13

The Foreign Corrupt Practices Act and Its Impact on the Pharmaceutical Industry

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The U.S. Foreign Corrupt Practices Act (FCPA) is a far-reaching U.S. anti-bribery law that has been a major enforcement priority for drug manufacturers since at least 2009, when the U.S. government announced an industry-wide investigation into pharmaceutical sales abroad. In short, the FCPA prohibits multinational companies with a U.S. connection (and their officers, directors, employees, and third-party agents) from bribing non-U.S. government officials in order to win or keep business, or obtain some other business advantage. The FCPA contains two main components: (1) the anti-bribery provisions, which prohibit certain persons and companies from making corrupt payments to non-U.S. government officials to obtain or retain business;[1] and (2) the accounting provisions,

which require that U.S. exchange-listed companies maintain accurate books and records, and devise and maintain adequate internal accounting controls.[2]

In the pharmaceutical context, the FCPA governs most company interactions with individual Healthcare Professionals (HCPs) and government officials outside of the United States, particularly in countries with publicly funded healthcare systems. Such interactions include those related to research and development of new products, clinical trials, training seminars and educational conferences, grants and donations, fellowships, marketing and promotional activities, travel, gifts and hospitality, hospital tenders, product regulatory approvals and certifications, and product imports/exports, just to name a few.

As the U.S. Department of Justice (DOJ) warned in 2009, U.S. regulators are, and indeed have been, "intensely focused on rooting out foreign bribery" in the "high-risk" pharmaceutical industry.[3] Since then, U.S. regulators have settled FCPA cases with at least seven pharmaceutical and medical device companies, generating approximately $225 million in fines, penalties, and disgorgement of profits. Other healthcare companies reportedly are still under investigation in the United States, and anti-corruption industry sweeps in other countries—most recently in China and South Korea—may bring further scrutiny. In light of the significant increase in FCPA enforcement against healthcare companies—and the expenses associated with investigations, fines, and penalties—it has never been more critical that pharmaceutical companies take care to ensure compliance with the FCPA.

In the discussion below, all amounts are in U.S. dollars, unless otherwise specified.

FCPA Basics

Q 13.1 What FCPA basics should the pharmaceutical industry know?

Multinational pharmaceutical companies—particularly those that maintain significant operations outside the United States—should develop a basic understanding of the FCPA, including the law's elements and components, its jurisdictional provisions, and possible penalties and collateral consequences. This knowledge should not be limited to legal departments, but should extend to managers and others whose responses to FCPA challenges will be the first line of protection for their employers.

Q 13.2 Which U.S. regulators enforce the FCPA?

The DOJ and U.S. Securities and Exchange Commission (SEC) share responsibility for FCPA enforcement.

The DOJ is responsible for criminal enforcement of the FCPA. Within the DOJ, the Criminal Division, Fraud Section in Washington, D.C., maintains primary responsibility for enforcement. The Fraud

Section often works with local U.S. Attorney's offices throughout the country to prosecute FCPA violations.

The SEC is responsible for civil enforcement of the FCPA with respect to issuers. The SEC established a dedicated FCPA Unit in 2010, which has primary responsibility for all FCPA matters.

Q 13.3 Who is covered by the FCPA?

The FCPA's anti-bribery provisions cover three groups:

- *Issuers* (that is, companies whose securities are traded on a U.S. exchange) and certain individuals acting on their behalf that "make use of the mails or any means or instrumentality of interstate commerce."[4] For example, a non-U.S. pharmaceutical company that has American Depositary Receipts traded on the New York Stock Exchange is an "issuer."[5]
- *Domestic concerns* (that is, U.S. citizens, nationals, residents, or companies organized under the laws of the United States or with a principal place of business in the United States) and certain individuals acting on their behalf that "make use of the mails or any means or instrumentality of interstate commerce."[6] For example, a privately owned U.S. pharmaceutical company is a domestic concern.[7]
- *Anyone other than an issuer or domestic concern* that "make[s] use of the mails or any means or instrumentality of interstate commerce" or otherwise acts in furtherance of proscribed conduct "while in the territory of the United States."[8] For example, a non-U.S. pharmaceutical representative who, while traveling in the United States, engages in conduct that violates the FCPA falls within this category.[9] This jurisdictional basis is very broad and is largely untested.[10]

By contrast, the FCPA's accounting provisions apply only to "issuers."[11] However, the FCPA extends to the books of such companies' subsidiaries and affiliates where their books roll up into the parent's books. In other words, companies traded on U.S. exchanges have an obligation to ensure that their subsidiaries—both inside and outside

of the United States—comply with the FCPA's accounting provisions.[12] Moreover, certain individuals also may face personal liability for the acts of foreign subsidiaries that affect the company's books and records based on a theory of "control person" liability.[13]

Each of the three categories above (that is, issuers, domestic concerns, and other persons) also includes "any officer, director, employee, or agent" of such entity.[14] Accordingly, the FCPA's jurisdictional embrace reaches beyond U.S. borders to include entities such as non-U.S. subsidiaries of a U.S. company, or under certain circumstances, non-U.S. joint venture partners not otherwise subject to the FCPA.

Q 13.4 What do the FCPA's anti-bribery provisions prohibit?

The FCPA's anti-bribery provisions prohibit:

- Offering, promising, authorizing, or paying;
- Money or anything of value;
- Directly or indirectly;
- To a "foreign official" or non-U.S. political party, party official, or candidate;
- When such offers, promises, authorizations, or payments are made corruptly;
- To obtain or retain business, or to gain some other business advantage.[15]

The DOJ and SEC have taken a broad view of the definition of "foreign official" to encompass employees of non-U.S. government-owned or operated entities, including doctors, pharmacists, and lab technicians. Employees of public international organizations are also considered foreign officials. According to the DOJ, "it is entirely possible, under certain circumstances and in certain countries, that nearly every aspect of the approval, manufacture, import, export, pricing, sale and marketing of a drug product in a foreign country will involve a foreign official' within the meaning of the FCPA."[16]

It is unlawful under the FCPA to make payments or provide benefits to third parties—including distributors, dealers, carrying and forwarding agents, travel agents, conference organizers, design institutes, medical associations, and foundations—knowing that some or all of those payments or benefits will be provided to foreign officials in violation of the FCPA. "Knowing" is defined as actual knowledge or conscious disregard of facts indicating a high probability that improper conduct will occur.[17] In other words, pharmaceutical executives and employees cannot evade FCPA liability by putting their "heads in the sand" and ignoring "red flags," or facts or circumstances that indicate a probable risk, possible violation, or actual violation of the FCPA.

Q 13.5 Does the FCPA contain any affirmative defenses?

Yes. The FCPA contains two affirmative defenses relative to the antibribery provisions. The first affirmative defense applies to payments, gifts, offers, or promises of anything of value that are lawful under the written laws in the foreign official's country.[18] This affirmative defense matters little because it is illegal to bribe government officials in every country.

The second is an affirmative defense for reasonable and bona fide expenditures that are directly related to the (1) promotion, demonstration, or explanation of the company's products or services, or (2) execution or performance of a contract with a non-U.S. government or government agency.[19] Reasonable and bona fide expenditures may take many forms, and the analysis is necessarily fact specific. The DOJ has explicitly acknowledged that certain expenditures, when appropriate in size and directly related to the promotion or demonstration of products, or performance of a contract, do not create criminal liability under the FCPA. For example, the DOJ has stated that, depending on the circumstances, the following expenditures may be appropriate:

- Travel and expenses for non-U.S. officials to visit company facilities or operations;[20]
- Travel and expenses for non-U.S. officials to receive training;[21] and
- Product demonstration or other promotional activities, including travel and reasonable expenses to attend meetings.[22]

Q 13.6 Does the FCPA contain any exceptions?

The FCPA contains one exception under the anti-bribery provisions for "facilitating payments," which are small payments made to foreign officials for the purpose of expediting or securing the performance of a routine governmental action.[23] Examples of routine government action include providing mail services, utilities, or processing visa applications. They do not include acts that are within a foreign official's discretion.[24] The purpose of the payment may help determine whether it is truly a facilitating payment.

Facilitating payments often present unique and difficult challenges for companies because analyzing whether a payment may qualify as a facilitating payment is particularly complex. Moreover, although the FCPA provides an exception for facilitating payments, such payments are not expressly permitted under other anti-bribery or local laws. For example, the U.K. Bribery Act does not contain an exception for facilitating payments.[25] As a result, many multinational pharmaceutical companies have prohibited making facilitating payments in their compliance policies.

Q 13.7 What do the FCPA's accounting provisions require?

The FCPA's accounting provisions require "issuers" to maintain accurate books and records, and to have internal controls adequate to detect and prevent violations of the law.[26] In many cases, it is easier for U.S. enforcement authorities to prove a civil violation of the accounting provisions because there is no requirement to establish knowledge or intent. However, "knowing" or intentional violations of the books and records and internal controls provisions can be enforced criminally.[27]

Q 13.8 What fines and penalties may be assessed for FCPA violations?

The FCPA carries significant fines and penalties. Corporations and other business entities are subject to fines of up to $2 million for each violation of the anti-bribery provisions,[28] and up to $25 million for each violation of the accounting provisions.[29] Individuals are subject to fines of up to $250,000 and imprisonment for up to five years for violations of the anti-bribery provisions,[30] and fines of up to $5 million and imprisonment for up to twenty years for violations of the accounting provisions.[31]

Courts may also impose fines up to twice the benefit that the defendant obtained through the corrupt payment.[32] To impose fines pursuant to this statute, either (1) the defendant must admit to the facts supporting the increased fine in a plea proceeding, or (2) the prosecution has proven the facts supporting the increased fine to a jury beyond a reasonable doubt.[33]

In practical terms, fines, penalties, and disgorgement of profits have ranged greatly based on the unique circumstances of each case. The largest penalty ever imposed under the FCPA was in 2008, when Siemens AG and its subsidiaries agreed to pay $800 million in fines and penalties to U.S. enforcement authorities.[34] Since the start of the pharmaceutical industry sweep in late 2009, fines, penalties, and disgorgement paid by healthcare companies have ranged from $7.4 million to $70 million.[35]

Q 13.9 What collateral consequences might arise from an FCPA violation?

