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The Foreign Corrupt Practices Act and Clinical Trials: A Trap for the Unwary

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I. INTRODUCTION

Many U.S. and foreign companies subject to the Foreign Corrupt Practices Act (FCPA)¹ are devoting significant resources to bring their corporate activities into compliance with the law's requirements. Most companies focus their efforts on traditional sales and marketing activities, including overseeing the conduct of international sales agents and distributors.² However, our experience suggests that despite broadening enforcement activity of the U.S. government, companies are devoting relatively fewer FCPA compliance resources to those activities falling outside the purview of sales or marketing activity.³ In fact, third parties who are not involved in sales or marketing, such as lawyers, accountants and tax advisors, to name just a few, can create FCPA exposure as readily as sales or marketing personnel.

In particular, the clinical trial arena is ripe for exactly the type of fraud and corruption that the FCPA seeks to address, but global corporate awareness remains low because of the aforementioned focus on sales and marketing personnel. As discussed more fully below, Clinical Research Organizations (CROs), Principal Investigators (PIs), and even Institutional Review Boards (IRBs) may create FCPA liability, and corporations may fail to take the steps to ensure compliance because they have limited FCPA compliance programs. The focus of this paper is to discuss the FCPA implications of conducting clinical trials in foreign countries and the retention of third parties to oversee those trials.

II. BACKGROUND OF THE FOREIGN CORRUPT PRACTICES ACT

In 1977, after extensive hearings by the Senate Committee on Banking, Housing, and Urban Affairs in connection with improper payments to foreign government officials,⁴ Congress passed the FCPA. The hearings revealed that over 400 com-

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¹ 15 U.S.C. §§ 78dd-1, *et seq.*

² See, e.g., Steven R. Salbu, *Bribery in the Global Market: A Critical Analysis of the Foreign Corrupt Practices Act*, 54 WASH. & LEE L. REV. 229, 260 (1997)(recommending "the development of written company policies for selecting and retaining foreign sales representatives, [and the] use of written agreements governing relationships with foreign marketing representatives" to address FCPA compliance concerns); Lucinda A. Low, et al., *The Foreign Corrupt Practices Act: Coping with Heightened Enforcement Risks Fall 2007*, 1619 PLI: CORPORATE LAW AND PRACTICE COURSE HANDBOOK Series 95, 102 (2007)(Companies with "publicly-traded stock in the United States[] have devoted increased attention to FCPA compliance in the wake of the first enforcement actions against them" leading to an increased focus on marketing and sales concerns).

³ See, e.g., Donald Zarin, *Project Financing Update 2004: Reworking & Building New Projects in Developing Markets*, 1448 PLI: CORPORATE LAW AND PRACTICE COURSE HANDBOOK Series 125, 132 (2004)(recognizing that U.S. companies must increase their legal assets to address increasing FCPA concerns).

⁴ Senate Report, No. 95-114.

panies admitted to questionable or illegal payments to foreign entities.⁵ According to the House Report,

[t]he abuses disclosed r[a]n the gamut from bribery of high foreign officials in order to secure some type of favorable action by a foreign government to so-called facilitating payments that were made to ensure that government functionaries discharge certain ministerial [sic] or clerical duties.⁶

The FCPA was passed to address practices that, in Congress' opinion, eroded the public's confidence in the free market system, and to ensure that efficiency was rewarded over corruption.⁷

The legislation has two principal parts: anti-bribery and record keeping provisions.⁸ First, the anti-bribery provisions prohibit U.S. corporations and nationals from making improper payments to foreign government officials for the purpose of obtaining or retaining business. The Department of Justice (DOJ) enforces the anti-bribery provisions.⁹ Second, the record keeping requirements, which apply only to companies registered on U.S. stock exchanges, require the maintenance of accurate books and records and internal fiscal controls regarding all transactions. The Securities and Exchange Commission (SEC) oversees enforcement of these provisions. The SEC also maintains jurisdiction over civil enforcement of the anti-bribery provisions with respect to issuers.¹⁰ A violation of any of these provisions carries significant civil and criminal penalties, including fines and/or imprisonment. The DOJ and the SEC have concurrent authority to seek injunctions.¹¹

A. *The Anti-Bribery Provisions*

The FCPA's anti-bribery provisions apply to three separate classes of persons. First, the prohibitions apply to any company that is registered with a U.S. stock exchange or that files reports with the SEC.¹² The statute terms this class, "issuers." Second, the provisions also apply to "domestic concerns," defined as any individual citizen, national or resident of the United States or any company having its principal place of business in the United States, or organized under the laws of a State of the United States.¹³ Third, the FCPA prohibits bribery by any "person," defined as a natural person other than a national of the United States or any company organized under the laws of a foreign country.¹⁴

A violation of the anti-bribery provisions of the FCPA has five basic elements:¹⁵

1. A payment, either directly or through a third party, of anything of value
2. to any foreign official, political party or candidate

⁵ House Report, No. 95-640.

⁶ *Id.* (House Report)

⁷ *Id.* (House Report); Senate Report, No. 95-114.

⁸ 15 U.S.C. §§ 78m, 78dd-1 - 78dd-3, 78ff, as amended.

