



**BUSINESS LAW AND GOVERNANCE
PRACTICE GROUP
MEMBER BRIEFING: SPECIAL EDITION**

DOING BUSINESS IN THE GLOBAL HEALTHCARE SECTOR

May 2009

TABLE OF CONTENTS

An Overview of the Foreign Corrupt Practices Act for Healthcare Companies.....	4
Medical Tourism: An Industry in Evolution	19
Opportunities for U.S. Academic Medical Centers in the Persian Gulf	30
Arbitration Clauses in International Agreements: Why and How?	37

Business Law and Governance Practice Group

HIGHLIGHTS

Doing Business in the Global Healthcare Sector

The AHLA Business Law and Governance Practice Group is pleased to issue this Member Briefing as a special edition.

Healthcare is no longer confined by geography. Financial opportunity facilitated by the electronic transmission of digital images, records, ease of global communication, and travel is now transforming healthcare into a global enterprise. Many U.S. healthcare organizations are entering into joint ventures, affiliations, and clinical and management relationships in other countries. These new business relationships require an understanding of the unique laws and regulations governing the participation of American healthcare interests in other countries. Similarly, as many foreign healthcare organizations seek to treat Americans and do other business in the United States, they will be faced with legal and regulatory issues unique to the United States.

The articles in this Member Briefing address some of the myriad issues confronted in the global healthcare market place.

An Overview of the Foreign Corrupt Practices Act for Healthcare Companies

Joel C. Rush, Esquire
Epstein Becker & Green
Washington, DC

The globalization of healthcare has resulted in U.S. healthcare companies working with government agencies and government healthcare systems in foreign countries, the officers, employees, and agents of which may be classified as “foreign officials” under the Foreign Corrupt Practices Act (FCPA). This business relationship with government-owned and government-controlled entities and foreign officials creates a potentially high level of exposure to violations of the FCPA. As recent enforcement actions and investigations demonstrate, the healthcare industry is not exempt from prosecution for FCPA violations. U.S. healthcare companies need to be aware of and understand the impact the FCPA has on doing business around the world and should view FCPA compliance in the same light as they view healthcare fraud and abuse compliance. FCPA anti-bribery prosecutions and enforcement actions rose from five in 2004 to thirty-eight in 2007.¹ In September 2008, Mark Mendelsohn, the Department of Justice’s (DOJ) chief prosecutor of foreign bribery said,

The number of individual prosecutions has risen—and that’s not an accident. That is quite intentional on the part of the Department. It is our view that to have a credible deterrent effect, people have to go to jail. People have to be prosecuted where appropriate. This is a federal crime. This is not fun and games.²

To prevent FCPA violations from occurring and to mitigate a company’s liability when violations have already taken place, U.S. healthcare companies should adopt a comprehensive compliance program to address the potential FCPA risks associated with conducting business internationally.

¹ Ed Rial, *Beyond Reproach: Why compliance with anti-corruption laws is increasingly critical for multinational businesses*, Deloitte Review, Issue 4, Deloitte Development LLC (2009).

² *Mendelsohn Says Criminal Bribery Prosecutions Doubled in 2007*, 22 Corporate Crime Reporter 36, vol. 1, Sept.16, 2008, available at www.corporatecrimereporter.com/mendelsohn091608.htm.

FCPA Background

Congress enacted the Foreign Corrupt Practices Act of 1977³ as an amendment to the Securities Exchange Act of 1934⁴ (Exchange Act) in an attempt to eliminate the practice of bribery as a way of obtaining and retaining foreign business. The FCPA is the result of an SEC-initiated investigation into undisclosed payments to domestic and foreign governments and politicians, triggered by the Watergate scandal.⁵ Congress later passed the Foreign Corrupt Practices Act Amendments of 1988⁶ (1988 Amendments), adding an exception and affirmative defenses. The FCPA was again amended in 1998, when Congress passed the International Anti-Bribery and Fair Competition Act of 1998⁷ (1998 Amendments) that implemented the Organization of Economic Cooperation and Development (OECD) Convention on Combating Bribery of Foreign Officials in International Business Transactions (OECD Convention). Upon signing the 1998 Amendments, President Bill Clinton stated:

Since the enactment in 1977 of the Foreign Corrupt Practices Act, U.S. businesses have faced criminal penalties if they engaged in business-related bribery of foreign public officials. Foreign competitors, however, did not have similar restrictions and could engage in this corrupt activity without fear of penalty. Moreover, some of our major trading partners have subsidized such activity by permitting tax deductions for bribes paid to foreign public officials. As a result, U.S. companies have had to compete on an uneven playing field, resulting in losses of international contracts estimated at \$30 billion per year. The OECD Convention—which represents the culmination of many years of sustained diplomatic effort—is designed to change all that. Under the Convention, our major competitors will be obligated to criminalize the bribery of foreign public officials in international business transactions.⁸

³ Pub. L. No. 95-213, 91 Stat. 1494 (1977).

⁴ 15 U.S.C. § 78a *et seq.*

⁵ DON ZARIN, DOING BUSINESS UNDER THE FOREIGN CORRUPT PRACTICES ACT 1-1 (Practicing Law Institute 2008) (1995) (referencing Theodore C. Sorenson, *Improper Payments Abroad: Perspectives and Proposals*, 54 FOREIGN AFFAIRS 719 (1976)).

⁶ Pub. L. No. 100-418, §§ 5001-5003, 102 Stat. 1415 (1988).

⁷ Pub. L. No. 105-366, 112 Stat. 3302 (1998).

⁸ William J. Clinton, Statement by the President (Nov. 10, 1998), available at www.usdoj.gov/criminal/fraud/fcpa/history/1998/amends/signing.html.

