

## As Hospitals And Hospital Systems Expand Overseas, FCPA Risks Loom

By David W. Simon, Maria Gonzalez Knavel & Brandi F. Walkowiak, Foley & Lardner LLP

U.S. hospitals and healthcare systems have been exploring opportunities to expand their operations overseas. Indeed, many of the premiere domestic hospitals, such as University of Pittsburgh Medical Center, Harvard Medical (aka Partners Harvard Medical), Johns Hopkins Medicine, and Cleveland Clinic, have already expanded internationally.<sup>1</sup>

This developing trend is in part attributable to the need to find new sources of income as traditional revenue streams diminish in the wake of the Affordable Care Act and other changes in the industry. Hospitals and health systems moving operations into international markets, or even considering such an expansion, need to understand the compliance risks that exist in doing so, particularly with respect to the Foreign Corrupt Practices Act (FCPA).

This article explains the contours of the FCPA and discusses the kind of arrangements that may raise FCPA concerns for hospitals as they consider global expansion. A look at the types of enforcement actions the U.S. Department of Justice (DOJ) and the U.S. Securities and Exchange Commission (SEC) have pursued in the past in the healthcare industry, particularly in the medical device and pharmaceutical segments, provides valuable guidance about potential liability as hospitals and health systems expand abroad. Finally, this article suggests compliance best practices for minimizing FCPA risk.

The good news for hospitals and healthcare systems is that the principles of the FCPA should be familiar as a result of decades of compliance with domestic fraud and abuse laws and regulations. The concepts and prohibitions are basically the same. The challenge for FCPA risk management is implementation, applying these concepts in very different environments with very different challenges. As described below, the risk posed by foreign partners and third parties is especially acute and requires special compliance attention.

### Understanding the FCPA

The FCPA has two principal components that address international corruption and bribery: (1) its anti-bribery provisions, and (2) its accounting provisions, which address record keeping and internal controls.<sup>2</sup>

#### 1. Anti-Bribery Provisions

The FCPA's anti-bribery provisions<sup>3</sup> prohibit:

- » Paying or offering to pay “anything of value”
- » Directly or indirectly

- » To a “foreign official,” or to any other person “while knowing” that all or part of the thing of value will be paid or offered to a foreign official
- » Corruptly
- » For the purpose of influencing the official in some official act or to secure any improper advantage
- » In order to “obtain or retain business”

The anti-bribery provisions of the FCPA go beyond a stereotypical bribery scheme involving cash bribes paid to foreign government officials to secure a government contract. The DOJ and SEC, the two agencies that enforce the FCPA, broadly construe many of the statute's terms.

#### “Anything of Value” Means, Literally, Anything of Value

The term “anything of value,” for example, can mean gifts, meals, entertainment expenditures, travel expenses, commissions, honorariums, referrals, use of medical equipment or facilities, loans, services, and even charitable donations. The definition of this term is consistent with the interpretation of the term “remuneration” under the federal anti-kickback statute<sup>4</sup> (AKS), with which health entities in the United States have been dealing since its enactment in 1972.

#### “Foreign Official” Includes Almost Everyone Hospitals Interact with Abroad

The term “foreign official” also is broadly interpreted. The term is not limited to traditional government officials, but rather includes “any officer or employee of a foreign government or any department, agency or instrumentality thereof . . . or any person acting in an official capacity for or on behalf of any such government department, agency, or instrumentality . . .”<sup>5</sup> The term “foreign official” includes employees of state-owned or state-controlled entities. Indeed, once a foreign company is deemed an instrumentality of a foreign government, all of its employees, regardless of rank or title, will be considered foreign officials.

Because many healthcare providers outside of the United States are government-owned and/or operated, many providers—doctors, nurses, and administrators—qualify as “foreign officials.” By one commentator's calculations, half of the corporate FCPA enforcement actions announced in 2012 involved foreign healthcare providers (such as physicians, nurses, midwives, lab personnel) as the “foreign officials.”<sup>6</sup>

For example, in the *Smith & Nephew* enforcement action, providers in Greek hospitals were deemed “foreign officials” for purposes of the FCPA.<sup>7</sup> This same approach was taken in

the *Biomet* case, where public doctors employed by Argentina's public hospitals were deemed "foreign officials."<sup>8</sup> This interpretation will have a significant impact in the area of international healthcare expansion because many foreign hospitals, medical schools, and laboratories likely will be state-owned or state-controlled, even in part, and their employees, administrators, nurses, midwives, lab personnel, and doctors therefore will be considered foreign officials.

