**An Overview of the Foreign Corrupt Practices Act for Healthcare Companies**

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The globalization of healthcare has resulted in U.S. healthcare companies working with government agencies and government healthcare systems in foreign countries, the officers, employees, and agents of which may be classified as "foreign officials" under the Foreign Corrupt Practices Act (FCPA). This business relationship with government-owned and government-controlled entities and foreign officials creates a potentially high level of exposure to violations of the FCPA. As recent enforcement actions and investigations demonstrate, the healthcare industry is not exempt from prosecution for FCPA violations. U.S. healthcare companies need to be aware of and understand the impact the FCPA has on doing business around the world and should view FCPA compliance in the same light as they view healthcare fraud and abuse compliance. FCPA anti-bribery prosecutions and enforcement actions rose from five in 2004 to thirty-eight in 2007.[1] In September 2008, Mark Mendelsohn, the Department of Justice's (DOJ) chief prosecutor of foreign bribery said,

> The number of individual prosecutions has risen—and that's not an accident. That is quite intentional on the part of the Department. It is our view that to have a credible deterrent effect, people have to go to jail. People have to be prosecuted where appropriate. This is a federal crime. This is not fun and games.[2]

To prevent FCPA violations from occurring and to mitigate a company's liability when violations have already taken place, U.S. healthcare companies should adopt a comprehensive compliance program to address the potential FCPA risks associated with conducting business internationally.

[1] Ed Rial, *Beyond Reproach: Why compliance with anti-corruption laws is increasingly critical for multinational businesses*, Deloitte Review, Issue 4, Deloitte Development LLC (2009).
[2] *Mendelsohn Says Criminal Bribery Prosecutions Doubled in 2007*, 22 Corporate Crime Reporter 36, vol. 1, Sept.16, 2008, *available at* www.corporatecrimereporter.com/mendelsohn091608.htm.

## FCPA Background

Congress enacted the Foreign Corrupt Practices Act of 1977[3] as an amendment to the Securities Exchange Act of 1934[4] (Exchange Act) in an attempt to eliminate the practice of bribery as a way of obtaining and retaining foreign business. The FCPA is the result of an SEC-initiated investigation into undisclosed payments to domestic and foreign governments and politicians, triggered by the Watergate scandal.[5] Congress later passed the Foreign Corrupt Practices Act Amendments of 1988[6] (1988 Amendments), adding an exception and affirmative defenses. The FCPA was again amended in 1998, when Congress passed the International Anti-Bribery and Fair Competition Act of 1998[7] (1998 Amendments) that implemented the Organization of Economic Cooperation and Development (OECD) Convention on Combating Bribery of Foreign Officials in International Business Transactions (OECD Convention). Upon signing the 1998 Amendments, President Bill Clinton stated:

> Since the enactment in 1977 of the Foreign Corrupt Practices Act, U.S. businesses have faced criminal penalties if they engaged in business-related bribery of foreign public officials. Foreign competitors, however, did not have similar restrictions and could engage in this corrupt activity without fear of penalty. Moreover, some of our major trading partners have subsidized such activity by permitting tax deductions for bribes paid to foreign public officials. As a result, U.S. companies have had to compete on an uneven playing field, resulting in losses of international contracts estimated at $30 billion per year. The OECD Convention—which represents the culmination of many years of sustained diplomatic effort—is designed to change all that. Under the Convention, our major competitors will be obligated to criminalize the bribery of foreign public officials in international business transactions.[8]

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[3] Pub. L. No. 95-213, 91 Stat. 1494 (1977).
[4] 15 U.S.C. § 78a *et seq*.
[5] DON ZARIN, DOING BUSINESS UNDER THE FOREIGN CORRUPT PRACTICES ACT 1-1 (Practicing Law Institute 2008) (1995) (referencing Theodore C. Sorenson, *Improper Payments Abroad: Perspectives and Proposals*, 54 FOREIGN AFFAIRS 719 (1976)).
[6] Pub. L. No. 100-418, §§ 5001-5003, 102 Stat. 1415 (1988).
[7] Pub. L. No. 105-366, 112 Stat. 3302 (1998).
[8] William J. Clinton, Statement by the President (Nov. 10, 1998), *available at* www.usdoj.gov/criminal/fraud/fcpa/history/1998/amends/signing.html.

The 1988 Amendments, the OECD Convention, and the 1998 Amendments were all attempts to level the international playing field by eliminating the competitive advantage held by international competitors that were not subject to U.S. anti-bribery laws.

## Overview of the Key Provisions of the FCPA

The FCPA criminalizes the bribery of foreign officials by U.S. companies and citizens or other persons acting in the United States, and requires publicly traded companies with a class of securities registered and traded on a U.S. exchange to meet standards relating to accounting, book and record keeping, and internal controls. The FCPA is jointly enforced by the DOJ and the Securities Exchange Commission (SEC), and is presently being actively enforced by the DOJ and SEC.