The 1988 Amendments, the OECD Convention, and the 1998 Amendments were all attempts to level the international playing field by eliminating the competitive advantage held by international competitors that were not subject to U.S. anti-bribery laws.

Overview of the Key Provisions of the FCPA

The FCPA criminalizes the bribery of foreign officials by U.S. companies and citizens or other persons acting in the United States, and requires publicly traded companies with a class of securities registered and traded on a U.S. exchange to meet standards relating to accounting, book and record keeping, and internal controls. The FCPA is jointly enforced by the DOJ and the Securities Exchange Commission (SEC), and is presently being actively enforced by the DOJ and SEC.

Anti-Bribery Provisions

The “anti-bribery” provisions of the FCPA apply to issuers,⁹ domestic concerns,¹⁰ any officer, director, employee, agent, or stockholder thereof acting on behalf of such issuer or domestic concern, or any person acting within the United States (collectively Covered Persons).¹¹ Issuers and domestic concerns also may be held liable for acts of foreign subsidiaries when such acts have been authorized, directed, or controlled by the parent.¹² Additionally, a foreign company or individual can be subject to the FCPA 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.”¹³

⁹ 15 U.S.C. § 78dd-1.

¹⁰ 15 U.S.C. § 78dd-2. Domestic concern is defined as “any individual who is a citizen, national, or resident of the United States” and “any corporation, partnership, association, joint-stock company, business trust, unincorporated organization, or sole proprietorship which has its principal place of business in the United States, or which is organized under the laws of a State of the United States or a territory, possession, or commonwealth of the United States.” 15 U.S.C. § 78dd-2(h)(1).

¹¹ 15 U.S.C. §§ 78dd-1(a)(for issuers), 78dd-2(a)(for domestic concerns).

¹² *Lay-Person’s Guide to FCPA* (hereinafter, Lay Person’s Guide), United States Department of Justice, www.usdoj.gov/criminal/fraud/docs/dojdocb.html (last visited January 6, 2009).

¹³ *Id.* See 15 U.S.C. § 78dd-3. This article will focus primarily on U.S. healthcare companies and not FCPA liability for independent foreign persons.

Violations of the anti-bribery provisions of the FCPA have the following elements:

(1) A Covered Person¹⁴

(2) Makes “use of the mails or any means or instrumentality of interstate commerce *corruptly*¹⁵ in furtherance of an offer, payment, promise to pay, or authorization of the payment of any money, or offer, gift, promise to give, or authorization of the giving of anything of value;”¹⁶

(3) To a foreign official,¹⁷ foreign political party or official thereof, or any candidate for foreign political office,¹⁸ or any person, while *knowing* that all or a portion of the payment will be passed on directly or indirectly to a foreign official, foreign political party or official thereof, or candidate for foreign political office;¹⁹

(4) To influence any official act or decision, to induce an act or omission to act in violation of the law, to secure an improper advantage, or to induce the use of influence with a foreign government to affect or influence an act or decision of the foreign government;²⁰

(5) In order to obtain or retain business for or with, or direct business to any person.²¹

Foreign officials include “any officer or employee of a foreign government or any department, agency or instrumentality thereof, or of a public international organization,²² or any person acting in an official capacity for or on behalf of any such government or

¹⁴ 15 U.S.C. §§ 78dd-1(a) (for issuers), 78dd-2(a) (for domestic concerns), 78dd-3(a) (for all others while in a territory of the U.S.).

¹⁵ The term “corruptly” suggests a bad intent or purpose and “encompasses a quid pro quo element: a nexus between the illicit payment and the expected conduct of the foreign official.” ZARIN, *supra* note 5, at 4-15 (discussing the legislative history of the term “corruptly”).

¹⁶ 15 U.S.C. §§ 78dd-1(a) (for issuers), 78dd-2(a) (for domestic concerns), 78dd-3(a) (for all others while in a territory of the U.S.).

¹⁷ 15 U.S.C. §§ 78dd-1(a)(1) (for issuers), 78dd-2(a)(1) (for domestic concerns), 78dd-3(a)(1) (for all others while in a territory of the U.S.).

¹⁸ 15 U.S.C. §§ 78dd-1(a)(2) (for issuers), 78dd-2(a)(2) (for domestic concerns), 78dd-3(a)(2) (for all others while in a territory of the U.S.).

¹⁹ 15 U.S.C. §§ 78dd-1(a)(3) (for issuers), 78dd-2(a)(3) (for domestic concerns), 78dd-3(a)(3) (for all others while in a territory of the U.S.).

²⁰ 15 U.S.C. §§ 78dd-1(a)(1)-(3) (for issuers), 78dd-2(a)(1)-(3) (for domestic concerns), 78dd-3(a)(1)-(3) (for all others while in a territory of the U.S.).

²¹ *Id.*

²² “Public International Organization” means (i) an organization designated by an Executive Order pursuant to 22 U.S.C. § 288, or (ii) any other international organization designated by the President by Executive Order for the purpose of the FCPA. 15 U.S.C. §§ 78dd-1(f)(1) (for issuers), 78dd-2(h)(2) (for domestic concerns), 78dd-3(f)(2) (for all others while in a territory of the U.S.).

department, agency or instrumentality, or for or on behalf of such public international organization.”²³ The FCPA applies to payments to *any* foreign official, regardless of rank or position, and focuses on the *purpose* of the payment instead of the particular duties of the foreign official receiving the payment.²⁴

