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by Vince Farhat, Esq. and David Kirman, Esq.

# Current trends in FCPA enforcement in the healthcare industry

- » Healthcare companies doing business in foreign countries must comply with the Foreign Corrupt Practices Act (FCPA), which prohibits payments or offers to pay anything of value to a foreign official in order to secure an improper advantage.
- » DOJ recently increased the size of its FCPA unit by 50% and FCPA enforcement of healthcare companies is increasing.
- » Healthcare companies' frequent interactions with doctors, pharmacists, and administrators from foreign public hospitals expose them to particularly high FCPA risk.
- » The Department of Justice recently created a counsel position to evaluate the FCPA compliance programs of companies under investigation.
- » Healthcare companies doing business in foreign countries should reexamine their anti-bribery compliance policies to ensure they are doing enough to prevent and minimize FCPA violations.

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Healthcare companies doing business in foreign countries must comply with the Foreign Corrupt Practices Act (FCPA), which prohibits payments or offers to pay anything of value to a foreign official in order to secure an improper advantage. FCPA investigations brought by the Department of Justice (DOJ) and the Securities and Exchange Commission (SEC) expose healthcare companies to potentially harsh penalties, including criminal prosecution, disgorgement of profits, fines, interest, legal fees, negative publicity, ongoing governmental scrutiny, and other negative financial consequences. Other countries, such as the United Kingdom, have similar anti-bribery laws.

FCPA enforcement of healthcare companies—from multi-national pharmaceutical companies, to start-up medical device companies with only minimal international connections—is increasing. Healthcare is already a high-risk FCPA industry and, with increased governmental scrutiny and resources dedicated to FCPA enforcement, robust anti-bribery compliance programs are more critical now than ever before. Companies that invest in FCPA compliance will minimize the likelihood of an FCPA violation, increase the likelihood of finding FCPA issues early, and, with the creation of a DOJ counsel to evaluate compliance programs of companies under FCPA investigation, may also minimize damage if an FCPA allegation or violation occurs. This article summarizes trends and some of the significant



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FCPA enforcement actions in the healthcare industry over the previous three years in an effort to highlight healthcare-specific FCPA compliance challenges.

### FCPA overview

The FCPA makes it illegal for domestic companies and individuals to make payments to foreign officials to obtain an improper business advantage, such as facilitating the approval of a permit, retaining business, or obtaining new business.<sup>1</sup> The FCPA also prohibits the use of third parties, such as agents, to accomplish the same objective, by prohibiting payments made to any person knowing that all or some of the funds will be offered or paid to foreign government officials. The FCPA broadly defines the term “foreign official” as:

[A]ny officer or employee of a foreign government or any department, agency, or instrumentality thereof, or of a public international organization, or any person acting in an official capacity for or on behalf of any such government or department, agency, or instrumentality or for or on behalf of any such public international organization.<sup>2</sup>

The FCPA does not define what it means to be an “instrumentality” of a foreign government, and that term has been the subject of recent litigation. On its face, the FCPA applies to “domestic concerns” (i.e., citizens, nationals, and residents of the United States and companies, broadly defined) with principal places of business in the United States or companies organized under US state laws; and

to “issuers” (i.e., companies that issue securities registered on US stock exchanges). The FCPA may also apply to foreign individuals and companies with a sufficient jurisdictional connection to the United States. An FCPA violation may occur anywhere in the world.

The DOJ enforces the FCPA’s criminal anti-bribery provisions. The SEC may bring civil FCPA charges and also enforces certain accounting and recordkeeping provisions of the FCPA on publicly held companies. The DOJ and SEC frequently work together on FCPA investigations.

