Legal Backgrounder

WLF Washington Legal Foundation

Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

Vol. 23 No. 48 October 24, 2008

THE FOREIGN CORRUPT PRACTICES ACT TAKES AIM AT MEDICAL DEVICES

by

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Over the past two years, the U.S. Department of Justice ("DOJ") and Securities and Exchange Commission ("SEC") have begun actively using the Foreign Corrupt Practices Act ("FCPA") to target U.S. medical device companies' overseas marketing and business practices. In fact, during the 30 years following the passage of the FCPA in 1977, the SEC only brought 15 cases against medical device companies under the Act, but in the last year has already prosecuted 12 FCPA cases against device companies. Now, the SEC is investigating major medical device firms for possible FCPA violations. Thus, the message to the U.S. medical device industry is clear: take steps to effectively manage all monetary aspects of your marketing and distribution efforts in foreign countries to avoid being caught up in an FCPA enforcement action.

The Expanding Global Market Presents Opportunities and Challenges for Medical Device Companies. With the global medical device market experiencing its most dynamic growth in history, device companies are actively increasing their marketing efforts to take advantage of emerging opportunities abroad. China, India and Russia, where over 35% of the world's population live, are experiencing significant economic growth in comparison to western nations. Improvements in the standard of living, including the delivery of healthcare services, offer growing markets for medical device sales. The successful penetration of foreign markets, however, presents unique challenges, as U.S. companies must navigate differences in language, culture, business practices and regulatory/legal requirements. What is more, device firms, particularly smaller firms with fewer global resources, must rely on a network of foreign consultants, agents, distributors, and other types of business facilitators to effectively market their products in emerging foreign markets. In developing countries with huge markets, such as India and China, bribery of foreign officials, particularly local or low-level officials, is sometimes "business as usual" and dissuading such practices can prove difficult.

Moreover, device companies operating overseas are particularly vulnerable to FCPA enforcement because, in many cases, foreign health care providers work at government-owned hospitals and clinics, and are considered government officials within the meaning of the FCPA. Though physician contact, in many cases, is educational and may include sponsoring a physician's evaluation of the company's products or subsidizing presentations at medical seminars, even modest payments to foreign doctors, nurses, or hospital technicians could trigger FCPA liability, unless they are expressly permitted by written laws of the host country. Thus, medical device companies that deal with health care providers in high-growth overseas markets where corruption is commonplace face the greatest risk of violating the FCPA. While the FCPA naturally focuses on practices abroad, a medical device company's U.S.-based operations could provide the road map for a government regulator as an anti-kickback investigation could trigger an FCPA case.

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Overview of the FCPA. Congress enacted the FCPA[1] in response to SEC investigations of U.S. companies' questionable or illegal payments to foreign officials, politicians, and political parties.[2] The FCPA's accounting and antibribery provisions address such conduct. The accounting provisions apply to companies that have securities listed on a national securities exchange in the United States[3] and do not apply to privately-held companies. Rather, only publicly held corporations under the SEC's jurisdiction are subject to the accounting requirements.[4] In accordance with the accounting provisions, such companies must make and keep records "in reasonable detail" to accurately reflect the transactions and dispositions of the company's assets[5] and maintain a reasonable system of internal accounting controls.[6]

The FCPA's antibribery provisions are broader than its accounting provisions. The antibribery provisions apply to privately held companies, as well as publicly held ones.[7] Congress intended the FCPA to cover companies beyond the SEC's jurisdictional reach, as well as corporations' foreign subsidiaries, because it recognized that such entities could be used by domestic parents as a means for funneling questionable or unlawful foreign payments.[8] The FCPA's antibribery provisions prohibit individuals or companies from offering anything of value or making payments to foreign officials to obtain or maintain business.[9] They apply to any individual, firm, officer, director, employee, agent, or stockholder who acts on behalf of a firm.[10] They also ban individuals or firms from authorizing or approving these types of payments,[11] and domestic parent corporations from authorizing or directing their foreign subsidiaries' corrupt acts.[12]

FCPA liability applies to corrupt acts taking place in or outside the United States.[13] A U.S. company or citizen may be held liable for facilitating a corrupt payment to a foreign official using any means of interstate commerce,[14] or one authorized by its employees or agents acting *outside* the United States, even if personnel within the United States were not involved.[15] The FCPA also applies to foreign firms and individuals who take actions to further a corrupt payment taking place within the United States.[16]