Accounting Provisions

The “accounting” provisions of the FCPA amended Section 13(b)²⁵ of the Exchange Act by subjecting “issuers”²⁶ to record keeping and disclosure requirements and mandating adoption of internal accounting controls. The accounting provisions apply to all issuers regardless of whether or not they are engaged in foreign activities.²⁷ Under the FCPA, issuers are required to (i) make and keep books, records, and accounts which, *in reasonable detail*,²⁸ accurately and fairly reflect the transactions and dispositions of the assets of the issuer,²⁹ and (ii) devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that transactions are properly authorized, recorded, and audited.³⁰ These provisions are designed to prevent three key types of impropriety: (i) failure to record illegal transactions; (ii) falsification of records to conceal illegal transactions; and (iii) creation of records that are quantitatively accurate, but fail to specify qualitative aspects of the transaction.³¹ These provisions also require issuers to create a system of accounting controls that ensure issuers use accepted methods of accounting when recording economic transactions.³² The 1988 Amendments added provisions to the FCPA that heighten the state of mind requirement for liability under the statute. To be held criminally liable, an individual must knowingly

²³ *Id.*

²⁴ Lay Person’s Guide, *supra* note 12, at 5.

²⁵ 15 U.S.C. § 78m(b).

²⁶ See 15 U.S.C. § 78a. “Issuers” are those companies required to register their securities with the SEC.

²⁷ See 15 U.S.C. § 78m(b)(2).

²⁸ The term “reasonable detail” is defined as “such level of detail . . . as would satisfy prudent officials in the conduct of their own affairs.” 15 U.S.C. § 78m(b)(7).

²⁹ 15 U.S.C. § 78m(b)(2)(A).

³⁰ 15 U.S.C. §§ 78m(b)(2)(B)(i-iv).

³¹ Ned Sebelius, *Foreign Corrupt Practices Act*, 45 AM. CRIM. L. REV. 579, 584 (2008). See also JAY G. MARTIN, SUMMARY OF FOREIGN CORRUPT PRACTICES ACT OF 1977, 5 Presentation to Association of International Petroleum Negotiators (June 12, 2002) (citing *SEC v. World-Wide Com Inv. Ltd.*, 567 F. Supp. 724, 752 (N.D. Ga. 1983)).

³² Sebelius, *supra* note 31, at 585.

circumvent or fail to implement a system of internal accounting controls or knowingly falsify any record.³³

Application of the FCPA to Third Parties

The FCPA contains specific provisions aimed at eliminating illegal payments through third parties. U.S. companies may be held directly responsible for the activities of “any person” who made a payment to a foreign government official if the U.S. company authorized³⁴ or knew that the money or thing of value would be used by such person, directly or indirectly, to make an illegal payment.³⁵ “Any person” includes any entity or individual in the United States or abroad, and could include a marketing consultant, distributor, joint venture partner, foreign subsidiary, contractor, or subcontractor.³⁶ The definition of “knowing” used in the FCPA prevents companies from taking the “head in the sand” approach to dealing with third parties. For purposes of the FCPA, “knowing” means (i) being aware that (a) a person is engaging in the conduct, (b) a circumstance exists, or (c) a result is substantially certain to occur; or (ii) having a firm belief that the circumstances or results are substantially certain to occur.³⁷ Knowledge also means awareness of a high probability of the existence of circumstances that would result in a violation of the FCPA, unless the person actually believes the circumstances do not exist.³⁸

Exceptions and Affirmative Defenses

Facilitating Payments

The FCPA does not apply to “any facilitating or expediting payment to a foreign official, political party, or party official the purpose of which is to expedite or to secure

³³ 15 U.S.C. § 78m(b)(5). See Sebelius, *supra* note 31, at 585-586 (discussing criminal liability for violations of accounting standards).

³⁴ See 15 U.S.C. §§ 78dd-1(a) (for issuers), 78dd-2(a) (for domestic concerns), 78dd-3(a) (for all others while in a territory of the U.S.).

³⁵ See 15 U.S.C. §§ 78dd-1(a)(3) (for issuers), 78dd-2(a)(3) (for domestic concerns), 78dd-3(a)(3) (for all others while in a territory of the U.S.). It is also important to note that the foreign intermediary engaging in the illicit conduct may actually be outside of the scope of the FCPA, and therefore, not subject to liability. See ZARIN, *supra* note 5, at 4-35.

³⁶ ZARIN, *supra* note 5, at 4-35.

³⁷ 15 U.S.C. §§ 78dd-1(f)(2) (for issuers), 78dd-2(h)(3) (for domestic concerns), 78dd-3(f)(3) (for all others while in a territory of the U.S.).

³⁸ *Id.*

performance of a routine government action.”³⁹ “Routine governmental action” includes: (1) obtaining permits, licenses, or other official documents to qualify a person to do business in a foreign country; (2) processing governmental papers such as visas and work orders; (3) providing police protection, mail pick-up and delivery, or scheduling inspections associated with contract performance or inspections related to transit of goods across country; (4) providing phone service, power and water supply, loading and unloading cargo, or protecting perishable products or commodities from deterioration; or (5) actions of a similar nature.⁴⁰ Routine governmental action does not include a decision by a foreign official to award new business to or to continue business with a particular party, or any action taken by a foreign official to encourage a decision to award new business to or to continue business with a particular party.⁴¹ The exception does not include “those governmental approvals involving the exercise of discretion by a government official where the actions are the functional equivalent of obtaining or retaining business for or with, or directing business to, any person.”⁴²

Affirmative Defenses

In addition to the exception for facilitating payments, a few narrowly interpreted affirmative defenses exist. A payment does not violate the FCPA if it is lawful under the written laws and regulations of the foreign country in which it was made.⁴³ Another exception exists for reasonable and bona fide expenditures made as part of (i) the promotion, demonstration, or explanation of a product, or (ii) the execution or performance of a contract with a foreign government or agency thereof.⁴⁴ These expenditures could include reasonable and bona fide travel and lodging expenses used to bring foreign officials to a product demonstration or facility tour.⁴⁵

³⁹ 15 U.S.C. §§ 78dd-1(b) (for issuers), 78dd-2(b) (for domestic concerns), 78dd-3(b) (for all others while in a territory of the U.S.).

