A Malady in Search of a Cure—The Increase in FCPA Enforcement Actions Against Health-Care Companies

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Foreign Corrupt Practices Act ("FCPA") enforcement actions against companies for making improper payments to foreign officials in order to obtain or retain business were once thought to entangle only resource extraction companies operating in the third world. Nevertheless, several recent FCPA enforcement actions and inquiries demonstrate that U.S. enforcement agencies are "casting a wider net" across many different industries in an effort to combat foreign corruption and bribery. These enforcement actions and inquiries also demonstrate that health-care companies will not be immune from increased FCPA scrutiny as they continue to expand into overseas markets.

For this reason, any health-care company doing business or seeking to do business in a foreign market must recognize, understand, and appreciate the risk of doing business internationally in terms of FCPA compliance. In fact, FCPA compliance in the health-care industry poses a unique risk and challenge given the number of foreign hospitals, clinics, laboratories, and medical providers that are state-owned or state-controlled. Failure to recognize the unique FCPA risks of doing business or seeking to do business with state-owned or state-controlled entities can expose health-care companies and their personnel to significant criminal and civil liability under U.S. law, as well as cause harsh collateral sanctions and damage to a company's reputation. Thus, any health-care company with an international presence or seeking to do business in a foreign country should have in place effective, comprehensive, and well-communicated FCPA compliance policies and procedures.

This article explores the unique FCPA risks and challenges for health-care companies doing business or seeking to do business in foreign markets. While the risks and challenges are numerous, they are not unmanageable; the key to FCPA compliance is to adopt effective, comprehensive, and well-communicated FCPA compliance policies and procedures. While such policies and pro-

cedures will not guarantee a "clean bill of health," they may well prevent FCPA maladies from occurring in the first place.

I. THE INTERNATIONALIZATION OF HEALTH CARE

The health-care industry is increasingly global and establishing, maintaining, and expanding an international presence is a key long-term growth strategy for many leading health-care companies. For example, developing nations are spending more money on health care by building hospitals and clinics, establishing public health insurance programs, and focusing more attention on the health of its citizens; as a result, these accelerated health-care expenditures are driving the global demand for pharmaceuticals, medical devices, and supplies. Such expenditures are leading to double-digit growth rates in many non-U.S. markets and health-care companies recognize that they must increasingly look to developing markets for future growth. In fact, many leading health-care companies are working with government officials in emerging markets such as Latin America and Asia to encourage investments in health care and to improve access to their products and services.[1]

The internationalization of health care is clearly reflected in the financial filings and public information of leading health-care companies:

- Between 2001 and 2005, international sales by Abbott Laboratories, a diversified health-care company, nearly doubled from $5.8 billion in net sales in 2001 to $9.9 billion in net sales in 2005.[2]

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1. *See e.g.*, Merck & Co., Inc., FORM 10-K (Form 10-K), at 5, 16 (Feb. 28, 2007), *available at* http://www.merck.com/finance/reportsannual.html (follow "2006 FORM 10-K" hyperlink).

2. ABBOTT, 2006 FACT BOOK 3 (2006), *available at* http://www.abbott.com/static/content/microsite/annual_report/2005/2006FactBook.pdf.

- At pharmaceutical company Bristol Myers Squibb Co., approximately 45% of 2006 net sales were made outside of the U.S.[3]

- More than 50% of 2006 revenues at Baxter International Inc., a medical products and services company, were from outside the U.S.[4] The company distributes its products directly or through distributors in more than one hundred countries; global expansion and technological innovation are part of the company's growth strategy.[5]

- At Pfizer, Inc., the world's largest pharmaceutical company, 2006 revenues from operations outside the U.S. were $22.5 billion which accounted for approximately 47% of total revenues.[6]

- In 2006, non-U.S. sales at Boston Scientific Corp., a leading medical device manufacturer, accounted for approximately 38% of net sales—a 23% increase compared to non-U.S. sales in 2005.[7] The company has expanded its sales presence to take advantage of expanding foreign market opportunities and has direct marketing and sales operations in approximately forty-five countries.[8]

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3. *E.g.*, BRISTOL MYERS SQUIBB CO., 2006 ANNUAL REPORT 63 (2007), *available at* http://thomson. mobular.net/thomson/7/2218/2442/.

4. BAXTER INTERNATIONAL INC., 2006 ANNUAL REPORT 29 (2007), *available at* http://www.baxter .com/about_baxter/investor_information/ annual_report/2006/2006_annual_complete.pdf.

5. *Id.*

6. PFIZER INC., 2006 ANNUAL REVIEW 75 (2007), *available at* http://www.pfizer.com/files/ annualreport/2006/annual/review2006.pdf.

7. *E.g.*, BOSTON SCIENTIFIC CORP., 2006 ANNUAL REPORT 14 (2007), *available at* http://media.corporate-ir.net/media_files/irol/62/62272/reports/ AR06.pdf.

8. *Id.*

- Johnson & Johnson, a health-care conglomerate, has 250 operating companies around the world in fifty-seven countries and its products are sold in 175 countries.[9]

This internationalization of health care has created a "perfect storm" for FCPA non-compliance as more and more companies are aggressively seeking sales in emerging markets from state-owned or state-controlled entities. As described in more detail in Section II, employees of state-owned or state-controlled hospitals, clinics, and laboratories (while not being traditional elected officials) will be deemed "foreign officials" under the FCPA.

It should come as no surprise that in connection with Johnson & Johnson's February 2007 FCPA disclosure that certain of its foreign subsidiaries made improper payments in connection with the sale of medical devices,[10] an analyst stated as follows: "In countries with centralised [sic] health schemes you could also end up dealing with government officials. I am not surprised that in some places you have to lubricate the wheels. I would be surprised if such practices only went on at Johnson & Johnson."[11] These words were indeed prophetic. Since Johnson & Johnson's February disclosure, several orthopedic device makers have disclosed that they are the subjects of an informal Securities and Exchange Commission ("SEC") investigation into possible FCPA violations.[12] Against this backdrop, health-care executives would be wise to understand and appreciate the many nuances of the wide-ranging FCPA.

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9. JOHNSON & JOHNSON, INC., 2006 ANNUAL REPORT 2, 38 (2007), *available at* http://jnj.v1.papiervirtuel.com/report/2007030901/.

10. Avery Johnson et al., *J&J Executive Departs in Wake of Payments Disclosure*, WALL ST. J., Feb. 13, 2007, at A20; Johnson & Johnson Statement on Voluntary Disclosure, http://www.jnj.com/news/jnj_news/20070212_192452.htm (last visited Nov. 21, 2007); *see infra* note 112 and accompanying text.

11. Christopher Bowe et al., *J&J Acts to Push Its Reputation Back Into Joint*, FIN. TIMES U.K., Feb. 14, 2007, at 22.

12. Jon Kamp, *Several Orthopedic-Device Makers Get SEC Letters on Foreign Tales*, WALL ST. J., Oct. 15, 2007, at B9.

II. FCPA BACKGROUND

In response to widespread post-Watergate allegations that U.S. companies were securing foreign government contracts by making improper payments to foreign government officials, the FCPA was enacted in 1977 to halt the practice of bribery as a means of obtaining or retaining foreign business.[13] The statute, an amendment to the Securities Exchange Act of 1934 ("Exchange Act"), generally prohibits U.S. companies and citizens, foreign companies listed on a U.S. stock exchange, or any person acting in the U.S. from corruptly paying, offering to pay, or authorizing the payment of money, or a gift or anything of value, directly or indirectly to a foreign official in order to obtain or retain business ("Anti-Bribery provisions").[14] The Anti-Bribery provisions apply to all U.S. companies, not just public companies, a point emphasized by the FCPA enforcement action against Micrus Corporation, a privately held California medical device company.[15]

The FCPA also requires companies which have a class of securities registered with the SEC, and every company which is required to file reports with the SEC (collectively "Issuers"), to devise and maintain internal accounting controls and to keep books and records that accurately reflect the disposition of corporate as-

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13. Lay-Person's Guide to FCPA, http://www.usdoj.gov/criminal/fraud/docs/dojdocb.html (last visited Nov. 21, 2007) [hereinafter DOJ Brochure] ("As a result of SEC investigations in the mid-1970's, over 400 U.S. companies admitted making questionable or illegal payments in excess of $300 million to foreign government officials, politicians, and political parties. The abuses ran the gamut from bribery of high foreign officials to secure some type of favorable action by a foreign government to so-called facilitating payments that allegedly were made to ensure that government functionaries discharged certain ministerial or clerical duties. Congress enacted the FCPA to bring a halt to the bribery of foreign officials and to restore public confidence in the integrity of the American business system.").

14. *See* 15 U.S.C. §§ 78dd-1 to -3 (2000).

15. 15 U.S.C. § 78dd-2(h)(1)(B) (2000). Specifically, in addition to public companies, the FCPA's Anti-Bribery provisions also apply to "domestic concerns," a defined term that includes "any corporation, partnership, association, joint-stock company, business trust, unincorporated organization, or sole proprietorship" with a principal place of business in the U.S. *Id.*; *see also supra* Section III.

sets ("Books and Records and Internal Control provisions").[16] The Department of Justice ("DOJ") and the SEC jointly enforce the FCPA. The DOJ is responsible for criminal enforcement of the statute and for civil enforcement of the Anti-Bribery provisions against private U.S. companies and foreign companies and nationals, whereas the SEC is responsible for civil enforcement of the Anti-Bribery provisions with respect to U.S. public companies as well as overall responsibility for the Books and Records and Internal Control provisions.