⁹ *Id.* (78m, 78dd-1-78dd-3, 78ff)

¹⁰ 15 U.S.C. §§ 78m(b)(2)(A) and (B)

¹¹ 15 U.S.C. § 78dd-2(d)(applicable to DOJ); 15 U.S.C. § 78u(d)(1)(applicable to the SEC).

¹² 15 U.S.C. § 78dd-1(a)(3).

¹³ 15 U.S.C. § 78dd-2(a)(3).

¹⁴ 15 U.S.C. § 78dd-3(a)(3).

¹⁵ See 15 U.S.C. § 78dd-1(a)(3) ("issuers"); 15 U.S.C. § 78dd-2(a)(3) ("domestic concerns"); 15 U.S.C. § 78dd-3(a)(3) ("any person").

3. through the use of an instrumentality of interstate commerce or by the actions of a U.S. person or domestic concern outside the United States or an act inside the United States by any other person (other than a U.S. national)
4. for the corrupt purpose of influencing an official act or decision of the recipient
5. in order to obtain or retain business or to secure an improper advantage.

The Government will evaluate all five elements to determine if a violation has, in fact, occurred.

B. *Payment*

The Act does not limit itself to actual payments, prohibiting “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 Therefore, even if the corrupt payment is unsuccessful in obtaining or retaining business, the mere offer or promise is enough to satisfy the element. Moreover, the payment or offer need not be made directly by a covered entity. Third parties who make or offer payments may trigger FCPA liability equally both for the third party and the entity for whom the third party acted.

While money is the most obvious form of payment, the statute expressly includes “giving of anything of value.” While there are no FCPA cases addressing this element specifically, the Courts have analyzed other criminal statutes containing similar “thing-of-value” language. These decisions interpret the term broadly to include “non-competition or exclusivity agreements,”¹⁷ the bartering of certain electronic images,¹⁸ a loan with favorable terms,¹⁹ and sports equipment.²⁰

With respect to payments effected by third-party agents, the FCPA does not require that the principal have actual knowledge that an improper payment will be made. Rather, one may be held liable if he is aware that the agent is “engaging in such conduct, that such circumstance exists, or that such result is substantially certain to occur.”²¹ Liability will also attach if the principal has a “firm belief that such circumstance exists or that such result is substantially certain to occur.”²² Therefore, a principal cannot avoid liability through willful blindness or deliberate ignorance of the realities of doing business in a particular country or the reputation of a particular agent.

C. *Foreign Officials, Political Party, or Candidate*

The FCPA defines a foreign official as:

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 or on behalf of any such government

¹⁶ 15 U.S.C. § 78dd-1(a) (*See also* §§ 78dd-2(a); 78dd-3(a)).

¹⁷ *U.S. v. Gotti*, 459 F.3d 296, 323 (2nd Cir. 2006).

¹⁸ *U.S. v. Oldham*, 177 Fed.Appx. 842, 846 (10th Cir. 2006).

¹⁹ *U.S. v. Hare*, 618 F.2d 1085, 1086 (4th Cir. 1980).

²⁰ *U.S. v. McDade*, 827 F.Supp. 1153, 1173 (E.D. Pa. 1993).

²¹ 15 U.S.C. §§ 78dd-1(f)(2)(A)(i); 78dd-2(h)(3)(A)(i); 78dd-3(f)(3)(A)(i).

²² 15 U.S.C. §§ 78dd-1(f)(2)(A)(ii); 78dd-2(h)(3)(A)(ii); 78dd-3(f)(3)(A)(ii).

department, agency, or instrumentality or for, on the behalf of any such public international organization.²³

Despite this definition, little clear guidance exists to assist in the determination of who is a foreign official for purposes of the FCPA. The DOJ and SEC have considered a broad range of people as qualifying as foreign officials, ranging from the more obvious positions, such as a president, prime minister or oil minister²⁴ to the less obvious, such as customs officials,²⁵ a director of a regional health fund,²⁶ officials of a state-owned bank,²⁷ engineers at a state-owned oil company²⁸ and doctors and laboratory workers at state-owned hospitals.²⁹ Therefore, even low-level employees—regardless of the function—are likely to be deemed foreign officials under the Act.

D. *Use of an Instrumentality of Interstate Commerce or by an Agent*

The FCPA specifically includes making “use of the mails or any means or instrumentality of interstate commerce,” which is commonly understood to include telephone, faxes, air transportation or, arguably, e-mail. This section also includes the use of an agent, that is, “any person” or an act outside of the United States by a “domestic concern” or a U.S. national; or an act inside the United States by a non-U.S. national.³⁰ A key component of the analysis is that the agent must have knowledge with respect to his conduct, but such knowledge may be ascribed to the agent based on the attendant circumstances.³¹ In a country where corruption in a given industry is common and the agent makes a payment, the “knowledge” may be imputed to the agent’s principal.

E. *For a Corrupt Purpose*

The Government must also establish that the payment or offer of payment was made corruptly, but the Act does not define the word “corrupt.” The legislative history indicates that the word “corruptly” connotes an evil motive or purpose.³² Only the Eighth Circuit has addressed the term by affirming a jury instruction that stated:

An act is “corruptly” done if done voluntarily and intentionally, and with a bad purpose of accomplishing either an unlawful end or result, or a lawful end or result by some unlawful method or means.³³

²³ 15 U.S.C. §§ 78dd-1(f)(1)(A); 78dd-2(h)(2)(A); 78dd-3(f)(2)(A).