⁴⁰ 15 U.S.C. §§ 78dd-1(f)(3) (for issuers), 78dd-2(h)(4) (for domestic concerns), 78dd-3(f)(4) (for all others while in a territory of the U.S.).

⁴¹ *Id.*

⁴² H.R. CONF. REP. NO. 576, 100th Cong., 2d Sess. 921 (1988).

⁴³ 15 U.S.C. §§ 78dd-1(c)(1) (for issuers), 78dd-2(c)(1) (for domestic concerns), 78dd-3(c)(1) (for all others while in a territory of the U.S.).

⁴⁴ 15 U.S.C. §§ 78dd-1(c)(2) (for issuers), 78dd-2(c)(2) (for domestic concerns), 78dd-3(c)(2) (for all others while in a territory of the U.S.).

⁴⁵ *Id.*

Fines and Penalties

Accounting Provisions

Civil remedies and penalties available for violations of the accounting provisions are the same as those available to the SEC under the general enforcement authority for a violation of the federal securities laws.⁴⁶ Enforcement actions involving the accounting provisions generally accompany allegations of other substantive securities violations, making it difficult to accurately assess specific civil remedies for accounting violations.⁴⁷ In addition to potential civil penalties, individuals and companies may be subject to criminal penalties under the Exchange Act for knowingly (i) circumventing or failing to implement internal controls, or (ii) falsifying books and records.⁴⁸ Individuals are subject to a maximum fine of \$5 million and/or imprisonment of not more than twenty years, and companies are subject to a maximum fine of \$25 million.⁴⁹

Anti-Bribery Provisions

The anti-bribery section of the FCPA is a criminal statute and provides a maximum fine of \$2 million *per* violation for entities,⁵⁰ and a maximum fine of \$100,000⁵¹ or imprisonment of not more than five years—or both—for individuals.⁵² Ultimately, within the limitations of the statutory maximums, the determination of the amount of the fine and imprisonment is governed by the Federal Sentencing Guidelines (Sentencing Guidelines).⁵³ Alternatively, the government could seek fines of \$500,000 for entities and \$250,000 for individuals, or double the gross gain or loss from the unlawful activity, whichever is greater.⁵⁴ In addition to criminal penalties, a Covered Person who violates

⁴⁶ ZARIN, *supra* note 5, at 8-1 (citing 15 U.S.C. § 78u).

⁴⁷ *Id.* at 8-2.

⁴⁸ 15 U.S.C. § 78m(b)(5).

⁴⁹ 15 U.S.C. § 78ff(a).

⁵⁰ 15 U.S.C. §§ 78dd-2(g)(1)(A), 78dd-3(e)(a)(A), 78ff(c)(1)(A). Where an offense results in pecuniary gain or loss, the provisions of 18 U.S.C. § 3571(d) provide an alternative statutory maximum fine of the greater of twice the gross gain or twice the gross loss. 18 U.S.C. § 3571(b), (e) (setting forth maximum fines).

See ZARIN, *supra* note 5, at 8-5.

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

⁵² *Id.*

⁵³ See United States Sentencing Commission, GUIDELINES MANUAL § 8C3.1 (2008), *available at* www.ussc.gov/2008guid/GL2008.pdf. See also ZARIN, *supra* note 5, at 8-6 (discussing the impact of the Sentencing Guidelines); Sebelius, *supra* note 31, at 595-597 (discussing the impact of the Sentencing Guidelines).

⁵⁴ 18 U.S.C. § 3571 (setting forth maximum alternative fines). See ZARIN, *supra* note 5, at 8-5.

the bribery provisions of the FCPA is subject to a civil penalty of not more than \$10,000 in an action brought by the SEC.⁵⁵ Of potentially greater consequence for healthcare companies, a violation of the FCPA by a U.S. company can result in the company being barred from doing business with the federal government⁵⁶ or subjected to mandatory outside supervision.

FCPA and the Healthcare Industry

The increased globalization of healthcare has created the potential for serious FCPA compliance risks for U.S. healthcare companies. Developing nations are increasing spending on healthcare, resulting in increased demand for pharmaceuticals, medical devices, and medical supplies.⁵⁷ U.S. providers are beginning to expand operations abroad and new healthcare companies, in the areas of outsourcing, medical tourism, and electronic medical records, are fully engaged in the global marketplace. In addition to the significant criminal and civil penalties imposed for violating the FCPA, healthcare companies could potentially be barred from the Medicare⁵⁸ and Medicaid⁵⁹ programs, which could have far broader commercial and financial consequences than the fines and penalties assessed to the company.⁶⁰

Recent FCPA enforcement actions and inquiries by DOJ and SEC demonstrate the emerging trend of “casting a wider net” across many different industries in an increased effort to combat foreign corruption and bribery.⁶¹ U.S. healthcare companies are at a particularly high risk of violating the FCPA because of an increasing number of government-owned or -controlled global customers and business partners. Under the FCPA, government-owned or -controlled health systems may be considered “instrumentalities” of a foreign government, and as such, officers and employees of

⁵⁵ 15 U.S.C. §§ 78ff(c).

⁵⁶ “Under guidelines issued by the Office of Management and Budget, a person or firm found in violation of the FCPA may be barred from doing business with the Federal government.” See Lay Person’s Guide, *supra* note 12, at 8.