One potential consequence associated with FCPA violations is the imposition of an independent compliance monitor as part of a negotiated settlement with U.S. regulators. A corporate compliance monitor is an independent third-party that assesses a company's adherence to the ongoing compliance requirements set forth in settlement agreements. Although not appropriate in all circumstances, the DOJ has issued an internal guidance suggesting that appointment of a monitor may be appropriate where a company's existing compliance program is unsatisfactory or where internal controls need to be significantly tightened.[36] In civil cases, the SEC similarly can require a company to retain an independent compliance consultant or monitor.[37] In circumstances where both the DOJ and SEC require a company to retain a monitor, the agencies have coordinated their requirements so the company may retain one monitor to fulfill both sets of requirements.[38]

Corporate monitors can be extremely expensive and disruptive for companies, as they strain internal company resources and report directly to the government without oversight from company personnel. Over the past several years, the government has imposed corporate monitors in a number of settlements,[39] while other companies have managed to avoid monitorships all together. In the settlements where a

monitor has not been imposed, the government has touted the companies' remedial actions, improvements to their compliance programs and internal controls, and specific compliance undertakings in settlement agreements.[40]

Other potential collateral consequences include: enhanced compliance obligations, debarment, cross-debarment by multilateral development banks, loss of export privileges, dilution of share price; loss of talent, and reputational damage.[41]

Q 13.10 What other laws are used in conjunction with the FCPA?

The DOJ also may bring anti-corruption cases under the Travel Act, which generally prohibits individuals and companies from using communications and travel facilities to commit U.S. state or federal crimes. More specifically, the Travel Act provides, in relevant part, that any entity or person who:

> travels in interstate or foreign commerce or uses the mail or any facility in interstate or *foreign commerce*, with the intent to—(1) distribute the proceeds of any unlawful activity; or (2) commit any crime of violence to further any unlawful activity; or (3) otherwise promote, manage, establish, carry on, or facilitate the promotion, management, establishment, or carrying on, of any unlawful activity . . . and thereafter performs or attempts to perform an act [described above in paragraphs (1), (2), or (3)]

is subject to criminal liability.[42] The statute describes "unlawful activity" to include violations of state commercial bribery laws.[43] This is a useful tool for the government where, for example, it may be difficult to determine whether an individual qualifies as a foreign official but bribery has occurred. In 2004, the DOJ indicted a number of healthcare executives for violations of the FCPA and Travel Act in connecion with bribes paid to the Director General of a Saudi foundation that built and administered a hospital.[44]

Other laws that may be used in conjunction with the FCPA include anti-money laundering statutes, mail and wire fraud statutes, certification or reporting violation statutes, and tax statutes.[45]

Anti-Bribery Provisions in Detail

Anything of Value

Q 13.11 What does the phrase "anything of value" mean?

While the FCPA specifically prohibits bribes in their most common forms (for example, money and gifts), the statute also contains a catch-all clause to address "anything of value." Congress included this language recognizing that bribes may be disguised as any number of improper benefits, and can come in any number of sizes. Moreover, items or payments that might appear relatively benign in the United States may be considered more significant in a foreign country. The prohibition on "anything of value" under the FCPA has been construed broadly by the DOJ and SEC, but necessarily is dependent on the facts and circumstances of each case. Regardless of the form of payment, it should be noted that the statute requires corrupt intent before criminal liability will attach.

Q 13.12 How have cash and cash equivalents featured in FCPA actions?

When most people imagine bribes, they envision a bad actor passing a bag or briefcase of cash to the recipient. Although cash payments may not always occur in quite so dramatic a fashion, cash and cash equivalents remain the most obvious forms of "value" that can be passed to foreign officials. A number of FCPA enforcement actions in the healthcare industry have centered on cash payments to HCPs and other foreign officials.[46] For example:

- A healthcare company's Taiwanese subsidiary provided sealed envelopes of cash to HCPs at public hospitals to encourage product sales and patient referrals;[47]
- A medical device company made payments in cash and stock options to an HCP at a public hospital center that were "proportional to purchases made by the public hospital" and intended to increase sales;[48] and
- A healthcare company allegedly provided a personal loan to an HCP that was never repaid.[49]

In most cases, the source of the cash is disguised in an effort to avoid detection from the business or auditors. For example, cash payments may be made by providing HCPs with "rebates" or "commissions" equivalent to a percentage of the HCP's total purchases, which is in reality a disguised kickback to the HCP for purchasing the company's products.[50] In several cases, distributors have made cash payments to HCPs after obtaining product rebates or discounts from pharmaceutical or medical device companies.[51]

Q 13.13 Are travel and entertainment considered "anything of value"?

Yes. U.S. enforcement authorities have brought FCPA enforcement actions based on the provision of travel, lodging, meals, and other expenses to foreign officials. Travel, lodging, meals, and related expenses have featured in FCPA enforcement actions involving the healthcare industry.[52] Some of the more common risk areas that have been targeted by U.S. regulators include travel upgrades, international travel unrelated to legitimate business activities, travel provided for spouses or other companions, and repeat international travel for the same individual.[53] Examples include:

- Allegedly providing international travel to HCPs (either directly or through third parties) to influence prescriptions, provide hospital formulary listing, or obtain unfair advantages;[54]
- Reportedly agreeing to provide international travel to HCPs based on the HCPs' promises to prescribe the company's products;[55]
- Sending an official on a "motivational trip" in order for certain products to be included on the government's list of reimbursable medications;[56]
- Allegedly providing travel packages to public hospital employees in order to secure contracts;[57]
- Allegedly providing travel for HCPs to tourist locations rather than to the locations of legitimate education activities, and including their family members;[58] and
- Reportedly sending an official and her spouse for a six-day stay in New York City that included two Broadway shows, followed

by a five-day stay in Aruba, in connection with a single-day site tour in New Jersey.[59]

One particular danger is that entertainment and travel expenses may be falsified easily to create cash funds. For example, in two recent cases, employees of major healthcare companies allegedly submitted fake receipts and travel itineraries to seek reimbursement for improper expenses.[60]

It should also be noted that companies are, in fact, permitted to provide legitimate travel, lodging, and related expenses. In the absence of corrupt intent, many expenses are perfectly acceptable. Moreover, many expenses may fall under the affirmative defense for bona fide expenditures (see Question 13.5 above). Nonetheless, healthcare companies must remain vigilant about the risks associated with these activities, and familiarize themselves with travel guidelines contained in relevant pharmaceutical codes (see Question 13.43 below).

Q 13.14 Are gifts considered "anything of value"?

The DOJ and SEC have targeted companies that provided gifts to HCPs in order to improperly influence them. In many instances, improper gifts are part of a larger scheme or are symptomatic of other FCPA issues. In one action, the SEC noted that the dollar amount of each alleged gift was relatively small, but the volume of improper payments was significant.[61] The DOJ and SEC brought enforcement actions against companies that reportedly directly, or through third-party distributors and/or sales representatives, provided the following gifts to HCPs:

- Wine and specialty foods;[62]
- Jewelry;[63]
- Meals;[64]
- Visits to bathhouses, spas, and karaoke bars;[65]
- Publication fees;[66]
- Televisions, laptops, and appliances;[67]
- Car leases;[68]

- "Points" based on the number of prescriptions issued, which were redeemable for items ranging from medical books to cell phones, reading glasses, and tea sets;[69] and
- English language classes.[70]

Q 13.15 Are sponsorships and trainings considered "anything of value"?

In the healthcare industry, companies often provide training to or sponsor training for HCPs. The DOJ and SEC have brought enforcement actions where companies provide international travel for training that is tied to the purchase or use of company products,[71] or based on activities undertaken in connection with otherwise legitimate sponsorship or training activities for HCPs, such as side trips, sightseeing activities, and other non-business-related entertainment activities.[72]

In one recent enforcement action, a healthcare company reached a $77 million combined settlement based on improper conduct that included travel sponsorships for HCPs that "contributed significantly to [the company's tender] win" and was a "fulfillment of the post tender obligations."[73]

Q 13.16 Are clinical trials and observational studies considered "anything of value"?

Yes. Clinical trials and observational studies present particularly significant corruption risks for healthcare companies because government officials are involved in nearly every aspect of the clinical development process, from giving regulatory approval to conducting the trials and studies. Moreover, a significant amount of the clinical trials conducted for FDA-regulated products are conducted in foreign countries. These arrangements can present particularly significant corruption risks as companies may select and engage particularly influential HCPs to conduct trials or studies, in an effort to influence their purchasing/prescribing decisions. Moreover, the risk of consulting arrangements where the HCP is paid in excess of fair market value only heightens the scrutiny that these arrangements should receive.

Clinical trials and observational studies have received increased regulatory attention in the past several years. The DOJ and SEC

have brought enforcement actions against a number of healthcare companies based, in part, on improper payments to HCPs that have facilitated or participated in clinical trials. For example, the DOJ has entered into deferred prosecution agreements with major medical device and pharmaceutical companies based on:

- Improper payments made to HCPs in Argentina, Brazil, and China, including commissions and cash incentives to HCPs for conducting clinical trials, where the company also improperly recorded these expenses in its books and records to conceal the nature of the improper payments;[74]
- Improper payments made to Polish HCPs through "civil contracts" to conduct, among other things, clinical trials, in an effort to influence tender awards;[75] and
- Improper payments for "observational studies" that lacked scientific value and were designed to influence HCPs to purchase company products.[76]

Q 13.17 Are employment and/or consulting agreements considered "anything of value"?

Yes. The DOJ and SEC have examined employment and consulting arrangements with HCPs and other non-U.S. government officials to determine whether the contractual arrangements are being used to disguise the flow of improper benefits. A number of enforcement actions have centered on agreements with HCPs whereby the HCPs were paid more than fair market value for their services, or conducted little, if any, legitimate work for the company in exchange for payment. In one matter, a company allegedly provided stock options to members of its scientific advisory board who also were employed by public hospitals. There, the value of the stock options exceeded the value of the services provided.[77] The company also made payments to a physician at a university hospital center under a consulting agreement for services that were not performed.[78]

It should be remembered that HCPs can be engaged legitimately pursuant to employment or consulting agreements for a variety of purposes. Companies should remain aware of the potential dichotomy

between HCPs as customers and as consultants, and the potential appearance that HCP consultants are being paid or rewarded (for example, travel, meals, and entertainment) in exchange for the purchase, recommendation, or prescription of products.

Q 13.18 Are charitable donations considered "anything of value"?

Yes. The DOJ and SEC carefully scrutinize charitable donations to ensure that charitable donations are not being made for the benefit of foreign officials. In one recent matter, a pharmaceutical company reportedly gave approximately $39,000 in donations to a small charitable organization that restored castles in Poland. However, the charitable organization was "founded and administered by the head of one of the regional government health authorities," and the donations allegedly were made "at the same time that [the company] was seeking the official's support for placing [the company's] drugs on the government reimbursement list."[79] Moreover, according to the SEC, the purpose of the payments was falsely described in the company's books and records.[80]

Certain internal controls can be put in place to minimize the risk that charitable donations will be used improperly. See Question 13.37 below. For example, in one Opinion Procedure Release,[81] the DOJ indicated that it did not intend to take enforcement action with respect to a proposed donation of 100 sample medical devices and related items to a series of hospitals in a foreign country, in part because the products would be provided to the foreign government rather than to individual foreign officials.[82] Moreover, the company described a thorough and transparent patient selection process that would mitigate the risk of corruption.[83]

Third Parties

Q 13.19 How do third parties pose FCPA risks?