²⁴ U.S. v. Giffen, 326 F.Supp.2d 497 (S.D.N.Y. 2004).

²⁵ U.S. v. Kay, 359 F.3d 738 (5th Cir.).

²⁶ In the matter of Schering-Plough Corporation, SEC Admin. Proc. Rel. No.34-49838 (June 9, 2004).

²⁷ SEC v. IBM, Corp., SEC Lit. Rel. No. 16839 (Dec. 21, 2000).

²⁸ U.S. v. Liebo, 923 F.2d 1308 (8th Cir. 1991); U.S. v. Bodmer, 342 F.Supp.2d 176 (S.D.N.Y. 2004).

²⁹ SEC v. Diagnostic Products Corporation, SEC Admin. Proc. Rel. No. 34-51724 (May 20, 2005); SEC v. Syncor International Corporation, SEC Lit. Rel. No. 17887 (Dec. 10, 2002).

³⁰ 15 U.S.C. §§ 78dd-1(a)(3); 78dd-2(a)(3); 78dd-3(a)(3).

³¹ 15 U.S.C. §§ 78dd-1(f)(2); 78dd-2(h)(3); 78dd-3(f)(3).

³² House Report No. 95-640.

³³ U.S. v. Liebo, 923 F. 2d 1308, 1312 (8th Cir. 1991).

F. *To Obtain or to Retain Business*

Based on the legislative history, Congress' motivation for passing the Act was to ensure that American businesses adhered to a higher standard of business ethics. The FCPA, therefore, prohibits corrupt practices for the purpose of "obtaining or retaining business for or with, or directing business to, any person."³⁴ While "obtaining or retaining business" seems to have a clear meaning, recent cases have demonstrated that, as discussed in greater detail below, the government is more than willing to take a broader approach proving this element of a violation.³⁵

G. *Defenses*

Not all payments violate the FCPA, and there are instances where payments are permitted. The major exception is commonly known as "facilitating" or "grease" payments, which are made "to expedite or to secure the performance of a routine governmental action."³⁶ These are generally paid to low-level officials for the purpose of processing certain ministerial or routine functions such as obtaining permits and licenses or setting up utility services.³⁷

There are also two statutory affirmative defenses. First, a person or company charged with an FCPA violation can claim a defense if the written laws of the country permit the payment.³⁸ Neither the DOJ nor the SEC has provided much guidance in this area of the FCPA, and this point has not been litigated. Second, a payment for a bona-fide business expenditure, such as an expense related to "the promotion, demonstration or explanation of products and services or the execution or performance of a contract with a foreign government" is a defense to a charge of an FCPA violation.³⁹ Although the limits of this defense have yet to be defined with any precision, it would appear to have greater potential applicability than the written law defense.

H. *Books and Records and Internal Controls*

The Act requires that issuers "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; and...devise and maintain a system of internal accounting controls...."⁴⁰ Therefore, bribes that are not recorded in the company's books and records, or records that are falsified or otherwise obscure the true purpose of a payment, will constitute an FCPA violation. For the purposes of clinical trials, a company must ensure that its expenditures are accurately reflected in its financial record keeping.

³⁴ 15 U.S.C. §§ 78dd-1(a); 78dd-2(a); 78dd-3(a).

³⁵ *U.S. v. Kay*, 359 F.3d 738, 740 (5th Cir. 2004).

³⁶ 15 U.S.C. §§ 78dd-1(b); 78dd-2(b); 78dd-3(b).

³⁷ 15 U.S.C. §§ 78dd-1(f)(3); 78dd-2(h)(4); 78dd-3(f)(4).

³⁸ 15 U.S.C. §§ 78dd-1(c)(1); 78dd-2(c)(1); 78dd-3(c)(1).

³⁹ 15 U.S.C. §§ 78dd-1(c)(2); 78dd-2(c)(2); 78dd-3(c)(2).

⁴⁰ 15 U.S.C. § 78m(b)(2).

I. *Opinion Procedure Releases*

In an effort to proactively assist with FCPA guidance, the DOJ has issued regulations that allow issuers and domestic concerns to request a prospective opinion on whether certain actions and transactions violate the FCPA.⁴¹ The responses, called Opinion Procedure Releases, provide basic fact patterns and provide DOJ's reasoning on a particular scenario. While "an FCPA Opinion [has] no application to any party which does not join in the request for the opinion,"⁴² the opinion releases do provide some insight into how DOJ understands the applicability of the FCPA. While an FCPA Opinion request in the first instance may help an issuer or a domestic concern identify problems right away, there are a few caveats. For example, the DOJ requires that information be provided so that the totality of the transaction is understood, and the DOJ is permitted to request supplementary information.⁴³ The Opinion Releases are valid so long as the factual circumstances, in the opinion of the DOJ, are not altered.⁴⁴ Yet, the Opinion Releases are not binding on the SEC, who may find problems with the transaction based on that agency's understanding.⁴⁵ Finally, to the extent that the violation has already occurred, the Opinion Procedure is of no use. Therefore, in general, a company will find that there may be more benefit and flexibility in simply reviewing applicable Opinion Releases for guidance instead of requesting one for its own situation.