### *Anti-Bribery Provisions*

The "anti-bribery" provisions of the FCPA apply to issuers,[9] domestic concerns,[10] any officer, director, employee, agent, or stockholder thereof acting on behalf of such issuer or domestic concern, or any person acting within the United States (collectively Covered Persons).[11] Issuers and domestic concerns also may be held liable for acts of foreign subsidiaries when such acts have been authorized, directed, or controlled by the parent.[12] Additionally, a foreign company or individual can be subject to the FCPA if it "causes, directly or through agents, an act in furtherance of the corrupt payment to take place within the territory of the United States."[13]

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[9] 15 U.S.C. § 78dd-1.

[10] 15 U.S.C. § 78dd-2. Domestic concern is defined as "any individual who is a citizen, national, or resident of the United States" and "any corporation, partnership, association, joint-stock company, business trust, unincorporated organization, or sole proprietorship which has its principal place of business in the United States, or which is organized under the laws of a State of the United States or a territory, possession, or commonwealth of the United States." 15 U.S.C. § 78dd-2(h)(1).

[11] 15 U.S.C. §§ 78dd-1(a)(for issuers), 78dd-2(a)(for domestic concerns).

[12] *Lay-Person's Guide to FCPA* (hereinafter, Lay Person's Guide), United States Department of Justice, www.usdoj.gov/criminal/fraud/docs/dojdocb.html (last visited January 6, 2009).

[13] *Id*. *See* 15 U.S.C. § 78dd-3. This article will focus primarily on U.S. healthcare companies and not FCPA liability for independent foreign persons.

Violations of the anti-bribery provisions of the FCPA have the following elements:

(1) A Covered Person[14]

(2) Makes "use of the mails or any means or instrumentality of interstate commerce *corruptly*[15] in furtherance of an offer, payment, promise to pay, or authorization of the payment of any money, or offer, gift, promise to give, or authorization of the giving of anything of value;"[16]

(3) To a foreign official,[17] foreign political party or official thereof, or any candidate for foreign political office,[18] or any person, while *knowing* that all or a portion of the payment will be passed on directly or indirectly to a foreign official, foreign political party or official thereof, or candidate for foreign political office;[19]

(4) To influence any official act or decision, to induce an act or omission to act in violation of the law, to secure an improper advantage, or to induce the use of influence with a foreign government to affect or influence an act or decision of the foreign government;[20]

(5) In order to obtain or retain business for or with, or direct business to any person.[21]

Foreign officials include "any officer or employee of a foreign government or any department, agency or instrumentality thereof, or of a public international organization,[22] or any person acting in an official capacity for or on behalf of any such government or

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[14] 15 U.S.C. §§ 78dd-1(a) (for issuers), 78dd-2(a) (for domestic concerns), 78dd-3(a) (for all others while in a territory of the U.S.).

[15] The term "corruptly" suggests a bad intent or purpose and "encompasses a quid pro quo element: a nexus between the illicit payment and the expected conduct of the foreign official." ZARIN, *supra* note 5, at 4-15 (discussing the legislative history of the term "corruptly").

[16] 15 U.S.C. §§ 78dd-1(a) (for issuers), 78dd-2(a) (for domestic concerns), 78dd-3(a) (for all others while in a territory of the U.S.).

[17] 15 U.S.C. §§ 78dd-1(a)(1) (for issuers), 78dd-2(a)(1) (for domestic concerns), 78dd-3(a)(1) (for all others while in a territory of the U.S.).

[18] 15 U.S.C. §§ 78dd-1(a)(2) (for issuers), 78dd-2(a)(2) (for domestic concerns), 78dd-3(a)(2) (for all others while in a territory of the U.S.).

[19] 15 U.S.C. §§ 78dd-1(a)(3) (for issuers), 78dd-2(a)(3) (for domestic concerns), 78dd-3(a)(3) (for all others while in a territory of the U.S.).

[20] 15 U.S.C. §§ 78dd-1(a)(1)-(3) (for issuers), 78dd-2(a)(1)-(3) (for domestic concerns), 78dd-3(a)(1)-(3) (for all others while in a territory of the U.S.).

[21] *Id*.