Penalties and Fines. The FCPA's civil penalties and criminal fines are significant. In a civil action, a firm, officer, director, employee, agent, or stockholder who acts on behalf of the firm may be fined up to $10,000 for violating the antibribery provisions.[17] A court may also choose to impose an additional fine for a natural person.[18] In many enforcement actions, the government has disgorged company profits from corrupt payments, allowing it to recover substantial damages. In a criminal action, corporations and business entities that violate the antibribery provisions may be fined up to $2 million, while officers, directors, stockholders, employees, and agents may be subject to a $100,000 fine and/or imprisonment for up to five years.[19] Furthermore, there are important non-monetary sanctions for persons or firms found guilty of violating the Act. For example, they may be ineligible to receive an export license, and the SEC may suspend or prohibit such persons from working in the

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[1] 15 U.S.C. §§ 78m, 78dd, 78ff (1977) (amended 1998 and 2002).
[2] H.R. Rep. No. 95-640, at 4 (1977).
[3] 15 U.S.C. § 78m(a).
[4] *Id.* § 78m(a)-(b). *See also* Presidential Statement upon Signing S.305 into Law, 52 Weekly Comp. Pres. Doc. 1909 (Dec. 20, 1977) ("[This law] requires publicly held corporations to keep accurate books and records . . . .").
[5] 15 U.S.C. § 78m(b)(2)(A) (2002).
[6] *Id.* § 78m(b)(2)(B).
[7] 15 U.S.C. § 78dd-2(a) and (h)(1).
[8] H.R. Rep. 95-640, at 12 (1998).
[9] 15 U.S.C. §§ 78dd-1 to -3 (1998).
[10] *Id.*
[11] 15 U.S.C. § 78dd-1(a), -2(a), -3(a) (1998).
[12] *See* Dep't. of Justice, Lay-Person's Guide to FCPA, http://www.usdoj.gov/criminal/fraud/docs/dojdocb.html (last visited July 22, 2008).
[13] 15 U.S.C. §§ 78dd-1(g), 78dd-2(i).
[14] *Id.* §§ 78dd-1(a), -2(a).
[15] *Id.* §§ 78dd-1(g), -2(i).
[16] 15 U.S.C. §§ 78dd-1(a), -2(a) (1998).
[17] *Id.* §§ 78dd-2(g), -3(e).
[18] *Id.* § 78dd-2(g)(2)(B).
[19] 15 U.S.C. §§ 78dd-2(g), -3(e) (1998).

  ISBN 1056 3059

securities business.[20]

FCPA Enforcement. The SEC and DOJ work together to enforce the Act.[21] The SEC is responsible for the civil enforcement of the antibribery provisions with respect to issuers, and investigating corporations suspected of violating such provisions.[22] Because these corporations already file reports with the SEC, the SEC has immediate access to a great deal of pertinent information.[23] The SEC, however, may only bring an injunctive action against a corporation that violates either the accounting or the antibribery provisions of the Act.[24] Thus, if the SEC believes it has compiled sufficient evidence to initiate a criminal action, it will refer the case to the DOJ for criminal prosecution.[25] DOJ is responsible for investigating any allegations of bribery involving individuals or companies beyond the SEC's jurisdiction.[26]

Disclosure of FCPA Violations. FCPA violations are usually brought to the government's attention through company self-disclosures or through informants. There is an emerging trend of companies discovering FCPA violations through merger and acquisition due diligence and then reporting these violations to the SEC and DOJ. There are benefits to such self-disclosure because the government takes self-reporting into account when it negotiates the resolution of a FCPA case. In criminal cases, the government may reduce a sentence where a defendant has self-disclosed. In civil cases, disclosure could reduce fines and allow a company to have some control over the investigation.

DOJ Opinion Procedure. There is little guidance providing insight into DOJ's views on whether it would prosecute certain activities under the FCPA's antibribery provisions. Through its Opinion Procedure Releases, DOJ sheds light on its interpretation of what conduct violates these provisions. However, DOJ will not issue an FCPA Opinion Release to any company that requests one. A requestor must present an actual scenario to DOJ, rather than a hypothetical question. DOJ releases very few opinions, and they may not be relied upon by a party unless they have joined in the request, but they are widely instructive. For example, in DOJ's Opinion Procedure Release 08-02, issued on June 13, 2008, DOJ clarified that if an acquiring company does not have time to conduct thorough due diligence prior to closing, it may still mitigate its risk of successor liability by engaging in certain processes. The Requestor of that opinion committed to a comprehensive post-closing due diligence and voluntary disclosure process in which it was required to complete its due diligence within 180 days after closing, impose its Code of Business on the target of the acquisition, provide FCPA training to relevant employees, execute new third party contracts containing FCPA clauses, fire any agents or employees suspected of wrongdoing, and disclose all evidence of wrongdoing found during due diligence.