For purposes of the FCPA, third parties such as distributors, dealers, sales agents, carrying and forwarding agents, and consultants are considered "agents" of the company. There are many instances in which companies have settled FCPA actions based on the alleged

conduct of these third parties.[84] The FCPA prohibits payments to third parties if the company *knew* or *should have known* that the third party corruptly passed on all or part of the payments directly or indirectly to a foreign official.[85] Knowledge is defined very broadly to include conscious disregard or deliberate ignorance, so that purposely turning a blind eye to corruption can constitute knowledge.[86] As such, there are significant FCPA and anti-corruption risks associated with (1) these third parties' interactions with foreign officials and (2) the company's and its subsidiaries' interactions with third parties who, themselves, might be considered foreign officials (for example, physician consultants or distributors owned by physicians).

Many enforcement actions are brought by the DOJ and SEC based on the actions of a company's third-party agents. For example, a pharmaceutical company's subsidiary in Russia allegedly paid off-shore companies for "services" that rarely were provided so that distributors and government officials would purchase drugs. The SEC specifically noted that "[i]n some instances, the off-shore entities appear to have been used to funnel money to government officials or others with influence in the government in order to obtain business for the subsidiary."[87] In another example, a Mexican subsidiary of a medical device company allegedly paid bribes to third-party entities that were each controlled by Mexican government officials in return for agreements with the entities and its hospitals to purchase millions of dollars of the company's products.[88]

Companies should remain skeptical of third parties specifically selected or recommended by foreign officials with whom the company wishes to do business or from whom the company is seeking approvals. For information on how to mitigate FCPA risk presented by third parties, see Question 13.44 below.

Q 13.20 Do joint venture partners pose FCPA risks?

Yes. Under the anti-bribery provisions, joint venture partners may be liable for their partners' illicit activities if they have actual or constructive knowledge of the activities. Although the level of ownership or control in the joint venture does not specifically determine the level of liability, it may be relevant in determining whether a joint venture partner knew or should have known about its partners' activities.

Companies should undertake appropriate due diligence on all prospective joint venture partners to ensure that there have been no past corruption issues that may result in liability for the entire joint venture, confirm that the joint venture agreement contains audit rights, and consider whether including an exit clause (in the event that FCPA issues are discovered) is appropriate.

Under the FCPA's accounting provisions, majority owners of joint ventures can be held liable for violations by the joint venture.[89] Minority owners are still liable for the joint venture's books and records and internal controls, but may avoid liability if they demonstrate good faith efforts to cause the joint venture to comply with the accounting provisions.[90]

Q 13.21 Do local agents and consultants pose FCPA risks?

Yes. Many companies rely on local agents to navigate regional regulations and bureaucracy, and to interface with customers and foreign officials. In some instances, laws and regulations require the use of local agents for various tasks. Because companies may be held criminally liable for the acts of third parties acting on their behalf, local agents can pose significant FCPA risks. One of the more common examples of local agents that present significant risk for the healthcare industry is customs brokers. In a recent case, the Brazilian subsidiary of a healthcare company allegedly made payments to customs brokers who in turn paid customs officials to allow the importation of unregistered products.[91]

Local sales agents also present significant FCPA risks. For example, a healthcare company recently settled with the SEC based on the alleged actions of a local sales agent. In that case, the company's Italian subsidiary reportedly offered cash to a hospital director through a local sales agent to influence his upcoming decision regarding whether to renew his hospital's contract for supplies.[92] According to the SEC, the sales agent described the payment as "overdue compensation" for a conference.[93]

Companies may enter into consulting agreements with third parties for any number of legitimate reasons, including research and development, scientific advice, and sales and marketing. Like other

third-party agents, companies must take care to ensure that consultants comply with the FCPA and other relevant laws. For example, a pharmaceutical company recently settled an enforcement action based, in part, on a consulting arrangement with a registration official who assisted with product registrations in Croatia.[94] In another enforcement action, a major multinational company allegedly made a number of improper payments to various government officials via several local consultants, including:

- Payments to the Vietnamese Ministry of Health through a Hong Kong consultant;
- Payments through consultants to government-owned hospital employees, and lavish "study trips" for physicians at state-owned hospitals in China; and
- Payments through consultants to government-owned customers in Russia.[95]

Q 13.22 Do distributors present unique FCPA risks?

Yes. Many companies utilize a distributor business model for purposes of efficiency or, in some cases, to comply with local laws and regulations. For example, it is common or required in some countries for local distributors to hold product registrations. The DOJ and SEC have demonstrated an interest in the relationship between companies and distributors.[96] For example, a pharmaceutical company agreed to a $22.2 million combined settlement with the DOJ and SEC in 2012 to resolve charges that subsidiaries had bribed government-employed doctors in Greece.[97] According to the SEC complaint, from 1997 to 2008, company subsidiaries used agents, affiliates, and employees to sell products to a Greek distributor at list price, after which they paid the distributor a rebate into an off-shore account.[98] These funds then allegedly were used by the distributor to pay cash or offer gift incentives to government-employed Greek HCPs in order to induce them to use the company's products.[99]

A number of enforcement actions have centered on allegations related to company distributors:

- A pharmaceutical company allegedly sold certain drugs at "unusually large discounts" to its Brazilian distributor so that

the distributor could use approximately 6% of the purchase price to bribe Brazilian government officials to purchase the company's product;[100]

- A pharmaceutical company selected an exclusive distributor that reportedly funneled money to government officials to obtain product registrations in Kazakhstan;[101]
- A medical device company's distributor paid cash kickbacks to physicians with authority to make purchasing decisions at a public hospital in China, on a per-product-purchased basis;[102]
- A company distributor in China made payments to patent officials to speed up the patent review process, "solve some problems" with the relevant applications, and ultimately obtain patent approvals;[103]
- A pharmaceutical company's Russian distributors allegedly made direct payments to hospital administrators and doctors for purchasing products, and falsely recorded the payments as "discounts" in the company's books and records;[104] and
- A medical device company's Greek distributor paid cash incentives to orthopedic surgeons in the Greek public health system[105] and a 35% commission in advance of all purchases by the Greek distributor to an Isle of Man-registered company.[106]

Q 13.23 Are the FCPA risks associated with travel agents and conference organizers?

Travel agencies, in particular, have been used to create "slush funds" through which improper payments have been made. Several companies have settled with U.S. regulators based on improper payments through travel agents. For example, one pharmaceutical company reportedly:

- Reimbursed distributors for improper expenses by instructing travel agencies and conference organizers to pay distributors and obtain reimbursement from the company by submitting false invoices for continuing medical education activities in Indonesia;[107] and

- Generated funds by paying vendors' falsified invoices, including travel agencies that submitted false or inflated invoices related to "large-scale consumer education events," and receiving cash kickbacks in Pakistan and China.[108]

More recently, executives at a major pharmaceutical company were detained in China over allegations that the company had used travel agencies "as money-laundering shops to funnel bribes to doctors, hospitals, medical associations, foundations and government officials."[109] The company allegedly fabricated fictitious medical conferences, overbilled for educational training, and obtained false receipts from travel agencies to facilitate the bribery.

Q 13.24 Do medical foundations and societies present FCPA risks?

Yes. Pharmaceutical companies regularly work with, present to, and provide educational grants and donations to foundations and other medical societies. These foundations and societies are often led by, and/or are comprised of, practicing physicians who may, in the ordinary course, purchase, recommend, or prescribe certain company products. As a result, there is a risk that U.S. enforcement authorities might perceive a grant or donation to be an inducement or reward for purchasing company products. In one case, officers of a large healthcare provider were prosecuted for paying the Director General of a Saudi Arabian foundation responsible for hospital contracting $500,000 per year in exchange for securing major hospital contracts.[110]

Medical associations have also attracted the attention of foreign regulators. Chinese authorities recently announced an audit of the Chinese Medical Association (CMA) based on concerns over significant conference fees and donations that the association received from pharmaceutical companies, totaling $132 million over the past two years.[111] It is possible that the authorities may ultimately decide that corporate conference sponsorships—which are commonly made in China and in other countries around the world—are improper, and potentially illegal, sparking scrutiny by other regulators including the DOJ and SEC. This would be a wholesale change in the way in which pharmaceutical companies interact with medical associations and create a new area of risk under the FCPA.

Foreign Officials

Q 13.25 What is a "foreign official" for purposes of the FCPA?

The FCPA defines a "foreign official" to include any officer, employee, or person acting on behalf of "a foreign government or any department, agency, or instrumentality thereof."[112] The statute thus applies to a broad range of individuals, including any official or employee regardless of his or her rank or title. Examples range from professors at public universities to customs and immigration officials.

The term "instrumentality" has been construed by U.S. enforcement authorities to include wholly or partially state-owned or controlled enterprises, including state-owned or controlled hospitals.[113] Whether an institution qualifies as an instrumentality of a non-U.S. government is not always obvious, and often requires investigation and a fact-specific analysis. The U.S. government has taken a broad view of the term's meaning despite recent challenges in federal court.

Depending on the circumstances, providing anything of value—including education, travel, lodging, meals, and incidental expenses—to HCPs employed by or affiliated with public hospitals or universities could trigger the FCPA.[114] The DOJ has explicitly warned healthcare companies:

> As important for your clients, consider the possible range of "foreign officials" who are covered by the FCPA: Some are obvious, like health ministry and customs officials of other countries. But some others may not be, such as the doctors, pharmacists, lab technicians and other health professionals who are employed by state-owned facilities. Indeed, it is entirely possible, under certain circumstances and in certain countries, that nearly every aspect of the approval, manufacture, import, export, pricing, sale and marketing of a drug product in a foreign country will involve a "foreign official" within the meaning of the FCPA.[115]

Q 13.26 Are HCPs foreign officials?

Yes, depending on the circumstances. Over the past several years, the DOJ and SEC have advanced the theory that HCPs employed by non-U.S. public hospitals, medical facilities, or universities qualify as foreign officials for purposes of the FCPA.

The DOJ and SEC have brought enforcement actions against a number of companies based on improper payments to HCPs.[116] Doctors and surgeons have been cited as the most obvious examples of HCPs for purposes of the FCPA. However, there are a multitude of other medical professionals or hospital/university employees that may also qualify.

Q 13.27 Are pharmacists foreign officials?

Yes, depending on the circumstances. The DOJ explicitly identified pharmacists as possible foreign officials in announcing the pharmaceutical sweep in 2009.[117]

Q 13.28 Are laboratory technicians foreign officials?

Yes, depending on the circumstances. If laboratory technicians are employed by public hospitals or facilities, they would likely be considered a "foreign official" by the DOJ and SEC. The DOJ and SEC settled one case, in part, on cash commission payments made to laboratory technicians at state-owned hospitals.[118]

Q 13.29 Are hospital administrators and employees foreign officials?