[22] "Public International Organization" means (i) an organization designated by an Executive Order pursuant to 22 U.S.C. § 288, or (ii) any other international organization designated by the President by Executive Order for the purpose of the FCPA. 15 U.S.C. §§ 78dd-1(f)(1) (for issuers), 78dd-2(h)(2) (for domestic concerns), 78dd-3(f)(2) (for all others while in a territory of the U.S.).

department, agency or instrumentality, or for or on behalf of such public international organization."[23] The FCPA applies to payments to *any* foreign official, regardless of rank or position, and focuses on the *purpose* of the payment instead of the particular duties of the foreign official receiving the payment.[24]

### *Accounting Provisions*

The "accounting" provisions of the FCPA amended Section 13(b)[25] of the Exchange Act by subjecting "issuers"[26] to record keeping and disclosure requirements and mandating adoption of internal accounting controls. The accounting provisions apply to all issuers regardless of whether or not they are engaged in foreign activities.[27] Under the FCPA, issuers are required to (i) make and keep books, records, and accounts which, *in reasonable detail,*[28] accurately and fairly reflect the transactions and dispositions of the assets of the issuer,[29] and (ii) devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that transactions are properly authorized, recorded, and audited.[30] These provisions are designed to prevent three key types of impropriety: (i) failure to record illegal transactions; (ii) falsification of records to conceal illegal transactions; and (iii) creation of records that are quantitatively accurate, but fail to specify qualitative aspects of the transaction.[31] These provisions also require issuers to create a system of accounting controls that ensure issuers use accepted methods of accounting when recording economic transactions.[32] The 1988 Amendments added provisions to the FCPA that heighten the state of mind requirement for liability under the statute. To be held criminally liable, an individual must knowingly

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[23] *Id*.
[24] Lay Person's Guide, *supra* note 12, at 5.
[25] 15 U.S.C. § 78m(b).
[26] *See* 15 U.S.C. § 78a. "Issuers" are those companies required to register their securities with the SEC.
[27] *See* 15 U.S.C. § 78m(b)(2).
[28] The term "reasonable detail" is defined as "such level of detail . . . as would satisfy prudent officials in the conduct of their own affairs." 15 U.S.C. § 78m(b)(7).
[29] 15 U.S.C. § 78m(b)(2)(A).
[30] 15 U.S.C. §§ 78m(b)(2)(B)(i-iv).
[31] Ned Sebelius, *Foreign Corrupt Practices Act*, 45 AM. CRIM. L. REV. 579, 584 (2008). *See also* JAY G. MARTIN, SUMMARY OF FOREIGN CORRUPT PRACTICES ACT OF 1977, 5 Presentation to Association of International Petroleum Negotiators (June 12, 2002) (citing *SEC v. World-Wide Com Inv. Ltd*., 567 F. Supp. 724, 752 (N.D. Ga. 1983)).
[32] Sebelius, *supra* note 31, at 585.

circumvent or fail to implement a system of internal accounting controls or knowingly falsify any record.[33]

### *Application of the FCPA to Third Parties*

The FCPA contains specific provisions aimed at eliminating illegal payments through third parties. U.S. companies may be held directly responsible for the activities of "any person" who made a payment to a foreign government official if the U.S. company authorized[34] or knew that the money or thing of value would be used by such person, directly or indirectly, to make an illegal payment.[35] "Any person" includes any entity or individual in the United States or abroad, and could include a marketing consultant, distributor, joint venture partner, foreign subsidiary, contractor, or subcontractor.[36] The definition of "knowing" used in the FCPA prevents companies from taking the "head in the sand" approach to dealing with third parties. For purposes of the FCPA, "knowing" means (i) being aware that (a) a person is engaging in the conduct, (b) a circumstance exists, or (c) a result is substantially certain to occur; or (ii) having a firm belief that the circumstances or results are substantially certain to occur.[37] Knowledge also means awareness of a high probability of the existence of circumstances that would result in a violation of the FCPA, unless the person actually believes the circumstances do not exist.[38]

### *Exceptions and Affirmative Defenses*

#### *Facilitating Payments*

The FCPA does not apply to "any facilitating or expediting payment to a foreign official, political party, or party official the purpose of which is to expedite or to secure

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[33] 15 U.S.C. § 78m(b)(5). *See* Sebelius, *supra* note 31, at 585-586 (discussing criminal liability for violations of accounting standards).
[34] *See* 15 U.S.C. §§ 78dd-1(a) (for issuers), 78dd-2(a) (for domestic concerns), 78dd-3(a) (for all others while in a territory of the U.S.).
[35] *See* 15 U.S.C. §§ 78dd-1(a)(3) (for issuers), 78dd-2(a)(3) (for domestic concerns), 78dd-3(a)(3) (for all others while in a territory of the U.S.). It is also important to note that the foreign intermediary engaging in the illicit conduct may actually be outside of the scope of the FCPA, and therefore, not subject to liability. *See* ZARIN, *supra* note 5, at 4-35.
[36] ZARIN, *supra* note 5, at 4-35.
[37] 15 U.S.C. §§ 78dd-1(f)(2) (for issuers), 78dd-2(h)(3) (for domestic concerns), 78dd-3(f)(3) (for all others while in a territory of the U.S.).
[38] *Id*.