III. THIRD-PARTY AGENTS IN THE CLINICAL TRIAL CONTEXT

While companies can generally identify red flags when they are dealing directly with the foreign government, the risk of FCPA violations grows markedly when a third-party agent is introduced. Often, the use of an agent increases FCPA concerns because a company has less ability to oversee and to direct a third party's actions, and yet the company retains the ultimate responsibility for the agent's actions.

Traditionally, FCPA compliance efforts have focused on sales and marketing agents or distributors. These individuals are hired largely because of their familiarity with the industry or the country or both, and the company seeking to do business is often left in a position of reliance upon the representations of the agent. Some countries require having local agents as a condition of doing business locally. Where the company has a reasonable understanding that there is a high probability that an agent may have offered payment to a foreign government, the company may be held liable for an FCPA violation, as the government will likely impute knowledge of the improper payment or offer of a payment.

GE InVision, Inc. is an example of an FCPA case where the payment was made by a sales agent with apparent knowledge of the U.S. entity. Between 2002 and 2004, GE InVision, Inc. (then known as InVision Technologies, Inc.), a manufacturer of explosive detection systems to scan checked baggage at airports, hired local sales agents in China, the Philippines, and Thailand. In order to avoid certain contractual penalties due to delayed delivery, a senior InVision executive authorized the payment of foreign travel and other benefits for Chinese airport officials. Sales agents and distributors in the Philippines and Thailand offered gifts or other benefits,

⁴¹ See 28 C.F.R. § 80

⁴² 28 C.F.R. § 80.5

⁴³ 28 C.F.R. §§ 80.6; 80.7.

⁴⁴ 28 C.F.R. § 80.10.

⁴⁵ 28 C.F.R. § 80.11.

such as reduced prices to government officials in those countries to influence their decision to purchase the machines.

In addition to communications between the foreign agents and the U.S.-company officials that suggested an awareness of the potential FCPA violations, the SEC also alleged in its complaint that InVision's lack of internal controls also violated the FCPA. According to the SEC, InVision performed almost no investigation into the background of the agents, provided no formal training in the FCPA, and failed to establish a program to monitor foreign agents' compliance with the Act. InVision and the SEC settled the case without a trial, and the company, without admitting or denying the charges, disgorged \$589,000 in profits, along with \$28,700 in interest, and paid a \$500,000 civil penalty.⁴⁶

Other types of third-party agents can also present potential problems. In particular, third-party individuals or entities involved in conducting clinical trials may present FCPA concerns similar to those encountered by the more traditional sales and marketing paradigm. There are three common ways for a company to transfer many of its responsibilities for conducting or otherwise complying with the FDA's regulatory requirements for reviewing a clinical study under third parties.

First, companies may choose to manage clinical trials through the use of CRO. Under the U.S. Food and Drug Administration (FDA) regulations, the sponsor of a study is permitted to transfer many of its responsibilities for a study to a CRO.⁴⁷ The sponsor must still continue monitoring the investigators to ensure compliance with established protocols and study criteria and, if necessary, correct errors or misunderstandings arising during the study.⁴⁸

Second, a company may contract with clinical investigators who are responsible for the actual conduct of the study. The FDA regulations require that a PI be identified as the lead clinical investigator, and the regulations permit sub-investigators to work for PIs.⁴⁹

Third, an entity may rely on an IRB, a committee designated by an institution, such as a university medical center, a CRO, or a hospital to review clinical research. Under FDA's regulations, among the many requirements, the IRB "must continue to monitor the research as it progresses."⁵⁰

Companies may seek out CROs, PIs, or IRBs in other countries. In many foreign nations these clinicians and laboratory workers may, in fact, be employees of the foreign government, and, therefore, "foreign officials" for purposes of the FCPA.⁵¹

IV. APPLICATION OF THE FCPA TO CLINICAL TRIALS

As discussed above, the most frequent FCPA paradigm is a payment made to an official in exchange for official action (or inaction). For example, between 1999 and 2002, the Polish subsidiary of the U.S.-based pharmaceutical company Schering-Plough made charitable contributions totaling approximately \$76,000 to the

⁴⁶ SEC Lit. Rel. No. 19708 (Feb. 14, 2005).

⁴⁷ 21 C.F.R. § 312.52 (2002).

⁴⁸ See DRUGS AND THE PHARMACEUTICAL SCIENCES, Vol. 144, *Clinical Research Requirements for New Drug Applications*, by Gary Yingling & Ann Begley at 355.

⁴⁹ See note 41, *supra*, at 357-8. (Yingling)

⁵⁰ 21 C.F.R. § 56; See also A PRACTICAL GUIDE TO FOOD AND DRUG LAW AND REGULATION, 2d Ed., Chapter 5, at 93.

⁵¹ See, e.g., SEC v. Diagnostic Products Corporation, SEC Admin. Proc. Rel. No. 34-51724 (May 20, 2005); SEC v. Syncor International Corporation, SEC Lit. Rel. No. 17887 (Dec. 10, 2002) (finding that doctors and laboratory workers were foreign officials).

