The Perils Of Pharma: The Pharmaceutical Industry And The FCPA

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Statement of intent

In recent years, the pharmaceutical industry has been subjected to increased scrutiny and enforcement by US authorities in the context of the Foreign Corrupt Practices Act (FCPA). In an effort to gain an understanding of the situation, this paper reviews some of the relevant case studies and concludes with steps that companies can take to mitigate risk.

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Introduction

The Foreign Corrupt Practices Act ("FCPA" or "Act") casts a wide net. It has broad personal jurisdiction, covering U.S. domestic concerns that file with the U.S. Securities and Exchange Commission ("SEC"), persons or entities who do business in the U.S. and any person or entity that uses a U.S. instrumentality, such as a bank, in furtherance of an illegal end. The subject matter jurisdiction of the Act is also very broad. The U.S. Department of Justice ("DOJ"), which enforces the criminal aspects of the Act, and the SEC, the civil enforcement arm, have been very aggressive in charging companies and individuals for activities that appear to be beyond the face of the statute. While the Act prohibits a bribe to foreign officials "to obtain or retain business", DOJ, supported by a U.S. Appellate court in United States v. Kay, charges virtually every fact pattern that involves a bribe to a foreign official. These jurisdictional realities, coupled with a significant expansion of investigations and prosecutions under the Act over the past 8 years, should put every business that engages in international business on notice.

The pharmaceutical industry has been no stranger to the increased enforcement activity by the U.S. enforcement authorities.

Enforcement: Pharmaceutical case studies

Syncor International Corporation
As early as 2002, Syncor International Corporation, then a U.S. publically traded radio pharmaceutical company, and its Taiwan subsidiary, settled enforcement proceedings with the SEC involving allegations of improper payments to doctors employed by hospitals controlled by foreign authorities in Taiwan, Mexico, Belgium, Luxembourg and France, in order to influence their decision to give business to Syncor. Syncor was also charged with failure to maintain proper books and records and internal controls. Syncor settled the matter and paid a civil penalty of $500,000. In related action initiated by the DOJ, the Taiwan subsidiary pled guilty a violation of the anti-bribery provisions of the Act and paid a $2,000,000 fine.

Schering-Plough Corporation
In 2004, Schering-Plough Corporation, then a publically traded global pharmaceutical company based in the U.S., settled an enforcement action with the SEC and agreed to pay a $500,000 civil penalty for violations of the books and records and internal controls provisions of the Act. The action was based upon numerous contributions to a charity in Poland that were made by a Schering-Plough European subsidiary. The founder of the charity was also the Director of the Silesian Health Fund in Poland. This government-funded entity made purchasing decisions and provided funds for pharmaceutical products in its geographical area. The SEC alleged, and Schering-Plough did not contest, that payments were made to the charity, and solicited by the Director, from Schering-Plough over a period of 3 years. The SEC alleged that payments to a charity founded and run by a government decision-maker, were inducements to cause that decision maker to cause Schering–Plough products to be purchased. In fact, during the period in question, the sale of two of Schering-Plough's products went up disproportionately in the

Director's region in comparison to other regions in Poland.

Micrus Corporation
In 2005, Micrus Corporation, a U.S. privately held medical device manufacturer settled a criminal matter with the DOJ. The matter involved potential criminal charges of violations of the Act based upon payments disguised as stock options honorariums, and commission to doctors employed at state-owned hospitals in France, Germany, Turkey and Spain to induce them to cause their hospitals to purchase Micrus products. In exchange for a payment of $450,000 in penalties, adoption of a compliance program, and appointment of a monitor, the DOJ agreed not to prosecute the disclosed conduct. (a "non prosecution agreement" or "NPA")

Diagnostic Products Corporation
Later in 2005, Diagnostic Products Corporation, then a U.S. publically traded medical device company and its Chinese subsidiary settled parallel actions with the SEC and DOJ involving payments to doctors and laboratory employees who controlled purchasing decisions at these state-owned hospitals in China. The SEC alleged, and Diagnostic Products did not contest, that the purpose of the improper payments was to influence these individuals' official decisions and to induce them to use their influence with the hospitals to assist the Chinese subsidiary to obtain or retain business. The Chinese subsidiary pled guilty to violation of the FCPA and paid a criminal penalty of $2,000,000. Diagnostic Products paid a disgorgement and prejudgment interest amount of $2,800,000 and agreed to an independent monitor for violations of the anti-bribery, books and records, and internal controls provisions of the Act.

Akzo Nobel
In 2007, Akzo Nobel, a Dutch multinational, settled charges of violations of the books and records and internal controls provisions of the Act with the SEC and DOJ. The allegations came as part of a larger investigation of the U.N. Oil for Food Program for Iraq prior to 2003. DOJ and SEC alleged that two subsidiaries of Akzo Nobel made improper payments to Iraqi officials via third parties to facilitate sales of pharmaceuticals in Iraq. Akzo Nobel paid $3,000,000 in fines, disgorgement and prejudgment interest in order to settle with the SEC and receive an NPA from the DOJ.

Immucor, Inc
Also in 2007, Immucor, Inc. U.S. publically traded diagnostics substances company and its Chief Operating Officer settled a matter with the SEC involving improper payments to the director of a public hospital in Italy to influence his decision to purchase Immucor's products and services for his hospital. To settle allegations of violations of the books and records and internal controls provisions of the FCPA, the Chief Operating Officer paid a civil penalty of $30,000 and Imuccor and the Chief Operating Officer agreed to a cease and desist order against future violations of the FCPA.