Proof of a U.S. territorial nexus is not required for the FCPA to be implicated against U.S. companies and citizens, and FCPA violations can, and often do, occur even if the prohibited activity takes place entirely outside of the U.S.[17] For this reason, health-care executives must be knowledgeable about all business activity, including activity that takes place thousands of miles away from corporate headquarters, because how a company obtains and retains business in Beijing, Istanbul, and Paris is as relevant as how it obtains or retains business in Boston, Indianapolis, and Portland.

A. Anti-Bribery Provisions

The FCPA's Anti-Bribery provisions prohibit 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 influencing any act or decision of such official in his official capacity, inducing the official to do any act in violation of the lawful duty of such official, or to secure any improper advantage in order to assist the

16. 15 U.S.C. § 78m(a)–(b) (2000).

17. 15 U.S.C. §§ 78dd-1(g), –2(i) (2000). The 1998 amendments to the FCPA expanded the jurisdictional reach of the statute to include an alternative nationality test. Prior to the amendments, "use of the mails or any means of instrumentality of interstate commerce in furtherance of" an improper payment was needed for the FCPA to apply. 15 U.S.C. §§ 78dd-1(g), –2(i) (1977). Under the alternative nationality test, the FCPA also applies to improper payments made by U.S. companies and citizens without regard to whether "the mails or any other means of instrumentality of interstate commerce" were used in furtherance of the improper payment. 15 U.S.C. § 78dd-1(g), -2(i) (2000).

payor in ***obtaining or retaining business*** for or with any person, or in directing business to any person.[18]

Health-care executives no doubt understand and appreciate that delivering a "suitcase full of cash" to an elected foreign official to induce the official to use his influence in securing government business is improper, even without fully understanding or appreciating the FCPA. However, several elements of an FCPA Anti-Bribery violation have broad application, are likely not well-understood by health-care executives, yet can result in FCPA liability for a whole range of conduct less serious than the scenario set forth above.

1. "Anything of Value"

The term "anything of value" is not defined in the FCPA nor is the statute's legislative history illuminating. The term, however, has been broadly construed and can include not only cash or a cash equivalent, but also, among other things, discounts, gifts, use of materials, facilities or equipment, entertainment (including tickets and passes), drinks, meals, transportation, lodging (and accommodation upgrades), insurance benefits and a promise of future employment.[19] Further, there is no de minimis value associated with the "anything of value" element of an FCPA Anti-Bribery violation.[20] Rather, the perception of the recipient and the

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18. 15 U.S.C. § 78dd-1 (2000).

19. ***See, e.g.***, United States v. Liebo, 923 F.2d 1308, 1312 (8th Cir. 1991) (including airline tickets); Opinion Procedure Release, Op. Dep't of Justice No. 00-01 (Mar. 29, 2000), ***available at*** http://www.usdoj.gov/criminal/fraud/fcpa/opinion/2000/0001.html (including insurance benefits and promise of future employment); Complaint at 6, United States v. Metcalf & Eddy, No. 99-12566 (D. Mass. 1999) (including accommodation upgrades). Pursuant to 15 U.S.C. § 78dd-1(e), parties may submit contemplated actions or business activity to the DOJ and obtain a DOJ opinion whether the contemplated action or business activity violates the FCPA. 15 U.S.C. § 78dd-1(e) (2000). However, the DOJ's opinion has no precedential value, and its opinion that the contemplated conduct is in conformance with the FCPA is entitled only to a rebuttable presumption should an FCPA enforcement action be brought as a result of the contemplated conduct. ***See*** 28 CFR §§ 80.1–16 (1999).

20. ***See, e.g.***, ***In re*** The Dow Chem. Co., Exchange Act Release No. 55281 (Feb. 13, 2007), 2007 SEC LEXIS 286 (noting that although certain improper payments "were in small amounts—well under $100 per payment—the

subjective valuation of the thing conveyed is often a key factor in determining whether "anything of value" has been given to a foreign official.[21]

For example, a June 2004 FCPA enforcement action against pharmaceutical company Schering-Plough Corporation ("Schering-Plough") represents perhaps the broadest interpretation of the "anything of value" element of an FCPA Anti-Bribery violation. While the Schering-Plough matter involved violations of the FCPA Books and Records and Internal Control provisions only, it is commonly viewed as broadening the "anything of value" element of an FCPA-Anti-Bribery violation.[22] The SEC alleged that Schering-Plough violated the FCPA when its wholly-owned Polish subsidiary ("S-P Poland") improperly recorded a bona fide charitable donation to a Polish foundation where the founder/president of the foundation was also the director of a government health fund which provided money to hospitals throughout Poland for the purchase of pharmaceutical products.[23]

The SEC's tacit interpretation of the term "anything of value" in the Schering-Plough action is significant because there was no allegation or indication that any tangible monetary benefit accrued to the director of the government health fund who was deemed a "foreign official" under the FCPA. Rather, the SEC brought the enforcement action on the basis of its apparent conclusion that S-P Poland's bona fide charitable donations constituted a "thing of value" to the "foreign official" because the donations were subjectively valued by the official and provided him with an intangible benefit of enhanced prestige.

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payments were numerous and frequent"); Complaint, SEC v. Titan Corp., No. 05-0411 (D.D.C. 2005) (finding the improper payments included, among other things, a $1,850 pair of earrings for the wife of the President of Benin).

21. *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), 2004 SEC LEXIS 1183.

22 . *See supra* note 21.

23. *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), 2004 SEC LEXIS 1183; *see also supra* Section III.

2. "Obtain or Retain Business"

The "obtain or retain business" element of an FCPA Anti-Bribery violation also has broad application and can result in FCPA non-compliance if not properly understood by health-care executives. In *United States v. Kay*,[24] the court held that making improper payments to foreign officials to lower corporate taxes and custom duties could satisfy the "obtain or retain business" element of an FCPA Anti-Bribery violation by providing an unfair advantage to the payor over competitors.[25] The court concluded that there was "little difference" between this type of improper payment and improper payments to a foreign official for the purpose of inducing the official to award a government contract or commercial agreement.[26] In short, the *Kay* court was convinced that Congress, by passing the FCPA, intended to prohibit a wide range of improper payments, not just those that directly influence the acquisition or retention of government contracts or similar arrangements.[27]

Similarly, the broad application of the "obtain or retain business" element is also evident in a February 2007 FCPA enforcement action against Vetco International Ltd. ("Vetco") in which the DOJ secured a $26 million settlement—the largest criminal FCPA fine at the time.[28] In this action, the alleged improper payments were made by one of the company's foreign subsidiaries to foreign customs officials via a major international freight forwarder and customs clearance company.[29] The DOJ concluded that the payments were intended to induce the customs officials to provide the company preferential treatment during the customs process and allowed the company to secure an improper

24. 359 F.3d 738 (5th Cir. 2004).

25. *Id.* at 743–56.

26. *Id.* at 749.

27. *See id.* at 748–50.

28. *Id.*

29. Criminal Information at 2–20, United States. v. Vetco Gray Controls, Inc., No. CR H07-04 (S.D. Tex. 2007); Press Release, Dep't of Justice, Three Vetco International Ltd. Subsidiaries Plead Guilty to Foreign Bribery and Agree to Pay $26 Million in Criminal Fines (Feb. 6, 2007), *available at* http://www.usdoj.gov/opa/pr/2007/February/07_crm_075.html.

advantage in connection with a Nigerian government deepwater oil-drilling project.[30]

It is also clear that the business to be "obtained or retained" does not need to be with a foreign *government* for this element of an FCPA Anti-Bribery violation to be satisfied. For instance, in the February 2007 FCPA enforcement action, the SEC alleged that DE-Nocil Corporation Protection Ltd. ("DE-Nocil"), a "fifth tier subsidiary" of The Dow Chemical Corporation ("Dow Chemical") in India, improperly recorded payments to various Indian officials with discretionary authority over whether DE-Nocil's products would receive various government registrations required before the company could sell its product in that country.[31] Based on the alleged improper conduct, Dow agreed to pay a $325,000 civil penalty.[32]

Similarly, in July 2007, Delta & Pine Land Co. ("Delta & Pine"), along with its wholly-owned subsidiary Turk Deltapine, Inc., agreed to settle an FCPA enforcement action for improperly recording approximately $43,000 in payments from 2001 through 2006 to officials of the Turkish Ministry of Agricultural and Rural Affairs in order to obtain various governmental report and certification needed to operate its business in Turkey.[33] Based on the alleged improper conduct, Delta & Pine, which has since been acquired by Monsanto Co., agreed to pay a $300,000 civil penalty.[34]

Even unsuccessful bribery attempts violate the FCPA's Anti-Bribery's provisions. In January 2005, Monsanto Co. ("Monsanto") agreed to pay $1.5 million to settle an FCPA enforcement action based on allegations that it made improper payments to a

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30. Press Release, Dep't of Justice, *supra* note 29.

