

Foreign Corrupt Practices Act Enforcement Blitz Snarcs Health Care Companies

By Michael B. Himmel and Melissa Toner Lozner, Lowenstein Sandler PC

In November 2008, the U.S. Securities & Exchange Commission (SEC) announced that it would impose record sanctions in a number of Foreign Corrupt Practices Act (FCPA) cases. According to Scott Friestad, deputy director of the SEC's Enforcement Division, these monetary penalties "will dwarf the disgorgement and penalty amounts that have been obtained in prior cases."¹ To say that the Government has followed through on that threat would be an understatement. In the months since that announcement, the SEC and U.S. Department of Justice (DOJ) have settled two separate FCPA cases for a total of nearly \$1.4 billion. These settlements are the culmination of an explosion in FCPA investigations and prosecutions by the SEC and DOJ in recent years that has rocked the health care industry in general, and medical device manufacturers in particular.

The FCPA at a Glance

The FCPA was enacted in 1977, after SEC investigations in the early 1970's revealed that hundreds of United States companies had been making substantial illegal or questionable payments to foreign officials.² The purpose of the statute was to stop these practices and to restore public confidence in the integrity of the American business system.³

The FCPA consists of anti-bribery provisions and certain accounting requirements. The anti-bribery provisions apply to United States companies (both private and public), United States citizens, foreign companies listed on a United States stock exchange, and any person acting in the United States. This portion of the statute prohibits those subject to its jurisdiction from corruptly paying, offering to pay, or authorizing the payment of money, a gift, or anything of value, to a foreign official or foreign political party, for purposes of obtaining or retaining business. A company can be held liable under the anti-bribery provisions not just for its own direct actions, but also for the actions of its foreign subsidiaries or other third parties, such as agents or distributors.⁴ Notably, however, the FCPA does not prohibit facilitating or expediting payments (often called "grease payments"), which merely facilitate performance of certain routine governmental actions such as the processing of licenses, paperwork, visas or other official documents.⁵ Certain affirmative defenses are available under the FCPA as well.⁶

The FCPA's accounting, or "books and records," requirements require all companies that have a class of securities registered with the SEC, as well as all companies that are required to file reports with the SEC, to devise and maintain internal accounting controls and to keep books and records that accurately reflect the disposition of corporate assets.⁷

The DOJ is responsible for all criminal enforcement of the anti-bribery provisions, as well as civil enforcement of the anti-bribery provisions with respect to private United States companies and foreign companies and nationals.⁸ The SEC is responsible for civil enforcement of the anti-bribery provisions with respect to United States public companies, as well as all civil enforcement of the accounting provisions.⁹

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FCPA Risk Factors Inherent in the Health Care Industry

For a number of reasons, the health care industry is particularly vulnerable to FCPA compliance problems.

First, the industry has become increasingly international in scope. As evidenced by the cases highlighted below, health care companies are marketing and selling their products and services to health care providers not just in the United States, but abroad as well.

Second, unlike in the United States, many foreign health care providers work at hospitals or clinics that are government-owned or controlled, thereby making them "foreign officials" within the meaning of the FCPA.

Third, for many health care companies, the nature of their business requires them to persuade health care providers to use their product or service, which presents the opportunity for legitimate persuasion to lead to improper inducement. This risk is particularly high in certain countries or cultures, where a certain *quid pro quo* is commonplace or even expected.

Fourth, many companies rely upon intermediaries, whether in the form of a distributor, agent, consultant, or other type of facilitator, to effectively market their products in foreign countries. Given the broad scope of the FCPA's anti-bribery provisions, a company cannot escape liability simply by doing business through third parties. In fact, the use of such intermediaries can heighten the risk for an FCPA violation, particularly where the company has failed to conduct adequate due diligence or implement the proper internal controls.