Yes, depending on the circumstances. If a hospital administrator or employee works in a public hospital or medical facility, he or she is likely to be considered a "foreign official" by U.S. regulators.[119] In one recent case, a medical equipment manufacturer settled with the SEC, agreeing to pay over $4.5 million, based on alleged cash payments to hospital administrators to help secure tender awards.[120]

Q 13.30 Are healthcare regulators foreign officials?

Yes. The DOJ and SEC have indicated that healthcare regulators are foreign officials for purposes of the FCPA. Healthcare regulators often are responsible for tasks such as product approval and registration, approval of product pricing in-country, product reimbursement rates, and product placement regulations. For example, one company allegedly entered into a consulting agreement with a registration official who assisted the company in securing product registrations.[121] Companies operating outside the United States should take great care

to ensure that third parties engaged to interface with healthcare and other relevant regulators are aware of the anti-corruption risks, and are compliant with the FCPA and other anti-bribery laws and regulations.

Corrupt Intent

Q 13.31 When are offers, promises, authorizations, or payments made corruptly?

At its most basic level, the word "corruptly" means intent to improperly influence the recipient of a payment. It is not defined in the statute. However, in enacting the FCPA in 1977, the U.S. Congress explicitly noted:

> [t]he word "corruptly" is used in order to make clear that the offer, payment, promise, or gift, must be intended to induce the recipient to misuse his official position; for example, wrongfully to direct business to the payor or his client, to obtain preferential legislation or regulations, or to induce a foreign official to fail to perform an official function. The word "corruptly" connotes an evil motive or purpose . . . .[122]

The FCPA criminalizes the intent to make an improper payment. The FCPA *does not* require that an improper payment be successfully made. Moreover, it is the intent to make the improper payment that is relevant, rather than the intent to violate the FCPA.

Criminal liability only will attach where a defendant acts "willfully," a term that is not defined in the FCPA. Courts have generally construed the term to mean an act committed purposefully and with improper purpose, and have noted that the government is not required to prove that a defendant was specifically aware of the FCPA.[123] Rather, a defendant must know generally that his conduct is unlawful to trigger criminal liability. Accordingly, even if an agent or employee was unaware of the FCPA, the company and individual still may be held criminally liable for the agent or employee's improper payments.

It is important to note that corrupt intent, like all of the FCPA's anti-bribery elements, can be proven circumstantially. Thus, in the absence of direct evidence of corrupt intent the DOJ often will conclude that corrupt intent existed if the surrounding circumstances suggest that payments or things of value were given to improperly influence an HCP.

Business Purpose

Q 13.32 What does it mean to obtain or retain business?

The requirement that payments must be intended to influence a foreign official to use his or her position to assist in retaining or obtaining business is known as the "business purpose test." Unsurprisingly, the business purpose test has been broadly construed to include everything from securing government contracts,[124] to reducing taxes or customs duties,[125] to preventing competitors from entering a market.[126] The key takeaway of this element is that it can include a wide range of business advantages.

Accounting Provisions in Detail

In General

Q 13.33 What do the accounting provisions require?

The accounting provisions require that U.S. exchange-listed companies maintain accurate books and records, and devise and maintain adequate internal accounting controls.

Books and Records

Q 13.34 What is the books and records provision?

The books and records provision requires 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."[127] In short, this means that issuers may not mischaracterize the true nature of transactions. Companies have faced books and records charges when, for example:

- Improper payments to customs brokers were described as "importation advances";[128]
- Improper cash, gifts, and travel expenses were recorded as cash advances, training and promotional expenses, meetings and congresses;[129]

- Improper payments allegedly were described as promotional activities, marketing, training, travel and entertainment, clinical trials, freight, conferences, and advertising;[130]
- Improper international "incentive trips" reportedly were recorded as educational or charitable support;[131]
- The true nature of improper payments purportedly was concealed with the assistance of distributors and vendors;[132]
- Company executives allegedly wrote checks to themselves to secure money for improper payments and described them as cash advances;[133] and
- There reportedly was no supporting documentation for improper cash payments.[134]

Internal Controls

Q 13.35 What is the internal controls provision?

The internal controls provision requires issuers to:

> devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that—
>
> (i) transactions are executed in accordance with management's general or specific authorization;
>
> (ii) transactions are recorded as necessary (I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and (II) to maintain accountability for assets;
>
> (iii) access to assets is permitted only in accordance with management's general or specific authorization; and
>
> (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences . . . .[135]

In practice, this means that issuers must implement effective anticorruption compliance programs (see Question 13.39 below); implement policies and procedures regarding financial controls (for example,

approvals, authority matrix, and segregation of duties); conduct risk assessments; and monitor and audit transactions on an ongoing basis.[136] Companies must tailor their internal controls to the unique nature of their business and to the environment in which their business operates.

Successor Liability

Q 13.36 Does an acquiring company assume a target's liability under the FCPA's anti-bribery provisions?

The text of the FCPA does not provide for successor liability, but the DOJ and SEC have indicated that "[s]uccessor liability applies to all kinds of civil and criminal liabilities, and FCPA violations are no exception."[137] In other words, according to the government, an acquiring company assumes liability for an acquired company's FCPA violations. Notwithstanding the official positions of the DOJ and the SEC, neither agency has taken action against any successor company *exclusively* on the basis of criminal conduct committed by its predecessor company *prior to* the successor company's involvement. Indeed, the "DOJ and SEC have only taken action against successor companies in limited circumstances, generally in cases involving egregious and sustained violations or where the successor company directly participated in the violations or failed to stop the misconduct from continuing after the acquisition."[138]

Q 13.37 What limitations are there on successor liability?

There must be FCPA jurisdiction over the target's improper conduct in order for successor liability to apply. The DOJ and SEC have stated:

> Successor liability does not . . . create liability where none existed before. For example, if an issuer were to acquire a foreign company that was not subject to the FCPA's jurisdiction, the mere acquisition of that foreign company would not retroactively create FCPA liability for the acquiring issuer.[139]

Analyzing whether there is jurisdiction over a target's actions can be a complicated inquiry. Companies and individuals need not be

aware that they are making "use of the mails . . . [or] interstate commerce" in furtherance of improper conduct in order for jurisdiction to attach. This could happen, for example, when wire transfers are made through correspondent bank accounts or when email is routed through the United States.[140]

Separate from jurisdiction, the structure of the transaction may limit successor liability. Under U.S. law, a corporation does not inherit the liabilities of another corporation in an asset purchase unless: (1) the purchasing company expressly or impliedly agrees to assume the other companies liabilities; (2) the transaction was fraudulent; (3) there was a de facto merger or consolidation of the companies; or (4) the purchasing company was a mere continuation of the selling company.[141] Asset purchasers should remain wary of misconduct that continues after the purchase and could trigger FCPA liability.

Q 13.38 What can an acquiring company do to protect itself from successor liability?

As discussed in Question 13.40 below, an acquiring company should conduct thorough pre-transaction anti-corruption due diligence (or post-transaction due diligence if pre-transaction due diligence is not possible), timely integrate the acquired company into the acquirer's anti-corruption compliance program, and conduct risk assessments of the newly acquired entity as necessary and appropriate.

The DOJ and SEC have indicated that, when possible, they are more likely to pursue enforcement against a predecessor company rather than the acquirer, "particularly when the acquiring company uncovered and timely remedied the violations."[142] In one case, a healthcare company discovered potentially improper payments made to doctors at state-owned hospitals by a target's foreign subsidiaries during pre-transaction anti-corruption due diligence. It promptly notified the target and the target began an investigation.[143] Ultimately, the target's foreign subsidiary pleaded guilty and the target settled with the SEC.[144] The acquirer avoided FCPA liability altogether.

In another matter, a pharmaceutical company had disclosed potentially improper conduct to the DOJ and SEC, and was cooperating in an investigation. When it acquired a target several years later, it

conducted risk-based due diligence, identified improper payments to HCPs at government hospitals, and reported its findings to the government. The pharmaceutical acquirer integrated the target's operations into its anti-corruption compliance program. When the acquirer settled with the government, the acquired company—which had been maintained as a separate subsidiary—came to a resolution with the SEC for pre-transaction conduct.[145]

Anti-corruption due diligence is also an important component in assessing the value of a target company. One medical device company discovered "irregular sales practices" in an acquired entity's overseas operations shortly after the acquisition. Upon announcing its discovery and that its full year sales would be reduced by $100 million, the acquirer's share price dropped 13%.[146] Ultimately, the acquirer reached an agreement with the vendors of the acquired entity to reduce the previous purchase price.[147]

Mitigating FCPA Risk and Anti-Corruption Compliance Programs

Q 13.39 How can effective anti-corruption compliance programs help companies mitigate FCPA risk?

In the words of the DOJ and SEC, "an effective compliance program is a critical component of a company's internal controls and is essential to detecting and preventing FCPA violations."[148] The government considers the efficacy of a company's anti-corruption compliance program when evaluating the scope of its investigation, whether the case can be resolved through a deferred prosecution agreement or non-prosecution agreement, whether a monitor should be imposed, and the amount of penalties imposed.[149]

Q 13.40 What does the government expect to see in an anti-corruption compliance program?

The DOJ and SEC expect companies to institute anti-corruption compliance programs that are "tailored to the company's specific business and the risks associated with that business," and "are dynamic and evolve as the business and the markets change."[150] While they are

careful to stress that there are "no formulaic requirements,"[151] the DOJ and SEC have consistently emphasized certain baseline requirements:

- A corporate policy against FCPA violations and violations of other anti-corruption laws;
- Compliance standards and procedures designed to address violations of the FCPA; other applicable anti-corruption laws; and the company's compliance policy that are applicable to directors, officers, employees and, "where necessary and appropriate, outside parties acting on behalf of [the company] in a foreign jurisdiction, including but not limited to, agents, consultants, representatives, distributors, teaming partners, and joint venture partners (collectively, 'agents and business partners')," and include:
  - Gifts;
  - Hospitality, entertainment, and expenses;
  - Customer travel;
  - Political contributions;
  - Charitable donations and sponsorships;
  - Facilitating payments; and
  - Solicitation and extortion;[152]
- Assigning one or more senior corporate executives to oversee implementation of the anti-corruption compliance policies, standards, and procedures, and giving them authority to report directly to the board of directors or an appropriate committee of the board of directors;
- Mechanisms to ensure that anti-corruption policies, standards, and procedures are effectively communicated, including: (1) periodic training for directors, officers, employees, and, where necessary, business partners; and (2) annual certifications by directors, officers, employees, and, where necessary and appropriate, agents and business partners;

- A system for reporting violations and suspected violations of anti-corruption laws and/or compliance policies, standards, and procedures, such as a hotline;
- Disciplinary procedures to address violations of anti-corruption laws and the company's compliance policies, standards, and procedures;
- Due diligence requirements related to agents and business partners, including:
    - Documenting "risk-based due diligence," informing agents and business partners of the company's commitment to complying with anti-corruption laws and the company's policy, standards, and procedures, and seeking a reciprocal commitment;[153]
- Standard contractual provisions with agents and business partners designed to prevent violations of anti-corruption laws, including: (1) representations and undertakings related to anti-corruption compliance; (2) audit rights to ensure anti-corruption compliance; and (3) termination rights in the event of a breach of anti-corruption laws, regulations, or representations; and
- Periodic testing of the compliance code, standards, and procedures.[154]

The government also expects companies engaging in mergers and acquisitions to take a number of steps and to reflect such steps in their anti-corruption compliance programs. Companies should complete extensive pre-transaction due diligence on any mergers and acquisitions, and, when pre-closing due diligence is not possible, should conduct extensive post-closing due diligence. Integrating the acquired or merged entity into the company's existing compliance program is equally important. Companies should implement anti-corruption policies and procedures and train new employees. Companies should also evaluate the acquired entity's existing third-party relationships. In some instances, it may be advisable to conduct an FCPA-related audit after closing.[155]

Companies should take steps to ensure that their anti-corruption compliance programs are not so-called "paper programs." It is critical

that employees understand anti-corruption compliance requirements. Translating policies and procedures to employees' local languages and providing training is essential.[156] Testing the efficacy of the compliance program at regular intervals through risk assessments also is advisable.

