ANDREWS LITIGATION REPORTER

THOMSON WEST

Medical Devices

COMMENTARY

REPRINTED FROM VOLUME 14, ISSUE 19 / NOVEMBER 12, 2007

The Foreign Corrupt Practices Act And the Medical Device Industry

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Upon reading Johnson & Johnson's Feb. 12 press statement announcing it had voluntarily disclosed to the Justice Department and the Securities and Exchange Commission that its subsidiaries outside the United States were believed to have made improper payments (translation: bribes) related to the sale of medical devices in two countries,[1] I paused, because it meant the company had likely violated the Foreign Corrupt Practices Act.[2]

This was news because I see Johnson & Johnson as a great company with a great brand, known for its integrity. But as an FCPA practitioner, I also know that some of the very best companies are becoming entangled in its enforcement web.

J&J's statement further advised that the improper payments violated its company policies and acknowledged that the payments may be covered by the FCPA. It also said it is providing additional information to the Justice Department and SEC and is fully cooperating in their review of the matter.

This payment activity was serious enough that the company's worldwide chairman of medical devices and diagnostics was apparently allowed to retire because the foreign subsidiaries involved in the improper payments were (in his own words) his "ultimate responsibility by virtue of this position."

The J&J announcement last February highlighted the fact that other medical products and services companies operating overseas are potentially at risk for an FCPA violation.

Makers of medical equipment and devices with sales and business development representatives operating overseas, or with international agents and consultants helping to facilitate business overseas, will usually face FCPA challenges. These challenges will occur even if the representative or consultant does not notify those in the U.S. parent or share-holding company of those public corruption challenges as they occur.

Thus, no matter how ethical the corporate culture, how strict and rigorous the controls, or how expansive the written procedures, medical equipment and device companies doing overseas business with foreign officials and ministries should assume that their business is at high risk for periodic FCPA-related activities. This assumption will vary depending on the public corruption risk profile of the country in question.

Immucor Inc.

The SEC announced Sept. 28 that it had filed a settled civil action against Gioacchino De Chirico, the president and COO of Immucor Inc., a U.S. public medical equipment company. He was accused of violating and aiding and abetting a violation of the FCPA[3] by paying 13,500 euros to the director of a Milan, Italy, public hospital in exchange for favorable consideration on a contract for providing goods and services. *See* SEC Litigation Release No. 20316 (Sept. 28, 2007).

The SEC alleged that the payment was falsely recorded in Immucor's books and records and was described in a manner that would enable the hospital director to avoid Italian income taxes. In particular, De Chirico allegedly approved an invoice that falsely described the payment as a consulting fee for services rendered even though he knew that the hospital director had never provided any services. *See SEC v. De Chirico*, No. 1:07-CV-2367, *complaint filed* (N.D. Ga. 2007).

De Chirico, without denying or admitting the SEC's allegations, agreed to pay a civil penalty of $30,000. De Chirico and Immucor separately agreed to an SEC cease-and-desist order related to the same allegedly improper payment activity. *See* SEC Litigation Release No. 20316 (Sept. 28, 2007).

Syncor

The SEC filed a settled civil injunctive action Sept. 27 against Monty Fu, the founder and chairman of Syncor International Corp. a U.S. public company providing radiopharmaceutical products and services, in connection with payments by Syncor Taiwan to doctors employed by private and public hospitals in Taiwan over a 17-year period. The SEC alleged that Fu aided and abetted Syncor's violations of the FCPA because he had the authority to maintain compliance with existing internal controls and to implement existing accounting controls but knew of the improper payments by Syncor Taiwan at least as early as 1994.[4]

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The SEC also said Fu knew, or was reckless in not knowing, that the payments were improperly recorded in the books and records of Syncor Taiwan and therefore Syncor. *See* SEC Litigation Release No. 20310 (Sept. 27, 2007).

The SEC complaint against Fu detailed that from 1985 until December 2002 Syncor, through Syncor Taiwan, began making payments to doctors totaling an average of $30,000 per year but increased from at least 1997 to $170,000 per year through the first six months of 2002. Syncor Taiwan allegedly recorded the payments to doctors as "advertising and promotions" expenses. *See SEC v. Fu*, No. 1:07-CV-0175, *complaint filed* (D.D.C. Sept. 27, 2007).

Fu agreed to settle the SEC's charges by consenting to the entry of a final judgment permanently enjoining him from future violations of federal securities laws and ordering him to pay a $75,000 civil penalty. In December 2002, however, Syncor had consented to pay a $500,000 civil penalty and be subject to a cease-and-desist order. *See generally SEC v. Syncor Int'l Corp.*, No. 1:02-CV-02421 (D.D.C. 2002). Importantly, the Justice Department's Criminal Division had also previously settled criminal FCPA charges against Syncor Taiwan, which agreed to a $2 million fine. *United States v. Syncor Taiwan Inc.*, No. 02-CR-1244-ALL (C.D. Cal. 2002).