31. *In re* The Dow Chem. Co., Exchange Act Release No. 55281 (Feb. 13, 2007), 2007 SEC LEXIS 286; SEC v. The Dow Chem. Co., Litigation Release No. 20000 (Feb. 13, 2007), 2007 SEC LEXIS 292, *available at* http://www.sec.gov/litigation/litreleases/2007/lr20000.htm.

32. SEC v. The Dow Chem. Co., Litigation Release No. 20000 (Feb. 13, 2007).

33. SEC v. Delta & Pine Land Co., Litigation Release No. 20214 (July 26, 2007), 2007 SEC LEXIS 1632, *available at* http://www.sec.gov/litigation/litreleases/2007/lr20214.htm; Complaint at 2, SEC v. Delta & Pine Land Co., 1:07-CV-01352 (D.D.C. 2007).

34. SEC v. Delta & Pine Land Co., Litigation Release No. 20214 (July 26, 2007), 2007 SEC LEXIS 1632, *available at* http://www.sec.gov/litigation/litreleases/2007/lr20214.htm.

senior Indonesian environmental official to persuade the official to repeal an environmental impact study requirement that was making it difficult for the company to sell its genetically modified crops in that country.[35] To increase the acceptance of genetically modified crops in Indonesia, Monsanto retained an Indonesian consulting firm to lobby for the repeal of the environmental impact study requirement which was having an adverse effect on its business interests in that country.[36] An employee of Monsanto's Indonesian subsidiary authorized the consulting company to make a $50,000 cash payment to the environmental official to "incentivize" him to repeal the requirement.[37] To fund the improper payment, a false invoicing scheme was devised with the consulting company and the $50,000 cash payment was ultimately made to the official by the consulting company.[38] However, despite the cash payment, the official never repealed the environmental impact study requirement.[39]

The *Kay* decision as well as the Vetco, Dow Chemical, Delta & Pine, and Monsanto enforcement actions demonstrate that, even where payments do not directly generate specific government business, or where they fail to successfully accomplish their intended result, U.S. enforcement agencies will not hesitate to bring an FCPA enforcement action when improper payments to a foreign official allow a company to secure an advantage over competitors. The Dow Chemical, Delta & Pine, and Monsanto FCPA enforcement actions are particularly relevant to health-care companies because health-care products and services must often receive regulatory approval by a foreign government entity before a company is able to sell the product or service in a foreign country.

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35. *In re* Monsanto Co., Exchange Act Release No. 50978 (Jan. 6, 2005), 2005 SEC LEXIS 10; SEC v. Monsanto Co., Litigation Release No. 19023, (Jan. 6, 2005), 2005 SEC LEXIS 7, *available at* http://www.sec.gov/litigation/litreleases/lr19023.htm; Press Release, Dep't of Justice, Monsanto Company Charged With Bribing Indonesian Government Official: Prosecution Deferred for Three Years (Jan. 6, 2005), *available at* http://www.usdoj.gov/opa/pr/2005/January/05_crm_008.htm.

36. *In re* Monsanto Co., Exchange Act Release No. 50978 (Jan. 6, 2005), 2005 SEC LEXIS 10.

37. *Id.*

38. *Id.*

39. *Id.*

3. "Foreign Official"

While the "anything of value" and "obtain or retain business" elements of an FCPA Anti-Bribery violation have broad application, it is the broad application of the "foreign official" element that makes FCPA compliance a unique challenge for healthcare companies given the number of foreign hospitals, clinics, laboratories and medical providers that are state-owned or state-controlled. The FCPA's Anti-Bribery provisions broadly define the term "foreign official" to include:

> any 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.[40]

A foreign national can generally be classified as a "foreign official" under the FCPA's Anti-Bribery provisions in one of two ways.[41] First, an individual can be deemed a "foreign official" directly in his own right by virtue of an appointment he may have with a government entity.[42] Second, and much more of a risk for the unwary, an employee of a foreign company can be deemed a "foreign official" under the FCPA when his employer is an "instrumentality" of a foreign government—a term not defined in the FCPA or delineated in the FCPA's legislative history. Once a foreign company is deemed an "instrumentality" of a foreign government, every single employee, from the lowest ranking medical assistant to the chairman of the board, will be considered a "for-

40. 15 U.S.C. §§ 78dd-1(f)(1)(A) (2000).
41. *Id.*
42. *Id.*

eign official" for purposes of the FCPA.[43] This is true regardless of how local law may characterize the employee.[44]

The recent FCPA enforcement actions against health-care companies, described more fully in Section III, demonstrate that U.S. enforcement agencies consider employees of state-owned or state-controlled hospitals, clinics and laboratories to be "foreign officials" under the broad definition of that term in the FCPA's Anti-Bribery provisions. For example, in the Diagnostic Products Corporation ("DPC") enforcement action, the "foreign officials" allegedly bribed were physicians and laboratory personnel of Chinese state-owned hospitals.[45] Similarly, in the Micrus Corporation, Syncor International Corporation, and Immucor, Inc. enforcement actions, the "foreign officials" allegedly bribed were also physicians or hospital personnel at state-owned facilities in France, Spain, Germany, Turkey, Taiwan, Mexico, Belgium, Luxembourg and Italy.[46] As discussed above, the "foreign official" in the

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43. *See* DOJ Brochure, *supra* note 13 ("The FCPA applies to payments to *any* public official, regardless of rank or position. The FCPA focuses on the *purpose* of the payment instead of the particular duties of the official receiving the payment . . . .").

44. *See* Opinion Procedure Release, Op. Dep't of Justice No. 94-01 (May 13, 1994), *available at* http://www.usdoj.gov/criminal/fraud/fcpa/opinion/1994/9401.html (opining that a general director of a state-owned enterprise being transformed into a joint stock company is a "foreign official" under the FCPA despite a foreign law opinion that the individual would not be regarded as either a government employee or a public official in the foreign country).

45. *In re* Diagnostic Prod. Corp., Exchange Act Release No. 51724 (May 20, 2005), 2005 SEC LEXIS 1185; Press Release, Dep't of Justice, DPC (Tianjin) Ltd. Charged with Violating the Foreign Corrupt Practices Act (May 20, 2005), *available at* http://www.usdoj.gov/criminal/fraud/press/2005/dpcfcpa.pdf.

46. SEC v. Micrus Corp., Litigation Release No. 17887 (Dec. 10, 2002), 2002 SEC LEXIS 3143 (involving physicians in Taiwan, Mexico, Belgium, Luxembourg and France); Immucor Inc., Quarterly Report (Form 10-Q) (Apr. 8, 2005), EDGAR Online (LEXIS) (involving a physician and hospital administrator in Italy); Press Release, Dep't of Justice, Micrus Corporation Enters into Agreement to Resolve Potential Foreign Corrupt Practices Act Liability, (Mar. 2, 2005) (involving physicians in France Spain, German and Turkey), *available at* http://www.usdoj.gov/criminal/pr/press_releases/2005/03/2005_3860_micruscorp030205.pdf.

Schering-Plough matter was a director of a Polish government health fund.[47]

FCPA enforcement actions against *non*-health-care companies also demonstrate the broad scope of the "foreign official" element of an FCPA Anti-Bribery violation. In October 2006, Schnitzer Steel Industries, Inc. ("Schnitzer Steel"), along with two of its foreign subsidiaries, agreed to settle an FCPA enforcement action for making approximately $205,000 in improper payments to managers of government-controlled steel mills in China in connection with 30 sales transactions.[48] As a result of this and other improper conduct, Schnitzer Steel and its foreign subsidiaries agreed to pay $15.2 million to resolve its FCPA liability (a $7.5 million criminal fine paid by the company's foreign subsidiary and a $7.7 million civil penalty paid by Schnitzer Steel).[49] Likewise, in a February 2005 FCPA enforcement action, GE InVision, Inc. (formerly known as InVision Technologies, Inc.) ("InVision"), a manufacturer of explosive detection systems used at airports, agreed to pay $1.3 million to resolve its FCPA liability in connection with improper payments made through foreign sales agents or distributors to various employees of government-owned and operated airports in China, the Philippines, and Thailand.[50]

As the above FCPA Anti-Bribery enforcement actions demonstrate, it is not the "suitcase full of cash" to an elected government official scenario that presents the greatest FCPA compliance risks for health-care companies doing business in overseas markets. Rather, the FCPA risks are greatest for U.S. health-care companies given the number of physicians, hospital administrators,

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47. *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), 2004 LEXIS 1183; Complaint at 5, SEC v. Schering-Plough Corp., 1:04CV00945 (D.D.C. 2004).

48. SEC v. Schnitzer Steel, Exchange Act Release No. 54606 (Oct. 16, 2006), 2006 LEXIS 2332; Criminal Information at 9–12, United States v. SSI Int'l Far East, Ltd., 3:06 cr 00398 (D. Or. 2006).

49. *Id.*

50. SEC v. GE InVision, Inc., Litigation Release No. 19078 (Feb. 14, 2005), 2005 LEXIS 356; Complaint at 1–7, SEC v. GE InVision, Inc., No. C 05 0660 (N.D. Cal. 2005); Press Release, Dep't of Justice, InVision Technologies, Inc. Enters Into Agreement with the United States (Dec. 6, 2004), *available at* http://www.usdoj.gov/opa/pr/2004/December/04_crm_780.htm.

and laboratory personnel who will be deemed "foreign officials" under the FCPA's Anti-Bribery provisions.