Recent Developments in FCPA Enforcement

Recent years have seen a dramatic increase in the United States Government's FCPA enforcement efforts. Since January 2006, the SEC has filed more FCPA actions than were filed during the prior 28 years combined, and has imposed hundreds of millions of dollars in penalties, disgorgement and prejudgment interest for FCPA violations.¹⁰ In October 2006, the head of the DOJ's Criminal Division described FCPA enforcement as a "high priority,"¹¹ and since that time the Government has imposed record-setting fines and penalties in a number of cases. Most notably, in December 2008, Siemens AG agreed to pay a record-breaking \$800 million to resolve DOJ and SEC charges arising from a worldwide bribery scheme.¹² Two months later, Kellogg Brown & Root LLC, along with its current and former parent companies (KBR Inc. and Halliburton Company, respectively), agreed to pay a total of \$579 million to resolve charges arising from a scheme to bribe Nigerian government officials to obtain engineering, procurement and construction contracts.¹³ In sum, as the Federal Bureau of Investigation has bluntly stated, FCPA enforcement "has never been more important — or more on our radar — than it is today."¹⁴

In addition to increasing the number of cases instituted and the degree of sanctions imposed, the Government has also changed the focus of its FCPA enforcement efforts. Recently, the SEC and DOJ have begun to target not just isolated companies and individuals, but entire industries. One industry that has caught the Government's attention is health care — and, in particular, orthopedic device manufacturers.

A number of medical device companies have been contacted by the Government concerning possible FCPA violations arising from their overseas marketing and business practices. Biomet Inc., Smith & Nephew, Inc., Zimmer Holdings, Inc., and Stryker Orthopedics, Inc. have all received requests from the SEC and/or DOJ for information concerning those companies' payments to government-employed doctors in connection with the sale of medical devices in foreign countries.¹⁵ Notably, just weeks before announcing the requests, these companies entered into agreements with the United States Attorney's Office for the District of New Jersey to resolve similar charges involving allegedly improper payments to surgeons in the United States.¹⁶ Likewise, in December 2007, Medtronic Inc. announced that it was cooperating with SEC and

DOJ requests for "information concerning certain types of payments made directly or indirectly to government-employed doctors."¹⁷ And in June 2008, Wright Medical Technology, Inc. announced that it was the latest orthopedic device company to become part of the Government's ongoing investigation of potential FCPA violations in that industry.¹⁸

In recent years, several other health care companies have settled FCPA actions arising from similar payments to doctors or other employees of state-owned hospitals in foreign countries.¹⁹ For example:

- In June 2008, AGA Medical Corporation settled criminal charges alleging that a company official made illegal payments to physicians employed by government-owned hospitals in China, as well as to Chinese patent officials, to induce them to buy AGA products and approve AGA patent applications.²⁰ Pursuant to a deferred prosecution agreement, AGA agreed to pay a \$2 million criminal penalty and to retain an independent compliance monitor for three years.²¹
- In September 2007, Gioacchino De Chirico, President and Chief Operating Officer of Immucor, Inc., settled an SEC civil action arising from an allegedly improper payment to the director of a public hospital in Italy in exchange for favorable consideration of a contract to provide products and services to the hospital.²² According to the Government, this payment was falsely recorded on Immucor's books and records as a consulting fee.²³ De Chirico agreed to pay a \$30,000 civil penalty,²⁴ and a cease and desist order was entered against De Chirico and Immucor against future FCPA violations.²⁵
- In May 2005, Diagnostics Products Corporation and its Chinese subsidiary agreed to settle DOJ and SEC enforcement actions alleging the payment of illegal "commissions" to employees of government-owned hospitals in China.²⁶ According to the Government, these payments were improperly recorded as "selling expenses."²⁷ As part of the agreements, the company and its subsidiary agreed to pay a total of \$4.8 million in criminal and civil penalties, and the company agreed to retain an independent monitor for three years.²⁸
- In March 2005, Micrus Corporation settled a DOJ enforcement action concerning payments to physicians employed by publicly owned and operated hospitals in several foreign countries in exchange for their purchase of the company's medical devices.²⁹ The company entered into a non-prosecution agreement pursuant to which it agreed to pay a \$450,000 penalty, to implement an FCPA compliance program, and to retain an independent monitor for three years.³⁰
- In June 2004, Schering-Plough Corporation agreed to pay \$500,000 to settle an SEC enforcement action arising from payments by the company's Polish subsidiary to the favorite charity of a Polish governmental official responsible for purchasing pharmaceutical products for hospitals.³¹ Notably, these payments were made without the knowledge or approval of any U.S. Schering-Plough employee.³² According to the SEC, this incident resulted from inadequate and insufficient internal controls, and the company was ordered to improve those controls with the assistance of an independent consultant.³³
- In December 2002, Syncor International Corporation settled an SEC enforcement action alleging that foreign subsidiaries made improper payments to physicians employed by state-owned hospitals in several different countries.³⁴ The settlement provided for Syncor to pay a \$500,000 civil penalty and to retain an independent FCPA monitor.³⁵ Syncor's Taiwanese subsidiary also agreed to plead guilty to violating the FCPA's anti-bribery provisions and to pay a \$2 million criminal fine.³⁶