Chudnow Castle Foundation (CCF), a Polish charity dedicated to the restoration of castles in the Silesia region of Poland. The Director of the CCF was also head of the regional health fund, an arm of the Polish government, and the payments were allegedly made so that the Director would buy Schering-Plough products for his regional health fund. Although the U.S. company did not know of the arrangement specifically, and there was no question that the charity was legitimate and that the Polish official did not line his own pockets, the SEC argued that the U.S. company's internal controls were weak and made the detection of this illicit transaction unlikely. Rather than contest the charges, Schering-Plough settled and paid a \$500,000 fine.⁵²

Even more recently, Johnson & Johnson released a statement that subsidiaries outside the U.S. may have "made improper payments in connection with the sale of medical devices in two small-market countries."⁵³ While details are not yet available, the SEC and the DOJ are currently investigating this voluntarily reported violation, which has caused at least one senior official in the Johnson & Johnson corporation to retire.⁵⁴

Unlike sales and marketing activity, the connection between the conduct of research or scientific activity such as clinical trials, and "obtaining or retaining business" is less obvious. In fact, recent decisions have challenged the notion of what many previously understood "obtaining or retaining business" to mean. In 2001, a grand jury indicted David Kay and Douglas Murphy, then a vice-president and president, respectively, of American Rice, Inc. The indictment charged that the two men authorized bribes to custom officials in Haiti for the purpose of lowering customs duties and taxes of rice shipments to Haiti from the U.S. company. Curiously, while the indictment detailed the facts surrounding the bribery allegations, the government did not specifically allege that the bribes were made for the purpose of obtaining or retaining business.

Initially, the District Court found that the actions of the American Rice executives did not violate the FCPA because of an ambiguity in the statute: Facilitating payments were permissible and the type of bribery alleged was not made for the purpose of obtaining or retaining business. In particular, the District Court found that the FCPA did not apply to "payments made to influence any and all government decisions."⁵⁵ The Appellate Court did not concur with the District Court's position.

On appeal, the Fifth Court found that payments to customs officials to avoid sales taxes and to obtain more favorable customs duties could fall under the FCPA's anti-bribery prohibitions, and reversed the lower court's decision stating that Congress intended the FCPA to be interpreted broadly, the Court opined that nothing in the law or legislative history suggested "how remote or how proximate the business nexus must be."⁵⁶ The Court reasoned that lowering taxes or dues "reduces operating costs ... and increases profit margins,"⁵⁷ and that funds that the company would spend on taxes and duties would become unencumbered and available for

⁵² In the matter of Schering-Plough Corporation, SEC Admin. Proc. Rel. No.34-49838 (June 9, 2004).

⁵³ *J&J Reports Improper Payments*, WALL STREET JOURNAL, Feb. 17, 2007; also see, J&J Statement on Payment's Disclosure, <http://online.wsj.com/article/SB117132484019006495.html?mod=US-Business-News>.

⁵⁴ *Id.* (WSJ)

⁵⁵ *U.S. v. Kay*, 200 F.Supp.2d 681, 684 (S.D. Tex. 2002).

⁵⁶ *U.S. v. Kay*, 359 F.3d 738, 749 (5th Cir. 2004).

⁵⁷ *Id.*

other purposes if such levies were lower. Yet, while this type of payment could constitute a violation of the FCPA, the Court's opinion ultimately required that the government prove that the bribes were offered for the purpose of obtaining or retaining business.

Prior to the *Kay* holding, the "obtaining or retaining business" requirement appeared more narrow and more obvious. Now, the definition of "obtaining or retaining" business is potentially much broader, and a company must consider how the payments or gifts to a foreign official might be construed in light of the holding in *Kay*.

Companies should also be concerned about payments that may be made at any level by any third party. The classic example occurs when a third party sales agent makes a corrupt payment to a government official. Yet, a PI, who himself may be a foreign official and retained directly by the company to conduct a clinical study, may corruptly pay or offer to pay something of value to secure the action of another government official.⁵⁸ This scenario would similarly trigger an FCPA violation where the company had reason to know that such a payment might be made. Thus, the payment or offer of something of value to a foreign official by a CRO, PI or IRB, with the purpose of facilitating the success of a clinical trial may constitute an action that is taken to obtain or retain business, depending on the circumstances. The fact that the payment was made by one government official to another government official does not immunize the U.S. company from exposure.

There are other statutes in the pharmaceutical arena that may provide some guidance for FCPA compliance by analogy. The Anti-Kickback Statute,⁵⁹ which prohibits certain solicitations or receipt of remuneration and the offer or payment of certain remuneration, has been found applicable to situations where an individual offers something of value to another for the purpose of recommending or referring the furnishing or arranging for an item or service.⁶⁰ Like the FCPA, whether a payment leads to a referral or recommendation is irrelevant; the inducement alone results in a violation.⁶¹

The U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) has issued compliance program guidance⁶² to assist pharmaceutical manufacturers in their compliance efforts with the Anti-Kickback law, and much of this advice may also be instructive when considering the FCPA's implications of clinical trial activities. For example, the compliance guidance suggests that manufacturers "identify any remunerative relationship between itself (or its representatives) and persons or entities in a position to generate federal healthcare business for the manufacturer."⁶³ Similarly, where a company is contracting with a third-party agent abroad, the company must be clear on the financial arrangements between itself and the agent and the agent and other governmental and business contacts in the foreign nation.

