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Commentary

THE FCPA AND THE HEALTH CARE SECTOR: ENTERING AN ERA OF HEIGHTENED AND UNPRECEDENTED ENFORCEMENT

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Stuart M. Gerson and Dale C. Van Demark of Epstein, Becker & Green take a close look at how the federal government is moving to apply the Foreign Corrupt Practices Act to pharmaceutical and medical device firms involved in global commerce.

Throwing down the gauntlet to health care providers, and most significantly, their executives who increasingly are doing business overseas, Acting Deputy Attorney General Gary G. Grindler recently told the National Institute on Healthcare Fraud that: “In some foreign countries, nearly every aspect of the approval, manufacture, import, export, pricing, sale and marketing of a drug product may involve a ‘foreign official’ within the meaning of the Foreign Corrupt Practices Act. ... [The Department of Justice] will not hesitate to charge [health care] companies and their senior executives under the FCPA if warranted to root out foreign bribery in the industry.” [\[FN1\]](#)

Grindler's words reiterate what has become increasingly obvious to those members of the health sector who have been tracking the Department of Justice and Securities and Exchange Commission's movements over the last half decade. The government has brought more actions under the FCPA in the last five years than in the previous 28 years of the act's existence.

Last year, for the fifth year in a row, the number of FCPA-enforcement actions brought by the DOJ and SEC increased and the trend of increased enforcement shows no signs of letting up. These agencies have taken a broad and expansive reading of the operative terms in the FCPA and both continue to expand their enforcement theories, resulting in new prosecutions of both companies and individuals.

An overview of the FCPA

In 1977, Congress enacted the FCPA [\[FN2\]](#) as an amendment to the Securities Exchange Act of 1934 [\[FN3\]](#) in response to a series of international and domestic bribery scandals; its purpose was to eliminate the practice of bribery as a way of obtaining and retaining foreign business. Since the FCPA's passage, it has been amended several times.

In 1988, the act was amended to include an exception and several affirmative defenses. [\[FN4\]](#) Ten years later, in an attempt to remove the competitive advantage held by international competitors not subject to the

anti-bribery laws of the United States, Congress expanded the jurisdiction of the federal government to prosecute foreign companies and nationals under the act. [FN5]

The FCPA contains two types of provisions: anti-bribery provisions, [FN6] which prohibit corrupt payments to foreign officials for the purposes of obtaining or retaining business or securing any improper advantage; and accounting provisions, [FN7] which require companies whose securities are listed in the U.S. to maintain accurate books and records and an effective system of internal controls.

The Justice Department is primarily responsible for enforcing the FCPA's anti-bribery provisions, and the SEC is primarily responsible for enforcing the accounting provisions.

Under the anti-bribery provisions, it is unlawful for a U.S. person, U.S. company or any other person in the U.S., with corrupt intent, to offer, pay, promise to pay or authorize payment of, directly or indirectly, anything of value to a foreign official, foreign political party, any candidate for foreign political office, or any other person while knowing that all or a portion of the payment will be offered, given or promised, directly or indirectly, to a "covered person" for the purpose of influencing any official act or decision, inducing any act or omission in violation of a lawful official duty, or securing an improper advantage in order to assist in obtaining, retaining or directing business to any person.

The FCPA anti-bribery provisions focus on the purpose of the payment instead of the particular duties of the foreign official receiving the payment. As a result, "foreign official" is interpreted broadly by Justice Department and SEC and in the health care sector can include doctors, nurses, technicians and pharmacists employed by state-controlled entities.

The FCPA's accounting provisions apply to any issuers, [FN8] regardless of whether they are engaging in foreign activities. The provisions subject issuers to record-keeping and disclosure requirements, and mandate they adopt internal accounting controls.

Under the FCPA, issuers are required to:

- Make and keep books, records and accounts that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets.
- Devise and maintain a system of internal accounting controls sufficient to provide reasonable assurance that transactions are properly authorized, recorded and audited.

These provisions are designed to prevent three key types of impropriety: failure to record illegal transactions, falsification of records to conceal illegal transactions and creation of records that are quantitatively accurate, but fail to specify qualitative aspects of the transaction. To be held liable under the accounting provisions of the FCPA, an individual must knowingly circumvent or fail to implement a system of internal accounting controls or knowingly falsify any record.

Note that while many of the entities developing or expanding overseas operations are not public companies, many of them follow accounting and reporting standards like those of companies whose shares are publicly traded. Guided by the standards of individual or trade associational codes of conduct, entities are able to produce the requisite transparency. And most importantly, the FCPA's anti-bribery provisions -- the ones that can send health care executives to jail and ruin a company -- are applicable to all entities, public or privately owned, for-

profit or not-for-profit.

Criminal and civil penalties for violating the FCPA can be severe for companies as well as individual officers, employees and agents. The Justice Department and SEC can impose monetary sanctions and disgorgement of profits, and FCPA investigations often spawn shareholder litigation, government debarment and suspension proceedings, and parallel investigations in foreign jurisdictions.