Still other health care companies have voluntarily disclosed activities or incidents that may trigger FCPA liability in the future. For example, in February 2007, Johnson & Johnson voluntarily disclosed to the DOJ and SEC that its "subsidiaries outside the United States are believed to have made improper payments in connection with the sale of medical devices in two small-market countries."³⁷ As the foregoing examples illustrate, the health care industry is at the forefront of the Government's FCPA enforcement efforts.

Ways to Avoid or Limit FCPA Liability

In light of the current climate, health care companies can — and must — take steps now to protect themselves, and their officers and employees, from FCPA liability. Although companies should develop a compliance program tailored to their own particular risk factors, the following is a general summary of important issues to consider when developing an FCPA compliance program:

- **Written Policies and Internal Controls.** A crucial aspect of any FCPA compliance program is the creation of written policies and internal controls designed to prevent FCPA violations. Though not a guarantee of FCPA compliance, the existence or absence of effective written policies and internal controls is a highly significant factor in the Government's determination of the appropriate fines and penalties in the event of a violation.
- **Training.** Even the best internal controls will not be effective unless they are communicated to those whose conduct could trigger FCPA liability. Thus, health care companies should ensure that their employees, as well as their agents, distributors, and business partners, receive comprehensive training on the applicable policies and procedures governing their behavior.
- **Due Diligence.** Prior to engaging the services of a third party to facilitate marketing and sales in foreign countries, health care companies must conduct adequate due diligence to identify and address any FCPA red flags associated with that third party.
- **Enforcement.** A company must take immediate and decisive action against any employee or third party who violates the FCPA or the company's FCPA compliance policies.
- **DOJ Opinion Procedure.** The DOJ's Opinion Procedure is an underutilized yet important tool at the disposal of all companies with questions about whether a particular course of action would, in the DOJ's view, implicate or violate the FCPA's anti-bribery provisions. Indeed, the head of the DOJ's Criminal Division encourages companies to use this procedure to obtain the DOJ's advice prior to undertaking questionable transactions, explaining that "[i]t serves both of our interests to avoid FCPA violations before they occur, and the opinion procedure is one way to make that happen."³⁸
- **Addressing Potential FCPA Violations.** In the event of the discovery of a potential FCPA violation, immediate consultation with an experienced and qualified attorney is essential to determining the best course of action. In appropriate cases, early and voluntary cooperation with the Government can forestall an official investigation or prosecution, or at least minimize the degree of sanctions imposed.³⁹

The recent explosion in FCPA enforcement activity is a wake-up call for the entire health care industry. Now is the time for health care companies to implement FCPA compliance programs, or

evaluate existing programs, to ensure that they are taking all appropriate steps to avoid or minimize liability.

Michael B. Himmel is a Member of the firm, and Chair of the firm's Litigation Department and White Collar Criminal Defense Practice Group. Melissa Toner Lozner is Counsel in the firm's Litigation Department, and a member of the firm's White Collar Criminal Defense Practice Group and Appellate Practice Area. The authors thank Associate Kristin Muir and Complex Case Manager Elizabeth Esposito for their research and editing assistance.