Q 13.41 What additional requirements have pharmaceutical companies agreed to include in their anti-corruption compliance programs when settling with the government?

Depending on the circumstances, companies may agree to implement compliance program enhancements designed to address issues that arose in the FCPA matter. Some of these enhancements may include:

- Implementing new policies and procedures concerning gifts, hospitality, and travel for government officials, including HCPs, administrators, and regulators;
- Conducting annual risk assessments of markets with government customers, including HCPs, and reviewing interactions with government officials;
- Identifying the top five "high-risk" operating companies and performing audits at least once every three years;
- Performing audits of other companies that pose a corruption risk at least once every five years, including—if possible—a review of the books and records of distributors that may present a corruption risk; and
- Updating due diligence reviews of third parties at least once every three years.[157]

Q 13.42 Do expectations for compliance programs vary depending on the jurisdiction and relevant government enforcement agency?

In recent years, there has been a growing international consensus on the essential elements of an effective compliance program.[158] This is important where, as in the United Kingdom, for example, proving that the company has an effective compliance program is a defense to certain charges.[159]

Q 13.43 How can industry codes inform anti-corruption compliance programs?

Industry codes are not intended to and do not supersede requirements under applicable laws and regulations, including the FCPA. Nonetheless, they can provide companies with much-needed guidance on the industry's view of conduct that has been the subject of FCPA enforcement actions, including guidance on interactions with and activities involving HCPs. Regional and country codes also may shed light on issues specific to a particular part of the world that could have FCPA implications. Separately, compliance with industry norms may lend credibility to the bona fide nature of expenditures on behalf of HCPs and the circumstances under which they are made.

In the pharmaceutical context, industry codes often address: permissible marketing activities and presentations to HCPs; company-sponsored medical education and speaking programs; engaging HCPs as consultants; fellowships and other educational scholarships; third-party educational conferences; the provision of gifts and educational items to HCPs; and the use of prescriber data.[160] In some cases, industry codes may impose requirements that are more restrictive than applicable laws and regulations. For example, one country's laws may permit certain types of non-educational gifts up to a limit (for example, Chinese laws permit government officials to accept non-cash gifts up to ¥200), whereas an applicable industry code may prohibit all non-educational gifts (for example, R&D-based Pharmaceutical Association Committee Code of Practice 2012 prohibits all gifts for the HCP's "personal benefit").

Multinational pharmaceutical companies often are subject to a number of industry codes in the regions and countries in which they operate and do business. The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) has collected and published relevant regional and country codes on its website (including links), and has also published a comparison of what kinds of interactions, products, and activities are covered in each code.[161] For example, section 3.3 of the comparison indicates whether a specific regional or country code addresses the provision of samples, educational items, cash, gifts, promotional aids, sponsorships, travel, hospitality, and entertainment to HCPs, as well as expenses on behalf of

HCPs' guests. It also indicates whether each code establishes specific monetary limits in connection with these activities.[162] These are precisely the topics that have arisen in FCPA enforcement actions involving pharmaceutical and other life sciences companies. In light of this complex and multi-faceted environment, multinational pharmaceutical companies need to try to harmonize laws, codes, and policy positions when establishing their own anti-corruption compliance policies and procedures.

Q 13.44 How can companies mitigate FCPA risk when engaging third parties?

As discussed in this chapter, companies cannot escape FCPA liability by taking a "head-in-the-sand" approach to the third parties they engage.[163] The government expects companies to conduct due diligence on third parties. Third-party due diligence should include investigating: the owners—including beneficial owners—of the third parties; the prospective third parties' qualifications; whether third parties have personal, professional, or familial ties to government personnel or officials (including physicians employed or compensated by public entities); the reputation of third parties and their clientele and other business associates; and the nature and scope of any existing so-called "red flags."

Red flags include, but are not limited to:

- Unusual payment patterns or financial arrangements, including requests for cash payments, payments to third-party designees, or payments outside of the recipient's country of residency;
- Unusually high commissions;
- Large discounts that are inconsistent with market norms;
- Vaguely described services;
- Requests that payments to the third party be made in an offshore jurisdiction;
- A lack of transparency and cooperation by the third party in terms of its general business operations;

- Indications that the third party is a shell organization incorporated in an off-shore jurisdiction;
- A lack of transparency in the third party's interactions with government officials and records;
- An apparent lack of qualifications or resources on the part of the third party to perform the services offered; and
- A foreign official insisting or expressly requesting that a third party be used.[164]

Q 13.44.1 What additional considerations are there when engaging and working with a distributor?

As discussed in Question 13.22 above, distributor conduct has been the focus of many FCPA actions in the pharmaceutical sector. Ensuring that there is transparency in distributor arrangements is critical from an FCPA risk-mitigation perspective. A company's lack of understanding with respect to its distributors' daily business operations and customer interactions may make it difficult to determine whether discounts and/or the extent of such discounts are warranted. The same is true of marketing arrangements. Many stocking distributors are responsible for marketing efforts in their territories or countries. Without knowing how distributors market products and the marketing methods used, companies do not know whether distributors incentivize HCPs to purchase their products by offering benefits that may create exposure under the FCPA and other anti-corruption laws.

Companies should also consider whether distributors are authorized to engage third parties. For example, if distributors are authorized to engage HCP consultants, companies should confirm that there are anti-corruption compliance safeguards in place. Without such transparency, companies cannot ascertain whether payments and other benefits provided by the distributors to physicians are appropriate. A distributor's sham consulting arrangements or improper payments could create FCPA and commercial bribery exposure for a company. The same is true of sub-distributors. If a distributor is engaging sub-distributors, the company should have some insight into how they are selected and the extent of their anti-corruption compliance obligations.

Companies should confirm that they have communicated with distributors about anti-corruption compliance, in particular with respect to travel, entertainment, and gifts. Companies can face FCPA exposure for side trips and companion travel provided by their distributors. Supporting documentation submitted to the company for reimbursements, credits, and/or discounts in connection with such expenses should be accurate. Inaccurate supporting documentation can have implications for the company under the FCPA's accounting provisions.

If a distributor holds a company's product registrations or is responsible for obtaining them in a particular country, the company should make certain it has insight into the process and the distributor's interactions with government officials. These kinds of interactions are ripe for bribery, where the process is complicated and tedious and a payment could expedite or simplify the process. It also may be difficult to terminate a distributor in the event compliance is an issue because it is not always possible to transfer registrations easily and obtaining new registrations can take a significant amount of time.

Q 13.44.2 What additional considerations are there when engaging an HCP?

Like relationships with distributors, companies should ensure that there is transparency in their relationships with HCPs that may serve as consultants and provide training and medical education, or sit on advisory panels, for example. As discussed throughout this section, companies should conduct due diligence around the engagement to confirm that there is a legitimate need for the services to be provided. The process of selecting HCPs should be transparent and divorced from the sales and marketing functions. Companies should enter into written agreements with HCPs that clearly delineate the tasks for which the HCPs have been engaged and corresponding deliverables. Payments in exchange for the services rendered should be commensurate with the work performed and should be appropriate for the market in which the HCP works. Companies would be wise to conduct a fair market value assessment to support the payments made to HCP consultants. They also should assess local laws to ensure that the amounts paid to HCP consultants are permissible.

Q 13.45 How can companies mitigate the FCPA risk associated with meals, gifts, and travel?

As discussed above, having clear policies and procedures that address meals, gifts, entertainment, and travel are essential. Some companies institute monetary thresholds and frequency limits on meals and gifts for foreign officials, with advance written permission from legal or compliance personnel needed to exceed such limits. Travel presents its own unique challenges. Side trips and companion travel provided to foreign officials have featured prominently in FCPA actions over the years. Companies should take steps to confirm that travel arrangements made for foreign officials do not include side trips, that the class of travel is appropriate for the duration of the trip, and that travel expenses are not made on behalf of a foreign official's spouse, child, or other companion. Expenses for meals and accommodations during the foreign official's travel should be controlled and per diems should be avoided. The company should maintain appropriate supporting documentation for such expenditures. When travel is provided in conjunction with sponsorship, the company should take steps to confirm and document the HCP's attendance at the event.