#### The "Obtain or Retain Business" Element Is Satisfied by Any Payment That Has a Business Purpose

The "obtain or retain business" element of the FCPA also has broad application and can be satisfied even if the improper payment to a foreign official does not lead to a government contract. Promotional or other payments made to, or for the benefit of, physicians to incentivize referrals or the use of certain products certainly qualify. Indeed, courts have held that Congress intended to prohibit a wide range of improper payments and not just those that directly influence the acquisition or retention of government contracts.<sup>9</sup> Everything from influencing a procurement process, circumventing import rules, and avoiding contract termination satisfies this element. Payments to obtain special tax treatment, or government licenses or permits, or to otherwise secure an improper advantage over competitors, also would satisfy this statutory element.

In the healthcare context, a broad array of payments may satisfy this standard. Payments made for regulatory approvals or for favorable licensing terms, or payments made to doctors to use a medical device, steer testing to certain laboratories, or to prescribe a certain drug, could meet this standard, commonly referred to as the business purpose test. Indeed, these types of payments have been the predicate for millions of dollars of FCPA penalties. This concept is familiar to health providers in the United States through the AKS, which prohibits knowingly and willfully soliciting or receiving any remuneration for ordering, referring, purchasing, arranging for, or recommending any item or service that may be paid, wholly or partly, under federal healthcare programs.

#### FCPA Risks Posed by Partners, Agents, and Other Third Parties

Companies are not insulated from FCPA risk by doing business in foreign countries through third parties such as agents, consultants, distributors, or joint venture partners. This is an area fraught with risk for hospitals expanding overseas. Many hospitals and healthcare systems have, or are considering, partnerships with local providers. These alliances or joint ventures present enormous risk, since most overseas partners are themselves government instrumentalities. Thus, all payments made, or benefits given to, employees or representatives of these entities implicate the FCPA. Perhaps even more worrisome is the fact that the U.S. partner can be held liable for corrupt payments made by the partner on behalf of the joint venture.

## The good news for hospitals and healthcare systems is that the principles of the FCPA should be familiar as a result of decades of compliance with domestic fraud and abuse laws and regulations.

The anti-bribery provisions of the FCPA expressly prohibit improper payments made through third parties. Indeed, the majority of recent enforcement actions have involved improper payments made through third parties.

What's more, regulators do not need to prove that the third party acted on the company's direct order or even that a company actually knew the third party engaged in prohibited conduct. Rather, under the FCPA, knowledge is not limited to actual knowledge. Failure to investigate suspicious circumstances or turning a blind eye to wrongful conduct can be sufficient to establish knowledge under the FCPA.

In the healthcare context, medical device and pharmaceutical companies have been particularly vulnerable here given their regular dealings with government entities and their frequent use of agents. This vulnerability will extend to hospitals as well for many of the same reasons.

#### Limited Exception for Certain Meals, Entertainment, and Other Business Courtesies

While the FCPA's provisions are broadly construed, the statutory affirmative defenses to the FCPA are of limited value. The only truly meaningful exception is for payments made for expenses that benefit foreign officials that are directly related to the promotion or demonstration of the company's products or services or to the negotiation, execution, or performance of a contract. Examples of such payments include travel and expenses relating to visiting a company facility, for training, or for meetings with a legitimate business purpose. These expenses must be reasonable and bona fide and, importantly, directly related to a business purpose. To establish that payments are covered by this defense, hospitals should ensure payments are reasonable, necessary, and transparent. They should pay costs directly to vendors and keep accurate records of all such payments.