performance of a routine government action."[39] "Routine governmental action" includes: (1) obtaining permits, licenses, or other official documents to qualify a person to do business in a foreign country; (2) processing governmental papers such as visas and work orders; (3) providing police protection, mail pick-up and delivery, or scheduling inspections associated with contract performance or inspections related to transit of goods across country; (4) providing phone service, power and water supply, loading and unloading cargo, or protecting perishable products or commodities from deterioration; or (5) actions of a similar nature.[40] Routine governmental action does not include a decision by a foreign official to award new business to or to continue business with a particular party, or any action taken by a foreign official to encourage a decision to award new business to or to continue business with a particular party.[41] The exception does not include "those governmental approvals involving the exercise of discretion by a government official where the actions are the functional equivalent of obtaining or retaining business for or with, or directing business to, any person."[42]

*Affirmative Defenses*

In addition to the exception for facilitating payments, a few narrowly interpreted affirmative defenses exist. A payment does not violate the FCPA if it is lawful under the written laws and regulations of the foreign country in which it was made.[43] Another exception exists for reasonable and bona fide expenditures made as part of (i) the promotion, demonstration, or explanation of a product, or (ii) the execution or performance of a contract with a foreign government or agency thereof.[44] These expenditures could include reasonable and bona fide travel and lodging expenses used to bring foreign officials to a product demonstration or facility tour.[45]

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[39] 15 U.S.C. §§ 78dd-1(b) (for issuers), 78dd-2(b) (for domestic concerns), 78dd-3(b) (for all others while in a territory of the U.S.).
[40] 15 U.S.C. §§ 78dd-1(f)(3) (for issuers), 78dd-2(h)(4) (for domestic concerns), 78dd-3(f)(4) (for all others while in a territory of the U.S.).
[41] *Id*.
[42] H.R. CONF. REP. NO. 576, 100th Cong., 2d Sess. 921 (1988).
[43] 15 U.S.C. §§ 78dd-1(c)(1) (for issuers), 78dd-2(c)(1) (for domestic concerns), 78dd-3(c)(1) (for all others while in a territory of the U.S.).
[44] 15 U.S.C. §§ 78dd-1(c)(2) (for issuers), 78dd-2(c)(2) (for domestic concerns), 78dd-3(c)(2) (for all others while in a territory of the U.S.).
[45] *Id*.

### *Fines and Penalties*

*Accounting Provisions*

Civil remedies and penalties available for violations of the accounting provisions are the same as those available to the SEC under the general enforcement authority for a violation of the federal securities laws.[46] Enforcement actions involving the accounting provisions generally accompany allegations of other substantive securities violations, making it difficult to accurately assess specific civil remedies for accounting violations.[47] In addition to potential civil penalties, individuals and companies may be subject to criminal penalties under the Exchange Act for knowingly (i) circumventing or failing to implement internal controls, or (ii) falsifying books and records.[48] Individuals are subject to a maximum fine of $5 million and/or imprisonment of not more than twenty years, and companies are subject to a maximum fine of $25 million.[49]

*Anti-Bribery Provisions*

The anti-bribery section of the FCPA is a criminal statute and provides a maximum fine of $2 million *per* violation for entities,[50] and a maximum fine of $100,000[51] or imprisonment of not more than five years—or both—for individuals.[52] Ultimately, within the limitations of the statutory maximums, the determination of the amount of the fine and imprisonment is governed by the Federal Sentencing Guidelines (Sentencing Guidelines).[53] Alternatively, the government could seek fines of $500,000 for entities and $250,000 for individuals, or double the gross gain or loss from the unlawful activity, whichever is greater.[54] In addition to criminal penalties, a Covered Person who violates

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[46] ZARIN, *supra* note 5, at 8-1 (citing 15 U.S.C. § 78u).
[47] *Id*. at 8-2.
[48] 15 U.S.C. § 78m(b)(5).
[49] 15 U.S.C. § 78ff(a).
[50] 15 U.S.C. §§ 78dd-2(g)(1)(A), 78dd-3(e)(a)(A), 78ff(c)(1)(A). Where an offense results in pecuniary gain or loss, the provisions of 18 U.S.C. § 3571(d) provide an alternative statutory maximum fine of the greater of twice the gross gain or twice the gross loss. 18 U.S.C. § 3571(b), (e) (setting forth maximum fines). *See* ZARIN, *supra* note 5, at 8-5.
[51] 15 U.S.C. §§ 78dd-2(g)(2)(A), (2)(B), 78dd-3(e)(2)(A), (2)(B), 78ff(c)(2)(A), (c)(2)(B).
[52] *Id*.
[53] *See* United States Sentencing Commission, GUIDELINES MANUAL § 8C3.1 (2008), *available at* www.ussc.gov/2008guid/GL2008.pdf. *See also* ZARIN, *supra* note 5, at 8-6 (discussing the impact of the Sentencing Guidelines); Sebelius, *supra* note 31, at 595-597 (discussing the impact of the Sentencing Guidelines).
[54] 18 U.S.C. § 3571 (setting forth maximum alternative fines). *See* ZARIN, *supra* note 5, at 8-5.

the bribery provisions of the FCPA is subject to a civil penalty of not more than $10,000 in an action brought by the SEC.[55] Of potentially greater consequence for healthcare companies, a violation of the FCPA by a U.S. company can result in the company being barred from doing business with the federal government[56] or subjected to mandatory outside supervision.