B. Books and Records and Internal Control Provisions

The FCPA's Books and Records provisions, which supplement a public health-care company's Sarbanes-Oxley obligations, require Issuers to "make and keep ***books, records, and accounts***, which, in ***reasonable detail***, ***accurately and fairly*** reflect the transactions and dispositions of the assets of the Issuer."[51] The phrase "books, records, and accounts" is very broad and includes most corporate record keeping. The Exchange Act defines "records" to include "accounts, correspondence, memorandum, tapes, discs, papers, books, and other documents or transcribed information of any type, whether expressed in ordinary or machine language."[52] The addition of the term "books" and the term "accounts" in the FCPA further broadens the scope. The SEC has specified a limitation on the scope of the FCPA's Books and Records provisions; records which are not related to internal or external audits or to the internal control objectives set forth in the FCPA are not within the purview of the provisions.[53] However, one of the FCPA's internal control provisions[54] is that a system of internal accounting controls must exist which is sufficient to provide reasonable assurances that transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting practices ("GAAP"). This limitation is rendered trivial in most instances because auditors, both internal and external, need access to most corporate records to permit preparation of financial statements.

The term "reasonable detail" in the FCPA's Books and Records provisions was intended as a qualification to the requirement to make and keep books, records, and accounts. Congress intended to make clear that "the Issuer's records should reflect transactions in conformity with accepted methods of recording economic events and effectively prevent off-the-book slush funds and the payment

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51. 15 U.S.C. § 78m(b)(2)(A) (2000) (emphasis added).

52. 15 U.S.C. § 78c(a)(37) (2000).

53. Foreign Corrupt Practices Act of 1977, Exchange Act Release No. 17500, 21 SEC Docket 1466 (Jan. 29, 1981), 1981 SEC LEXIS 2167.

54. *See infra* note 47 and accompanying text.

of bribes."[55] "Reasonable detail" means "such level of detail as would satisfy prudent officials in the conduct of their own affairs."[56] The FCPA's Books and Records provisions also require that the books, records, and accounts of Issuers "accurately and fairly reflect the transactions and dispositions of assets."[57] Congress did not intend the word "accurately" to mean exact precision as measured by some abstract principle, but "rather . . . that Issuer's records should reflect transactions in conformity with accepted methods of recording economic events."[58]

The FCPA's Internal Control provisions require Issuers to "devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that," among other things, "transactions are executed in accordance with management's general or specific authorization" and "transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles . . . and to maintain accountability for assets."[59] In sum, the FCPA's Books and Records and Internal Control provisions give the SEC broad enforcement authority over the foreign business practices of Issuers, often providing the jurisdictional basis for an FCPA enforcement action.

In many cases, improper payments to a "foreign official" to "obtain or retain business" result not only in a DOJ criminal enforcement action for violations of the FCPA's Anti-Bribery provisions, but also a parallel SEC enforcement action against the Issuer for violations of the FCPA's Books and Records and Internal Control provisions. This is because improper payments are often disguised or inaccurately recorded on the company's books and records as "miscellaneous" expenses, "costs of goods sold," or under some other vaguely described account, and the company's internal controls failed to prevent the payments.

Indeed, the recent FCPA enforcement actions against health-care companies, described more fully in Section III, demon-

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55. H.R. REP. NO. 95-831, pt. 2(a), at 10 (1977) (Conf. Rep.), *reprinted in* 1977 U.S.C.C.A.N. 4120, 4122.

56. *Id.*

57. 15 U.S.C. § 78m(b) (2000).

58. S. REP. NO. 94-1031, at 23 (2d Sess. 1976).

59. 15 U.S.C. § 78m(b)(2)(A) (2000).

strate that a company's books and records and internal controls will generally be subject to scrutiny anytime there is an improper payment to a "foreign official." For instance, in the Immucor, DPC, Micrus, Schering-Plough, and Syncor enforcement actions, the improper payments to "foreign officials" were all disguised on the company's books and records as either "consulting expenses," "selling expenses," "stock options, honorariums and commissions," "charitable donations," or "promotional and advertising expenses."[60]

Enforcement actions for violating the FCPA's Books and Records and Internal Control provisions can also occur in isolation when violations of the Anti-Bribery provisions are not alleged. This is often the case where the DOJ lacks jurisdiction against the individual or entity making the improper payment, or where the DOJ lacks evidence to prove its case beyond a reasonable doubt to satisfy the elements of an FCPA Anti-Bribery violation.

A February 2007 FCPA enforcement action against El Paso Corporation ("El Paso"), a Texas-based energy company, is representative of an FCPA enforcement action based solely on the FCPA's Books and Records and Internal Control provisions.[61] In this matter, the SEC alleged that El Paso indirectly paid nearly $5.5 million in illegal surcharges to Iraq in connection with purchases of crude oil from third parties under the United Nations Oil

60. SEC v. Gioacchino de Chirico, Litigation Release No. 20316 (Sept. 28, 2007), 2007 SEC LEXIS 2326; *In re* Immucor, Inc. and Gioacchino de Chirico, Exchange Act Release No. 56558 (Sept. 27, 2007), 2007 SEC LEXIS 2285, *available* at http://www.sec.gov/news/digest/2007/dig092807.htm; *In re* Diagnostic Prod. Corp., Exchange Act Release No. 51724 (May 20, 2005), 2005 SEC LEXIS 1185 (selling expenses); *In re* Schering-Plough Corp., Exchange Act Release No. 49838 (June 9, 2004), 2004 SEC LEXIS 1185 (charitable donations); *In re* Syncor Int'l Corp., Exchange Act Release No. 46979 (Dec. 10, 2002), 2002 SEC LEXIS 3151 (promotional and advertising expenses); Complaint, SEC v. Gioacchino de Chirico, No. 1:07–CV–236 (D. Ga. Sept. 28, 2007) (consulting expenses); Press Release, Dep't of Justice, *supra* note 50 (stock options, honorariums and commission).

61. SEC v. El Paso Corp., No. 1:07-cv 00899 (S.D.N.Y. 2007), *available at* http://www.sec.gov/litigation/complaints/2007/comp19991.pdf; SEC v. El Paso Corp., Litigation Release No. 19991, 2007 SEC LEXIS 255 (Feb. 7, 2007), *available at* http://www.sec.gov/litigation/litreleases/2007/lr19991.htm.

for Food Program.[62] The SEC concluded that the company, after becoming aware of Iraqi demands for illegal surcharges on oil sales, failed to maintain a system of internal controls sufficient to ensure that the company's transactions were recorded in accordance with management's authorization and that the transactions were recorded as necessary to maintain accountability of the company's assets.[63] The SEC also found that the company failed to accurately record the payments in its books, records, and accounts because the illegal surcharge payments were recorded as "cost of goods sold."[64] El Paso agreed to settle the matter by paying a civil penalty of $2.25 million and by disgorging profits of approximately $5.5 million.[65]

C. Fines and Penalties

FCPA violations can expose health-care companies and its personnel to significant criminal and civil penalties. For instance, companies can be criminally fined up to $2 million per violation of the Anti-Bribery provisions, and culpable individuals can be subject to a criminal fine of up to $250,000 per violation as well as imprisonment for up to five years.[66] Willful violations of the Books and Records and Internal Control provisions can result in a criminal fine of up to $25 million for a company and a criminal fine of up to $5 million as well as imprisonment for up to twenty years for culpable individuals.[67] These fines and penalties are in addition to harsh collateral sanctions that can result from an FCPA violation, including termination of government licenses and debarment from government contracting programs.[68] For health-care

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62. Complaint at 1–12, SEC v. El Paso Corp., 1:07-cv 00899 (S.D.N.Y. 2007), *available at* http://www.sec.gov/litigation/complaints/2007/comp19991.pdf.

63. *Id.*

64. *Id.*

65. *Id.*

66. 15 U.S.C. § 78ff (2000).

67. *Id.*

68. *See* DOJ Brochure, *supra* note 13.

> Under guidelines issued by the Office of Management and Budget, a person or firm found in violation of the FCPA may be barred from doing business with the Federal government. *Indictment alone can lead to suspension of the right to do business with the government.* The President has directed that

companies, debarment from government health-care programs, such as Medicare and Medicaid, could very well put the company's long term viability and profitability on "life support."

Enforcement agencies are also increasingly seeking disgorgement of company profits on "tainted contracts" secured through improper payments to foreign officials. Such a penalty can be significant, as evidenced by the nearly $20 million disgorgement penalty (part of an FCPA record $44 million in combined fines and penalties) imposed on Baker Hughes, Inc. in April 2007 for making improper payments to foreign officials in Kazakhstan.[69]

Another FCPA enforcement trend that is particularly cumbersome for companies, not to mention expensive, is the appointment of an independent monitor to review and evaluate a company's internal controls, record-keeping, and financial reporting

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> no executive agency shall allow any party to participate in any procurement or nonprocurement activity if any agency has debarred, suspended, or otherwise excluded that party from participation in a procurement or nonprocurement activity. In addition, a person or firm found guilty of violating the FCPA may be ruled ineligible to receive export licenses; the SEC may suspend or bar persons from the securities business and impose civil penalties on persons in the securities business for violations of the FCPA; the Commodity Futures Trading Commission and the Overseas Private Investment Corporation both provide for possible suspension or debarment from agency programs for violation of the FCPA; and a payment made to a foreign government official that is unlawful under the FCPA cannot be deducted under the tax laws as a business expense.