The US government recovered over \$1.56 billion through FCPA enforcement actions in 2014.<sup>3</sup> In November 2015, DOJ announced it would increase the size of its FCPA unit by 50% by adding 10 new prosecutors.<sup>4</sup>

### FCPA enforcement in the healthcare industry

Healthcare is a high-risk industry in the FCPA space and FCPA enforcement of healthcare companies is increasing,<sup>5,6</sup> which is not surprising, given the healthcare industry has several features exposing it to more FCPA risk than other industries. For example, representatives from healthcare companies frequently have interactions with doctors, pharmacists, and administrators from public hospitals in foreign countries. These individuals control what foreign hospitals purchase and what doctors who work in these hospitals prescribe. Their decisions have significant fiscal impacts on healthcare companies. Although doctors and pharmacists who work in public hospitals in foreign countries are not typically thought of as “foreign officials,” government enforcers view them as foreign officials for purposes of the FCPA. Like other industries, healthcare

## The FCPA does not define what it means to be an “instrumentality” of a foreign government...

companies also have frequent contact with more traditional foreign officials to obtain regulatory approvals and government contracts.

FCPA violations for healthcare companies typically include payments to prescribe, to get on lists of approved drugs or other regulatory approvals, and to get government contracts. Between 2002 and 2015, there have been approximately 19 healthcare companies that have engaged in conduct alleged to have violated the FCPA.<sup>7</sup> In an effort to shed light on the increased enforcement actions of healthcare companies and to discern the types of activities targeted by the SEC and DOJ, six current FCPA actions brought against companies associated with the healthcare industry are examined below.

#### **Pfizer Inc.: August 2012**

The SEC charged Pfizer Inc. (Pfizer), a multinational pharmaceutical corporation headquartered in New York, with violating the FCPA, because its subsidiaries allegedly bribed doctors and other healthcare professionals employed by a foreign government. The SEC alleged that the violations occurred in Bulgaria, China, Croatia, Czech Republic, Italy, Kazakhstan, Russia, and Serbia. Pfizer allegedly made the bribes in an effort to obtain regulatory approval, formulary approval, sales, and increased prescriptions for the company's products. According to the government, Pfizer illegally recorded the bribes as expenses for promotional activities, training, travel and entertainment, clinical trials, freight, and conferences, as well as advertising.<sup>8,9</sup>

The SEC also charged Wyeth, a pharmaceutical company acquired by Pfizer, with similar allegations. In an effort to increase sales, Wyeth allegedly created a "points program" for doctors in China. According to the SEC, the points were directly correlated with the number of Pfizer prescriptions written. The SEC claimed that more prescriptions earned more points, and doctors could redeem the points for items

such as tea sets, cell phones, reading glasses, and medical books. In Croatia, a similar program was allegedly in place. The doctors in Croatia allegedly would be given a percentage of the value of the products purchased by the doctor's institution, incentivizing the writing of Pfizer prescriptions. Doctors allegedly received this percentage in the form of cash, free products, or international travel. The alleged misconduct was traced as far back as 2001. In 2004, Pfizer made an initial disclosure to both the DOJ and the SEC. Although neither admitting nor denying the allegations, Pfizer paid \$16,032,676 in disgorgement and a prejudgment interest of \$10,307,268 for a total of \$26,339,944, and Wyeth paid a disgorgement of \$17,217,831 and a prejudgment interest of \$1,658,793 for a total of \$18,876,624.

#### **Eli Lilly and Company: December 2012**

Eli Lilly and Company, an Indianapolis-based pharmaceutical company, settled an FCPA action brought by the SEC stemming from bribery allegations. The SEC alleged that Eli Lilly subsidiaries made improper payments to foreign government officials in Russia, China, Brazil, and Poland in an effort to win business in their respective countries. According to the SEC's allegations, a Russian subsidiary used offshore marketing agreements to pay millions of dollars to third parties who would then funnel the money to government officials. The SEC alleged that the transactions with offshore or government-affiliated entities did not receive specialized review for FCPA violations. Moreover, the SEC claimed that Eli Lilly failed to curtail the use of "marketing agreements" quickly enough. The SEC claimed that Eli Lilly subsidiaries paid approximately \$8.5 million in improper benefits to foreign officials. Eli Lilly, which did not admit or deny the allegations, agreed to pay a disgorgement of \$13,955,196, a prejudgment interest of \$6,743,538, and a penalty of \$8.7 million for a total payment of \$29,398,734.