There are other arrangements within the pharmaceutical arena where scrutiny for FCPA concerns is necessary, and third-party relationship may be implicated. For example, discounting arrangements are not uncommon in the industry, but a

⁵⁸ See, e.g., *United States v. Syncor Taiwan, Inc.*, (Cr. No. 02-1244) C.D. Cal., Dec. 2002 (Syncor Taiwan pleaded guilty to the bribing of doctors employed by state-owned hospitals.).

⁵⁹ 42 U.S.C. 1320a-7b.

⁶⁰ *Id.* at 1320a-7b(b)(2).

⁶¹ See *U.S. v. Greber*, 760 F.2d 68, 71 (3rd Cir.), cert. denied, 474 U.S. 988 (1985).

⁶² Department of Health and Human Services, Office of the Inspector General, Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003).

⁶³ 68 Fed. Reg. 23731, 23734 (May 5, 2003).

company cannot merely rely on the common practice of the discounting agreements without looking behind the arrangement. Rather, due diligence requires that the company ensure that foreign officials were not paid or otherwise given anything of value to induce the price reductions during the negotiations, especially if a third-party agent were employed for the negotiations.

Product support services or education grants are also areas of concern. Offers of anything of value, whether directly or by an agent, to create or to promote these agreements or grants can easily run afoul of the FCPA's prohibitions. Of particular concern, companies should be very careful with either the receipt of or the sponsoring of research funds. Again, this is particularly true where agents are employed in lieu of a company handling the arrangements directly.

In all of the aforementioned situations, there are legitimate ways to carry on this business, and, simultaneously, significant opportunities to ignore red flags that indicate a potential FCPA violation. An agent in these situations could certainly run afoul of both the Anti-Kickback statute and the FCPA.

The Anti-Kickback statute's regulations establish a "safe harbor" for common business arrangements, such as management contracts with third parties.⁶⁴ The regulations require that the agreement be in writing, that the contract specify all of the services provided, and that payment be fair-market value.⁶⁵ The HHS OIG guidance notes that contracts should be structured to fit the safe harbor regulations wherever possible and that "payments...should be fair market value for legitimate, reasonable and necessary services."⁶⁶ While the FCPA does not have a "safe harbor," per se, these agreements can have a nullifying effect of a key element of an FCPA violation: corruption.

As discussed above, "corruptly" carries a negative connotation that something unlawful is desired. By using the general guidance above, a company or a third-party can enter into a written contract with the foreign official or even the foreign government detailing the services to be performed and/or received. This written contract can serve to invalidate a corrupt motive by making the transaction clear and transparent. The U.S. government would have a much harder case to make where a document spells out the contractual relationship and all parties are signatories.

In short, companies must be aware that the arrangements most common in the pharmaceutical industry may be subject to FCPA problems. In many instances, a company's failure to properly investigate or monitor the various arrangements setup by its third-party contacts may result in inadvertent FCPA violations, the results of which could be quite harmful both professionally and financially, to both the company and to individuals.

V. COMPLIANCE IN THE CLINICAL TRIAL CONTEXT—AS A PRACTICAL MATTER

Aside from general awareness of the FCPA, there are concrete, practical steps that a company can take in its attempt to ensure compliance. While nothing can guarantee that a rogue employee will not violate the FCPA, either willfully or inadvertently, the Government will 1) have a harder time proving its case, or 2) be more willingly to overlook or to grant some leniency for an FCPA violation that

⁶⁴ 42 C.F.R. § 1001.952(d).

⁶⁵ *Id.*

⁶⁶ See 68 Fed. Reg. 23731 (May 5, 2003).

occurred where a proper FCPA compliance program is in place and functioning appropriately.

As an initial matter, FCPA compliance training should not be limited to sales representatives and marketing personnel. The FCPA affects the company globally, which means that all individuals who have contact with foreign government representatives or third-party agents should receive training in the FCPA and be provided contact information for those in the company who are responsible for or knowledgeable in FCPA compliance so that questions and concerns can be readily identified and investigated. Therefore, in addition to finance and accounting personnel, who may be on the front line to catch a suspicious expense report or an unusual invoice or billing record, research and development/clinical operations personnel must similarly be trained in the FCPA.

From a contractual perspective, research contracts should be handled and awarded separately from the sales and marketing function of the sponsoring company. As discussed above, sales and marketing are areas of concern because of the clear connection between the sales and marketing functions and the obtaining and retaining of business. Where the functions are separated, the research contract will not necessarily be viewed as a vehicle for addressing business.

Similarly, research grants should be treated separately from sales and marketing functions as well. The HHS OIG compliance guidance indicates that grant “funding that is conditioned...on the purchase of product implicates” the Anti-Kickback statute.⁶⁷ Similarly, agreements that require inducing a foreign official to purchase products—even under the guise of a research grant—may easily trigger the FCPA. Research grants should be issued to advance scientific and clinical goals, not to obtain or retain business, and insulated from the sales and marketing portions of the company, as well.