Notes

1. 15 U.S.C. §§ 77dd-1, 78dd-2, 78dd-3 (2012).
2. 15 U.S.C. § 78m.
3. Lanny A. Breuer, Then-Assistant Attorney General, U.S. Dep't of Justice, Prepared Keynote Address to The Tenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum (Nov. 12, 2009) [hereinafter Breuer Keynote Address], at 2, *available at* www.justice.gov/criminal/pr/speeches-testimony/documents/11-12-09breuer-pharmaspeech.pdf.
4. 15 U.S.C. § 78dd-1.
5. *See* Complaint, SEC v. Eli Lilly and Co., No. 12-cv-02045, at 3 (D.D.C. Dec. 20, 2012), *available at* www.sec.gov/litigation/complaints/ 2012/comp-pr2012-273.pdf.
6. 15 U.S.C. § 78dd-2.
7. Non-Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Micrus Corp. and Micrus S.A. (Feb. 28, 2005) (a private medical device company entering into a non-prosecution agreement and agreeing to a $450,000 civil penalty for alleged violations of the FCPA), *available at* www.justice.gov/criminal/fraud/fcpa/cases/micrus-corp/02-28-05micrus-agree.pdf.
8. 15 U.S.C. § 78dd-3.
9. *See, e.g.*, Information, United States v. Syncor Taiwan, Inc., No. 02-cr-1244, at 1–2 (C.D. Cal. Dec. 5, 2002), *available at* www.justice.gov/criminal/fraud/fcpa/cases/syncor-taiwan/12-05-02syncor-taiwan-info.pdf.
10. *Compare* Information, United States v. JGC Corp., No. 11-cr-260, at 18–19 (S.D. Tex. Apr. 6, 2011) (noting non-issuer, non-domestic concern's use of correspondent bank accounts but pursuing jurisdiction under theory of conspiring with and aiding and abetting domestic concern), *available at* www.justice.gov/criminal/fraud/fcpa/cases/jgc-corp/04-6-11jgc-corp-info.pdf, *with* Transcript of Jury Trial, United States v. Patel, No. 09-cr-0335 (D.D.C. June 6, 2011) (making ruling from bench that sending package from the United Kingdom to United States was an insufficient basis for jurisdiction under 15 U.S.C. § 78dd-3).
11. 15 U.S.C. § 78m.
12. *See* U.S. Dep't of Justice and SEC, A Resource Guide to the U.S. Foreign Corrupt Practices Act, 43 (Nov. 14, 2012) [hereinafter FCPA Guide], at 43, *available at* www.justice.gov/criminal/fraud/fcpa/guide.pdf.
13. *See, e.g.*, Complaint, SEC v. Nature's Sunshine Prods., Inc., No. 09-cv-0672, at 12–13 (C.D. Utah July 31, 2009) (charging COO and CFO with control person liability based on books and records violations and false filings with the SEC despite lack of personal knowledge or involvement in conduct), *available at* www.sec.gov/litigation/complaints/2009/comp21162.pdf; *see also* 15 U.S.C. § 78t(a) ("Every person who, directly or indirectly, controls any person liable under any provision of this

chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable . . . .").

14. *See* 15 U.S.C. §§ 77dd-1, 78dd-2, 78dd-3.

15. *Id.*

16. Breuer Keynote Address, *supra* note 3, at 2.

17. 15 U.S.C. §§ 77dd-1, 78dd-2, 78dd-3.

18. *See* 15 U.S.C. §§ 78dd-1(c)(1), 78dd-2(c)(1), 78dd-3(c)(1).

19. *See* 15 U.S.C. §§ 78dd-1(c)(2), 78dd-2(c)(2), 78dd-3(c)(2).

20. *See* U.S. Dep't of Justice, FCPA Op. Release 07-01 (July 24, 2007), *available at* www.justice.gov/criminal/fraud/fcpa/opinion/2007/0701.pdf.

21. *See* U.S. Dep't of Justice, FCPA Op. Release 07-02 (Sept. 11, 2007), *available at* www.justice.gov/criminal/fraud/fcpa/opinion/2007/0702.pdf.

22. *See* U.S. Dep't of Justice, FCPA Op. Release 11-01 (June 30, 2011), *available at* www.justice.gov/criminal/fraud/fcpa/opinion/2011/11-01.pdf.

23. *See* 15 U.S.C. §§ 78dd-1(b), 78dd-2(b), 78dd-3(b).

24. *See* FCPA GUIDE, *supra* note 12, at 25.

25. *See generally* U.K. Bribery Act, 2010, c. 23 (U.K.), *available at* www.legislation.gov.uk/ukpga/2010/23/pdfs/ukpga_20100023_en.pdf.

26. 15 U.S.C. § 78m; FCPA GUIDE, *supra* note 12, at 39–41.

27. 15 U.S.C. §§ 78m(b)(5), 78ff(a); *see, e.g.*, Information, United States v. Siemens Aktiengesellschaft, No. 08-cr-367 (D.D.C. Dec. 12, 2008), *available at* www.justice.gov/criminal/fraud/fcpa/cases/siemens/12-12-08siemensakt-info.pdf.

28. 15 U.S.C. §§ 78dd-2(g)(1)(A), 78dd-3(e)(1)(A), 78ff(c)(1)(A).

29. 15 U.S.C. § 78ff(a).

30. *See* 15 U.S.C. §§ 78dd-2(g)(2)(A), 78dd-3(e)(2)(A), 78ff(c)(2)(A); 18 U.S.C. § 3571(d); s*ee also* FCPA GUIDE at 68.

31. 15 U.S.C. § 78ff(a).

32. 18 U.S.C. § 3571(d).

33. S. Union v. United States, 132 S. Ct. 2344, 2350–51 (2012).

34. Press Release, U.S. 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 (Dec. 15, 2008), *available at* www.justice.gov/opa/pr/2008/December/08-crm-1105.html; Press Release, SEC, SEC Charges Siemens AG for Engaging in Worldwide Bribery (Dec. 15, 2008), *available at* www.sec.gov/news/press/2008/2008-294.htm.

35. Press Release, SEC, SEC Charges Orthofix International with FCPA Violations (July 10, 2012), *available at* www.sec.gov/News/PressRelease/Detail/Press-Release/1365171483164; Deferred Prosecution Agreement between the U.S. Dep't of Justice, Criminal Div., Fraud Section and Orthofix Int'l, at Attachment C, "Corporate Compliance Program" (July 10, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/or thofix/2012-07-10-orthofix-dpa.pdf; Press Release, Dep't of Justice, Johnson & Johnson Agrees to Pay $21.4 Million Criminal Penalty To Resolve Foreign Corrupt Practices Act and Oil for Food Investigations (Apr. 8, 2011), *available at* www.justice.gov/opa/pr/2011/April/11-crm-446.html; Press

Release, SEC, SEC Charges Johnson & Johnson with Foreign Bribery (Apr. 7, 2011), *available at* www.sec.gov/news/press/2011/2011-87.htm.

36. *See* Gary G. Grindler, Then-Acting Deputy Attorney General, U.S. Dep't of Justice, Additional Guidance on the Use of Monitors in Deferred Prosecution Agreements and Non-Prosecution Agreements with Corporations (May 25, 2010), *available at* www.justice.gov/dag/dag-memo-guidance-monitors.pdf; Craig S. Morford, Then-Acting Deputy Attorney General, U.S. Dep't of Justice, Memorandum to the Heads of Department Components and United States Attorneys on Selection and Use of Monitors in Deferred Prosecution Agreements and Non-Prosecution Agreements with Corporations (Mar. 7, 2008), *available at* www.justic.gov/dag/morford-useofmonitorsmemo-03072008.pdf; FCPA GUIDE, *supra* note 12, at 71.

37. *See* FCPA GUIDE, *supra* note 12, at 72.

38. *See id.*

39. *See, e.g.*, Deferred Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and AGA Medical Corp., at 8–9 (June 3, 2008), *available at* www.justice.gov/criminal/fraud/fcpa/cases/agamedcorp/06-03-08aga-agree.pdf; Non-Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Micrus Corp. and Micrus S.A., app. A at 4–5 (Feb. 28, 2005), *available at* www.justice.gov/criminal/fraud/fcpa/cases/micrus-corp/02-28-05micrus-agree.pdf; *see also* Deferred Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Biomet, Inc., at 6–7 (Mar. 26, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/biomet/2012-03-26-biomet-dpa.pdf; Deferred Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Smith & Nephew, Inc., at 6–7 (Feb. 1, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/smith-nephew/2012-02-01-s-n-dpa.pdf.

40. *See, e.g.*, Press Release, U.S. Dep't of Justice, Pfizer H.C.P. Corp. Agrees to Pay $15 Million Penalty to Resolve Foreign Bribery Investigation (Aug. 7, 2012), *available at* www.justice.gov/opa/pr/2012/August/12-crm-980.html.

41. *See* FCPA GUIDE, *supra* note 12, 69–71.

42. 18 U.S.C. § 1952 (emphasis added); *see* Perrin v. United States, 444 U.S. 37, 41 (1979).

43. 18 U.S.C. § 1952(b)(i)(2).

44. *See, e.g.*, Information, United States v. Nico, No. 04-cr-092 (N.D. Ala. Mar. 2, 2004), *available at* www.justice.gov/criminal/fraud/fcpa/cases/nico/03-02-04nico-info.pdf.

45. *See generally* FCPA GUIDE, *supra* note 12, at 48–49.

46. *See, e.g.*, Complaint, SEC v. Pfizer, Inc., No. 12-cv-01303, at 8 (D.D.C. Aug. 7, 2012) (describing the alleged wire transfer to a Croatian official's account to assist with product registrations), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-152-pfizer.pdf.

47. *See* Information, United States v. Syncor Taiwan, Inc., No. 02-cr-1244, at 2–5 (C.D. Cal. Dec. 5, 2002), *available at* www.justice.gov/criminal/fraud/fcpa/cases/syncor-taiwan/12-05-02syncor-taiwan-info.pdf; *see also* Complaint, SEC v. Syncor Int'l Corp., No. 02-cv-02421, at 2–3 (D.D.C. Dec. 10, 2002), *available at* www.sec.gov/litigation/complaints/comp17887.htm.

48. Non-Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Micrus Corp. and Micrus S.A., app. A at 1 (Feb. 28, 2005), *available at* www.justice.gov/criminal/fraud/fcpa/cases/micrus-corp/02-28-05micrus-agree.pdf.

49. *See* Complaint, SEC v. Syncor Int'l Corp., No. 02-cv-02421, at 2–3 (D.D.C. Dec. 10, 2002), *available at* www.sec.gov/litigation/complaints/comp17887.htm.

50. *See* Information, United States v. Biomet, Inc., No. 12-cr-00080, at 7 (D.D.C. Mar. 26, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/biomet/2012-03-26-biomet-information.pdf.

51. *See id.*; Information, United States v. DePuy, Inc., No. 11-cr-099, at 6 (D.D.C. Apr. 6, 2011), *available at* www.justice.gov/criminal/fraud/fcpa/cases/depuy-inc/04-08-11depuy-info.pdf.

52. *See* Deferred Prosecution Agreement between the U.S. Dep't of Justice, Criminal Div., Fraud Section and Biomet, Inc. (Mar. 26, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/biomet/2012-03-26-biomet-dpa.pdf; Complaint, SEC v. Tyco Int'l Ltd., No. 12-cv-01583 (D.D.C. Sept. 24, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-196.pdf.

53. *See, e.g.*, Complaint, SEC v. Lucent Techs. Inc., No. 07-cv-02301 (D.D.C. Dec. 21, 2007) (alleging Lucent improperly paid for "sightseeing, entertainment, and leisure activities" incurred by Chinese officials visiting tourist destinations in the U.S., including Hawaii, Las Vegas, the Grand Canyon, Niagara Falls, Disney World, Universal Studios, and New York), *available at* www.sec.gov/litigation/complaints/2007/comp20414.pdf; Non-Prosecution Agreement between Dep't of Justice, Criminal Div., Fraud Section and Lucent Technologies Inc. (Nov. 14, 2007), *available at* www.justice.gov/criminal/fraud/fcpa/cases/lucent-tech/11-14-07lucent-agree.pdf.