Entities that violate the anti-bribery provisions face a maximum fine of \$2 million per violation, and individuals face a maximum fine of \$100,000 and five years' imprisonment per violation. Alternatively, the federal government can seek fines of \$500,000 for entities and \$250,000 for individuals, or double the gross gain or loss from the unlawful activity.

For violations of FCPA accounting provisions, the SEC can impose the same civil remedies and penalties as those available under its general enforcement authority for a violation of the federal security laws. For falsifying books and records or knowingly circumventing -- or failing to implement -- internal controls, companies face fines of \$25 million and individuals face fines of \$5 million and 20 years of imprisonment.

Since 2005, the Justice Department and SEC have imposed over \$1 billion in fines under the FCPA. Furthermore, for health care companies, an FCPA violation can result in the company being barred from doing business with the federal government (such as through the Medicare program).

The impact of the FCPA on the health care sector

The increased globalization of health care has created serious FCPA-compliance risks for health care companies. Developing nations continue to increase their health care expenditures, which has resulted in greater demand for pharmaceuticals, medical devices and medical supplies. Health care companies are at a particularly high risk of violating the FCPA because of an increasing number of government-controlled business partners.

Under the FCPA, government-controlled health systems may be considered "instrumentalities" of foreign governments. As a result, offers, payments and gifts provided to physicians, nurses or laboratory technicians employed by government-controlled hospitals, laboratories or clinics could trigger liability under the FCPA.

In past few years, both the medical device and pharmaceutical industries have come squarely in the crosshairs of Justice Department and SEC enforcers.

Speaking at the Pharmaceutical Regulatory and Compliance Congress, Assistant Attorney General Lanny A. Breuer said the Justice Department "will be intensely focused on rooting out foreign bribery" in the pharmaceutical industry, highlighting that pharmaceutical companies generate approximately one-third of their total revenue, about \$100 billion, from sales outside the U.S. [\[FN9\]](#)

Because many health systems outside the U.S. are regulated, operated and financed by foreign governments, Breuer said, "it is entirely possible ... 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." [\[FN10\]](#)

In the last few years, multiple companies in the both the pharmaceutical and medical device industries have made public disclosures of ongoing FCPA investigations by both the Justice Department and SEC. And an in-

dustry-wide investigation of the orthopedic implant business provides further evidence of the agencies' increased focus.

In investigating and prosecuting FCPA violations in the health care sector, the Justice Department has been able to leverage the expertise of analysts with extensive industry knowledge in its health care fraud group in connection with FCPA investigations. This practice improves significantly the Justice Department's abilities to identify corrupt practices and investigate and prosecute complex FCPA cases in the pharmaceutical and device industries.

Additionally, the FBI has created a squad of dedicated FCPA agents in its Washington field office. The FBI's FCPA squad has grown significantly in size and expertise over the last two years and is expected to continue to grow. One of the most significant recent developments in FCPA enforcement has been the increased enforcement against individuals.

Breuer put individuals in the pharmaceutical and device industries on notice, saying, "We firmly believe that for our enforcement efforts to have real deterrent effect, culpable individuals must be prosecuted and go to jail where the facts and the law warrant." [FN11] If Breuer's warning of an increased Justice Department focus on individual prosecutions was not clear, it became crystal clear earlier this year when the department announced the indictment of 22 executives and employees of companies in the military and law enforcement products industries on charges that they engaged in schemes to bribe foreign government officials to obtain and retain business. [FN12]

These indictments were based on extensive investigational work and sophisticated undercover stings on the parts of the Justice Department and FBI, and they should serve as an important warning to all companies, but particularly those in health care that deal with foreign government officials. All such companies have been given a clear mandate to enhance their compliance efforts.

Health care companies also face a high risk of exposure to potential FCPA liability based on their relationships with foreign agents. Foreign sales agents are typically contracted to assist companies in soliciting the sales of products or services within a foreign country.

As such, medical device and pharmaceutical manufacturers attempting to sell products in foreign countries with government-controlled health care systems will often face risks related to foreign sales agents, creating an increased vulnerability to FCPA violations.

In 2008 AGA Medical Corp., a Minnesota-based maker of cardiac medical devices, agreed to pay \$2 million in criminal penalties and enter a three-year, deferred-prosecution agreement for authorizing its independent Chinese distributor to pay kickbacks to physicians employed by government-controlled hospitals to encourage the purchase of AGA devices. [FN13]

The illicit payments were not made directly by an AGA-controlled person, but the Justice Department took the position that the sale of goods by a U.S. company to a foreign distributor -- when the U.S. company has knowledge that the distributor had bribed a foreign official to purchase the goods -- is considered an "act in furtherance of" an illegal payment and subject to prosecution under the FCPA. Accordingly, mere knowledge or authorization of illicit payments made by an independent distributor may subject a health care company to FCPA liability.

