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The Foreign Corrupt Practices Act: The Sleeping Giant

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The Foreign Corrupt Practices Act (FCPA) is a U.S. anti-corruption law, jointly enforced by the Department of Justice (DOJ) and the Securities and Exchange Commission (SEC), that imposes criminal and civil penalties upon companies that make corrupt payments to foreign officials. The FCPA makes it a crime to pay, offer, or give anything of value to a foreign official, a foreign political party, or a candidate for foreign office for the purpose of obtaining or retaining business, or obtaining favorable or preferential treatment from the government.¹ Companies may not offer money or anything of value to a third party while knowing that some or all of the payment will be passed on to a foreign official for an improper purpose. Further, U.S. parent corporations may be held liable for the acts of foreign subsidiaries where they authorize, direct, or control the activity in question.

The prohibition on bribery is only the first component of the FCPA, and is usually prosecuted by the DOJ. The second component of FCPA is primarily enforced by the SEC, and requires that companies maintain accurate books and records of business transactions made in foreign countries. Where bribery payments are not recorded in company records or are disguised as legitimate expenses, two violations have simultaneously occurred: one for the bribe itself, and one for the inaccurate accounting. Consequently, bribery and records violations typically go hand-in-hand.

¹ 15 U.S.C. § 78-1 to -3.

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The FCPA applies to (a) U.S. companies, citizens, nationals and residents, as well as anyone located in the U.S., even temporarily, and (b) foreign-based “issuers” subject to U.S. securities law. In addition, the 1998 FCPA amendments provide jurisdiction over foreign companies and nationals. A foreign company is now subject to FCPA sanctions if it causes, directly or through agents, an act in furtherance of the corrupt payment to take place within the territory of the United States, including calling or sending e-mails to the United States.

Medical device companies who operate overseas are particularly vulnerable to FCPA violations since the term “foreign official” has been interpreted to include employees of government-owned health care entities (common in foreign countries), representatives of international entities such as the World Health Organization, and many European Union healthcare oversight bodies. With a growing demand for medical devices worldwide, many U.S. based companies manufacture and distribute their products in dozens of countries. Such international marketing requires recognition of potential FCPA risks and clear, effective procedures to monitor for and deal with FCPA violations.

INCREASED FCPA ENFORCEMENT IN THE MEDICAL DEVICE INDUSTRY

The risk of FCPA enforcement against medical device companies has increased significantly in the past two years. The DOJ and SEC periodically develop FCPA enforcement priorities, taking aim at certain industries. Previous enforcement targets have included the telecommunications, oil and pharmaceutical industries. These types of businesses operate in an environment that predisposes them to violations of the FCPA, because of entrenched business customs and/or intense governmental regulation. The medical devices industry

has similar characteristics; not surprisingly, the DOJ and SEC are currently setting their sights on the medical device industry. Within the past two months, five major orthopedic-product companies—Stryker, Zimmer, Biomet, Smith & Nephew, and Medtronic—have announced that they are under investigation for alleged violations of the FCPA (1 MELR 463, 10/24/07).

Focused FCPA enforcement in the medical device industry was set in motion in February 2007, when Johnson & Johnson voluntarily disclosed potential FCPA violations to the DOJ and the SEC. The company disclosed that its foreign subsidiaries may have made improper payments related to medical device sales in two small-market countries. Remember, an improper payment is any payment with the purpose of obtaining or retaining business, or obtaining favorable or preferential treatment from the government. As part of a carefully calibrated response to illustrate Johnson & Johnson's commitment to compliance and their cooperation with the SEC and DOJ investigations, they issued a public statement announcing the disclosure to the DOJ and SEC, stating that any improper payments violated Johnson & Johnson company policies. Further, Michael J. Dormer, Johnson & Johnson's Worldwide Chairman of Medical Devices & Diagnostics, stepped down, publicly asserting that he bore ultimate responsibility for any offending payments.

Johnson & Johnson's disclosure likely provided the impetus for an investigation into possible bribery issues with other large United States orthopedic device makers. However, rather than looking immediately to FCPA issues, the DOJ focused on more familiar territory—domestic bribery. The medical device companies Zimmer, DePuy (Johnson & Johnson subsidiary), Biomet, Smith & Nephew, and Stryker were investigated for violations of the federal Anti-Kickback statute relating to financial inducements paid to physicians. That statute prohibits the knowing or willful payment, solicitation or receipt of remuneration in order to induce business reimbursable under federal or state health care programs. The companies' illegal payments also impli-

cated the False Claims Act, which creates liability for knowingly presenting a false or fraudulent claim for payment or approval to the federal government.