⁵⁷ Mike Koehler, *A Malady in Search of a Cure – The Increase in FCPA Enforcement Actions Against Health-care Companies*, 38 U. MEM. L. REV. 261, 263 (2008) (discussing the increase in healthcare expenditures in developing nations and the corresponding increase in demand for healthcare products).

⁵⁸ See 42 U.S.C. § 1395 *et. seq.*

⁵⁹ See 42 U.S.C. § 1396 *et. seq.*

⁶⁰ *Id.* at 280. See also ZARIN, *supra* note 5, at 8-8 (discussing ineligibility for government programs).

⁶¹ Koehler, *supra* note 57, at 262.

these entities are deemed to be foreign officials.⁶² Offers, payments, and gifts provided to physicians, nurses, or laboratory technicians employed by state-owned or -controlled hospitals, laboratories, or clinics could trigger liability under the FCPA.

High Risk for Healthcare Companies: The Impact of the Third Party Payment Provisions

Healthcare Foreign Subsidiaries and Joint Ventures

In recent years, DOJ and SEC have actively prosecuted and investigated U.S. healthcare companies for the activities of their foreign subsidiaries.⁶³ U.S. healthcare companies cannot insulate themselves from FCPA liability by setting up foreign subsidiaries. If a company has “knowledge”⁶⁴ that a foreign subsidiary is violating the FCPA or authorizes the illegal payment by the foreign subsidiary, the parent company may be considered to be a participant in the illegal activity, and thus subject to FCPA liability.⁶⁵ The probability of parental liability for the actions of a subsidiary increases as the parent’s involvement in the activities of the subsidiary increase.⁶⁶

⁶² 15 U.S.C. §§ 78dd-1(f)(1)(A) (for issuers), 78dd-2(h)(2)(A) (for domestic concerns), 78dd-3(f)(2)(A) (for all others while in a territory of the U.S.). See Koehler, *supra* note 57, at 273-274.

⁶³ In 2002, Syncor International Corporation (Syncor) consented to the entry of a final judgment in a federal lawsuit requiring it to pay a \$500,000 civil penalty and the issuance of an administrative order requiring Syncor to obtain an independent monitor in connection with charges that foreign subsidiaries in Taiwan, Mexico, Belgium, Luxembourg, and France made a total of \$600,000 in illicit payments to doctors employed by state-controlled hospitals, with the purpose of influencing the doctors’ decisions so that Syncor could obtain or retain business with them and the hospitals. *In re Syncor Int’l Corp.*, Exchange Act Release No. 46979 (Dec. 10, 2002); *SEC v. Syncor Int’l Corp.*, Litigation Release No. 17887 (Dec. 10, 2002) available at www.sec.gov/litigation/litreleases/lr17887.htm; Complaint, *SEC v. Syncor Int’l Corp.*, No. 1:02CV02421 (D.D.C. 2002). In a related DOJ proceeding, Syncor Taiwan Inc. (Syncor Taiwan), a subsidiary of Syncor, agreed to plead guilty to violating the anti-bribery provisions of the FCPA and to pay a \$2 million fine. See *United States v. Syncor Taiwan, Inc.*, No. 02-CR-1244-ALL (C.D. Cal.). In 2005, DPC (Tianjin) Co. Ltd. (DPC Tianjin), agreed to plead guilty, adopt internal compliance measures, retain an independent monitor, pay a criminal penalty of \$2 million, disgorge approximately \$2.8 million in gains, and cooperate with ongoing DOJ and SEC investigations in connection with charges that it paid \$1.6 million in bribes to physicians and laboratory personnel employed by government owned hospitals in the People’s Republic of China (PRC). DPC Tianjin is the Chinese subsidiary of California based Diagnostic Products Corporation. The bribes were paid to laboratory personnel and physicians in exchange for agreements that the hospitals would obtain DPC Tianjin’s products and services. The bribes were recorded on the books of DPC Tianjin as “selling expenses” and were regularly reported to DPC on DPC Tianjin’s financial statements as sales expenses. See Press Release, Dep’t of Justice, DPC (Tianjin) Ltd. Charged with Violating the Foreign Corrupt Practices Act (May 20, 2005), available at www.usdoj.gov/criminal/fraud/press/2005/dpcfcpa.pdf.

⁶⁴ The key consideration is whether or not the parent company knew or believed that the foreign subsidiary was violating the FCPA. See ZARIN, *supra* note 5, at 6-10 to 6-13.

⁶⁵ Koehler, *supra* note 57, at 292.

⁶⁶ See ZARIN, *supra* note 5, at 6-12.

On December 15, 2008, German corporation Siemens Aktiengesellschaft (Siemens AG) and three of its subsidiaries pleaded guilty to violations of and charges related to the FCPA.⁶⁷ While Siemens AG's FCPA violations spanned the spectrum of the conglomerate's operational companies, Siemens Medical Solutions operating group (MED) was responsible for over \$90 million in illicit payments made to influence purchasing of medical devices in Vietnam, China, and Russia.⁶⁸ In total, Siemens AG has agreed to pay more than \$1.6 billion in fines, penalties, and disgorgement of profits in connection with cases brought by DOJ, SEC, and the Munich Public Prosecutor's Office—including over \$800 million to U.S. authorities—making it the largest monetary sanction ever imposed in an FCPA case.⁶⁹

International joint ventures also present risks under the FCPA. Foreign partners may not be familiar with the FCPA, and in many countries, the FCPA runs counter to customary business practices. As a result, foreign partners should be educated about the FCPA and its prohibitions. Joint ventures with government entities pose a unique set of FCPA challenges. While the FCPA does not prohibit joint ventures with government entities, U.S. healthcare companies need to be extremely diligent in structuring these entities to ensure that (i) foreign officials are not receiving any personal benefit from the relationship, and (ii) the government partner is not influencing government purchasing decisions.⁷⁰ As with foreign subsidiaries, if a U.S. healthcare company has knowledge that its joint venture partner is violating the FCPA or authorizes the illegal payment by the joint venture, the U.S. healthcare company may be considered to be a participant in

⁶⁷ Press Release, 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 (hereinafter Siemens Press Release) (December 15, 2008), available at www.usdoj.gov/opa/pr/2008/December/08-crm-1105.html. Although it is a German corporation, Siemens AG was subject to the FCPA because it is an "issuer."