Recent FCPA Enforcement against Medical Device Companies. As noted above, there have been a growing number of FCPA cases involving medical device manufacturers over the past few years. The most recent settlement occurred on June 3, 2008, when AGA Medical Corporation, a privately-held manufacturer of products designed for minimally invasive treatment of congenital heart defects, entered into a deferred prosecution agreement ("DPA") with DOJ to resolve allegations that it violated the FCPA's antibribery provisions. The government alleged in a criminal information that a high-ranking officer and part owner of AGA authorized the company's local Chinese distributor to make corrupt payments of at least $460,000 to physicians employed by government-owned hospitals in China to induce them to buy AGA products and Chinese patent officials to induce them to approve AGA patent applications. AGA agreed to pay a $2 million criminal penalty and to retain an independent compliance monitor for the three-year term of the agreement. The investigation was based on AGA's voluntary disclosure. After giving the results of an outside law firm's investigation to DOJ, AGA terminated its distributor and put a compliance program in place. If AGA complies with the terms of its DPA, DOJ will dismiss the criminal information when the term of the DPA ends.

DPAs have been used in a number of other cases to resolve criminal bribery allegations against medical

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[20] 15 U.S.C. §§ 78dd-2(d)(1), -3(d)(1). *See also* Dep't of Justice, *supra* note 14.
[21] 15 U.S.C. §§ 78dd-2(g), -3(e), 78ff (1998).
[22] *Id.* § 78ff(c).
[23] 123 Cong. Rec. S305, 7198 (daily ed. May 5, 1977).
[24] 123 Cong. Rec. S305, 7198.
[25] *Id.*
[26] 15 U.S.C. §§ 78dd-2(g), -3(e).

device companies. In September 2007, four leading manufacturers of orthopedic implants, DePuy Orthopaedics, Inc., Zimmer, Inc., Smith & Nephew, Inc., and Biomet Orthopedics, Inc., agreed to 18-month monitored DPAs, and paid $310 million to settle charges that they paid kickbacks to influence U.S. physicians to purchase their products. In addition, the companies all entered into corporate integrity agreements with the Office of Inspector General of the U.S. Department of Health and Human Services. DOJ and the SEC are now investigating these companies for potential FCPA violations as part of an industry-wide investigation into the group's payments to physicians in foreign countries.

This type of industry-wide investigation is a new and growing FCPA development. As one example, in late 2007, Medtronic was notified by the SEC and then DOJ that it was being included in the larger investigation into device makers' payment practices to government-employed physicians abroad. Likewise, Wright Medical Technology, Inc. announced on June 13, 2008 that it was the latest orthopedic device company to become part of that ongoing investigation.

What Payments are Legitimate under the FCPA. As noted above, U.S. companies doing business overseas are allowed to make payments that are expressly permitted under local laws and regulations. Further permissible payments could include: (1) routine expenses, such as obtaining required government permits, the processing of official papers, mail pick-up/delivery, and police protection; and (2) legitimate promotional expenses, such as food, travel, and lodging for doctors and/or government officials attending a training seminar or visiting a company office or facility, as long as the expenses are "reasonable" and "proportional" to the activity and/or stature of the persons involved. Payments related to a decision to award new business or purchase products, vacations, charitable donations on behalf of a doctor/official, or construction work on a home, however, are prohibited.

Implementing an Effective Company Compliance Program. Given the current active enforcement climate, U.S. medical device companies that market significantly overseas should implement effective FCPA and international antibribery procedures to minimize the risk of being subject to enforcement under the statute. To this effect, companies should take the following actions to bolster their compliance programs: (1) develop written compliance policies, procedures and internal controls that incorporate an FCPA code of conduct; (2) include FCPA training for all relevant employees; (3) track, review, and analyze all payments to foreign health care practitioners and medical charities to ensure that they do not violate the statute; (4) review compliance programs of third parties, such as consultants, agents, distributors and vendors; (5) perform due diligence before entering into business arrangements with third parties to determine whether they have engaged in any problematic activities; (6) develop training and communication programs with third party contractors to guard against potential FCPA violations; (7) implement contractual provisions requiring third parties to certify that they have been advised of FCPA requirements and intend to follow such requirements; (8) conduct annual audits of third party marketing activities; (9) monitor employee contact with foreign officials; (10) take into account cultural norms of a particular country; and (11) take swift and decisive action, such as termination, against any employee or third party operative who violates the FCPA.

Conclusion. When one considers the expanding global marketplace for medical devices, the challenges involved in penetrating these emerging foreign markets, U.S. device manufacturers' intensifying efforts to market products overseas, and the rise in U.S. government FCPA enforcement, it becomes incumbent on U.S. device companies conducting business abroad to take note of the U.S. government's increasing enforcement activities and implement compliance practices that can help prevent FCPA violations. As federal investigators ramp up their scrutiny of healthcare fraud committed in the U.S. by medical device companies, it is reasonable to expect that FCPA investigations will increasingly follow healthcare fraud cases.

  ISBN 1056 3059