### **Stryker Corporation: October 2013**

The SEC charged Stryker Corporation, a Michigan-based medical technology company, with violating the FCPA in five different countries. Stryker's subsidiaries in Argentina, Greece, Mexico, Poland, and Romania allegedly spent \$2.2 million in bribing doctors, healthcare professionals, and other government-employed officials in order to retain or obtain their business.<sup>10</sup> Stryker allegedly recorded bribes as legitimate expenses in its records. The SEC claimed that Stryker profited by approximately \$7.5 million through the alleged bribes. The SEC claimed that Stryker failed to have a "robust compliance program" and that this misconduct led to illicit profits.<sup>11</sup>

The alleged bribes dated back as far as 2003. For example, a subsidiary in Mexico is alleged to have had a law firm pay \$46,000 to a Mexican government employee to ensure that the subsidiary won a government contract. The subsidiary reimbursed the law firm for the bribe and the subsidiary listed the payment as a legal expense, although, according to the allegations, no legal services were provided. In Greece, another subsidiary allegedly made a donation of \$200,000 to a public university to fund a laboratory. A doctor allegedly agreed to provide Stryker with business in exchange for the donation. In the end, Stryker paid disgorgement of \$7,502,635, a prejudgment interest of \$2,280,888 and a penalty of \$3.5 million. Stryker never admitted or denied the allegations.

### **Bio-Rad Laboratories Inc.: November 2014**

Bio-Rad Laboratories Inc., a California-based clinical diagnostic and life science research company, settled SEC enforcement actions after Bio-Rad self-reported misconduct. Bio-Rad reported that its subsidiaries made improper payments to officials in Russia, Vietnam, and Thailand in order to win business. An SEC investigation claimed that Bio-Rad did not

have sufficient internal controls to prevent or detect bribes. Furthermore, the SEC claimed that Bio-Rad did not address red flags that a bribing scheme may have existed; instead it "condoned an atmosphere of secrecy."<sup>12</sup> Over a five-year period, \$7.5 million in alleged bribes were illegally recorded as legitimate expenses, including commissions, advertising, and training fees. For example, the SEC claimed that a Bio-Rad-acquired company operating in Thailand would inflate the commissions of some of its agents and these agents would then use some of their commission for bribes. Furthermore, Bio-Rad allegedly had foreign agents, with inflated commissions to pay bribes, stationed in Russia. The SEC claimed that the agents had phony Moscow addresses and offshore bank accounts and that Bio-Rad retained the agents primarily to influence Russia's Ministry of Health to award government contracts to Bio-Rad. According to the SEC, to conceal the scheme, the agents had at least 10 personal email addresses with aliases. These bribes resulted in \$35 million in alleged illicit profits. Ultimately, Bio-Rad agreed to pay \$40.7 million in disgorgement and prejudgment interest to the SEC, as well as a \$14.25 million criminal fine to the DOJ.

### **Bruker Corporation: December 2014**

Bruker Corporation is a Massachusetts-based global manufacturer of scientific instruments including x-ray machines and preclinical imaging devices that assist in neurology and cardiology.<sup>13</sup> The SEC charged Bruker with providing improper payments and non-business related travel to government officials to win business. An office in China allegedly paid over \$111,000 to Chinese officials and attempted to hide the transaction by calling it a collaboration agreement. In exchange, the officials would allegedly ensure that state-owned entities provided research on Bruker products and would use Bruker products

for laboratory demonstrations. Also, the SEC claimed that Bruker would reimburse Chinese government officials for international leisure travel and that these costs were improperly recorded as legitimate business and marketing expenses. Although Bruker self-reported the misconduct, the SEC faulted the corporation for having “lax internal control” which allowed their offices to enter into sham collaboration agreements to aid in directing money to foreign officials.<sup>14</sup> Furthermore, according to the SEC, Bruker lacked internal controls to prevent and to detect improper payments. Bruker neither admitted nor denied the allegations. In the end, the company agreed to pay \$1,714,852 in disgorgement, \$310,117 in prejudgment interest, and a \$375,000 penalty.