AGA Medical Corporation
And in 2008, AGA Medical Corporation, a U.S. privately held medical device manufacturer, settled conspiracy and FCPA violation charges with DOJ. The charges involved payments to Chinese doctors who were employed by government-owned hospitals in China, to induce these doctors to direct the purchase of AGA's products, as well as payments to a Chinese government official at the State Intellectual Property Office in order to have certain patents approved. In exchange of a payment of $2,000,000 criminal penalty and the appointment of an independent compliance monitor, DOJ agreed to defer prosecution for 3 years with a dismissal if there were no further violations of the Act.

Besides these enforcement actions, there have been other investigations initiated or disclosed to the enforcement authorities. In 2007, Johnson & Johnson, a U.S. publically traded health conglomerate, made a disclosure that it had disclosed to the DOJ and SEC that subsidiaries outside the United States may have made improper payments in connection with the sale of medical devices in two foreign countries that may be within the jurisdiction of the FCPA. The announcement confirmed the resignation of a senior manager of Johnson & Johnson who had

ultimate responsibility for the subsidiaries involved in the disclosure. A number of other medical device manufacturers also announced in 2007, that they had received letters from the DOJ or SEC requesting information concerning payments to government-employed physicians in various foreign countries, including Germany, Greece, and Poland. This came on the heels of the settlement buy many of these companies of domestic charges of violations of domestic anti-kickback statutes in the sale of their products.

Health care industry not immune

It is clear that companies in the health care industry are not immune to scrutiny and enforcement in the FCPA area. It is also clear that the recent enforcement strategy of DOJ and SEC targets industries for particular scrutiny. On November 4, 2010 the DOJ and SEC announced $236,000,000 in fines and disgorgements involving 7 entities, a freight forwarder and 6 entities in the oil and oil services industries for corrupt conduct in at least 7 countries. An FBI sting occurred in January, 2010, targeting the military and law enforcement products industry, charging sixteen entities and twenty two individuals with conspiracy to violate the FCPA, conspiracy to engage in money laundering, and substantive violations of the FCPA.

Specific industries targeted

It is widely believed that the pharmaceutical and medical device industry has been targeted for close review by the U.S. enforcement authorities. DOJ Assistant Attorney General Lanny Breuer set the stage in a speech before a pharmaceutical industry group in November, 2009. He stated, "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. Cheryl Scarboro has been appointed to lead a new SEC unit on FCPA enforcement. She stated in an interview, "We have areas and industries we are focusing on – pharmaceutical is one."

Why the Pharmaceutical industry?

One may speculate as to the reasons why pharma is currently a targeted industry. As stated above, individual cases have regularly been brought by the SEC and DOJ since at least 2001. Certain domestic practices of the industry, including the kickback scandal in 2007 have highlighted improper practices which, if they occurred overseas with foreign officials, would violate the FCPA. The industry may have unique FCPA risks, especially as it tries to market its products in many countries whose health care systems have significant government involvement. The nature of the industry involves significant government regulation in the research, testing and production phases of a product lifecycle. In those countries that have comprehensive government involvement in the delivery of health care, most, if not all of the participants in the delivery system of health care may be government employees. If these employees are deemed to be "foreign officials" under the Act, the industry could interface with governments in every part of the business. Assistant Attorney General Breuer recognized this in November 2009, when he stated, "In some foreign countries and under certain circumstances, nearly every aspect of approval, manufacture, import, export, pricing, sale and marketing of a drug product may involve a foreign official within the meaning of the FCPA."

Protective action

With the scrutiny that has been applied to the industry, how does a conscientious company mitigate the risk? The following would be prudent measures to adopt:

- Adopt a comprehensive corporate ethics and compliance program to conform to the guidance contained in Chapter 8 Part B of the U.S. Sentencing Guidelines. An effective

program will not only reduce the likelihood of a violation but also lessen the adverse impact on the entity if there is a violation.

- If a program is already in existence, ensure that it is broad enough to address the interface with foreign officials in all aspects of the business. While most programs concentrate on the sales function, current enforcement strategies will charge violations of the FCPA for virtually any improper payment of a foreign official in any aspect of the business, to include the approval, importation or patent phases of a product.

- Review practices that may be permitted domestically with private healthcare providers, but, because the recipient may be a foreign official, would be deemed improper. These would include, for example, honoraria, consulting fees, or speaking fees. There must always be true value for the fee and it must be permitted by local law.

- Review travel and entertainment policies. If the recipient may be a government official, all travel, expense and entertainment expenditures must comply with local law, be related to a legitimate business purpose, and be limited to the official (not the family).

- Perform due diligence on all agents, distributors, acquisition targets, joint ventures, consultants and representatives. Pay particular attention to those who may interface with any level of government. These representatives would include local counsel and financial consultants. Ensure that any red flags discovered are resolved and that all agreements are transparent.

- Train employees and third party representatives on the Act, red flags, and company expectations. Obtain written commitment from all that only legal and ethical means will be used to advance the company's interests.

- Consult with outside counsel or a compliance professional for specific advice on the risk and mitigation for each foreign country in which the company does business.

The industry is under scrutiny now and may be for some time. But strict adherence to ethical and legal principles by all employees and third party representatives will minimize the risks of violation of the FCPA.

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