Id.

69. SEC v. Baker Hughes, Litigation Release No. 20094 (April 26, 2007), 2007 SEC LEXIS 858, *available at* http://www.sec.gov/litigation/litreleases/2007/lr20094.htm; Press Release, Dep't of Justice, 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/criminal/pr/press_releases/2007/04/CRM_07-296_baker_hughes_042607.pdf; Press Release, SEC, Sec. & Exch. Comm'n, Charges Baker Hughes with Foreign Bribery and With Violating 2001 Commission Cease-and-Desist Order (April 26, 2007), *available at* http://www.sec.gov/news/press/2007/2007-77.htm.

for purposes of ensuring future compliance with the FCPA.[70] The independent monitor that the SEC ordered DPC to retain for a period of three years is representative of such an undertaking.[71] Per the SEC's order, DPC was required to retain an independent monitor acceptable to the SEC to review the company's compliance with its FCPA policies and procedures.[72] The work of the monitor, which includes inspection of relevant documents and procedures, onsite observation of various controls and procedures, and meetings and interviews with relevant personnel, must be independent from the company. No attorney-client relationship may be formed between the monitor and the company, and the monitor may not withhold any information or documents from the SEC on the basis of any applicable privileges.[73] The SEC order also contemplates that the monitor will provide a written report to DPC and the SEC setting forth the monitor's assessment and making recommendations reasonably designed to improve the company's programs, policies, and procedures for ensuring compliance with the FCPA which the company shall adopt.[74]

The above-described penalties, sanctions, and collateral effects of an FCPA violation are in addition to the obvious damage a company's reputation suffers when it, or its employees, agents, or other affiliates are alleged to have bribed foreign officials. It is against this backdrop that health-care companies are increasingly becoming entangled in FCPA enforcement actions.

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70. Independent monitors are now ordered by the SEC as a condition of settlement in most settled FCPA enforcement actions. ***See, e.g.***, SEC v. Schnitzer Steel, Exchange Act Release No. 54606 (Oct. 16, 2006), 2006 SEC LEXIS 2332; SEC v. Schering-Plough, Exchange Act Release No. 49838 (June 9, 2004), 2004 SEC LEXIS 1185.

71. ***In re*** Diagnostic Prod. Corp., Exchange Act Release No. 51724 (May 20, 2005), 2005 SEC LEXIS 1185.

72. SEC v. Diagnostic Prod. Corp., Exchange Act Release No. 54606 (Oct. 16, 2006), 2006 SEC LEXIS 2332.

73. ***Id.***

74. ***Id.***

III. THE INCREASE IN FCPA ENFORCEMENT ACTIONS AGAINST HEALTH-CARE COMPANIES

The health-care industry has been particularly vulnerable to FCPA enforcement actions. Since 2002, approximately ten health-care companies have either settled FCPA enforcement actions or disclosed improper business activity to U.S. enforcement agencies that could implicate the FCPA. In each instance, the "foreign official" allegedly bribed was not a traditional elected official, but rather a physician, hospital, or laboratory personnel of a state-owned or state-controlled entity—individuals who are deemed "foreign officials" under the FCPA's broad Anti-Bribery provisions.

A. Immucor, Inc.

In September 2007, the SEC filed a settled civil action against Gioacchino De Chirico. De Chirico, an Italian citizen and legal resident of Georgia, was President and Chief Operating Officer of Immucor, Inc., a Georgia based global diagnostics company, and was sued in connection with an approximate $16,000 improper payment made by Immucor in 2004 to the director of a public hospital in Italy.[75] The SEC alleged that the payment was made to the director as a quid pro quo for the director giving the company favorable consideration with regard to a contract to provide products and services to the hospital.[76] According to the SEC, the payment was falsely recorded on Immucor's books and records and made in a manner enabling the director to avoid Italian income taxes.[77] The SEC alleged that De Chirico approved an invoice that falsely described the payment as a consulting fee for services rendered even though De Chirico knew that the director never performed any services.[78] Based on the above conduct, the SEC alleged that De Chirico knowingly circumvented Immucor's internal accounting controls, knowingly falsified a book and a record, and aided and abetted Immucor's violations of the FCPA's Books and Records and Internal Control provisions.[79] Without admitting or denying

75. *See supra* note 60.
76. *See supra* note 60.
77. *See supra* note 60.
78. *See supra* note 60.
79. *See supra* note 60.

the SEC's allegations, De Chirico agreed to entry of a final judgment ordering him to pay a $30,000 civil penalty.[80] Separately, Immucor and De Chirico consented, without admitting or denying the SEC's allegations, to an SEC cease-and-desist order against future FCPA violations.[81]

B. Diagnostic Products Corporation

In May 2005, DPC, a California producer and seller of diagnostic medical equipment, along with its Chinese subsidiary DPC (Tianjin) Co. Ltd., agreed to settle an FCPA enforcement action in connection with approximately $1.6 million in illegal "commission" payments to physicians and laboratory personnel employed by state-owned hospitals in China.[82] According to the DOJ, the improper payments were allegedly paid between 1991 and 2002 to assist DPC in obtaining and retaining business from the Chinese hospitals.[83] The improper payments were typically calculated as a percentage of sales made to the hospitals and were often paid in cash and hand-delivered by DPC Tianjin salespersons, with the authorization of DPC Tianjin's general manager, to the individuals who controlled purchasing decisions for the hospitals.[84] DPC Tianjin recorded the improper payments on its books and records as "selling expenses," and its financials, including the false sales expenses, were part of the consolidated financial statements included with DPC's public filings.[85] As a result of this conduct, DPC Tianjin agreed to pay a criminal penalty of $2 million to resolve its FCPA liability. In a related and parallel SEC enforcement action, DPC agreed to pay a $2.8 million civil penalty and retain an independent monitor for a period of three years to review and report on its annual compliance with the FCPA.[86]

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80. *See supra* note 60.

81. *See supra* note 60.

82. *In re* Diagnostic Prod. Corp., Exchange Act Release No. 51724 (May 20, 2005), 2005 SEC LEXIS 1185; Press Release, Dep't of Justice, *supra* note 45.

83. *In re* Diagnostic Prod. Corp., Exchange Act Release No. 51724 (May 20, 2005), 2005 SEC LEXIS 1185; Press Release, Dep't of Justice, *supra* note 45.

84. *Id.*

85. *Id.*

86. *Id.*

C. Micrus Corporation

In March 2005, Micrus Corporation ("Micrus"), a privately held California company that develops and sells medical devices in both domestic and foreign markets, agreed to settle a DOJ enforcement action in connection with improper payments to physicians employed by publicly owned and operated hospitals in France, Spain, Germany and Turkey.[87] According to the DOJ, "Micrus, through the conduct of certain officers, employees, agents and salespeople, paid more than $105,000" to physicians in these countries in exchange for their purchase of the company's medical devices.[88] The payments to the physicians were allegedly disguised in the company's books and records as stock options, honorariums and commissions.[89] The DOJ alleged that an additional $250,000 paid by Micrus to the foreign physicians "did not obtain the necessary . . . administrative or legal approval as required under the [local] laws of the relevant foreign jurisdiction."[90] Micrus agreed to resolve its FCPA liability for the above conduct by entering into a non-prosecution agreement with the DOJ (an increasingly common FCPA settlement procedure with corporate entities) wherein the DOJ agreed not to file criminal charges against the company if it agreed to: (i) accept responsibility for its misconduct; (ii) continue to cooperate with the DOJ in its investigation of the wrongdoing; (iii) pay a $450,000 monetary penalty; (iv) adopt an FCPA compliance program, where previously it had none, as well as a set of internal controls designed to prevent FCPA violations in the future; and (v) retain an independent monitor for a period of three years to ensure that the company's compliance program and internal controls were effective.[91]

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87. Press Release, Dep't of Justice, *supra* note 45.

88. *Id.*

89. *Id.*

90. *Id.*

91. Agreement between Micrus Corp. and DOJ, Feb. 28, 2005, at 8, *available at* http://www.usdoj.gov/dag/cftf/chargingdocs/micrusagreement.pdf. The non-prosecution agreement is to remain in effect for a period of two years. *Id.*

D. Schering-Plough Corporation

In June 2004, Schering-Plough, a worldwide pharmaceutical company, settled an SEC enforcement action by agreeing to pay $500,000 to settle charges that it violated the FCPA's Books and Records and Internal Control provisions in connection with the improper recording of payments its wholly-owned Polish subsidiary made to a Polish government health official.[92] The SEC found that Schering-Plough violated the FCPA's Books and Records and Internal Controls provisions when S-P Poland, a branch office of Schering-Plough's wholly-owned subsidiary Schering-Plough Central East AG, made approximately $76,000 in donations between February 1999 and March 2002 to the Chudow Castle Foundation ("Foundation"), a Polish charitable organization dedicated to restoring historic sites including castles in the Silesian region of Poland.[93] The founder and president of the Foundation was the Director ("Director") of the Silesian Health Fund ("Fund"), a Polish government body and one of sixteen regional health authorities in Poland that, among other things, provided money for the purchase of pharmaceutical products by hospitals throughout the Silesian region.[94]

S-P Poland's donations to the Foundation commenced shortly after the Director began his tenure at the Fund and constituted between 20% and 40% of S-P Poland's total promotional donations budget between 2000 and 2001.[95] While all of S-P Poland's payments to the Foundation were recorded as donations, and while the Foundation was a bona fide charity, the SEC alleged that the payments, which it noted were not made with the knowledge or approval of any U.S. Schering-Plough employee, were made to the Foundation to influence the Director to purchase Schering-Plough's products and were not accurately reflected on the books

92. *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), 2004 SEC LEXIS 1183; Complaint, SEC v. Schering-Plough Corp., No. 1:04CV00945 (D.D.C. 2004).