Before engaging an agent to handle any type of business in a country, a sponsor company should satisfy its due diligence obligations. Indeed, effective due diligence on third parties is a critical component of a successful compliance program. While the FCPA itself does not specifically mandate what is required to satisfy due diligence, the U.S. government has, especially recently, looked to the steps a company took to ensure FCPA compliance in the first instance.

In December 2006, the DOJ issued an Opinion Procedure Release detailing the due diligence taken in hiring a law firm.⁶⁸ The Release explained the background check performed by the company, including soliciting others about the firm’s reputation and background. The company also “discussed [plans] for the project, [the firm’s] understanding and commitment to performing the representation under rigorous ethical standards, and [the firm’s] comprehension of the FCPA.”⁶⁹ The DOJ also focused on the fact that “several provisions designed to prevent corruption from occurring” were included in the written contract between the parties.⁷⁰

Thus, the DOJ shed some light on what it expects by way of due diligence on third parties. The same standard employed in the context of hiring a law firm, as indicated in the Opinion Procedures Release, can be applied in clinical trials. An appropriate and successful compliance program will require that the sponsor company know the third-party agent. For example, the sponsor company should ask about the types of contracts held by the agent so the company understands

⁶⁷ 68 Fed. Reg. 23731, 23735 (May 5, 2003).

⁶⁸ DOJ Op. Proc. Rel. No. 06-02 (Dec. 31, 2006).

⁶⁹ *Id.*

⁷⁰ *Id.*

the third party's position in the clinical trials community, generally. This is often accomplished through the use of a questionnaire asking the agent to identify its owners, officers and significant managers. Verification of the information through public sources and references, and, in many cases, conducting in-person interviews with potential third parties is also recommended. If the CRO is new to the field, this is a red flag. In addition, a company is advised to try to obtain a listing of key personnel, including physicians or laboratory workers that will be involved in the project. A complete due diligence should investigate the agent's background and reputation in the field, including the reputations of the doctors and clinicians running the trials. In general, a company wants to collect as much information relating to the third-party's reputation for ethical and professional conduct.

In addition to the background investigation, the services to be provided by the CRO, IRB or third-party PI should be reduced to a comprehensive writing. This writing should include all services that the parties expect will be required in as much detail as practicable. Anti-corruption provisions should be included. For example, a company could include a provision that indicates that the agent has not and will not ever make any improper payment to any official and will comply with all applicable laws and regulations, including the FCPA. All relevant parties should be signatories to the agreement. Reducing all understandings to writing, especially those regarding the FCPA is essential, particularly in those countries with a history of corruption.

Background checks and written agreements are not the only ways in which a company can ensure FCPA compliance. A company can require reports to be generated at reasonable intervals (e.g., weekly or monthly) that detail events outside of the actual clinical trial. For example, a report of all visitors to the facilities and their business connection, or a report detailing all contacts made with any employee of the foreign nation's government, may alert a company to potential FCPA problems. The written agreement mentioned above should also include provisions allowing the sponsor company to audit the agent's records and require a full accounting of payments made and/or expenses incurred. Moreover, the company should undertake audits randomly and on an unscheduled basis.

Concern should be paid to the type of fee arrangement into which the sponsor company enters with the agent. At the outset, avoid cash payments or upfront or accelerated payments. Flat-fee arrangements tend to be the least problematic. While arrangements allowing for incentives or bonuses are not per se problematic, a sponsor must be sure that the bonuses or incentives are not likely to be earned through inappropriate actions on the part of the agent. In addition to the fee, a company must monitor expenses such as travel, gifts or entertainment, or wherever there are expenditures without supporting documentation or clear explanation for the purpose.

In short, the sponsor company must do its homework with respect to the country where the clinical trial is to take place. Sales and marketing campaigns, directed at penetrating a new market, comprehensively research the foreign nation's customs, laws, and trends. A sponsor company's clinical operations department must investigate the regulatory and research compliance culture as extensively as the sales and marketing departments would investigate the market.

Overall, an FCPA compliance program cannot be limited to a few words in a code of conduct or even just reviewing an agreement with a third party and receiving a few periodic reports. FCPA compliance is an on-going endeavor. Red flags can be

raised in a variety of ways, and all sponsor-company employees should be sensitized to look for and report issues of concern. The warnings may come in subtle and non-subtle ways. A company employee may realize that the doctors and laboratory workers are foreign government employees, even though there is no nationalized healthcare system in the particular country. Another warning may be familial or business connection to the foreign nation's government. Or, the sponsor company may become aware of prior prosecutions or investigations that were not uncovered during its initial due diligence review, or the finance department realizes that there are unusual or unsubstantiated billing or payment requests. Regardless of the red flag, employees must be educated and trained in how to respond to the signs that something may be amiss.

As discussed above, often third-party agents⁷¹ have responsibility for the day-to-day running of the clinical trials, but this does not necessarily insulate the sponsor company from FCPA concerns. Therefore, a company should provide to its agents the same detailed FCPA training that it provides its employees, with appropriate contract resources for FCPA experts within the sponsor company. Sponsors carry the ultimate responsibility for the clinical trials, including FCPA compliance. In that vein, the company should train and get attestations from the agents and foreign investigators indicating an understanding of adherence to the FCPA. An attestation absent the requisite training will not provide sufficient coverage in the event an FCPA violation is uncovered.