54. Complaint, SEC v. Pfizer, Inc., No. 12-cv-01303, at 14–17 (D.D.C. Aug. 7, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-152-pfizer.pdf.

55. Complaint, SEC v. Wyeth, LLC, No. 12-cv-01304, at 6 (D.D.C. Aug. 7, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-152-wyeth.pdf.

56. Information, United States v. Pfizer H.C.P. Corp., No. 12-cr-00169, at 9 (D.D.C. Aug. 7, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/pfizer/2012-08-07-pfizer-info.pdf.

57. Complaint, SEC v. Orthofix Int'l N.V., No. 12-cr-150, at 4 (E.D. Tex. July 10, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-133.pdf.

58. Complaint, SEC v. Johnson & Johnson, No. 11-cv-00686, at 12 (D.D.C. Apr. 8, 2011), *available at* www.sec.gov/litigation/complaints/2011/comp21922.pdf.

59. SEC, *In re* Stryker Corp., Order Instituting Cease-and-Desist Proceedings, Cease and Desist Order, at 4 (Oct. 24, 2013), *available at* www.sec.gov/litigation/admin/2013/34-70751.pdf.

60. Complaint, SEC v. Tyco Int'l Ltd., No. 12-cv-01583, at 11–12 (D.D.C. Sept. 24, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-196.pdf; Complaint, SEC v. Johnson & Johnson, No. 11-cv-00686, at 12 (D.D.C. Apr. 8, 2011), *available at* www.sec.gov/litigation/complaints/2011/comp21922.pdf.

61. Complaint, SEC v. Eli Lilly and Co., No. 12-cv-02045, at 8 (D.D.C. Dec. 20, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-273.pdf.
62. *Id.* at 7.
63. *Id.*
64. *Id.*
65. *Id.*
66. *Id.*
67. Complaint, SEC v. Orthofix Int'l N.V., No. 4:12-cr-150, at 4 (E.D. Tex. July 10, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-133.pdf; *see also* Deferred Prosecution Agreement between the U.S. Dep't of Justice, Criminal Div., Fraud Section and Johnson & Johnson, at 25 (Jan. 14, 2011), *available at* www.justice.gov/criminal/fraud/fcpa/cases/depuy-inc/04-08-11depuy-dpa.pdf.
68. Complaint, SEC v. Orthofix Int'l N.V., No. 12-cr-150, at 4.
69. Complaint, SEC v. Pfizer, Inc., No. 12-cv-01303, at 7 (D.D.C. Aug. 7, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-152-pfizer.pdf.
70. Non-Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Micrus Corp. and Micrus S.A., app. A at 3 (Feb. 28, 2005), *available at* www.justice.gov/criminal/fraud/fcpa/cases/micrus-corp/02-28-05micrus-agree.pdf.
71. Information, United States v. Pfizer H.C.P. Corp., No. 12-cr-00169, at 7–8 (D.D.C. Aug. 7, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/pfizer/2012-08-07-pfizer-info.pdf.
72. *See* Information, United States v. Biomet, Inc., No. 12-cr-00080, at 13 (D.D.C. Mar. 26, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/biomet/2012-03-26-biomet-information.pdf.
73. *See* Deferred Prosecution Agreement, United States v. DePuy, Inc., No. 11-cr-00099, at 23 (D.D.C. Apr. 8, 2011), *available at* www.justice.gov/criminal/fraud/fcpa/cases/depuy-inc/04-08-11depuy-dpa.pdf.
74. *See* Deferred Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Biomet, Inc., at 20 (Mar. 26, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/biomet/2012-03-26-biomet-dpa.pdf.
75. Deferred Prosecution Agreement between the U.S. Dep't of Justice, Criminal Div., Fraud Section and Johnson & Johnson, at 22–24 (Jan. 14, 2011), *available at* www.justice.gov/criminal/fraud/fcpa/cases/depuy-inc/04-08-11depuy-dpa.pdf.
76. Deferred Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Pfizer H.C.P. Corp., (Aug. 7, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/pfizer/2012-08-07-pfizer-dpa.pdf.
77. Non-Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Mircus Corp. and Micrus S.A., app. A at 2, 4 (Feb. 28, 2005), *available at* www.justice.gov/criminal/fraud/fcpa/cases/micrus-corp/02-28-05micrus-agree.pdf.
78. *Id.* at 2.
79. Complaint, SEC v. Eli Lilly and Co., No. 12-cv-02045, at 1–2 (D.D.C. Dec. 20, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-273.pdf; *see also* Complaint, SEC v. Schering-Plough Corp., No. 04-cv-945, at 3–4 (D.D.C. June 9, 2004), *available at* www.sec.gov/litigation/complaints/compl18740.pdf.

80. Complaint, SEC v. Eli Lilly and Co., No. 12-cv-02045, at 4.

81. *See* FCPA GUIDE, *supra* note 12, at 86–87 (explaining the opinion procedure release process).

82. *See* U.S. Dep't of Justice, FCPA Op. Release 09-01 (Aug. 3, 2009), *available at* www.justice.gov/criminal/fraud/fcpa/opinion/2009/0901.pdf.

83. *See id.*

84. *See* SEC, *In re* Stryker Corp., Order Instituting Cease-and-Desist Proceedings, Cease and Desist Order (Oct. 24, 2013), *available at* www.sec.gov/litigation/admin/2013/34-70751.pdf; Deferred Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Biomet, Inc., at 6–7 (Mar. 26, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/biomet/2012-03-26-biomet-dpa.pdf; Complaint, SEC v. Tyco Int'l Ltd., No. 12-cv-01583 (D.D.C. Sept. 24, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-196.pdf; Information, United States v. DePuy, Inc., No. 11-cr-099 (D.D.C. Apr. 6, 2011), *available at* www.justice.gov/criminal/fraud/fcpa/cases/depuy-inc/04-08-11depuy-info.pdf.

85. The Department of Justice has broadly interpreted the knowledge requirement of the FCPA and the obligations it imposes. *See* FCPA GUIDE, *supra* note 12, at 14.

86. *See* 15 U.S.C. §§ 78dd-l(f)(2), 78dd-2(h)(3), 78dd-3(f)(3); H.R. CONF. REP. NO. 100-576, at 916, 919–21, *reprinted in* 1988 U.S.C.C.A.N. (102 Stat. 1415) 1949 (explaining that the FCPA does not excuse the "head-in-the-sand" approach and management cannot "take refuge from the Act's prohibitions by their unwarranted obliviousness to any action (or inaction), language or other 'signaling device' that should reasonably alert them of the 'high probability' of an FCPA violation").

87. Complaint, SEC v. Eli Lilly and Co., No. 12-cv-02045, at 2 (D.D.C. Dec. 20, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-273.pdf.

88. Complaint, SEC v. Orthofix Int'l N.V., No. 12-cr-150, at 4 (E.D. Tex. July 10, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-133.pdf.

89. 15 U.S.C. § 78(m)(b)(2).

90. 15 U.S.C. § 78(m)(b)(6).

91. Complaint, SEC v. Nature's Sunshine Prods., Inc., No. 09-cv-0672, at 2 (C.D. Utah July 31, 2009), *available at* www.sec.gov/litigation/complaints/2009/comp21162.pdf.

92. SEC, *In re* Immucor, Inc., Order Instituting Cease-and-Desist Proceedings, Cease and Desist Order, at 2 (Sept. 27, 2007), *available at* www.sec.gov/litigation/admin/2007/34-56558.pdf.

93. *Id.* at 2–3.

94. Information, United States v. Pfizer H.C.P. Corp., No. 12-cr-00169, at 8 (D.D.C. Aug. 7, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/pfizer/2012-08-07-pfizer-info.pdf.

95. Complaint, SEC v. Siemens Aktiengesellschaft, No. 08-cv-02167 (D.D.C. Dec. 18, 2008), *available at* www.sec.gov/litigation/complaints/2008/comp20829.pdf.

96. *See* Information, United States v. Biomet, Inc., No. 12-cr-00080 (D.D.C. Mar. 26, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/biomet/2012-03-26-biomet-information.pdf; Complaint, SEC v. Johnson & Johnson, No. 11-cv-00686, at 12 (D.D.C. Apr. 8, 2011), *available at* www.sec.gov/litigation/complaints/2011/comp21922.pdf; Information, United States v. Smith & Nephew, Inc., No. 12-cr-00030 (D.D.C. Sept. 24, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/smith-nephew/2012-02-06-s-n-information.pdf.

97. Complaint, SEC v. Smith & Nephew plc, No. 12-cv-00187 (D.D.C. Feb. 6, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp22252.pdf; Deferred Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Smith & Nephew, Inc. (Feb. 1, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/smith-nephew/2012-02-01-s-n-dpa.pdf.

98. Complaint, SEC v. Smith & Nephew plc, No. 12-cv-00187, at 3–7 (D.D.C. Feb. 6, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp22252.pdf.

99. *Id.* at 4.

100. Complaint, SEC v. Eli Lilly and Co., No. 12-cv-02045, at 9 (D.D.C. Dec. 20, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-273.pdf.

101. Complaint, SEC v. Pfizer, Inc., No. 12-cv-01303, at 12–13 (D.D.C. Aug. 7, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-152-pfizer.pdf.

102. Information, United States v. AGA Med. Corp., No. 08-cr-172, at 5 (D. Minn. June 3, 2008), *available at* www.justice.gov/criminal/fraud/fcpa/cases/agamed corp/06-03-08aga-info.pdf.

103. *Id.* at 7.

104. Complaint, SEC v. Pfizer, Inc., No. 12-cv-01303, at 13–19.

105. Deferred Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Johnson & Johnson, at 17 (Jan. 14, 2011), *available at* www.justice.gov/criminal/fraud/fcpa/cases/depuy-inc/04-08-11depuy-dpa.pdf.

106. *Id.*

107. Complaint, SEC v. Wyeth, LLC, No. 12-cv-01304, at 5 (D.D.C. Aug. 7, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-152-wyeth.pdf.

108. *Id.* at 6–8.

109. David Barboza, *Glaxo Used Travel Firms for Bribery, China Says*, N.Y. TIMES, July 15, 2013, *available at* http://mobile.nytimes.com/2013/07/16/business/global/glaxo-used-travel-firms-in-bribery-china-says.html.

110. Information, United States v. Carman, No. 04-J-0093-S, at 3 (N.D. Ala. Mar. 2, 2004), *available at* www.justice.gov/criminal/fraud/fcpa/cases/carman/03-02-04carman-info.pdf.

111. *Rectifications Needed, Not Excuses*, CHINA DAILY, July 4, 2014, *available at* www.chinadaily.com.cn/opinion/2014-07/04/content_17646638.htm.