## 2. Books & Records and Internal Controls Provisions

The FCPA's record-keeping provisions<sup>10</sup> require that books, records, and accounts be kept in reasonable detail that accurately and fairly reflect transactions and disposition of assets. This provision works in tandem with the anti-bribery provisions since bribes are often mischaracterized in companies' books and records. For example, bribes characterized as consulting fees, commissions, sales and marketing expenses, discounts, or write-offs all could trigger a violation of these provisions of the FCPA.

## FCPA Enforcement in the Healthcare Industry

FCPA enforcement in the healthcare industry has been aggressive, particularly in the medical device and pharmaceutical segments. In particular, cases involving payments, gifts, and relationships with doctors of state-owned or state-controlled hospitals intended to influence their medical device and pharmaceutical purchases, or arrangements that improperly pay or otherwise reward doctors for referrals, raise issues.

- » In December 2012, Eli Lilly was assessed \$29 million in penalties for various payments made to government-employed physicians and government health officials, among others, in China, Russia, Brazil and Poland.<sup>11</sup> Some payments at issue went through third parties, and the SEC, in its complaint and public statements, was critical of the company's compliance efforts at the time. According to the complaint, the government stated that "Lilly did not curtail the use of marketing agreements by its subsidiary . . ." despite two internal reviews that suggested improper use of such agreements.<sup>12</sup>
- » In August 2012, the SEC filed a complaint against Pfizer and the company subsequently consented to the entry of a final judgment and agreed to pay multiple fines in the tens of millions of dollars.<sup>13</sup> The allegations involved improper payments to influence regulatory and formulary approvals and prescription decisions. Payments included rewarding doctors for past purchases and incentives for future purchases and prescriptions. Pfizer China allegedly paid for international travel, hospitality, and gifts to doctors employed by government institutions in order to influence prescribing decisions.
- » In July 2012, Orthofix International settled with the SEC and DOJ and entered into a deferred prosecution agreement for FCPA allegations involving its Mexican subsidiary Promeca S.A., which made payments to employees of the Mexican government-owned healthcare and social services provider Instituto Mexicano del Seguro Social.<sup>14</sup>

**Having a vibrant and effective compliance program is one of the most effective ways a hospital can protect itself from FCPA liability if it can demonstrate that the program was effective, robust, and supported by the most senior levels of management.**

- » In April 2011, Johnson & Johnson entered into a deferred prosecution agreement and agreed to pay \$21.4 million to the DOJ in criminal fines for allegations of improper payments made by company subsidiaries to public-employed health providers in Greece and Poland.<sup>15</sup> Johnson & Johnson subsidiaries and agents also allegedly made improper payments to public doctors and pharmacists in Romania to prescribe the company's pharmaceutical products. J&J also agreed to pay the SEC \$48.6 million in disgorgement of profits, including pre-judgment interest.
- » In March 2005, Micrus Corporation, a medical device company, entered into a deferred prosecution agreement with the DOJ.<sup>16</sup> Micrus admitted to paying stock options, honorariums, and commissions to doctors at state-owned hospitals in France, Turkey, Spain, and Germany. Moreover, these payments were not accurately reflected in the company's books. Micrus made these payments through officers, employees, agents, and sales personnel in order to influence doctors to purchase embolic coils.
- » In June 2002, during its pre-merger due diligence with Syncor International Corporation, Cardinal Health discovered payments to doctors at state-owned hospitals in Taiwan that violated the FCPA. Specifically, Syncor Taiwan had made payments, in the form of commissions, to Taiwanese doctors who worked for state-owned hospitals in order to influence the purchase of radiopharmaceutical products. Syncor Taiwan also made payments to doctors who referred

clients to its medical imaging centers. In addition, Syncor Mexico had supported doctors at state-owned hospitals by sponsoring seminars and providing computer equipment, software, and medical and office supplies. Meanwhile, Syncor's European subsidiary, The Medcon Group, made payments and provided gifts and expensive travel to doctors at state-owned hospitals. Syncor Taiwan paid \$2 million in criminal fines.<sup>17</sup>

## FCPA Compliance Best Practices for Hospitals and Health Systems

As these enforcement actions demonstrate, operation in an international setting presents numerous challenges for hospitals and hospital systems. Any payments to doctors of state-owned or state-controlled hospitals could open hospitals up to FCPA liability. Referrals, honorariums, advisory training, and contracts that may be acceptable when dealing with private providers in the domestic context are not necessarily acceptable when dealing with foreign doctors from state-owned or controlled hospitals. It is important for hospitals and health systems to maintain the same level of due diligence in overseeing foreign relationships as they do in ensuring compliance with the AKS in the United States.