¹ Lynne Marek, Larger Foreign Corrupt Practices Act Fines Ahead, *available at* <http://www.law.com/jsp/ihc/PubArticleIHC.jsp?id=1202426269051> (Nov. 25, 2008) (last visited March 17, 2009).

² H.R. Rep. No. 95-640, at 4-5 (1977); S. Rep. No. 95-114, at 3-4 (1977).

³ *Id.*

⁴ 15 U.S.C. § 78dd-1(a)(3) (2000) (prohibiting improper payments made to "any person, while knowing that all or a portion of such money or thing of value will be offered, given, or promised, directly or indirectly to any foreign official") (emphasis added).

⁵ 15 U.S.C. §§ 78dd-1(b), 78dd-2(b), and 78dd-3(b) (2000).

⁶ 15 U.S.C. §§ 78dd-1(c), 78dd-2(c), and 78dd-3(c) (2000).

⁷ 15 U.S.C. § 78m(a)-(b) (2000).

⁸ DOJ Layperson's Guide to the FCPA, *available at* <http://www.usdoj.gov/criminal/fraud/docs/dojdocb.html> (last visited March 11, 2009).

⁹ *Id.*

¹⁰ Linda Chatman Thomsen, Director, Division of Enforcement, U.S. Securities and Exchange Commission, Speech by SEC Staff: Remarks Before the Minority Corporate Counsel 2008 CLE Expo (Mar. 27, 2008), at 5, *available at* <http://www.sec.gov/news/speech/2008/spch0327081ct.htm> (last visited March 11, 2009).

¹¹ Prepared Remarks of Alice S. Fisher, Assistant Attorney General, United States Department of Justice, at the American Bar Association National Institute on the Foreign Corrupt Practices Act (October 16, 2006), at 1; *see also* Thomsen, *supra* n.10, at 5, *available at* <http://www.usdoj.gov/criminal/fraud/docs/reports/speech/2006/10-16-AAGFCPASpeech.pdf> (last visited March 11, 2009).

¹² *See* Siemens AG and Three Subsidiaries Plead Guilty to Foreign Corrupt Practices Act Violations And Agree to Pay \$450 Million in Combined Criminal Fines (December 15, 2008), *available at* http://www.usdoj.gov/usao/dc/Press_Releases/2008%20Archives/December/08-1105.pdf (last visited March 12, 2009); SEC Files Settled Foreign Corrupt Practices Act Charges Against Siemens AG for Engaging in Worldwide Bribery With Total Disgorgement and Criminal Fines of Over \$1.6 Billion, SEC Litigation Release No. 20829, Accounting and Auditing Enforcement Release No. 2911 (December 15, 2008), *available at* <http://sec.gov/litigation/litreleases/2008/lr20829.htm> (last visited March 12, 2009). Prior to the Siemens settlement, the largest financial penalty imposed in an FCPA case was \$44 million, in a 2007 settlement involving Baker Hughes. *See* Baker Hughes Subsidiary Pleads Guilty to Bribing Kazakh Official and

Agrees to Pay \$11 Million Criminal Fine as Part of Largest Combined Sanction Ever Imposed in FCPA Case (April 26, 2007), *available at* http://www.usdoj.gov/opa/pr/2007/April/07_crm_296.html (total of \$44 million in fines, penalties and disgorgement of profits imposed upon Baker Hughes for payments to the state-owned oil company of Kazakhstan in connection with obtaining a contract to develop and operate an oil field).

¹³ Kellogg Brown & Root LLC Pleads Guilty to Foreign Bribery Charges and Agrees to Pay \$402 Million Criminal Fine; Enforcement Actions By DOJ and SEC Result in Penalties of \$579 Million for KBR's Participation in a Scheme to Bribe Nigerian Government Officials to Obtain Contracts

(February 11, 2009), *available at* <http://www.usdoj.gov/opa/pr/2009/February/09-crm-112.html> (last visited March 17, 2009).