93. *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), 2004 SEC LEXIS 1183; Complaint, SEC v. Schering-Plough Corp., No. 1:04CV00945 (D.D.C. 2004).

94. *See supra* note 93.

95. *See supra* note 93.

and records of Schering-Plough Central East AG.[96] During the time period in which the payments were made, S-P Poland's sales of two oncology products within the Silesian region increased disproportionately compared to sales of the products in other regions in Poland.[97] The SEC alleged that Schering-Plough's FCPA violations resulted from inadequate and insufficient internal controls and ordered Schering-Plough to engage an independent consultant to review and evaluate Schering-Plough's internal controls, record-keeping, financial reporting policies and procedures, and to adopt the recommendations of the independent consultant to ensure future compliance with the FCPA.[98]

E. Syncor International Corporation

In December 2002, Syncor International Corporation ("Syncor"), a California-based radiopharmaceutical company subsequently purchased by Cardinal Health, Inc., agreed to settle an FCPA enforcement action in connection with various improper payments made by its foreign subsidiaries in Taiwan, Mexico, Belgium, Luxembourg and France to physicians employed by various state-owned hospitals.[99] According to the SEC, the improper payments were made with the purpose and effect of influencing the purchasing decisions of the physicians so that Syncor could obtain or retain business with the physicians and the hospitals that employed them.[100] The SEC further alleged that the payments were made with the knowledge and approval of senior officers at certain foreign subsidiaries of Syncor and, in some cases, with the knowledge and approval of Syncor's founder and chairman of the board.[101]

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96. *See supra* note 93.

97. *See supra* note 93.

98. *See supra* note 93.

99. *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) *available at* http://www.sec.gov/litigation/litreleases/lr17887.htm; Complaint, SEC v. Syncor Int'l Corp., No. 1:02CV02421 (D.D.C. 2002).

100. *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) *available at* http://www.sec.gov/litigation/litreleases/lr17887.htm; Complaint, SEC v. Syncor Int'l Corp., No. 1:02CV02421 (D.D.C. 2002).

101. *See supra* note 100.

In Taiwan, the SEC alleged that Syncor, through a subsidiary called Syncor Taiwan, Inc. ("Syncor Taiwan"), made improper commission payments totaling at least $400,000 to physicians, some of whom were employed at hospitals owned by Taiwanese authorities that controlled the purchasing decisions for the nuclear medicine departments of certain hospitals.[102] Syncor Taiwan also allegedly paid approximately $115,000 in improper fees to certain physicians at hospitals owned by Taiwanese authorities for referral of patients to medical imaging centers owned and operated by Syncor Taiwan.[103]

In Mexico, the SEC alleged that Syncor, through a subsidiary called Syncor de Mexico ("Syncor Mexico"), made improper payments in the amount of $23,000 to physicians at state-owned hospitals for the purpose of obtaining or retaining business with the physicians and the hospitals that employed them.[104] According to the SEC, the improper payments were accomplished through unpaid personal loans to the physicians, reimbursement of personal expenses claimed by the physicians, and inflated invoices.[105] In addition, Syncor Mexico also allegedly had a general practice of providing "support" payments to the physicians for such items as computer equipment and software, office furniture and other medical supplies.[106] These improper "support" payments totaled approximately $200,000 during a two-year period.[107]

Finally, in Belgium, Luxembourg and France, the SEC alleged that four Syncor subsidiaries, operating collectively as the Medcon Group, made improper payments to physicians employed by state-owned hospitals for the purpose of retaining business with the physicians and their hospitals.[108] During a two-year period, the improper payments totaled approximately $45,000 and included gifts of computers, digital cameras, expensive wine, watches, and leisure travel.[109] Based on this conduct, Syncor agreed to an SEC settlement by which it agreed to pay a $500,000 civil penalty and

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102. *See supra* note 100.
103. *See supra* note 100.
104. *See supra* note 100.
105. *See supra* note 100.
106. *See supra* note 100.
107. *See supra* note 100.
108. *See supra* note 100.
109. *See supra* note 100.

retain an independent monitor to review and make recommendations regarding its FCPA compliance policies and procedures.[110] In a related DOJ criminal proceeding, Syncor Taiwan agreed to plead guilty to one count of violating the FCPA's Anti-Bribery provisions and agreed to pay a $2 million criminal fine for making improper payments to physicians at hospitals owned by Taiwanese authorities for referral of patients to medical imaging centers owned and operated by Syncor Taiwan.[111]

In addition to these FCPA enforcement actions, several health-care companies have also recently disclosed that they are the subjects of DOJ and/or SEC FCPA investigations. These disclosures concern payments made in connection with overseas sales of medical products and are likely to lead to formal FCPA enforcement actions.

F. Johnson & Johnson

In February 2007, health-care conglomerate Johnson & Johnson voluntarily disclosed to U.S. enforcement agencies that certain of its foreign subsidiaries made "improper payments in connection with the sale of medical devices in two small-market countries."[112] The company said that the actions of the foreign subsidiaries were contrary to company policy and may fall within the jurisdiction of the FCPA.[113] The company also disclosed that the worldwide chairman of its Medical Devices and Diagnostics division retired from the company in connection with an internal review of the improper payments because he had "ultimate responsibility" for the foreign subsidiaries that were the subject of the FCPA disclosure.[114]

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110. *See supra* note 100.

111. Complaint, U.S. v. Syncor Taiwan, Inc., No. 02-CR-1244 (C.D. Cal. 2002).

112. Johnson, *supra* note 10; Johnson & Johnson Statement on Voluntary Disclosure, http://www.jnj.com/news/jnj_news/20070212_192452.htm (last visited Nov. 21, 2007).

113. Johnson, *supra* note 10; Johnson & Johnson Statement on Voluntary Disclosure, http://www.jnj.com/news/jnj_news/20070212_192452.htm (last visited Nov. 21, 2007).

114. *Id.*

G. Biomet, Inc., Zimmer Holdings, Inc., Smith & Nephew PLC, Stryker Corporation, and Medtronic, Inc.

More recently, in October 2007, several orthopedic device makers disclosed that they are subjects of informal SEC investigations concerning possible FCPA violations.[115] The companies, Biomet, Inc., Zimmer Holdings, Inc., Smith & Nephew PLC, Stryker Corporation, and Medtronic, Inc. all confirmed that they have received inquiries from the SEC regarding overseas sales of medical devices.[116] For example, in a regulatory filing, Medtronic disclosed:

> On September 25, 2007, the Company received a letter from the SEC requesting information relating to any potential violations of the U.S. Foreign Corrupt Practices Act in connection with the sale of medical devices in an unspecified number of foreign countries, including Greece, Poland and Germany. The letter notes that the Company is a significant participant in the medical device industry, and seeks any information concerning certain types of payments made directly or indirectly to government-employed doctors. A number of competitors have publicly disclosed receiving similar letters. On November 16, 2007, the Company received a letter from the Department of Justice requesting any information provided to the SEC. The Company intends to cooperate with both requests.[117]

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115. Kamp, *supra* note 12.

116. *Id.*; *see also* Zimmer Holdings, Inc., Current Report Filing (Form 8-K) (Oct. 11, 2007), EDGAR Online (Lexis); Press Release, Biomet, Inc., Preliminary First Quarter Financial Information (Oct. 11, 2007), *available at* http://www.businesswire.com/portal/site/biomet/ (follow the "10/11/2007" hyperlink); Press Release, Stryker Corp., Stryker Discloses Informal Inquiry Made by United States Securities and Exchange Commission (Oct. 12, 2007), *available at* www.stryker.com (click "Investor"; click "Press Releases"; follow the "10/12/2007" hyperlink).

117. Medtronic, Quarterly Report, (Form 10-Q) (December 4, 2007), EDGAR Online (LEXIS).

As these recent FCPA enforcement actions and inquiries demonstrate, FCPA non-compliance has infected the health-care industry. Such non-compliance likely developed not because of a deliberate ignorance of the FCPA or a lack of a compliance ethic, but because of the failure of health-care companies to recognize the unique FCPA risks of doing business with foreign hospitals, clinics, laboratories, and medical providers that are state-owned or state-controlled. Although health-care companies likely do not view individuals working for these entities as "foreign officials," and these individuals likely do not even view themselves as "foreign officials," they will nevertheless be deemed "foreign officials" under the FCPA's Anti-Bribery provisions, and interaction with these individuals will be subject to close scrutiny under the FCPA by U.S. enforcement agencies.

As Section IV demonstrates, health-care companies can not overcome the FCPA compliance challenges of doing business internationally by simply doing business through foreign subsidiaries or other third parties. Such a "band-aid" approach will not be effective because of yet another broad-reaching FCPA provision—the third party payment provisions.

