was a bit more specific.

- **A “rigorous FCPA compliance policy.”** In his address, Breuer underscored the imperative of a comprehensive FCPA compliance policy that is “faithfully enforced,” and not “mere paper.”
- **The Compliance Program must be implemented globally.** Corporate FCPA compliance programs must apply not only to the U.S. entity and its employees, but also to agents, consultants, distributors, joint venture partners, or other business affiliates, in the countries in which it is doing business.
- **Global application of your FCPA compliance program should be combined with frequent training and oversight.** Each company must ensure that its compliance program is robust, by implementing effective training programs along with objective reviews by those expert in FCPA compliance matters.
- **Voluntary disclosures.** Not surprisingly, DOJ recommends voluntary disclosure in the event that your company discovers a potential FCPA violation. Voluntarily disclosing an FCPA violation means that your company may receive “meaningful credit” for that disclosure, such as “no action” against the company, or other preferred dispositions, such as deferred or non-prosecution agreements, or a reduced fine under the Sentencing Guidelines, depending on the circumstances. Voluntary disclosures, however, should not be undertaken without the advice of counsel expert in the FCPA.
- **Cooperation with DOJ.** Again, not surprisingly, DOJ posits that in the event a company discovers an FCPA violation, “full cooperation” with DOJ is central. If you cooperate with the Department’s investigation, you may receive a “meaningful benefit” for that cooperation.
- **Further Remedial Measures.** In the event that your company does find itself in an FCPA investigation, undertaking remedial measures to overhaul your company’s compliance structure and ensure that such issues do not recur, is essential.

DOJ’s direct initiative targeting U.S. pharmaceutical and life sciences industries, combined with the current overhaul of the U.S. healthcare system and fierce competition abroad, makes remaining competitive and compliant with U.S. laws and regulations, such as the FCPA, more important than ever. DOJ emphasizes enormous fines and penalties that can accompany an FCPA violation, and cautions: “doing the right thing... also makes good business sense.”

### **How and When Will the FCPA Affect my Business?**

The FCPA has a broad reach, which includes penalties such as disgorgement of profits and civil and criminal fines, that have recently cost companies hundreds of millions of dollars, and executives and employees, several years in prison. Therefore, if your business is in this targeted industry, undertake a review of your company’s payments and activities to and through your customers, agents and representatives, both here and abroad. Don’t wait until DOJ has opened an investigation into your company before taking steps to ensure that your FCPA house is in order.

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**To find out how your business may be affected in the coming year and how Venable may be able to assist you, contact Lindsay B. Meyer, [lbmeyer@venable.com](mailto:lbmeyer@venable.com), or at 202.344.4829 or William H. Devaney, [whdevaney@venable.com](mailto:whdevaney@venable.com), or at 212.983.8204.**

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