In September 2007, four of the companies executed deferred prosecution agreements to avoid criminal prosecution. The fifth company, Stryker, negotiated a non-prosecution agreement in exchange for their early and voluntary cooperation with the DOJ investigation. These five companies, which collectively represent about 95 percent of the hip and knee surgical implants market, allegedly used lucrative consulting agreements with surgeons in return for the use of their products (1 MELR 436, 10/10/07).

As part of the deferred prosecution agreements, the four companies paid a combined \$311 million civil fine to the DOJ, Department of Health and Human Services and the Office of the Inspector General. Each company also entered into a five-year corporate integrity agreement. Those agreements require reforms and monitoring aimed at compliance as well as an appointed federal monitor to review ongoing compliance efforts. Notably, some very high-profile persons were assigned as federal monitors. Zimmer, who paid the largest share of the civil fine (\$169.5 million) will be monitored by former United States Attorney General John Ashcroft. Despite the massive fines, resolution of the domestic bribery offenses was not the end of the road; rather, it simply provided momentum for an investigation into foreign bribery offenses.

Less than two weeks after the settlements with Zimmer, Smith & Nephew, Biomet, Stryker, and DePuy, the SEC informed Zimmer, Smith & Nephew, Biomet, Stryker, and Medtronic of an informal investigation into possible violations of the FCPA.

RELATIONSHIP BETWEEN THE ANTI-KICKBACK STATUTE AND THE FCPA

In recent enforcement actions, the similarities between the Anti-Kickback law and the FCPA provided an easy transition from a domestic bribery enforcement action to an FCPA investigation.

Table 1: Comparison of Two Laws

	Anti-Kickback Statute	Foreign Corrupt Practices Act
Prohibited Act	Offer, pay, solicit or receive	Pay, offer, promise to pay or authorize payment
Applies To	Individuals and entities	U.S. companies, citizens, nationals and residents; people permanently or temporarily located in the U.S.; foreign-based "issuers" under U.S. securities law
Knowledge Requirement	"knowingly and willfully"	"with corrupt intent"
Object of Fraud	Businesses for which payment may be made under a federal health care program	Foreign officials (including government owned/employed hospital administrators and doctors), foreign political party or party official or candidate for political office; any person, knowing it will be passed on to those described above
Type of Payment	Remuneration	Anything of value
Purpose of Payment	To induce business (referrals, purchasing, leasing, ordering or arranging for any good, facility, service or item)	Obtaining or retaining business, obtaining favorable or preferable treatment from a government
Manner of Payment	Directly, indirectly, overtly, covertly	Any

Table 1: Comparison of Two Laws

	Anti-Kickback Statute	Foreign Corrupt Practices Act
Exceptions	Safe Harbors	Facilitating payments, payments permissible under local law, reasonable and bona fide expenses
Penalty	Civil and criminal	Civil and criminal
Maximum Penalty	For each offense: Fine up to \$25,000, prison up to five years, exclusion from government health programs	Fine up to \$2,000,000 or twice the benefit obtained by the corrupt payment, exclusion from conducting any business with the federal government (There are a variety of penalty options under the FCPA: there are separate criteria for the civil, criminal and exclusion penalties, and maximums also differ depending on whether the violator is a natural person or a corporation and whether the violator is a domestic concern, issuer, or other person covered by the FCPA)
Attempt		Constitutes a crime

For medical device companies, the similarities between the laws also provide a simplified path to a comprehensive compliance program.

Medical device companies familiar with the Anti-Kickback law will have a good base of knowledge from which to build an effective FCPA compliance program. Many medical device companies already have policies in place for Anti-Kickback law compliance. There is a significant amount of overlap between the Anti-Kickback statute and the FCPA. Consequently, medical device companies can build on existing policy to achieve FCPA compliance rather than starting from scratch. However, companies must realize that compliance with Anti-Kickback laws does not automatically translate to FCPA compliance. There are a number of common practices in the medical device industry that are allowable under Anti-Kickback's safe harbors but are expressly prohibited by the FCPA. For example, many discount and purchase incentives fall under Anti-Kickback safe harbors that may not be allowable under the FCPA. Companies will want to be certain to cover these gaps and maintain a compliance plan that also appropriately addresses the FCPA.

AN ACTION PLAN FOR MEDICAL DEVICE COMPANIES

Medical device companies looking to attain FCPA compliance should undertake two main tasks: a comprehensive risk assessment and the development of a compliance plan. The risk of noncompliance should be assessed, so as to tailor the compliance plan to particular vulnerabilities. The compliance plan will provide a strategy for identifying and reporting any problems, dealing with issues that arise, and continuous improvement of the compliance plan itself. Outside of these two primary compliance activities, many medical device companies are finding it necessary to address the FCPA in their merger and acquisition activities. Understanding how the FCPA relates to transactions is crucial for medical device companies that are expanding internationally. Finally, medical device companies should take

immediate action to minimize civil and criminal penalties if an FCPA violation does occur.