⁶⁸ See Complaint, *SEC v. Siemens Aktiengesellschaft*, No. 08-2167 (D.D.C. Dec. 12, 2008); Information, *United States v. Siemens Aktiengesellschaft*, No. 08-367 (D.D.C. Dec. 12, 2008). Siemens AG's illegal activities included "using off-the-books slush fund accounts and shell companies to facilitate bribes, making false entries on the company's books and records by, for example, falsely recording bribes as consulting fees." Acting Assistant Attorney General Matthew W. Friedrich, Press Conference Announcing Siemens AG Guilty Plea (Dec. 15, 2008), available at www.usdoj.gov/opa/pr/2008/December/08-opa-1112.html.

⁶⁹ Siemens Press Release, *supra* note 67. In connection with the DOJ settlement, Siemens AG and its subsidiaries agreed to pay a \$450 million criminal fine, retain an independent monitor for four years, and cooperate in ongoing investigations by DOJ. *Id.* Siemens AG also settled a related civil complaint with SEC, charging Siemens AG with violating the FCPA's anti-bribery, books and records, and internal controls provisions, by agreeing to pay \$350 million in disgorgement of profits. *Id.*

⁷⁰ See ZARIN, *supra* note 5, at 6-25 to 6-27.

the illegal activity, and thus could be subject to FCPA liability. Due diligence of the joint venture partner, adequate disclosure of the joint venture arrangement, and requisite government approval are all essential steps in structuring international joint ventures.⁷¹

Foreign Agents and Distributors

Relationships with foreign agents can subject U.S. healthcare companies to potential FCPA liability. Foreign sales agents are typically contracted to assist a U.S. company in soliciting the sale of products or services within a foreign country by acting as an intermediary between the company and a foreign customer.⁷² Medical device and pharmaceutical manufacturers attempting to sell products in foreign countries with government-owned and -controlled healthcare systems are very likely to face risks related to foreign sales agents.⁷³ In addition, U.S. hospitals attempting to set up international operations may engage a foreign agent in order to find a suitable venture partner, acquire assets, obtain patient referrals, and build relationships with local constituencies. These activities can be problematic in countries with government-owned or -controlled healthcare systems or other related industries.

In a recent example, on June 3, 2008, DOJ announced that it had entered into an agreement with AGA Medical Corporation (AGA), under which the privately held Minnesota-based manufacturer of cardiac medical devices agreed to pay a \$2 million criminal penalty and enter a three-year Deferred Prosecution Agreement (DPA) for FCPA violations.⁷⁴ AGA was alleged to have authorized its independent Chinese distributor to pay kickbacks or rewards to physicians employed by government-owned

⁷¹ *Id.*

⁷² *Id.* at 6-6 to 6-7.

⁷³ In 2005, Micrus Corporation (Micrus), a privately held California corporation that develops and sells embolic coils used in the treatment of intracranial aneurysms agreed to resolve its criminal liability related to potential FCPA violations by paying \$450,000 in penalties. Press Release, Dep't of Justice, Micrus Corporation Enters into Agreement to Resolve Potential Foreign Corrupt Practices Act Liability, (Mar. 2, 2005), available at www.usdoj.gov/criminal/pr/press_releases/2005/03/2005_3860_micruscorp030205.pdf. The DOJ investigation revealed that officers, employees, agents, and salespeople paid more than \$150,000, disguised as honorariums and commissions, to physicians employed at publicly owned hospitals in the French Republic, the Republic of Turkey, the Kingdom of Spain, and the Federal Republic of Germany in return for the hospitals' purchase of embolic coils from Micrus. *Id.*

⁷⁴ Press Release, Dep't of Justice, AGA Medical Corporation Agrees to Pay \$2 Million Penalty and Enter Deferred Prosecution Agreement for FCPA Violations, (Jun. 3, 2008), available at www.usdoj.gov/opa/pr/2008/June/08-crm-491.html. AGA entered into the three-year DPA and agreed to pay a \$2 million fine and retain an independent compliance monitor to review improvements to the company's internal control procedures. *Id.*

hospitals to encourage the purchase of AGA devices.⁷⁵ DOJ's announcement of its agreement with AGA demonstrates its willingness to broadly interpret the third-party payment provisions of the FCPA. The illicit payments were not made directly by an AGA-owned or -controlled person. DOJ stated that the sale of goods by a U.S. company to a foreign distributor—when the U.S. company had knowledge that the distributor had bribed a foreign official to purchase the products—would be considered an “act in furtherance of” an illegal payment and would be subject to prosecution under the FCPA.⁷⁶ Accordingly, mere knowledge or outright authorization of illicit payments made by an independent distributor may subject a U.S. healthcare company to liability under the FCPA.⁷⁷

Compliance: A Familiar Concept for U.S. Healthcare Companies

For U.S. healthcare companies, FCPA compliance should be viewed in the same familiar light as healthcare fraud and abuse corporate compliance. U.S. healthcare companies frequently deal with corporate compliance issues relating to fraud and abuse under the federal False Claims Act,⁷⁸ Stark Law,⁷⁹ and Anti-kickback Law,⁸⁰ and most have adopted comprehensive corporate compliance programs to address potential compliance issues. DOJ has placed a significant emphasis on compliance by requiring independent compliance monitors in many of its recent FCPA settlements. A comprehensive compliance program⁸¹ is essential for a U.S. healthcare company to minimize FCPA exposure and mitigate liability for FCPA violations. U.S. healthcare

⁷⁵ *Id.*

⁷⁶ *Id.* at 6-10 (citing Statement of Peter B. Clark, Deputy Chief of the Fraud Section, Criminal Division, Department of Justice, at a conference on the FCPA in Washington, D.C. (Apr. 20, 1995)).