¹⁴ Federal Bureau of Investigation, *Bribes Beyond the Border: Stemming the Export of Corruption* (Feb. 5, 2007), *available at* <http://www.fbi.gov/page2/feb07/fcpa020507.htm> (last visited March 11, 2009).

¹⁵ Biomet Inc., Quarterly Report (Form 10-Q) (October 15, 2008), at 19; Smith & Nephew, Inc., 2007 Annual Report, at 24; Zimmer Holdings, Inc., Quarterly Report (Form 10-Q) (November 9, 2007), at 15; Stryker Corporation, Quarterly Report (Form 10-Q) (November 9, 2007), at 21; Stryker Corporation, Annual Report (Form 10-K) (February 28, 2008), at 40-41.

¹⁶ See *Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring* (Sept. 27, 2007), *available at* <http://www.usdoj.gov/usao/nj/press/index.html> (last visited March 10, 2009) (explaining that the companies avoided criminal prosecution under the federal anti-kickback statute by paying a combined \$311 million and agreeing to be subject to new corporate compliance procedures and eighteen months of federal monitoring); see also Maureen A. Ruane, Michael T.G. Long, and Syron A. Jack, *An Ounce of Prevention: Lessons Learned from Recent Enforcement Actions in the Pharmaceutical and Medical Device Industry*, *Mealey's Emerging Drugs and Devices* (April 2, 2009).

¹⁷ Medtronic, Quarterly Report (Form 10-Q) (December 4, 2007), at 41.

¹⁸ Wright Medical Group, Inc., Disclosure Filing (Form 8-K) (June 10, 2008).

¹⁹ See generally Mike Koehler, *A Malady In Search Of A Cure: The Increase In FCPA Enforcement Actions Against Health-Care Companies*, 28 U. Mem. L. Rev. 261 (Winter 2008).

²⁰ Agreement between AGA Medical Corp. and DOJ, June 3, 2008, *available at* <http://www.usdoj/opa/pr/2008/June/08-crm-491.html> (last visited March 5, 2009).

²¹ *Id.*

²² SEC v. Gioacchino de Chirico, Litigation Release No. 20316 (Sept. 28, 2007).

²³ *Id.*

²⁴ *Id.*

²⁵ See *In re Immucor, Inc. and Gioacchino de Chirico*, Exchange Act Release No. 56558 (Sept. 27, 2007).

²⁶ See *In re Diagnostic Prod. Corp.*, Exchange Act Release No. 51724 (May 20, 2005).

²⁷ *Id.*

²⁸ *Id.*

²⁹ Agreement between Micrus Corp. and DOJ, Feb. 28, 2005, at 8, *available at* <http://www.usdoj.gov/dag/cftf/chargingdocs/micrusagreement.pdf> (last visited March 5, 2009).

³⁰ *Id.*

³¹ *In re Schering-Plough Corp.*, Exchange Act Release No. 49838 (June 9, 2004), 2004 SEC LEXIS 1185; SEC v. Schering-Plough Corp., Litigation Release No. 18740 (June 9, 2004); Complaint, SEC v. Schering-Plough Corp., No. 1:04CV00945 (D.D.C. 2004).

³² *Id.*

³³ *Id.*

³⁴ *In re Syncor Int'l Corp.*, Exchange Act Release No. 46979 (Dec. 10, 2002); SEC v. Syncor Int'l Corp., Litigation Release No. 17887 (Dec. 10, 2002); Complaint, SEC v. Syncor Int'l Corp., No. 1:02CV02421 (D.D.C. 2002).

³⁵ *Id.*

³⁶ *Id.*

³⁷ Johnson & Johnson Statement on Voluntary Disclosure, Current Report Filing (Form 8-K) (February 12, 2007).

³⁸ Fisher remarks, *supra* n.11, at 8.

³⁹ According to the head of the DOJ's Criminal Division, "there is always a benefit to corporate cooperation . . ." *Id.* at 6 (emphasis in original). See also *id.* ("There have been cases where companies have come in and voluntarily disclosed real FCPA violations that we have not prosecuted at all.")