FCPA compliance

A comprehensive and effective FCPA-compliance program is essential for members of the health care sector engaged in international business. For health care companies, FCPA compliance should be viewed in the same familiar light as health care fraud and abuse corporate compliance. A broad-based compliance program can significantly reduce fines and penalties assessed to a company if a violation occurs.

Ultimately, however, the effectiveness of a health care company's compliance program can only be measured by the extent to which the company incorporates the standards of the program into its internal culture and emphasizes adherence to those standards. The Justice Department and SEC have also stated that an effective FCPA-compliance program should be "risk-based."

An effective risk-based compliance program should include the following elements:

- A bribery and corruption risk assessment: A company should conduct a comprehensive review and assess the potential bribery and corruption risks associated with its products and services, customers, third-party business partners and geographic locations in which it operates.
- A clearly articulated policy: A company should develop and document a clearly articulated policy against bribery and corruption that reinforces a tone of compliance from the board and management.
- A system of procedures: A company should develop a system of procedures and processes that addresses permitted and prohibited conduct, supervisory and compliance approvals for certain conduct, and documentation of such approvals.
- An internal financial controls system: A company should develop, document and maintain a system of internal financial controls to ensure that all payments are accurately recorded in the organization's books and records.
- A risk-based, third-party due-diligence component: A company should conduct investigative due diligence to assess the potential bribery and corruption risks associated with third parties, such as vendors, consultants, suppliers, agents and joint-venture partners. If a company has hired a smart, corrupt person, he might evade detection until it is too late. The better course is to have a due-diligence regime that maximizes the chances that such a person never will be hired in the first place.
- A compliance-monitoring program: A company should monitor employee compliance with the program and develop and document processes and controls to assess periodically its effectiveness and potential vulnerabilities.
- A training component: A company should develop training materials that clearly and concisely interpret applicable legal, regulatory, policy and procedural requirements, as well as the possible ramifications associated with noncompliance.
- A whistle-blower allegations and investigations component: A company should develop and maintain systems to receive complaints containing allegations of bribery and corruption and to investigate such allegations and document the actions taken with respect to such complaints and investigations.
- A local regulatory requirements compliance program: A company operating internationally should incorporate into the program the local anti-bribery and corruption regulations of the jurisdictions in which it operates.

Conclusion

Health care is becoming an increasingly globalized industry, resulting in health care companies frequently conducting business with foreign entities. These business relationships, combined with the recent statements and enforcement activity by the Justice Department and SEC, make health care companies extremely vulnerable to FCPA exposure.

Health care companies must continue to increase their awareness and understanding of the FCPA to minimize their risk of liability. The FCPA has the potential to affect every phase of a health care company's dealings around the world, and consequently, the implementation of an effective FCPA-compliance program is absolutely essential. Without one, health care companies may find themselves facing staggering fines and corporate executives may find themselves facing significant prison sentences.

[FN1]. Press Release, Gary G. Grindler, Acting Deputy Attorney Gen., U.S. Dep't of Justice, Acting Deputy Attorney General Gary G. Grindler Delivers Remarks at the National Institute on Health Care Fraud (May 13, 2010) (*available at* <http://www.justice.gov/dag/speeches/2010/dag-speech-100513.html>).

[FN2]. Pub. L. No. 95-213, 91 Stat. 1494 (1977).

[FN3]. 15 U.S.C. § 78a *et seq.*

[FN4]. Pub. L. No. 100-418, §§ 5001-5003, 102 Stat. 1415 (1988).

[FN5]. Pub. L. No. 105-366, 112 Stat. 3302 (1998).

[FN6]. *See* 15 U.S.C. §§ 78dd-1 *et seq.*

[FN7]. *See* 15 U.S.C. § 78m.

[FN8]. *See* 15 U.S.C. § 78(a) (defining “issuers” as those companies required to register their securities with the SEC).

[FN9]. Assistant Attorney Gen. Lanny A. Breuer, Keynote Address at the Tenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum (Nov. 12, 2009).

[FN10]. *Id.*

[FN11]. *Id.*

[FN12]. Press Release, U.S. Dep't of Justice, Twenty-Two Executives and Employees of Military and Law Enforcement Products Companies Charged in Foreign Bribery Scheme (Jan. 19, 2010) (*available at* <http://www.justice.gov/opa/pr/2010/January/10-crm-048.html>). The indictments are the result of an undercover FBI operation that represents the Justice Department's single largest FCPA case ever. Assistant Attorney General Lanny A. Breuer of the Criminal Division proclaimed that this case marks “the first large-scale use of undercover law enforcement techniques to uncover FCPA violations and the largest action ever undertaken by the Justice Department against individuals for FCPA violations.” *Id.* In addition to making 22 arrests, about 150 FBI agents executed 14 search warrants in locations across the country. *Id.*

[FN13]. Press Release, U.S. Dep't of Justice, AGA Medical Corporation Agrees to Pay \$2 Million Penalty and Enter Deferred Prosecution Agreement for FCPA Violations (June 3, 2008), (*available at* <http://www.usdoj.gov/opa/pr/2008/June/08-crm-491.html>).

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