#### **Mead Johnson Nutrition: July 2015**

Mead Johnson Nutrition Company manufactures pediatric nutrition products, such as Enfamil. It is headquartered in Glenview, Illinois, with subsidiaries around the world, including in China.<sup>15</sup> In July 2015, Mead Johnson agreed to settle the SEC’s allegations that it violated FCPA.<sup>16</sup> The settlement was based on allegations that Mead Johnson China improperly paid healthcare professionals at government-owned hospitals to recommend Mead Johnson’s infant formula to new and expectant mothers. According to the SEC, Mead Johnson employees exercised some control over third-party “distributor allowances,” which were used to pay healthcare professionals in China hospitals to recommend Mead Johnson Nutrition products. The healthcare professionals also allegedly provided the company with contact information for patients who were new or expectant mothers, so it could market its infant formula to them directly. The SEC claimed that Mead Johnson did not accurately reflect in its books and records the improper payments, which were made during a five-year period. Without

admitting or denying the SEC’s findings, Mead Johnson agreed to pay \$7.77 million in disgorgement, \$1.26 million in prejudgment interest, and a \$3 million penalty.

#### **FCPA compliance policies and procedures**

These enforcement actions show healthcare companies operate in a high-risk FCPA environment and improper payments made to officials or employees of government-owned entities will be subject to prosecution under the FCPA. They also show that FCPA enforcers will look to the substance of a transaction, regardless of whether it is characterized as a charitable contribution, allowance, consulting agreement, business travel, or some other expense that hides the payment’s true character. Healthcare companies doing business in foreign countries, therefore, should examine their anti-bribery compliance policies and procedures to ensure that they are doing enough to minimize potential FCPA exposure.

In November 2012, in an effort to describe the FCPA and what a company should do to ensure FCPA compliance, the DOJ and SEC published the *Resource Guide*, which states that there are nine factors considered in conducting an investigation and deciding whether to charge a corporation. A few of the factors are: (1) the nature and seriousness of the offense, (2) the pervasiveness of the wrongdoing within the company, and (3) the existence and effectiveness of the corporation’s pre-existing compliance program. Alongside this, the DOJ and SEC place a “high premium on self-reporting, along with cooperation and remedial efforts, in determining the appropriate resolution of FCPA matters.”<sup>17</sup>

It is important to have an effective compliance program, because it can be a factor when the DOJ and SEC consider an enforcement action. The DOJ and SEC emphasize that there is no “one-size-fits-all” when it comes to compliance programs. Nevertheless, the *Resource*

*Guide* lays out the “hallmarks” of an effective compliance program.

A key aspect in an effective compliance program is a clear policy against corruption. Furthermore, there should be a code of conduct that outlines compliance policies and procedures, which should be clear, concise, and accessible to all employees conducting business on the company’s behalf. Moreover, there should be periodic training and certification for all directors, officers, relevant employees, and possibly agents and business partners. Inclusively, there should be an assessment of risk with a focus on large government bids, questionable payments to third-party consultants, and excessive discounts to retailers. A company should also incentivize compliance through personnel evaluations and promotions, rewarding those who improve and develop a company’s compliance program, as well as those who take a leadership role in ethics and compliance. In sum, these are just a few of the many guidelines the *Resource Guide* provides. These guidelines are meant to provide insight rather than define what an ideal compliance program entails.

In August 2015, the DOJ reemphasized the importance of FCPA compliance with the creation of a counsel position for FCPA matters. According to the chief of the DOJ Fraud Section, the FCPA counsel position exists to assist prosecutors vet companies that are under FCPA investigation. One key aspect of that analysis—which includes whether charges should be brought, and if so, an appropriate disposition—is whether a company “get[s] it and [is] trying to implement a good compliance program from [companies that] have a near-paper program.”<sup>18</sup> These comments demonstrate that compliance is not only critical to prevent FCPA violations, but also to mitigate any damage if FCPA violations occur. Additionally, if an FCPA violation occurs, a proactive compliance function will also allow

a company the option to seek cooperation credit under DOJ’s recently published Yates Memorandum, which requires companies to proactively identify an discovery relevant information about the individuals involved in the misconduct.<sup>19</sup>

The DOJ’s recent addition of 10 new prosecutors to the Fraud Section’s FCPA unit—increasing its size by 50%—further highlights the importance of FCPA compliance. ☐

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*The opinions expressed in this article do not necessarily reflect the views of Holland & Knight LLP or O’Melveny & Myers LLP or their clients, and should not be relied upon as legal advice.*

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