In addition, if hospitals intend to grow their international practice through joint ventures or partnerships with, or acquisitions of, foreign hospitals or foreign medical schools, they will have to understand how these entities conduct their business or run the risk of being liable for any of their improper practices. As in the medical device enforcement actions, companies may be liable for the acts of their foreign joint venture partners or foreign subsidiaries or affiliates.

An effective FCPA compliance program for a hospital or healthcare system will look very similar to a domestic fraud and abuse compliance program. The FCPA enforcement authorities have identified their own "hallmarks" of an effective compliance program, which echo the essential elements of any effective corporate compliance program. The DOJ and SEC have noted the importance of:

- » A commitment by senior management and clearly articulated policy against corruption
- » A Code of Conduct and compliance policies and procedures
- » Oversight, autonomy, and resources
- » Risk assessment
- » Training and continuing advice
- » Incentives and disciplinary measures
- » Third-party due diligence and compliance enforcement measures
- » A mechanism for confidential reporting and internal investigations

- » Continuous improvement: periodic testing and review
- » For mergers and acquisitions, pre-acquisition due diligence and post-acquisition integration

Given the high FCPA risk posed to hospitals and health systems by third parties, compliance programs should focus heavily on this area. It is critical that before expanding internationally, domestic concerns conduct meaningful due diligence prior to any acquisition, agreement, or partnership with foreign entities such as hospitals, medical schools, or other healthcare systems.

The first step in the due diligence process is assessing the partner entity's relationship with its government and whether there is any direct or indirect government ownership, control, or influence. If there is, all payments made to that entity need scrutiny and must be subject to procedures and processes to ensure such payments do not create FCPA liability.

Due diligence should also include an inquiry into whether the entity maintains a compliance program that addresses bribery issues and an evaluation of that compliance program's effectiveness and robustness. Hospitals should ensure that their partner entities and third-party agents have rigorous Codes of Business Conduct and Ethics in place. Hospitals considering partnership with a foreign entity should also look at that entity's own contracts with third parties, distributors, and any joint-venture arrangements.

All relationships with third parties should be memorialized in writing. Any commissions or payments should be reasonable and consultant contracts should include specific and unambiguous descriptions of the services to be performed. Companies should evaluate third-party arrangements and look for any red flags—excessive commissions, unreasonably large discounts, consulting agreements with vague descriptions of services, third parties with close ties to the government or government officials, or indicia that the third party is a shell corporation or not equipped to perform the function for which it was retained.

Contracts with third parties should include anti-corruption representations and warranties and, ideally, should provide the hospital with audit rights of the foreign partner entity or third party. The hospitals should also require certifications of compliance with the FCPA and local law from any partner entity or third-party intermediary. In third-party agent agreements, the contracts should also include termination clauses that would allow for immediate, unilateral termination if the third party fails to comply with the FCPA or other anti-corruption laws.

Once operations are established in the international market, hospitals need to continue to perform FCPA risk assessments and monitor the conduct of their employees, agents, and partners. Safeguards need to be in place to ensure that expenditures are transparent and that payments are not conditioned on any official action. Hospitals must also ensure that expenses are being accurately recorded in their books and records.

Having a vibrant and effective compliance program is one of the most effective ways a hospital can protect itself from FCPA liability if it can demonstrate that the program was effective, robust, and supported by the most senior levels of management. An effective compliance program helps on the front end in preventing improper conduct. It also helps detect any improper conduct so that the hospital can stop it and limit its losses. And, in the worst case scenario, if an FCPA violation does occur, an effective compliance program is one factor that may persuade a prosecutor not to indict a company.

## Conclusion

Hospitals and healthcare systems cannot enter international markets blindly. While the bones of an effective compliance program are likely in place given the requirements of U.S. law, hospitals must be thoughtful about how they will achieve their expansion while mitigating FCPA risk. A solid understanding of the anti-corruption laws and the FCPA compliance risks is critical. And a robust, FCPA-specific compliance program will save money, hassle, and heartache in the long run. 