**FCPA and the Healthcare Industry**

The increased globalization of healthcare has created the potential for serious FCPA compliance risks for U.S. healthcare companies. Developing nations are increasing spending on healthcare, resulting in increased demand for pharmaceuticals, medical devices, and medical supplies.[57] U.S. providers are beginning to expand operations abroad and new healthcare companies, in the areas of outsourcing, medical tourism, and electronic medical records, are fully engaged in the global marketplace. In addition to the significant criminal and civil penalties imposed for violating the FCPA, healthcare companies could potentially be barred from the Medicare[58] and Medicaid[59] programs, which could have far broader commercial and financial consequences than the fines and penalties assessed to the company.[60]

Recent FCPA enforcement actions and inquiries by DOJ and SEC demonstrate the emerging trend of "casting a wider net" across many different industries in an increased effort to combat foreign corruption and bribery.[61] U.S. healthcare companies are at a particularly high risk of violating the FCPA because of an increasing number of government-owned or -controlled global customers and business partners. Under the FCPA, government-owned or -controlled health systems may be considered "instrumentalities" of a foreign government, and as such, officers and employees of

[55] 15 U.S.C. §§ 78ff(c).
[56] "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." *See* Lay Person's Guide, *supra* note 12, at 8.
[57] Mike Koehler, *A Malady in Search of a Cure – The Increase in FCPA Enforcement Actions Against Health-care Companies*, 38 U. MEM. L. REV. 261, 263 (2008) (discussing the increase in healthcare expenditures in developing nations and the corresponding increase in demand for healthcare products).
[58] *See* 42 U.S.C. § 1395 *et. seq*.
[59] *See* 42 U.S.C. § 1396 *et. seq*.
[60] *Id*. at 280. *See also* ZARIN, *supra* note 5, at 8-8 (discussing ineligibility for government programs).
[61] Koehler, *supra* note 57, at 262.

these entities are deemed to be foreign officials.[62] Offers, payments, and gifts provided to physicians, nurses, or laboratory technicians employed by state-owned or -controlled hospitals, laboratories, or clinics could trigger liability under the FCPA.

### *High Risk for Healthcare Companies: The Impact of the Third Party Payment Provisions*

*Healthcare Foreign Subsidiaries and Joint Ventures*

In recent years, DOJ and SEC have actively prosecuted and investigated U.S. healthcare companies for the activities of their foreign subsidiaries.[63] U.S. healthcare companies cannot insulate themselves from FCPA liability by setting up foreign subsidiaries. If a company has "knowledge" [64] that a foreign subsidiary is violating the FCPA or authorizes the illegal payment by the foreign subsidiary, the parent company may be considered to be a participant in the illegal activity, and thus subject to FCPA liability.[65] The probability of parental liability for the actions of a subsidiary increases as the parent's involvement in the activities of the subsidiary increase.[66]

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[62] 15 U.S.C. §§ 78dd-1(f)(1)(A) (for issuers), 78dd-2(h)(2)(A) (for domestic concerns), 78dd-3(f)(2)(A) (for all others while in a territory of the U.S.). *See* Koehler, *supra* note 57, at 273-274.

[63] In 2002, Syncor International Corporation (Syncor) consented to the entry of a final judgment in a federal lawsuit requiring it to pay a $500,000 civil penalty and the issuance of an administrative order requiring Syncor to obtain an independent monitor in connection with charges that foreign subsidiaries in Taiwan, Mexico, Belgium, Luxembourg, and France made a total of $600,000 in illicit payments to doctors employed by state-controlled hospitals, with the purpose of influencing the doctors' decisions so that Syncor could obtain or retain business with them and the hospitals. *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* www.sec.gov/litigation/litreleases/lr17887.htm; Complaint, *SEC v. Syncor Int'l Corp*., No. 1:02CV02421 (D.D.C. 2002). In a related DOJ proceeding, Syncor Taiwan Inc. (Syncor Taiwan), a subsidiary of Syncor, agreed to plead guilty to violating the anti-bribery provisions of the FCPA and to pay a $2 million fine. *See United States v. Syncor Taiwan, Inc.*, No. 02-CR-1244-ALL (C.D. Cal.). In 2005, DPC (Tianjin) Co. Ltd. (DPC Tianjin), agreed to plead guilty, adopt internal compliance measures, retain an independent monitor, pay a criminal penalty of $2 million, disgorge approximately $2.8 million in gains, and cooperate with ongoing DOJ and SEC investigations in connection with charges that it paid $1.6 million in bribes to physicians and laboratory personnel employed by government owned hospitals in the People's Republic of China (PRC). DPC Tianjin is the Chinese subsidiary of California based Diagnostic Products Corporation. The bribes were paid to laboratory personnel and physicians in exchange for agreements that the hospitals would obtain DPC Tianjin's products and services. The bribes were recorded on the books of DPC Tianjin as "selling expenses" and were regularly reported to DPC on DPC Tianjin's financial statements as sales expenses. *See* Press Release, Dep't of Justice, DPC (Tianjin) Ltd. Charged with Violating the Foreign Corrupt Practices Act (May 20, 2005), *available at* www.usdoj.gov/criminal/fraud/press/2005/dpcfcpa.pdf.