Comprehensive Risk Assessment

The purpose of a risk assessment is to gather information that will help determine the areas within a company where noncompliance with the FCPA is most likely to occur. As with all components of FCPA compliance, the manner and scope of the risk assessment will vary depending on the nature of the medical device company's relationship with foreign officials. The best source of this information is often directly from employees with international responsibility and/or contact.

Medical device companies with international operations should pay particular attention to the relative perception of corruption in the countries where they do business. The nonprofit company Transparency International publishes a Corruption Perception Index of 180 countries, which ranks the degree to which corruption is perceived to exist among public officials and politicians.² A company that operates in a country like Somalia, Myanmar, Iraq or Haiti (the countries with the most perceived corruption) will require a much more extensive risk analysis and compliance plan than international operations in Denmark, Finland, New Zealand or Singapore (the countries with the least perceived corruption). Medical device companies with operations in the riskier countries may find that their agents in that country face repeated solicitation for bribes.

Most risk assessments should attempt to identify the following:

- Existing anti-bribery compliance functions (including Anti-Kickback policies)
- All international sales and dealings in high-risk countries
- All international dealings which involve government officials
- All employees who interact with foreign officials

² www.transparency.org

- All uses of third parties in international dealings

The answers to these questions, in combination with information collected from interviews and policy reviews, will shed light on the particular vulnerabilities faced by the business and inform the creation of a tailored compliance plan.

Compliance Plan

The next step in building institutional FCPA compliance is the development of a tailored compliance plan. Compliance plans not only help prevent FCPA violations, but also provide evidence of a company's commitment to good business ethics and compliant practices. These latter benefits can help a company reduce penalties it may ultimately face for violations. The SEC recognizes the existence of a compliance plan as a factor in the decision to even press charges for FCPA violations and, under the Federal Sentencing Guidelines, an organization that had an effective compliance and ethics program in place at the time of the crime is entitled to a three point reduction in its sentencing calculation.³

The first decision to make regarding the creation and implementation of a compliance plan is how it will fit within the company's overall organization. As with any important initiative, executive buy-in and integration into the corporate structure is key to the success of the compliance program. Three common models for adding an FCPA compliance function are: 1) adding FCPA compliance duties to an existing legal department; 2) adding FCPA to an existing or newly created internal audit or compliance department; or 3) creating an FCPA compliance officer, who reports to the Board's audit committee.

Second, the company must determine the appropriate provisions for its written compliance policies. These policies should synch with the company's existing policies— especially those relevant to Anti-Kickback. The policies should also consider the anti-corruption laws in the countries where the company does business.⁴ The compliance plan should be practically oriented. It should be written in clear, simple language, and organized in a useful manner.

An FCPA compliance plan should include the following:

- **Describe the FCPA** - Outline exactly what behaviors are prohibited by the FCPA, for both the bribery and recordkeeping components.
- **Outline of Situations in Which FCPA Issues are Likely to Arise** - For medical device companies, it is often relevant to identify which healthcare customers are government owned and which countries have state-run health systems.
- **Process for Identifying "Red Flags"** - Ongoing monitoring system for detection of unusual payments or other accounting irregularities. Internal auditors should receive sufficient training to recognize FCPA violations.

³ See Federal Sentencing Guidelines, Section 8C2.5(f).

⁴ For example, the UN Convention Against Corruption, adopted by the United Nations General Assembly on 31 October 2003 (Resolution 58/4), now has over 100 signatories. In addition, the European Union, Australia, Brazil, Canada, Japan and Mexico are among the signatories to the Organisation for Economic Co-operation and Development (OECD) Convention on Combating Bribery of Foreign Public Officials in International Business Transactions.

- **Procedure for Dealings with Foreign Partners / Affiliates** - Companies are liable for payments to foreign officials that are made by agents on behalf of the company. Precautions should be taken when engaging such agents. A checklist approach is often helpful, and may include: due diligence procedures, obtaining opinion of counsel, and incorporating standard FCPA provisions in all such contracts.

- **Procedure for Dealings with Foreign Officials** - Describe the type of payments that *are* permissible under the FCPA, the extent to which the company permits them, and which individuals are authorized to make them. There are two primary exceptions to the FCPA: (1) the use of small payments that are used to expedite or secure routine government action, and (2) certain bona fide expenses for travel, entertainment, and gifts. Oversight and specific recording procedures for all situations in which these payments are made is necessary.

- **Procedure for Mergers & Acquisitions** - FCPA due diligence is an important part of FCPA compliance; see below for details.

- **Mechanism for Obtaining Legal Advice** - Explains where employees can get legal guidance on FCPA compliance questions. Provide access to an attorney that is well-versed in both the company's policies and in FCPA provisions, such as an in-house attorney. Medical device companies with significant international operations should provide a list of local counsel in each country in which they do business.