## About the Authors



**David Simon** ([dsimon@foley.com](mailto:dsimon@foley.com)) is a partner of Foley & Lardner LLP. He specializes in FCPA compliance and enforcement defense and is a member of the Government Enforcement, Compliance & White Collar Defense practice and the Health Care Industry team.



**Maria Gonzalez Knavel** ([mgonzalezknavel@foley.com](mailto:mgonzalezknavel@foley.com)) is a partner in the Milwaukee, WI, office of Foley & Lardner LLP. She is a member of the Health Care and Life Sciences Industry teams and Government Enforcement, Compliance & White Collar Defense practice.



**Brandi Walkowiak** ([bwalkowiak@foley.com](mailto:bwalkowiak@foley.com)) is a senior counsel in the Detroit, MI, office of Foley & Lardner LLP. Her practice focuses on corporate compliance, internal investigations, white-collar defense, as well as complex civil litigation.

## An effective FCPA compliance program for a hospital or healthcare system will look very similar to a domestic fraud and abuse compliance program.

## Endnotes

- 1 Lindsey Dunn, *International Partnership Opportunities Gaining Interest, But Challenges Await Hospitals*, Apr. 5, 2011, available at [www.beckerhospital-review.com](http://www.beckerhospital-review.com).
- 2 *A Resource Guide to the U.S. Foreign Corrupt Practices Act*, Criminal Division of the U.S. Department of Justice and Enforcement Division of the U.S. Securities and Exchange Commission, Nov. 14, 2012.
- 3 15 U.S.C. § 78dd-1, *et seq.*
- 4 42 U.S.C. § 1320a-7b(b).
- 5 15 U.S.C. § 78dd-1(f)(1); 15 U.S.C. § 78dd-2(h)(2).
- 6 See [www.fcraprofessor.com](http://www.fcraprofessor.com), Jan. 10, 2013.
- 7 Press Release, U.S. Department of Justice, *Medical Device Company Smith & Nephew Resolves Foreign Corrupt Practices Act Investigation*, Feb. 6, 2012; Press Release, U.S. Securities and Exchange Commission, *SEC Charges Smith & Nephew PLC with Foreign Bribery*, Feb. 6, 2012; see also [www.traceinternational.org](http://www.traceinternational.org).
- 8 Press Release, U.S. Department of Justice, *Third Medical Device Company Resolves Foreign Corrupt Practices Act Investigation*, Mar. 26, 2012; Press Release, U.S. Securities and Exchange Commission, *SEC Charges Medical Device Company Biomet with Foreign Bribery*, Mar. 26, 2012; see also [www.traceinternational.org](http://www.traceinternational.org).
- 9 *United States v. Kay*, 359 F.3d 738, 743-56 (5th Cir. 2004).
- 10 15 U.S.C. § 78m(b)(2)(A).
- 11 *U.S. Securities and Exchange Commission v. Eli Lilly and Company*, Complaint, Dec. 20, 2012; see also Press Release, U.S. Securities and Exchange Commission, *SEC Charges Eli Lilly and Company with FCPA Violations*, Dec. 20, 2012.
- 12 *U.S. Securities and Exchange Commission v. Eli Lilly Company*, Complaint, Dec. 20, 2012.
- 13 Press Release, U.S. Securities and Exchange Commission, *SEC Charges Pfizer with FCPA Violations*, Aug. 7, 2012.
- 14 Press Release, U.S. Securities and Exchange Commission, *SEC Charges Orthofix International with FCPA Violations*, July 10, 2012.
- 15 Press Release, U.S. Department 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.
- 16 Press Release, U.S. Department of Justice, *Micrus Corporation Enters Into Agreement to Resolve Potential Foreign Corrupt Practices Act Liability*, Mar. 2, 2005.
- 17 Press Release, U.S. Department of Justice, *Sincor Taiwan Inc. Pleads Guilty to Violating the Foreign Corrupt Practices Act*, Dec. 10, 2002.