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# Pharmaceutical Executive

## Pharma Companies Face Scrutiny Over Foreign Physician Relationships

Misconduct on the part of international employees could create problems.



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**F**inancial relationships with physicians outside the United States present a growing compliance risk for pharmaceutical companies. In this country, pharmaceutical manufacturers have been the subject of government enforcement and legislative activity regarding physician relationships for several years. Accordingly, the industry has devoted substantial attention to compliance with the Anti-Kickback Statute and other laws designed to govern its relationships with doctors.

Recent developments, though, suggest that financial relationships with physicians outside the United States also pose substantial compliance risks under both American and foreign law. Financial relationships with physicians employed by foreign governments (physicians in many foreign countries are commonly government employees) are likely to be regulated by the United States Foreign Corrupt Practices Act (FCPA). In addition, foreign countries may have their own laws that limit or prohibit the provision of financial and other benefits to physicians.

### Foreign Corrupt Practices Act

The FCPA makes it a crime to pay, offer, authorize, or promise to award anything of value to a foreign government official in order to assist in obtaining business.

Violations of the FCPA are felonies prosecuted by the US Department of Justice (DOJ). The Securities and Exchange Commission (SEC) also has enforcement

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authority over companies that have issued securities in the United States or that file reports with the SEC.

The anti-bribery provisions of the FCPA apply to a broad range of companies and individuals with ties to the United States, including:

- » Corporations and other business organizations formed under the laws of the United States
- » Individuals who are citizens or residents of the United States
- » Companies and individuals who take any action in furtherance of an FCPA violation in the United States
- » Companies with securities registered in

the United States or that otherwise are required to file reports with the SEC.

Corporations and individuals otherwise subject to the FCPA can be held liable for bribes paid to foreign officials *even if no actions or decisions took place within the United States*. At the same time, many non-US corporations are subject to the law if the unlawful activity touches this country, or if they access US capital markets. In other words, the FCPA potentially applies to the entire pharmaceutical industry worldwide.

The risk to the industry is not limited to US law. An increasing number of countries outside the United States have adopted laws modeled after the FCPA. Thirty-six countries, including the entire European Union, have obligated themselves to enact and enforce similar laws. And China has announced an initiative to crack down on commercial bribery, specifically identifying corruption in the procurement of medicine and medical equipment.

The DOJ and SEC have viewed state-employed physicians as foreign officials

under the FCPA. When these physicians are in a position to influence government or hospital purchasing decisions, payments from pharma companies that could influence their judgment may be viewed as unlawful under the FCPA.

### Consequences

The criminal penalties for FCPA violations can be substantial. Individuals who violate the statute face up to five years imprisonment, or ten years for certain willful violations. Individuals also can be fined up to \$1 million per violation. Business entities may be fined upwards of \$2.5 million for each violation, or twice the amount gained

as a result of the violation.

In addition to potential criminal liability, civil penalties may be imposed. Depending on the circumstances, the SEC can seek to impose an additional fine of up to either \$500,000 per violation or the gain obtained as a result of the violation.

Individuals and corporations that violate the FCPA may suffer collateral consequences, such as exclusion or debarment from certain federal programs and ineligibility to receive export licenses. Moreover, because an FCPA violation is a predicate act under the Racketeer Influenced and Corrupt Organizations Act (RICO), violators may be subject to additional civil or criminal actions, including a private RICO action by a competitor or forfeiture proceedings brought by the government.

company's net profit in the People's Republic of China, plus interest, for the period of the alleged misconduct. As a condition of the settlement and plea, Diagnostic Products Corporation was required to adopt internal compliance policies and hire an independent consultant to audit and monitor its adherence to these policies.

Also in 2005, Micrus Corporation, a US medical device company, settled an FCPA investigation by agreeing to pay \$450,000 in civil penalties and adopting an FCPA internal compliance program. Micrus allegedly paid \$105,000 to physicians employed by government-owned hospitals in France, Turkey, Spain, and Germany in return for the hospitals' purchase of Micrus' embolic coils. Citing Micrus' self-disclosure of the matter, the

Luxembourg, and France of improperly paying roughly \$600,000 to physicians to convince them to persuade their government-owned hospital employers to purchase Syncor's products. In addition, the Taiwanese subsidiary allegedly paid the physicians in exchange for their referral of patients to Syncor imaging centers.

In the Syncor case, the American parent agreed to pay a \$500,000 fine and to retain an independent consultant to make recommendations concerning the company's FCPA compliance policies and procedures. The Taiwanese subsidiary pled guilty to a criminal FCPA violation and agreed to a \$2 million penalty. The SEC announced that in accepting Syncor's civil settlement offer, it considered the company's cooperation with the investigation, as well as the fact that Syncor promptly brought the matter to the attention of the SEC and DOJ after being alerted to the questionable conduct.

Other FCPA investigations of pharmaceutical companies are pending. For example, in an SEC filing, Bristol-Myers Squibb reported that the SEC is conducting an inquiry into the activities of its German pharmaceutical subsidiaries.

## Compliance Programs

Pharmaceutical manufacturers may consider taking several discrete, yet highly important, steps to ensure that their current operations and policies do not create an undue risk of violating the FCPA.

First, companies should review their existing compliance policies and procedures to ensure that they adequately address the financial relationships that they or their foreign subsidiaries may enter with foreign physicians.

Second, pharmaceutical companies may wish to conduct an internal assessment to identify potential risk areas under the FCPA. This evaluation should include all of the company's foreign operations, including distributors, sales representatives, consultants, and others acting on their behalf, as well as the nature of the company's relationship with foreign business partners.

Finally, companies should carefully review the adequacy of ongoing FCPA training and monitoring procedures in their compliance programs. ■

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## Enforcement Actions

Enforcement action is likely to increase in the coming year. Already, the DOJ and SEC have punished some pharmaceutical companies for FCPA violations related to financial relationships with foreign physicians and hospitals.

In 2005, the DOJ charged the Chinese subsidiary of Diagnostic Products Corporation for violating the FCPA. Through the subsidiary, the US company allegedly paid \$1.6 million to doctors and laboratory personnel employed by government-owned hospitals in the People's Republic of China. The payments occurred between 1991 and 2002, and allegedly were made to obtain and retain business with the hospitals. The company called the payments "commissions," which typically represented between 3 and 10 percent of sales.

The Diagnostic Products Corporation subsidiary pled guilty and paid a \$2 million criminal fine. Simultaneously, the American parent settled a civil action by the SEC for \$2.8 million, an amount equal to the

DOJ declined to charge the company criminally, agreeing instead to enter a deferred prosecution agreement under which Micrus must abide by certain FCPA compliance obligations for at least two years.

In 2004, Schering-Plough entered into a settlement with the SEC over an alleged FCPA violation. Schering-Plough's Polish subsidiary purportedly paid approximately \$75,000 to a Polish charitable organization headed by a government official. That individual also directed a government agency that influenced pharmaceutical purchasing decisions of Polish government-owned hospitals. In its settlement, Schering-Plough agreed to pay a \$500,000 civil penalty, to retain a consultant to review the company's FCPA policies and procedures, and to follow the consultant's recommendations.

In 2002, Syncor International Corporation, a US radiopharmaceutical company, and its Taiwanese subsidiary settled criminal and civil FCPA charges. The federal government accused Syncor and its foreign subsidiaries in Taiwan, Mexico, Belgium,