- **Mechanism for Reporting Possible Violations** - Means for employees to anonymously report possible FCPA violations.

- **Investigating Possible Violations** - Conduct and oversee any internal FCPA investigations.

- **Procedure for Discipline** - One way to ensure a message of commitment to compliance is to outline consequences for FCPA violations, and make certain that they are carried out.

- **Procedure for Communicating Compliance Program** - All potentially affected employees and agents must be educated on the principles of the FCPA compliance plan.

- **Regular Review of Compliance Program** - In order to maintain effectiveness, a company's compliance program must be reviewed on a regular basis.

Even medical device companies that have instituted tailored compliance plans sometimes overlook situations where the FCPA is relevant. Few companies properly appreciate the role of the FCPA in corporate transactions. In fact, including FCPA compliance in due diligence checks can prove vital to the success of a business deal.

FCPA Due Diligence

Global mergers and acquisitions are becoming increasingly common for medical device manufacturers and distributors. This has significant FCPA implications. Companies that overlook FCPA issues during due diligence could end up buying an enforcement action. The concept of "successor liability" means that purchasing companies become responsible for the existing legal problems of the target company.

Also, violations discovered during due diligence can pose deal-breaking problems. During the attempted

\$2.2 billion acquisition of Titan Corporation by Lockheed Martin in 2004, FCPA issues were uncovered in due diligence. Titan failed to resolve the issue promptly, ultimately causing Lockheed Martin to bow out of the deal, rather than inherit the liability associated with pending FCPA violations.

There are two options for companies looking to evaluate FCPA compliance in due diligence. First, a medical device company can engage outside counsel that has expertise in the FCPA area. This is often essential for particularly risky or fast-moving transactions. Alternately, a thorough due diligence checklist may provide enough checks to evaluate the FCPA risk of the transaction. The level of inquiry will vary considerably based on the scope and nature of the companies' international operations. Still, some general requirements are true for most transactions:

- Check for any previous or pending FCPA enforcement actions
- Review books and records for unusual payments
- Review internal controls regarding bribery (policies, training, audit, whistleblowers)
- Evaluate checks on third party agents, consultants, logistics and shipping companies, distributors, joint ventures, distribution partners
- Review government sales and risk of improper payments
- Review past practices associated with travel, gifts, entertainment, education expenses.

If the target company is not a U.S. registrant or foreign private issuer, it is unlikely that they were previously subject to FCPA provisions. Consequently, the due diligence should focus on whether the company is currently in compliance with its own country's anti-corruption laws, and whether it is feasible to bring it in compliance with FCPA post-acquisition. The parties should consider if compliance with FCPA will require changes to a company's business practices or business model, and if so, whether there would be a consequent loss of profitability.

FCPA due diligence is important not only for the acquiring company, but for the target as well. Target companies should always conduct an internal FCPA due diligence check before making any warranties or representations as to FCPA compliance. Should a violation

occur, it would likely constitute a material adverse event. Consequently, the acquiring company is released from the agreement and the deal is abandoned.

Finally, it is important to remember that the FCPA due diligence process should continue even after closing the deal. Post-closing due diligence can help an acquiring company avoid successor liability and demonstrate their commitment to compliance. Companies should ensure that there is a post-closing compliance policy that addresses the FCPA and local anti-corruption laws. Although FCPA due diligence is an intensive process, there tends to be a net benefit to the company. Companies that conduct FCPA due diligence often end up with strengthened compliance programs and much lower risk of FCPA violations going forward.

MINIMIZING THE IMPACT OF AN FCPA VIOLATION

Even a medical device company with a robust compliance program may encounter an FCPA violation. The response to the FCPA violation can make all the difference in its ultimate resolution. Recent cases indicate the DOJ and SEC's preference for self-disclosure and full cooperation.

A pre-existing compliance program and ethics policy will often serve to minimize the effects of an FCPA investigation. Recall, the SEC recognizes the existence of a compliance plan as a factor in the decision to even press charges for FCPA violations and, under the Federal Sentencing Guidelines, an organization that had an effective compliance and ethics program in place at the time of the crime is entitled to a three point reduction in its sentencing calculation.⁵ Experience has shown that careful attention to FCPA compliance now can significantly minimize civil and criminal penalties in the event of a violation.

Medical device companies facing enforcement actions should also make certain to take immediate and decisive action on any lapse in policy or procedure that caused the violation, and on any employee that contributed to or was responsible for the violation. These actions will illustrate dedication to compliant behavior, and, combined with a comprehensive risk assessment and tailored compliance plan, may minimize any civil penalties and prevent criminal charges.

⁵ See Federal Sentencing Guidelines, Section 8C2.5(f).