Zimmer Inc.

More recently, Zimmer Inc., an Indiana-based medical device maker, disclosed in its Form 8-K for the period ending Oct. 11 that it had received a warning letter from the SEC. The agency said it is informally investigating potential FCPA violations in the sale of medical devices in a number of foreign countries by companies in the medical devices industry. Zimmer's disclosure stated that it believed that other medical device companies had received similar letters and that it intended to fully cooperate with the SEC's informal investigation.

Biomet Inc.

Similarly, Biomet Inc., a U.S. public medical device company, disclosed Oct. 11 that it had received a letter Sept. 25 from the SEC informing the company that the SEC was conducting an informal investigation into possible violations of the FCPA in the sale of medical devices in a number of foreign countries. Biomet indicated that it intended to cooperate fully with the SEC's investigation.[5]

Stryker Corp.

Stryker Corp., a public medical device and medical technology company, disclosed Oct. 12 that the SEC made an informal inquiry of the company regarding possible violations of the FCPA. The investigation was in connection with the sale of medical devices in certain foreign countries. The company stated that it was fully cooperating with the investigation.[6]

Other SEC-Related FCPA Inquiries

By Oct. 15 the Wall Street Journal had picked up the SEC inquiry story and reported that several orthopedic-product makers had disclosed that they received letters from the SEC regarding investigations of possible improper payments to foreign officials. In addition to Zimmer and Biomet, the story listed Smith & Nephew, Stryker and Medtronic Inc. as companies that had confirmed receipt of SEC letters inquiring about possible FCPA violations.

The Journal article also said four big orthopedic firms had already entered into agreements with the Justice Department on FCPA issues and had paid a combined $311 million to resolve allegations that they had paid off surgeons through consulting deals. The firms that reportedly entered into the

settlements included Zimmer, Smith & Nephew, Biomet and Johnson & Johnson. These settlements would become known to the SEC enforcers.[7]

Next Steps for Medical Device Companies

Given all the FCPA investigative and enforcement activity in the medical device, medical equipment and services fields (along with other industries), company legal directors, governance officers, compliance officers, financial officers and internal auditors must be vigilant.

They should be focused on assessing compliance policies, procedures and controls on overseas anticorruption issues, as well as possible internal control processes for the detection and prevention of corrupt payments.

Failure to anticipate and address international public corruption risk will result in preventable misconduct in the key areas under the FCPA: anti-bribery provisions, books and record-keeping, and internal controls. A short summary of these key FCPA provisions is provided below to enable medical device companies to begin a thoughtful assessment of the nature and extent of their corruption risks and internal controls overseas.

The Anti-bribery Provisions

The most well known provision of the FCPA is the anti-bribery provision. This provision makes it a federal criminal offense to directly or indirectly promise, offer, authorize or pay bribes or anything of value to a foreign official in order to obtain or retain business or secure any improper advantage.[8] The anti-bribery provisions apply to "domestic concerns," "issuers" of securities regulated by the SEC or "any person" (U.S. or non-U.S.) who commits an act in furtherance of a bribe in the United States or a U.S. territory. A "domestic concern" is any U.S. citizen, resident, national or incorporated company, wherever located, or any company located in the United States.[9]

An FCPA anti-bribery offense is committed when a covered person (issuer or domestic concern) pays, offers, promises to pay or authorizes payment of money or anything of value to a:

- Foreign official;
- A foreign political party or party official;
- A candidate for foreign political office; or
- Any person while knowing that the payment or thing of value will be passed on to any of the people mentioned above.[10]

Under the FCPA, a foreign official is a legislative, administrative or judicial officer; an officer in a foreign government or its agencies (health minister, foreign hospital director, etc.); or any person acting on behalf of state agency or foreign enterprise; or any official of a foreign public organization or publicly funded organization (state hospital) or any officer or agent of a public international organization (for example, the United Nations, World Health Organization), including any close family relatives of any of those listed above.[11]

Payments involving "anything of value" under the FCPA can include cash, corporate jet air travel, shopping trips, home improvements, cars, jewelry, extravagant business entertainment or any other personal benefit to the foreign official, candidate or political party official.

Many companies are aware of the limited exceptions to the FCPA anti-bribery provisions,[12] as well as the two affirmative defenses for certain payments to foreign officials.[13] The risks and circumstances surrounding those exceptions and affirmative defenses are suitable for another detailed article and will not be the focus here.