IV. HEALTH-CARE COMPANIES ARE NOT IMMUNE FROM FCPA LIABILITY BY DOING BUSINESS THROUGH FOREIGN SUBSIDIARIES OR OTHER THIRD PARTIES

The FCPA's Anti-Bribery provisions contain broad third party payment provisions under which the actions of foreign subsidiaries and other third parties, such as agents, distributors, and joint venture partners, can result in FCPA liability for a parent company. In other words, health-care companies can not immunize themselves from FCPA liability by doing business internationally through foreign subsidiaries or third parties. Rather, health-care companies are responsible under the FCPA for ensuring that actions that they are directly prohibited from taking are not accomplished indirectly through others.

A. Third Party Payment Provisions

FCPA Anti-Bribery violations can be based on the wrongful acts of others because the Anti-Bribery provisions cover 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" ("Third Party Payment provisions").[118] Under the FCPA:

> a person's state of mind is "knowing" with respect to conduct, a circumstance, or a result if: (i) such person is aware that such person is engaging in such conduct, that such circumstance exists, or that such result is substantially certain to occur; or (ii) such person has a firm belief that such circumstances exist or that such result is substantially certain to occur.[119]

Moreover, under the FCPA, knowledge is also established "if a person is aware of a high probability of the existence of such circumstance, unless the person actually believes that such circumstance does not exist."[120] Thus, health-care companies can not be willfully blind to any action or fact that should reasonably alert it to a "high probability" of an FCPA violation occurring either directly by the company or indirectly through others. In such cases, knowledge may be inferred even if the company does not have actual knowledge of an improper payment being made to a "foreign official." Indeed, in the Schering-Plough FCPA enforcement action, the improper payments to the foreign official "were made without the knowledge or approval of any Schering-Plough employee in the United States."[121]

B. Foreign Subsidiaries

Given the potential for FCPA Anti-Bribery liability for the actions of others under the Third Party Payment provisions, reliance on foreign incorporation, when there is U.S. management and control over the foreign subsidiary, is a weak shield against parent corporation liability. Indeed, the FCPA's legislative history affirms that parent corporations may remain indirectly liable for FCPA violations by a foreign subsidiary, and the Third Party Payment provisions were enacted to prevent companies from adopting

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118. 15 U.S.C. § 78dd-1(a)(3) (2000) (emphasis added).

119. *Id.* § 78dd-1(f)(2)(A) (2000).

120. *Id.*

121. *In re* Schering-Plough Corp., Exchange Act Release No. 49838 (June 9, 2004), 2004 SEC LEXIS.

a "head-in-the-sand" approach to the activities of foreign business partners.[122] Consequently, if a health-care company controls a foreign entity and has actual or constructive knowledge that the foreign entity is engaging in improper activity under the FCPA, the U.S. parent corporation may be considered a participant in those actions and subject to prosecution by U.S. enforcement agencies.

Recent FCPA enforcement actions confirm that U.S. enforcement agencies, when assessing FCPA liability, often do not draw an exacting legal distinction between the actions of a foreign subsidiary, its employees, and a U.S. parent corporation. All of the FCPA enforcement actions against health-care companies described in Section III concerned improper business activity by a foreign subsidiary; yet, each resulted in FCPA liability for the U.S. parent corporation. Indeed, FCPA liability for a parent corporation can also result from the actions of "distant" subsidiaries, as demonstrated by the recent FCPA enforcement action against Dow Chemical for alleged improper payments made by DE-Nocil, a fifth-tier subsidiary of Dow, without the knowledge or approval of any Dow employee.[123] These FCPA enforcement actions make clear that health-care companies must ensure FCPA compliance by foreign subsidiaries through which they do business. These actions also provide ample reason to infer that anytime there is a questionable payment involving a foreign subsidiary, a health-care company's books and records, and internal controls, will be subject to close scrutiny under the FCPA by U.S. enforcement agencies.

C. Other Third Parties

Just as health-care companies must ensure FCPA compliance by foreign subsidiaries, they must also ensure compliance by all other third parties engaged internationally, including agents and distributors, because improper activity by such third parties can

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122. H.R. REP. NO. 95-831, at 14 (1977) (Conf. Rep.), *as reprinted in* 1977 U.S.C.C.A.N. 4120 ("[T]he conferees intend to make clear that any issuer or domestic concern which engages in bribery of foreign officials indirectly through any other person or entity would itself be liable under the bill"); H.R. REP. NO. 100-576, at 920 (1988) (Conf. Rep.), *as reprinted in* 1988 U.S.C.C.A.N. 1547.

123. *In re* The Dow Chem. Co., Exchange Act Release No. 55281 (Feb. 13, 2007), 2007 SEC LEXIS 286; SEC v. Dow Chem. Co., Litigation Release No. 20000 (Feb. 13, 2007), 2007 SEC LEXIS 292.

also be imputed to health-care companies under the FCPA's Third Party Payment provisions. While none of the health-care-related FCPA enforcement actions or disclosures discussed above appear to involve improper payments made by agents or distributors, the FCPA compliance risks of engaging foreign agents or distributors are wide-ranging and should not be ignored, a fact best demonstrated by a 2005 FCPA enforcement action against InVision.

According to the SEC, InVision was aware of a "high probability" that its agents or distributors in China, Thailand, and the Philippines paid or offered to pay money to foreign officials or political parties in connection with transactions or proposed transactions involving the sale of InVision's airport security screening machines.[124] In China, the SEC alleged that InVision agreed to sell two explosive detection machines through a Chinese distributor for use at a government owned and controlled airport.[125] Due to problems in obtaining an export license for its machines, InVision was unable to meet the intended delivery date of its product and was informed by the Chinese distributor that the airport authorities intended to impose a financial penalty on InVision.[126] However, the distributor informed InVision managers that the financial penalty could be avoided by offering foreign travel and other benefits to the airport officials.[127] Thereafter, the SEC alleged the distributor requested financial compensation from InVision to pay for the supposed penalties and costs the distributor claimed would be incurred as a result of the shipment delay.[128] InVision then authorized the payment to the distributor even though it was aware of a "high probability" that the distributor intended to use part of the funds it received from InVision to pay for foreign travel and other benefits for the airport officials.[129] According to the SEC, InVision recorded the improper payments to the distributor in its books and records as a "cost of goods sold."[130]

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124. Complaint, SEC v. GE InVision, Inc., Case No. C 05 0660 (N.D. Cal. 2005).
125. *Id.*
126. *Id.*
127. *Id.*
128. *Id.*
129. *Id.*
130. *Id.*

In the Philippines, the SEC alleged that InVision paid a Filipino sales agent a commission of approximately $100,000 even though the agent previously indicated that it intended to use part of the commission to buy gifts or make cash payments to officials of a government-owned and controlled airport to influence their decision to purchase additional InVision products.[131] According to the SEC, InVision authorized the payment, recorded on its books and records as a "sales commission," even though it was aware of the "high probability" that the sales agent intended to use part of the commission to make improper payments to the Filipino airport officials.[132]

Finally, the SEC's allegations as to Thailand concerned contemplated illegal payments to Thai officials funded not through actual payments from InVision to a third party, but rather generated by a foreign distributor's profit on resale.[133] Specifically, the SEC alleged that InVision retained a distributor in Thailand to lobby the Thai government and an airport corporation controlled by the government in connection with the construction of an airport in Bangkok.[134] Pursuant to the arrangement, the distributor would purchase InVision's airport detection machinery and then make its profit by reselling the machinery at a higher price to the airport authority.[135] According to the SEC, InVision was aware of the "high probability" that the distributor intended to offer gifts or other forms of payment to Thai officials with influence over the airport corporation and, further, that the distributor intended to fund such gifts (or other forms of payment) out of the difference between the price the distributor paid InVision to acquire the machinery and the price the distributor was able to resell the machinery.[136] Despite such awareness, the SEC alleged that InVision authorized the distributor to proceed with the transaction.[137]

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131. *Id.*
132. *Id.*
133. *Id.*
134. *Id.*
135. *Id.*
136. *Id.*
137. *Id.* Completion of the potential $35 million transaction with the Thai airport authority was deferred after InVision became aware of its potential FCPA liability. InVision agreed that if the transaction proceeded, it would proceed only through a direct sale to the airport corporation. *Id.*

The InVision enforcement action is unique and represents an expansion of the Third Party Payment provisions and is believed to be the first FCPA enforcement action against a U.S. company based on the actions of its foreign distributor. By including factual allegations in the complaint as to InVision's actions in Thailand, the SEC put U.S. companies on notice that they can no longer turn a blind-eye to the actions of their foreign distributors and that FCPA violations can also result even if the improper payments are wholly funded by a third party. The InVision enforcement action also highlights the need for health-care companies to vet all third parties they engage, including agents and distributors, through FCPA-compliant due diligence procedures described in Section V.

The FCPA compliance challenges for health-care companies doing business or seeking business internationally are unique and numerous. However, the challenges are not unmanageable and the key to FCPA compliance is effective, comprehensive, and well-communicated FCPA compliance policies and procedures. While such policies and procedures will not guarantee a "clean bill of health," they may well prevent FCPA maladies from occurring in the first place.