112. *See* 15 U.S.C. §§ 78dd-1(f)(1), 78dd-2(h)(2), 78dd-3(f)(2).

113. *See, e.g.*, Complaint, SEC v. Johnson & Johnson, No. 11-cv-00686 (D.D.C. Apr. 8, 2011), *available at* www.sec.gov/litigation/complaints/2011/comp21922.pdf.

114. While interactions with HCPs employed by or affiliated with private institutes may be outside of the FCPA's scope, other U.S. laws may be used to target improper interactions with private-sector HCPs. U.S. enforcement authorities increasingly are using the Travel Act, for example, as a way to prosecute international commercial bribery. *See* 18 U.S.C. § 1952. In essence, the Travel Act allows prosecutors to extend the reach of a given state's commercial bribery statute beyond U.S. borders. *See supra* Question 13.10.

115. Breuer Keynote Address, *supra* note 3, at 2.

116. *See, e.g.*, Information, United States v. Biomet, Inc., No. 12-cr-00080, at 13 (D.D.C. Mar. 26, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/biomet/2012-03-26-biomet-information.pdf; Deferred Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Johnson & Johnson (Jan. 14, 2011), *available at* www.justice.gov/criminal/fraud/fcpa/cases/depuy-inc/04-08-11depuy-dpa.pdf; Deferred Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Smith & Nephew, Inc., at 6–7 (Feb. 1, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/smith-nephew/2012-02-01-s-n-dpa.pdf.

117. Breuer Keynote Address, *supra* note 3.

118. *See* Plea Agreement for DPC (Tianjin) Co. Ltd., United States v. DPC (Tianjin) Co. Ltd., No. 05-CR-482 (C.D. Cal. May 20, 2005), *available at* www.justice.gov/criminal/fraud/fcpa/cases/dpc-tianjin/05-19-05dpc-tianjin-plea-agree.pdf; SEC, *In re* Diagnostic Prods. Corp., Order Instituting Cease-and-Desist Proceedings (May 20, 2005), *available at* www.sec.gov/litigation/admin/34-51724.pdf.

119. *See, e.g.*, Complaint, SEC v. Pfizer, Inc., No. 12-cv-01303 (D.D.C. Aug. 7, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-152-pfizer.pdf.

120. SEC, *In re* Koninklijke Philips Elecs. N.V., Order Instituting Cease-and-Desist Proceedings, Cease and Desist Order (Apr. 5, 2013), *available at* www.sec.gov/litigation/admin/2013/34-69327.pdf.

121. Information, United States v. Pfizer H.C.P. Corp., No. 12-cr-00169, at 20 (D.D.C. Aug. 7, 2012), *available at* hwww.justice.gov/criminal/fraud/fcpa/cases/pfizer/2012-08-07-pfizer-info.pdf.

122. H.R. REP. NO. 95-640, at 7, *reprinted in* 1977 U.S.C.C.A.N. 4120.

123. *See* United States v. Kay, 513 F.3d 432, 447–48 (5th Cir. 2007).

124. *See, e.g.*, Complaint, SEC v. Siemens Aktiengesellschaft, No. 08-cv-2167 (D.D.C. Dec. 12, 2008), *available at* hwww.sec.gov/litigation/complaints/2008/comp20829.pdf.

125. *See id.* at 21.

126. FCPA GUIDE, *supra* note 12, at 13.

127. 15 U.S.C. § 78m(b)(2)(A).

128. Complaint, SEC v. Nature's Sunshine Prods., Inc., No. 09-cv-0672, at 4 (C.D. Utah July 31, 2009), *available at* www.sec.gov/litigation/complaints/2009/comp21162.pdf.

129. Information, United States v. Orthofix Int'l, N.V., No. 12-cr-150, at 8 (E.D. Tex. July 10, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/orthofix/2012-07-10-orthofix-info.pdf.

130. Complaint, SEC v. Pfizer, Inc., No. 12-cv-01303, at 2 (D.D.C. Aug. 7, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-152-pfizer.pdf.

131. *Id.* at 5.

132. Complaint, SEC v. Wyeth, LLC, No. 12-cv-01304, at 5 (D.D.C. Aug. 7, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-152-wyeth.pdf.

133. Complaint, SEC v. Orthofix Int'l N.V., No. 12-cr-150, at 3–4.

134. Complaint, SEC v. Nature's Sunshine Prods., Inc., No. 09-cv-0672, at 5 (C.D. Utah July 31, 2009), *available at* www.sec.gov/litigation/complaints/2009/comp21162.pdf.

135. 15 U.S.C. § 78m(b)(2)(B).

136. FCPA GUIDE, *supra* note 12, at 40.

137. *Id.* at 28.

138. *Id.*

139. *Id.*

140. *Id.* at 11.

141. *E.g.*, Lippe v. Bairnco Corp., 99 F. App'x 274, 283–84 (2d Cir. 2004).

142. FCPA GUIDE, *supra* note 12, at 29.

143. Press Release, Cardinal Health Inc., Cardinal Health Responds to Syncor Announcement (Nov. 6, 2002), *available at* www.thefreelibrary.com/Cardinal+Health+Responds+to+Syncor+Announcement.-a0132315049.

144. *See* Plea Agreement, United States v. Syncor Taiwan, Inc., No. 02-cr-1244 (C.D. Cal. Dec. 3, 2002), *available at* www.justice.gov/criminal/fraud/fcpa/cases/syncor-taiwan/12-03-02syncor-taiwan-plea-agree.pdf.

145. Complaint, SEC v. Wyeth, LLC, No. 12-cv-01304, at 3 (D.D.C. Aug. 7, 2012), *available at* www.sec.gov/litigation/complaints/2012/comp-pr2012-152-wyeth.pdf.

146. Nick Huber, *Smith & Nephew Finds Suspect Sales Tactics at Plus Unit*, GUARDIAN (May 1, 2008), *available at* www.theguardian.com/business/2008/may/02/smithandnephew.pharmaceuticals#.

147. Smith & Nephew, Inc., 2009 Annual Report, at 5, *available at* www.smith-nephew.com/global/assets/pdf/corporate/annualreport2009.pdf.

148. FCPA GUIDE, *supra* note 12, at 56.

149. *Id.; see also* SEC, Report of Investigation Pursuant to Section 21(A) of the Securities Exchange Act of 1934 and Commission Statement on the Relationship of Cooperation to Agency Enforcement Decisions, SEC Release Nos. 34-44969 and AAER-1470 (Oct. 23, 2001), *available at* www.sec.gov/litigation/investreport/34-44969.htm; U.S. Dep't of Justice, U.S. Attorneys' Manual § 9-27.000 (2008), *available at* www.justice.gov/usao/eousa/foia_reading_room/usam; U.S. Sentencing Comm., U.S. Sentencing Guidelines § 8B2.1(b)(7) (2011), *available at* www.ussc.gov/guidelines-manual/guidelines-manual.

150. FCPA GUIDE, *supra* note 12, at 56.

151. *Id.*

152. *See* Deferred Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Orthofix Int'l, at Attachment C, "Corporate Compliance Program" (July 10, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/orthofix/2012-07-10-orthofix-dpa.pdf; Deferred Prosecution Agreement

between U.S. Dep't of Justice, Criminal Div., Fraud Section and Biomet, Inc., at Attachment C, "Corporate Compliance Program" (Mar. 26, 2010), *available at* www.justice.gov/criminal/fraud/fcpa/cases/biomet/2012-03-26-biomet-dpa.pdf.

153. *Id.*

154. *See, e.g.*, Deferred Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Johnson & Johnson, at Attachment C, "Corporate Compliance Program" (Jan. 14, 2011), *available at* www.justice.gov/criminal/fraud/fcpa/cases/depuy-inc/04-08-11depuy-dpa.pdf; Deferred Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Pfizer H.C.P. Corp., at Attachment C.1, "Corporate Compliance Program" (Aug. 7, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/pfizer/2012-08-07-pfizer-dpa.pdf; Deferred Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Orthofix Int'l, at Attachment C, "Corporate Compliance Program"; Deferred Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Biomet, Inc., at Attachment C, "Corporate Compliance Program" (Mar. 26, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/biomet/2012-03-26-biomet-dpa.pdf; *see also* FCPA GUIDE, *supra* note 12, at 56–65.

155. *See* FCPA GUIDE, *supra* note 12, at 62; *see also* Deferred Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Johnson & Johnson, at Attachment D, "Enhanced Compliance Obligations"; *see also* Deferred Prosecution Agreement, United States v. Orthofix Int'l, N.V., at Attachment C, "Corporate Compliance Program," (E.D. Tex. July 10, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/orthofix/2012-07-10-orthofix-dpa.pdf.

156. *See, e.g.*, Information, United States v. Orthofix Int'l, N.V., No. 12-cr-150, at 8 (July 10, 2012), *available at* www.justice.gov/criminal/fraud/fcpa/cases/orthofix/2012-07-10-orthofix-info.pdf.

157. Deferred Prosecution Agreement between U.S. Dep't of Justice, Criminal Div., Fraud Section and Johnson & Johnson, at Attachment D, "Enhanced Compliance Obligations."

158. *See, e.g.*, Working Group on Bribery, OECD, Good Practice Guidance on Internal Controls, Ethics, and Compliance 2010, *available at* www.oecd.org/investment/anti-bribery/anti-briberyconvention/44884389.pdf; Int'l Chamber of Commerce, ICC Rules on Combating Corruption (2011), *available at* www.iccwbo.org/advocacy-codes-and-rules/document-centre/2011/icc-rules-on-combating-corruption/; World Bank Group, Integrity Compliance Guidelines (2011), *available at* http://siteresources.worldbank.org/INTDOII/Resources/Integ-rity_Compliance_Guidelines.pdf.

159. United Kingdom Ministry of Justice, The Bribery Act of 2010, Guidance About Procedures Which Relevant Commercial Organisations Can Put Into Place to Prevent Persons Associated With Them From Bribing (2010), *available at* www.gov.uk/government/uploads/system/uploads/attachment_data/file/181762/bribery-act-2010-guidance.pdf.

160. *See, e.g.*, IFPMA Code of Pharmaceutical Marketing Practices, *available at* www.ifpma.org/fileadmin/content/Publication/2012/IFPMA_Code_of_Practice_2012_new_logo.pdf; PhRMA Code on Interactions with Health Care Professionals, *available at* www. phrma.org/principles-guidelines/code-on-interactions-with-health-care-professionals.

161. IFPMA Code Compliance Network (CCN) Global Code Comparison, *available at* www.ifpma.org/fileadmin/content/Ethics/IFPMA_Code_of_Practice/ifpma_global_code_051113_final.pdf.

162. *Id.*

163. *See* FCPA GUIDE, *supra* note 12, at 22.

164. *See, e.g., id.* at 22–23.