[64] The key consideration is whether or not the parent company knew or believed that the foreign subsidiary was violating the FCPA. *See* ZARIN, *supra* note 5, at 6-10 to 6-13.

[65] Koehler, *supra* note 57, at 292.

[66] *See* ZARIN, *supra* note 5, at 6-12.

On December 15, 2008, German corporation Siemens Aktiengesellschaft (Siemens AG) and three of its subsidiaries pleaded guilty to violations of and charges related to the FCPA.[67] While Siemens AG's FCPA violations spanned the spectrum of the conglomerate's operational companies, Siemens Medical Solutions operating group (MED) was responsible for over $90 million in illicit payments made to influence purchasing of medical devices in Vietnam, China, and Russia.[68] In total, Siemens AG has agreed to pay more than $1.6 billion in fines, penalties, and disgorgement of profits in connection with cases brought by DOJ, SEC, and the Munich Public Prosecutor's Office—including over $800 million to U.S. authorities—making it the largest monetary sanction ever imposed in an FCPA case.[69]

International joint ventures also present risks under the FCPA. Foreign partners may not be familiar with the FCPA, and in many countries, the FCPA runs counter to customary business practices. As a result, foreign partners should be educated about the FCPA and its prohibitions. Joint ventures with government entities pose a unique set of FCPA challenges. While the FCPA does not prohibit joint ventures with government entities, U.S. healthcare companies need to be extremely diligent in structuring these entities to ensure that (i) foreign officials are not receiving any personal benefit from the relationship, and (ii) the government partner is not influencing government purchasing decisions.[70] As with foreign subsidiaries, if a U.S. healthcare company has knowledge that its joint venture partner is violating the FCPA or authorizes the illegal payment by the joint venture, the U.S. healthcare company may be considered to be a participant in

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[67] Press Release, Dep't of Justice, Siemens AG and Three Subsidiaries Plead Guilty to Foreign Corrupt Practices Act Violations and Agree to Pay $450 Million in Combined Criminal Fines (hereinafter Siemens Press Release) (December 15, 2008), *available at* www.usdoj.gov/opa/pr/2008/December/08-crm-1105.html. Although it is a German corporation, Siemens AG was subject to the FCPA because it is an "issuer."

[68] *See* Complaint, *SEC v. Siemens Aktiengesellschaft*, No. 08-2167 (D.D.C. Dec. 12, 2008); Information, *United States v. Siemens Aktiengesellschaft*, No. 08-367 (D.D.C. Dec. 12, 2008). Siemens AG's illegal activities included "using off-the-books slush fund accounts and shell companies to facilitate bribes, making false entries on the company's books and records by, for example, falsely recording bribes as consulting fees." Acting Assistant Attorney General Matthew W. Friedrich, Press Conference Announcing Siemens AG Guilty Plea (Dec. 15, 2008), *available at* www.usdoj.gov/opa/pr/2008/December/08-opa-1112.html.

[69] Siemens Press Release, *supra* note 67. In connection with the DOJ settlement, Siemens AG and its subsidiaries agreed to pay a $450 million criminal fine, retain an independent monitor for four years, and cooperate in ongoing investigations by DOJ. *Id*. Siemens AG also settled a related civil complaint with SEC, charging Siemens AG with violating the FCPA's anti-bribery, books and records, and internal controls provisions, by agreeing to pay $350 million in disgorgement of profits. *Id*.

[70] *See* ZARIN, *supra* note 5, at 6-25 to 6-27.

the illegal activity, and thus could be subject to FCPA liability. Due diligence of the joint venture partner, adequate disclosure of the joint venture arrangement, and requisite government approval are all essential steps in structuring international joint ventures.[71]

*Foreign Agents and Distributors*

Relationships with foreign agents can subject U.S. healthcare companies to potential FCPA liability. Foreign sales agents are typically contracted to assist a U.S. company in soliciting the sale of products or services within a foreign country by acting as an intermediary between the company and a foreign customer.[72] Medical device and pharmaceutical manufacturers attempting to sell products in foreign countries with government-owned and -controlled healthcare systems are very likely to face risks related to foreign sales agents.[73] In addition, U.S. hospitals attempting to set up international operations may engage a foreign agent in order to find a suitable venture partner, acquire assets, obtain patient referrals, and build relationships with local constituencies. These activities can be problematic in countries with government-owned or -controlled healthcare systems or other related industries.