⁷⁷ See Koehler, *supra* note 57, at 292-295 (discussing the 2005 FCPA enforcement action against GE InVision Inc.). See also Complaint, *SEC v. GE InVision, Inc.*, Case No. C 05 0660 (N.D. Cal. 2005).

⁷⁸ 31 U.S.C. §§ 3729-3733.

⁷⁹ 42 U.S.C. § 1395nn.

⁸⁰ 42 U.S.C. § 1320a-7b(b).

⁸¹ According to the Sentencing Guidelines, a “compliance and ethics program shall be reasonably designed, implemented, and enforced so that the program is generally effective in preventing and deterring criminal conduct.” Under the Sentencing Guidelines, the following elements are critical to a comprehensive compliance program: (1) establishment of policies and procedures; (2) corporate governance oversight; (3) background checks/due diligence; (4) education and training; (5) monitoring, auditing, and evaluation of compliance program; (6) reporting system/employee hotline; and (7) discipline and corrective action for violations. See Sentencing Guidelines, *supra* note 53, at § 8B2.1. See DAVID E. MATYAS & CARRIE VALIANT, LEGAL ISSUES IN HEALTHCARE FRAUD AND ABUSE: NAVIGATING THE UNCERTAINTIES 324-336 (American Health Lawyers Association 2006) (1994).

companies should be well aware under the Sentencing Guidelines that a broad-based compliance program can significantly reduce fines and penalties assessed to a corporation if a violation occurs.⁸² Ultimately, however, the effectiveness of a company's compliance program can only be measured by the extent to which the company incorporates the standards into its internal culture and emphasizes adherence to the program.

Elements of an Effective FCPA Compliance Program

U.S. healthcare companies engaging in international business should adopt a clear and concise company policy statement on the FCPA stating the company's commitment to conduct business legally and ethically. More detailed and specific policies and procedures should be developed based on a comprehensive compliance risk assessment of the company's business.⁸³ In addition to a general FCPA policy, policies and procedures should be tailored to address high risk areas.⁸⁴ Training should be done periodically so that all employees have a practical understanding of the essential elements of the FCPA and understand their responsibilities with respect to the compliance program.⁸⁵ The company's governing body needs to be knowledgeable about the FCPA compliance program and exercise reasonable oversight of the compliance program. An FCPA compliance program can easily be incorporated into a U.S. healthcare company's existing compliance protocols and be overseen by the standing Compliance Committee and Chief Compliance Officer.⁸⁶ The company's compliance program should be evaluated and audited periodically to determine the effectiveness of the program, with specific attention to third-party contractual

⁸² See Sentencing Guidelines, *supra* note 53, at § 8C2.5(f).

⁸³ See Sharie A. Brown, *Practice note: US Foreign Corrupt Practices Act compliance program tips*, COMPLINET, Nov. 28, 2007, at 1, available at www.complinet.com/global/news/news/preview.html?ref=99639. In conducting a risk assessment, the company should consider (i) the amount of interaction with foreign officials and foreign governments, (ii) specific public corruption risks associated with their foreign locations, and (iii) the types of agents, consultants, and third parties involved in the business. *Id.*

⁸⁴ *Id.* at 2. High risk areas include the "facilitating payments" exception, the affirmative defenses, and the due diligence process for vetting agents, third parties, and potential business partners. *Id.*

⁸⁵ See MATYAS & VALIANT, *supra* note 81, at 332 (discussing the importance of training).

⁸⁶ The board of directors should establish a Compliance Committee that meets regularly and appoint a Chief Compliance Officer with direct responsibility for the day-to-day operations and monitoring of the compliance program. See MATYAS & VALIANT *supra* note 81, at 326-330 (discussing compliance committee and chief compliance officer).

arrangements, expense vouchers and reports, and an analysis of sample transactions.⁸⁷ U.S. healthcare companies should also implement a “hotline” that allows employees to anonymously report actual or suspected FCPA violations without fear of retaliation.⁸⁸

U.S. healthcare companies need to use reasonable efforts not to delegate substantial authority to any individual whom the company knew—or should have known through the exercise of due diligence—has engaged in illegal activities or other conduct inconsistent with the FCPA compliance program. Due diligence of agents, consultants, third parties, and potential joint venture partners is extremely important in the context of FCPA compliance because it allows a company to identify potential “red flags” by gathering background information on a potential partner’s business reputation, qualifications, reputation for ethical dealings, government official status, prior misconduct, and relationships with government entities and government officials.⁸⁹

Conclusion

As the globalization of the healthcare industry continues to expand, the FCPA is likely to have an increasingly larger impact on U.S. healthcare companies. Business relationships with government-owned and controlled entities and their officers, employees, and agents create a potentially high level of exposure to violations of the FCPA. The healthcare industry is not exempt from prosecution for FCPA violations and, at least as it pertains to the medical device industry, appears to be a major focus of enforcement activity. U.S. healthcare companies need to be aware of and understand the impact that the FCPA has on doing business around the world and should view FCPA compliance in the same light as they view healthcare fraud and abuse compliance. To prevent FCPA violations from occurring and to mitigate a company’s liability when violations have already taken place, U.S. healthcare companies should adopt a comprehensive compliance program to address the potential FCPA risks associated with doing business internationally.