V. FCPA MALADIES ARE BEST PREVENTED BY EFFECTIVE FCPA POLICIES AND PROCEDURES

Health-care companies should implement effective compliance policies and procedures for many reasons not just to ensure FCPA compliance. As an initial matter, it may be a breach of fiduciary duty for a health-care company to not have a meaningful and effective compliance program.[138] In addition, U.S. enforcement agencies will assess the effectiveness of a company's compliance program in determining whether to criminally charge a business organization.[139] Under the so-called McNulty Memorandum, the DOJ's policy for prosecuting business organizations, one

138. McCall v. Scott, 250 F.3d 997 (6th. Cir. 2001); *In re* Caremark Int'l Inc. Derivative Litigation, 698 A.2d 959 (Del. Ch. 1996).

139. Memorandum from Paul McNulty, Deputy Attorney Gen., U.S. Dep't of Justice, to Head of Dep't Components and United States Att'ys Regarding Principles of Fed. Prosecution of Business Orgs. (Dec. 12, 2006), *available at* http://www.usdoj.gov/dag/speeches/2006/mcnulty_memo.pdf.

of the nine factors prosecutors will consider when deciding whether to criminally charge a corporation, is the "existence and adequacy of the corporation's pre-existing compliance program."[140] While the existence of a compliance program will not be sufficient in and of itself to avoid criminal charges, federal prosecutors no doubt will view a health-care company with an effective compliance program more favorably than a company without such a program.[141] Per the McNulty Memorandum, the "critical factors" in evaluating a compliance program are: "whether the program is adequately designed for maximum effectiveness in preventing and detecting wrongdoing by employees and whether corporate management is enforcing the program or is tacitly encouraging or pressuring employees to engage in misconduct to achieve business objectives."[142] Finally, the U.S. Sentencing Guidelines encourage corporate compliance programs by allowing business organizations with such a program to receive a sentencing credit by way of a lower culpability score, which in turn can translate into a lower sentence upon conviction of a criminal offense.[143]

As previously mentioned, one component of an effective compliance program is effective, comprehensive, and well-communicated FCPA policies and procedures. Just like other compliance objectives, FCPA policies and procedures will not ensure that a health-care company will be 100% FCPA compliant. However, if FCPA non-compliance should occur, U.S. enforcement agencies will factor the absence of FCPA policies and procedures into its view of the conduct at issue and its assessment of appropriate fines and penalties.

For instance in the Micrus FCPA enforcement action, one of the conditions of the DOJ's non-prosecution agreement with the company was that Micrus adopt an FCPA compliance program—

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140. *Id.*

141. *Id.*

142. *Id.*

143. *See* U.S. SENTENCING GUIDELINES MANUAL § 8 (2004) [hereinafter MANUAL]. The Sentencing Guidelines set forth seven requirements of an effective compliance program: (1) policies and procedures; (2) senior management/board of director commitment; (3) avoiding the delegation of authority to the "ethically challenged"; (4) training and communication; (5) monitoring and auditing; (6) promotion and enforcement of the compliance program; and (7) response to violations.

implying that the company did not have a pre-existing FCPA compliance program.[144] Likewise, in describing the lack of internal controls at Schnitzer Steel, the SEC noted as follows: "Schnitzer provided no training or education to any of its employees, agents or subsidiaries regarding the requirements of the FCPA. Schnitzer also failed to establish a program to monitor its employees, agents and subsidiaries for compliance with the FCPA."[145]

Thus, a health-care company will be viewed less harshly by U.S. enforcement agencies if an FCPA violation occurs as a result of a "rogue employee" who was not complying with effective and well-communicated FCPA policies and procedures than if the violation occurred in the absence of any FCPA policies and procedures. While the full scope of a comprehensive and effective FCPA compliance program is beyond the scope of this article, set forth below is general guidance for health-care companies to consider in developing a comprehensive and effective FCPA compliance program, including practical pointers for engaging third parties.

A. FCPA Training

FCPA compliance, like any compliance objective, is best achieved by raising awareness of the issue throughout the company—this task is best achieved through in-depth FCPA training. In fact, one of the first questions a health-care company will likely be asked by U.S. enforcement agencies if FCPA non-compliance does occur is: "Tell me about your FCPA training program." At a minimum, an effective FCPA training program should accomplish the following objectives:

1. Inform that compliance with the FCPA is part of the company's overall ethical value;
2. Provide an overview of the FCPA's Anti-Bribery and Books and Records and Internal Control provisions, including the broad application of the "anything of value," "foreign official," and "obtain or retain business" elements and the Third Party Payment provisions;

144. Press Release, Dep't of Justice, *supra* note 45.

145. *In re* Schnitzer Steel Indus., Inc., Release No. 54606 (Oct. 16, 2006).

3. Provide an overview of recent FCPA enforcement actions to emphasize the "real-world" and serious nature of FCPA violations as well as the significant criminal liability, civil liability, collateral sanctions, and reputation damage that can result from such violations; and
4. Provide hypothetical factual scenarios that force trainees to understand and apply key FCPA concepts.

Raising FCPA awareness within a company is best accomplished by in-person group training led by a competent FCPA practitioner. Often times, valuable collective information or ideas about past or future conduct is learned during live training sessions, whereas such interplay is not easily accomplished through computer module training. Furthermore, FCPA training is too important to be relegated to an employee's lunch hour or to the end of a busy day before the training deadline—circumstances which often occur when a company relies exclusively on computer module FCPA training. Even if in-person FCPA training is not achievable, health-care companies should generally avoid the many "off-the-shelf" FCPA computer training tools that are on the market. Rather, training should be tailored to the specific objectives of the company and should be translated into relevant local languages to achieve maximum participation and understanding by all employees.

In terms of the scope of trainees, at a minimum, all business leaders and employees with international responsibilities, including most notably sales and marketing personnel, should participate in the FCPA training. Additionally, because FCPA "red flags" or compliance issues are often the type that could have been spotted by administrative assistants or other lower level employees, such employees should also participate in FCPA training even though their job functions may not be viewed as critical to the success of international sales. Further, because one of the requirements of an effective compliance program under the U.S. Sentencing Guidelines is that a company's governing authority be knowledgeable about the content and operation of the company's compliance program, health-care companies should seriously consider

company-wide FCPA training that includes members of the board of directors and/or audit committee.[146]

Finally, given the FCPA's Third Party Payment provisions, companies should also strongly consider training its agents, distributors or other business partners on FCPA compliance. A health-care company should also supplement its FCPA compliance program by vetting all business partners through specific FCPA due diligence procedures.

B. Due Diligence Procedures

Due diligence of foreign agents or distributors is best and most efficiently accomplished through a questionnaire to the third party and/or an on-site visit or interview with the third party. Among other issues, an FCPA due diligence questionnaire should be designed to elicit the following relevant information:

- Ownership structure, including the name, title, ownership percentage and nationality of all owners, partners, directors or shareholders of the third party;

- Other background information regarding the third party, including financial and business references, financial statements, office locations, the number of individuals employed by the third party, and other customers or clients of the third party, including whether any of the customers or clients are owned or controlled by the government;

- The name, title, and nationality of all employees of the third party who will be acting on behalf of the company in the country, including whether the employee is affiliated with any other organization or enterprise in the country and/or is or has been an employee or official of a government entity.

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146. MANUAL, *supra* note 143.

The third party questionnaire will be useful in identifying the following FCPA "red flags" prior to engaging the third party:

- Is the third party related to a "foreign official" (keeping in mind the broad definition of that term) or does it maintain close social or business relationships with foreign officials or family members?

- Was the third party recommended by a foreign official or family members of the foreign official?

- Does the third party place heavy reliance on political or government contacts versus knowledgeable and qualified staff, adequate facilities and investment of time?

- Is the third party willing and able to assist in developing or implementing a marketing plan?

- Is the third party willing to agree in writing to abide by the FCPA or other relevant anti-corruption laws?

- Does the third party want to keep the nature of the relationship with the company secret?

- Has the third party ever had an unexplained or inadequately explained breakup with another company in the country, or other relationship problems with other companies?

- Has the third party ever been investigated, charged, or convicted on previous corruption allegations in the country?

- Has the third party ever engaged in other suspicious conduct that would raise questions in the eyes of a rational, prudent person?

Existence of any of these FCPA "red flags" does not by itself suggest that the third-party business partner is corrupt or likely to make improper payments to "foreign officials" in violation of the FCPA's Anti-Bribery provisions. However, the existence of any one of these "red flags" should trigger concern and appropriate review by an FCPA practitioner.

Again, the above FCPA compliance policies and procedures will not ensure that a health-care company will be 100% compliant. However, should FCPA non-compliance occur, health-care companies with an effective and well-communicated FCPA compliance program will unquestionably be viewed less harshly by U.S. enforcement agencies than if non-compliance occurred in the absence of any FCPA policies and procedures.

VI. CONCLUSION

The internationalization of health care has created a "perfect storm" for FCPA non-compliance. The enforcement actions and disclosures described herein demonstrate that the healthcare industry is particularly vulnerable to FCPA enforcement actions given the expansive nature of the FCPA's "foreign official" element. By adopting and implementing the strategies discussed in this article, health-care companies will be better able to manage the many FCPA compliance risks of doing business internationally and avoid the costly and embarrassing shortcomings that have entangled other health-care companies. In sum, "an ounce of prevention is worth a pound of cure."