In a recent example, on June 3, 2008, DOJ announced that it had entered into an agreement with AGA Medical Corporation (AGA), under which the privately held Minnesota-based manufacturer of cardiac medical devices agreed to pay a $2 million criminal penalty and enter a three-year Deferred Prosecution Agreement (DPA) for FCPA violations.[74] AGA was alleged to have authorized its independent Chinese distributor to pay kickbacks or rewards to physicians employed by government-owned

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[71] *Id*.
[72] *Id*. at 6-6 to 6-7.
[73] In 2005, Micrus Corporation (Micrus), a privately held California corporation that develops and sells embolic coils used in the treatment of intracranial aneurysms agreed to resolve its criminal liability related to potential FCPA violations by paying $450,000 in penalties. Press Release, Dep't of Justice, Micrus Corporation Enters into Agreement to Resolve Potential Foreign Corrupt Practices Act Liability, (Mar. 2, 2005), *available at* www.usdoj.gov/criminal/pr/press_releases/2005/03/2005_3860_micruscorp030205.pdf. The DOJ investigation revealed that officers, employees, agents, and salespeople paid more than $150,000, disguised as honorariums and commissions, to physicians employed at publicly owned hospitals in the French Republic, the Republic of Turkey, the Kingdom of Spain, and the Federal Republic of Germany in return for the hospitals' purchase of embolic coils from Micrus. *Id*.
[74] Press Release, Dep't of Justice, AGA Medical Corporation Agrees to Pay $2 Million Penalty and Enter Deferred Prosecution Agreement for FCPA Violations, (Jun. 3, 2008), *available at* www.usdoj.gov/opa/pr/2008/June/08-crm-491.html. AGA entered into the three-year DPA and agreed to pay a $2 million fine and retain an independent compliance monitor to review improvements to the company's internal control procedures. *Id*.

hospitals to encourage the purchase of AGA devices.[75] DOJ's announcement of its agreement with AGA demonstrates its willingness to broadly interpret the third-party payment provisions of the FCPA. The illicit payments were not made directly by an AGA-owned or -controlled person. DOJ stated that the sale of goods by a U.S. company to a foreign distributor—when the U.S. company had knowledge that the distributor had bribed a foreign official to purchase the products—would be considered an "act in furtherance of" an illegal payment and would be subject to prosecution under the FCPA.[76] Accordingly, mere knowledge or outright authorization of illicit payments made by an independent distributor may subject a U.S. healthcare company to liability under the FCPA.[77]

**Compliance: A Familiar Concept for U.S. Healthcare Companies**

For U.S. healthcare companies, FCPA compliance should be viewed in the same familiar light as healthcare fraud and abuse corporate compliance. U.S. healthcare companies frequently deal with corporate compliance issues relating to fraud and abuse under the federal False Claims Act,[78] Stark Law,[79] and Anti-kickback Law,[80] and most have adopted comprehensive corporate compliance programs to address potential compliance issues. DOJ has placed a significant emphasis on compliance by requiring independent compliance monitors in many of its recent FCPA settlements. A comprehensive compliance program[81] is essential for a U.S. healthcare company to minimize FCPA exposure and mitigate liability for FCPA violations. U.S. healthcare

[75] *Id*.
[76] *Id*. at 6-10 (citing Statement of Peter B. Clark, Deputy Chief of the Fraud Section, Criminal Division, Department of Justice, at a conference on the FCPA in Washington, D.C. (Apr. 20, 1995)).
[77] *See* Koehler, *supra* note 57, at 292-295 (discussing the 2005 FCPA enforcement action against GE InVision Inc.). *See also* Complaint, *SEC v. GE InVision, Inc.*, Case No. C 05 0660 (N.D. Cal. 2005).
[78] 31 U.S.C. §§ 3729-3733.
[79] 42 U.S.C. § 1395nn.
[80] 42 U.S.C. § 1320a-7b(b).
[81] According to the Sentencing Guidelines, a "compliance and ethics program shall be reasonably designed, implemented, and enforced so that the program is generally effective in preventing and deterring criminal conduct." Under the Sentencing Guidelines, the following elements are critical to a comprehensive compliance program: (1) establishment of policies and procedures; (2) corporate governance oversight; (3) background checks/due diligence; (4) education and training; (5) monitoring, auditing, and evaluation of compliance program; (6) reporting system/employee hotline; and (7) discipline and corrective action for violations. *See* Sentencing Guidelines, *supra* note 53, at § 8B2.1. *See* DAVID E. MATYAS & CARRIE VALIANT, LEGAL ISSUES IN HEALTHCARE FRAUD AND ABUSE: NAVIGATING THE UNCERTAINTIES 324-336 (American Health Lawyers Association 2006) (1994).

companies should be well aware under the Sentencing Guidelines that a broad-based compliance program can significantly reduce fines and penalties assessed to a corporation if a violation occurs.[82] Ultimately, however, the effectiveness of a company's compliance program can only be measured by the extent to which the company incorporates the standards into its internal culture and emphasizes adherence to the program.