Companies should also recognize that enforcement may come from unexpected sources. While FDA likely lacks sufficient Congressional funding to police the Agency's multitude of responsibilities,⁷² the DOJ and SEC have well staffed and growing divisions dedicated to FCPA enforcement and those agencies recognize the centrality of fraud prevention to their mission.⁷³ While FDA is unlikely to receive more appropriations to address potential FCPA issues, there are other ways that specific acts of corruption may be reported to the Agency. In particular, whistleblowers can and do make FCPA allegations to FDA, the DOJ, or the SEC, all of which would likely begin investigations. Moreover, a company cannot discount competitors' desires to impede the progress made in what may appear to be a successful trial. Even the mere allegation of impropriety could raise the specter of a full scale DOJ or SEC FCPA investigation. Whatever the means, violations of the FCPA often come to the surface in one way or another.

VI. IMPACT OF AN FCPA VIOLATION ON THE CLINICAL TRIAL

FCPA violations alone will not automatically render the clinical trial invalid. In 1998, FDA issued a final rule requiring companies "to submit certain information concerning the compensation to, and financial interests of, any clinical investigator conducting certain clinical studies."⁷⁴ Under FDA rules,

⁷¹ "Agents," as used here, includes CROs, IRBs or independent PIs or other third-parties.

⁷² See, e.g., James T. O'Reilly, *Elders, Surgeons, Regulators, Jurors: Are Medical Experimentation's Mistakes Too Easily Buried?*, 31 *LOY. U. CHI. L.J.* 317 (2000) (commenting on the shortfall in the U.S. Federal Government's funding of FDA).

⁷³ See, e.g., <http://0225.0145.01.040/criminal/fraud/docs/reports/speech/2006/10-16-06AAGF-CPASpeech.pdf> (prepared remarks of Alice S. Fisher, Assistant Attorney General, at the American Bar Association, National Institute on the Foreign Corrupt Practices Act (Oct. 16, 2006)).

⁷⁴ 21 C.F.R. § 54.

FDA may consider clinical studies inadequate and the data inadequate if, among other things, appropriate steps have not been taken in the design, conduct, reporting and analysis of the studies to minimize bias.⁷⁵

FDA will evaluate the various fee arrangements to determine if there has been an unacceptable level of bias. The totality of the information available will be used "in the agency's assessment of the reliability of the data."⁷⁶

Under FDA regulations, a financial disclosure statement must be filed with the agency that details various financial arrangements with the clinical investigator.⁷⁷ The agency will evaluate such things as the compensation received, whether it was contingent on a favorable outcome, the interests of the parties, including the clinical investigator, and his/her spouse and/or children, and other significant payments, defined as over \$25,000, from the sponsor to the clinical investigator.⁷⁸ Above all, FDA endeavors to ensure the reliability of the data.⁷⁹ Where, in FDA's opinion, the financial interests of any clinical investigator raise a serious question about the integrity of the data, FDA may take action by

1. Initiating agency audits of the data derived from the clinical investigator in question;
2. Requesting that the applicant submit further analyses of data, e.g., to evaluate the effect of the clinical investigator's data on overall study outcome;
3. Requesting that the applicant conduct additional independent studies to confirm the results of the questioned study; and
4. Refusing to treat the covered clinical study as providing data that can be the basis for an agency action.⁸⁰

In short, the pharmaceutical and life sciences industry is highly regulated, and the intersection of the FCPA and other FDA regulations that govern clinical trial conduct may pose particular danger for companies operating/conducting trials outside the United States.

FCPA violations may call into question the credibility of the data, but FDA would have to evaluate all the attendant circumstances to determine whether the data was tainted. While some FCPA violations would clearly taint the study (e.g., a clinical investigator who is a foreign official was paid to falsify a study and recommended the purchase of the product by his country), other FCPA violations have a less clear impact under FDA regulations (e.g., a foreign official is paid to not enforce certain regulatory reporting requirements imposed by the foreign law but the science of the study is unaffected).⁸¹ Nevertheless, the chance that an FCPA violation will taint the trial with sufficient bias that FDA does not accept the findings remains a significant possibility.

⁷⁵ 21 C.F.R. § 54.1(b)

⁷⁶ *Id.*

⁷⁷ 21 C.F.R. § 54.4

⁷⁸ See 21 C.F.R. §§ 54.2(a) - (g).

⁷⁹ 21 C.F.R. § 54.5(c).

⁸⁰ *Id.*

⁸¹ This scenario may implicate a Current Good Manufacturing Practice (CGMP) violation, codified in Title 21 of the U.S. Code and in various sections of 21 C.F.R., but a discussion of this is outside the scope of this paper

VII. CONCLUSION

One of the primary lessons of recent FCPA enforcement activity is that violations can arise in many varied and unexpected ways. Violations are no longer limited to traditional sales and marketing activity. Rather, experience shows that activities of a company's trusted professional advisors such as attorneys, accountants and tax consultants can lead to exposure. Even in an area such as scientific research, which is not typically thought of as a hotbed of corruption, FCPA risks abound. Companies need to comprehensively review their research organizations to identify areas of FCPA risk and take proactive measures to protect themselves.