FCPA Record-Keeping and Internal Controls Provisions

As illustrated by the FCPA enforcement actions referenced above, medical device companies and their employees must give attention to the record-keeping and internal controls requirements of the FCPA while conducting the risk profile of the company for an FCPA violation. This second prong of the FCPA is a well-used enforcement tool against U.S. and non-U.S. issuers or covered persons. Specifically, the record-keeping provisions of the FCPA require companies to make and keep accurate books, records and accounts and to accurately reflect issuer transactions and asset dispositions in reasonable detail.[14]

The internal controls provision of the FCPA requires issuers to devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that:

- Transactions are executed in accordance with management's general or specific authorization;
- Transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements and to maintain accountability for assets;
- Access to assets is permitted only in accordance with management's general or specific authorization; and

- The recorded accountability for assets is compared with the existing assets at reasonable intervals, and appropriate action is taken regarding differences.[15]

FCPA record-keeping violations generally accompany anti-bribery violations, particularly as most companies do not accurately reflect the payment to the foreign official as a bribe or as a corrupt payment. Similarly, internal controls violations generally accompany anti-bribery violations because an inadequate or weak financial and management control system creates an environment that is ripe for financial fraud, misappropriation, embezzlement and bribery.

Conclusion

Medical device companies, like the rest of the multinational corporate world, must review their operations for corruption risk and update or develop rigorous procedures and policies that help prevent, detect and punish those who make or attempt to make corrupt payments to foreign officials on the company's behalf. The only way to detect the possibility of such improper payments is to also have tight internal controls for both domestic and overseas operations that are regularly tested for irregularities and suspicious payments and entries. Employees, agents and partners must be trained, and due diligence should be conducted before they are hired. Anti-corruption contract provisions for agents, consultants and partners should be rigorous and provide for termination upon suspected misconduct, as well as audit rights for review of the books and records of the third-party intermediaries and business partners.

Medical device companies, like their predecessors in the oil, telecommunications, technology and pharmaceutical industries, must give rigorous attention to these anti-corruption risk assessments and due diligence reviews with the assistance of experienced outside consultants. Those who do not, risk being blindsided by highly publicized and embarrassing criminal and civil misconduct overseas like many of the medical companies described in this article.

A discussion of how to develop an FCPA compliance program and how to detect FCPA "red flag" should be thoroughly examined during FCPA compliance and risk assessment. It is a topic so complex (along with FCPA exceptions and affirmative defense practice "minefields") that it should be addressed with the assistance of an FCPA legal adviser.

Notes

[1] http://www.jnj.com/news/jnj_news/20070212_192452.htm;jsessionid=FTQESWCJRQJS2CQPCB3WU3QKB2IIWTT1.

[2] 15 U.S.C. §§ 78m, 78dd-1, 78dd-2, 78dd-3 *et seq.*

[3] 15 U.S.C. § 78m(b)(5), 17 C.F.R. 240.13b2-1, and 15 U.S.C. §§ 78m(b)(2)(A) and (B).

[4] 15 U.S.C. § 78m(b)(2)(A) and 78m(B)(2)(B).

[5] http://home.businesswire.com/portal/site/biomet/index.jsp?epi-content=GENERIC&newsId=20071011005973&ndmHsc=v2*A1162818000000*B1194387357000*DgroupByDate*J2*N1002475&newsLang=en&beanID=1609619606&viewID=news_view.

[6] http://phx.corporate-ir.net/phoenix.zhtml?c=118965&p=irol-newsArticle&ID=1062119&highlight=.

[7] Jon Kamp, Several Orthopedic-Device Makers Get SEC Letters on Foreign Sales, Wall St. J., Oct. 15, 2007, B9.

[8] 15 U.S.C. §§ 78dd-1(a), 78dd-2(a), 78dd-3(a), *et seq.*

[9] 15 U.S.C. §§ 78dd-1(a), 78dd-2(a), 78dd-(3).

[10] *Id.*

[11] *Id.* § 78dd-1(f)(1).

[12] The FCPA has an exception for a "facilitating payment" or expediting payment to a low-level government employee in order to expedite or secure the performance of a routine governmental action. Typical permissible facilitating payments include payments to officials for mail delivery, trash collection, visa processing licenses or phone service. *See* 15 U.S.C. §§ 78dd-1(b), 78dd-2(b), 78dd-3(b).

[13] The FCPA provides an affirmative defense for payments to a foreign official where the payment made is lawful under the written local laws of the official's country. 15 U.S.C. § 78dd-2(c)(1). The second FCPA affirmative defense is for payments made by companies or individuals to foreign officials where the payments are reasonable and bona fide, directly related to promotion or demonstration of a company's products or services, or directly related to the performance of a particular contract between a company and the foreign government. 15 U.S.C. § 78dd-(2)(c)(2).

[14] 15 U.S.C. §§ 78c(37), 78m(b)(2)(A).

[15] 15 U.S.C. § 78m(b)(2)(B)(i)-(iv).

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