***Elements of an Effective FCPA Compliance Program***

U.S. healthcare companies engaging in international business should adopt a clear and concise company policy statement on the FCPA stating the company's commitment to conduct business legally and ethically. More detailed and specific policies and procedures should be developed based on a comprehensive compliance risk assessment of the company's business.[83] In addition to a general FCPA policy, policies and procedures should be tailored to address high risk areas.[84] Training should be done periodically so that all employees have a practical understanding of the essential elements of the FCPA and understand their responsibilities with respect to the compliance program.[85] The company's governing body needs to be knowledgeable about the FCPA compliance program and exercise reasonable oversight of the compliance program. An FCPA compliance program can easily be incorporated into a U.S. healthcare company's existing compliance protocols and be overseen by the standing Compliance Committee and Chief Compliance Officer.[86] The company's compliance program should be evaluated and audited periodically to determine the effectiveness of the program, with specific attention to third-party contractual

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[82] *See* Sentencing Guidelines, *supra* note 53, at § 8C2.5(f).
[83] *See* Sharie A. Brown, *Practice note: US Foreign Corrupt Practices Act compliance program tips*, COMPLINET, Nov. 28, 2007, at 1, *available at* www.complinet.com/global/news/news/preview.html ?ref=99639. In conducting a risk assessment, the company should consider (i) the amount of interaction with foreign officials and foreign governments, (ii) specific public corruption risks associated with their foreign locations, and (iii) the types of agents, consultants, and third parties involved in the business. *Id*.
[84] *Id*. at 2. High risk areas include the "facilitating payments" exception, the affirmative defenses, and the due diligence process for vetting agents, third parties, and potential business partners. *Id*.
[85] *See* MATYAS & VALIANT, *supra* note 81, at 332 (discussing the importance of training).
[86] The board of directors should establish a Compliance Committee that meets regularly and appoint a Chief Compliance Officer with direct responsibility for the day-to-day operations and monitoring of the compliance program. *See* MATYAS & VALIANT *supra* note 81, at 326-330 (discussing compliance committee and chief compliance officer).

arrangements, expense vouchers and reports, and an analysis of sample transactions.[87] U.S. healthcare companies should also implement a "hotline" that allows employees to anonymously report actual or suspected FCPA violations without fear of retaliation.[88]

U.S. healthcare companies need to use reasonable efforts not to delegate substantial authority to any individual whom the company knew—or should have known through the exercise of due diligence—has engaged in illegal activities or other conduct inconsistent with the FCPA compliance program. Due diligence of agents, consultants, third parties, and potential joint venture partners is extremely important in the context of FCPA compliance because it allows a company to identify potential "red flags" by gathering background information on a potential partner's business reputation, qualifications, reputation for ethical dealings, government official status, prior misconduct, and relationships with government entities and government officials.[89]

**Conclusion**

As the globalization of the healthcare industry continues to expand, the FCPA is likely to have an increasingly larger impact on U.S. healthcare companies. Business relationships with government-owned and controlled entities and their officers, employees, and agents create a potentially high level of exposure to violations of the FCPA. The healthcare industry is not exempt from prosecution for FCPA violations and, at least as it pertains to the medical device industry, appears to be a major focus of enforcement activity. U.S. healthcare companies need to be aware of and understand the impact that the FCPA has on doing business around the world and should view FCPA compliance in the same light as they view healthcare fraud and abuse compliance. To prevent FCPA violations from occurring and to mitigate a company's liability when violations have already taken place, U.S. healthcare companies should adopt a comprehensive compliance program to address the potential FCPA risks associated with doing business internationally.

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[87] ZARIN, *supra* note 5, at 10-11.

[88] U.S. healthcare companies are required to take reasonable steps to have a well publicized, anonymous and confidential reporting system that allows employees and agents to report or seek guidance regarding potential or actual criminal conduct without fear of retaliation. A "hotline" is a common reporting mechanism used by healthcare companies. Matyas & Valiant, *supra* note 81, at 333. *See also* ZARIN, *supra* note 5, at 10-10 (discussing "hotlines").

[89] *See* Brown, *supra* note 83, at 2; Koehler, *supra* note 57, at 299-301.