⁸⁷ ZARIN, *supra* note 5, at 10-11.

⁸⁸ U.S. healthcare companies are required to take reasonable steps to have a well publicized, anonymous and confidential reporting system that allows employees and agents to report or seek guidance regarding potential or actual criminal conduct without fear of retaliation. A “hotline” is a common reporting mechanism used by healthcare companies. Matyas & Valiant, *supra* note 81, at 333. See also ZARIN, *supra* note 5, at 10-10 (discussing “hotlines”).

⁸⁹ See Brown, *supra* note 83, at 2; Koehler, *supra* note 57, at 299-301.

Medical Tourism: An Industry in Evolution

Fredric J. Entin, Esquire
Polsinelli Shughart PC
Chicago, IL

Kevin Ryan, Esquire
Epstein Becker & Green PC
Chicago, IL

Medical tourism—traveling from one country to another for medical treatment—has received significant attention for several years. Last year alone, guidelines were issued by the American Medical Association (AMA); reports were published by the Deloitte Center for Health Solutions and McKinsey and Company attempting to quantify numbers; a *US News & World Report* cover story featured medical tourism; articles were published in *The Economist*, *Wall Street Journal*, *Business Week*, *FastCompany*, and numerous other national and regional magazines and newspapers; and the trend was featured on CNN, Fox News, and NBC. While medical tourism has long been a thriving industry globally and the United States has been a destination for international medical tourists, the phenomenon of U.S. residents traveling abroad for medical care is a fairly recent development. To date, the trend is a result of more and more uninsured and underinsured patients seeking quality healthcare providers that offer low-cost alternatives to medical treatment in the United States. The interest and impetus to obtain care abroad is about to change. Reports from the insurance industry indicate that insurance companies and employers are beginning to seriously consider travel to a foreign destination as an option.

This article will provide a brief overview of the U.S. medical tourism industry, where it may be headed, and some of the obstacles most cited by providers, employers, and insurers that must be resolved for the industry to evolve. Our discussion will be necessarily incomplete, as the subject is quite broad, constantly changing, and worthy of multiple articles.

United States Medical Tourism

The Current Model

Medical tourism for Americans emerged as a consumer-driven, cash-based phenomenon rather than a health regulatory or industry development. The majority of patients electing to obtain care outside of the United States are either uninsured or underinsured, who might otherwise have no option because of costs. Patients are traveling to Mexico, India, Thailand, Singapore, Turkey, and other countries principally to reduce medical expenses. Savings, compared to the cost of the same procedure in the United States, including the cost of travel, generally range between 40% and 80%. But savings alone are not what has driven the industry. Many foreign providers are international centers of excellence that offer high-quality medical services at levels to which those in the West are accustomed. As a result, international patients—many from the West—represent a significant and growing portion of the patients they treat.

As medical tourism developed in the United States, entrepreneurs identified a complementary business opportunity. Medical tourism facilitators, usually Internet-based, began to appear, offering assistance to Americans looking for medical options overseas. Some of these companies merely provide information or act as a conduit for communication between foreign providers and potential American patients. Others provide a greater range of services, including coordination of travel arrangements, communication of medical information between the patient and their foreign provider, and verification that the patient is fit to travel. However, few if any facilitators assume responsibility for the continuum of care. If they need it, patients generally have to make their own arrangements for follow-up care once they return home.

Response of Organized Medicine

AMA Guidelines

On June 16, 2008, at its annual policy-making meeting, the AMA adopted the first-of-its-kind guidelines for medical tourism. The AMA guidelines, rather than a knee jerk negative reaction or a set of protectionist proposals, address many of the key issues that participants in medical tourism deal with regularly, many of which are still not well

resolved. Among the guidelines is the recommendation that a patient deciding to travel abroad go voluntarily after having been informed of all of the treatment options and alternatives to medical care in another country. The AMA guidelines also address patient safety, the confidentiality of patient records, and the availability and payment for follow-up care in the United States. The final guideline implicates what many have expressed as a threshold issue for the growth and evolution of medical tourism. That guideline states that “[p]atients should be informed of their rights and legal recourse prior to agreeing to travel outside the United States for medical care.” As identified by the AMA guidelines, liability is a critical issue for those in the medical travel industry who will be treating Americans because legal systems abroad do not provide for the same type of legal recourse in the event of a bad outcome and because of the concern that involvement in the United States court system will add significant costs to providers, employers, and payors.

Government Regulation

With few exceptions, the medical tourism industry in the United States today is a self-payor, cash industry. It is an industry in which individual consumers of health services on their own seek out—perhaps using research resources such as web-based information from providers and facilitators—medical providers overseas where needed services can be provided at a lower price than in the United States. While no one expects the federal government to embrace medical tourism for Medicare or Medicaid reimbursement purposes any time soon,¹ specific government regulation of medical tourism does not seem imminent. In particular, there is no indication of state or federal government regulation of the industry that could impede the industry’s further development. The opposite is true, in fact. States such as West Virginia have considered embracing medical tourism and making it a part of government healthcare. Others such as Texas have considered changes to existing law to specifically allow for some cross-border plans. Only California has enacted legislation directly addressing the

¹ Some state legislative bodies have considered encouraging the use of foreign providers to help reduce the costs associated with healthcare coverage of state workers. In addition, there have been efforts to encourage the Centers for Medicare & Medicaid Services to consider extending reimbursement to foreign providers to serve the expatriate retirement community.

industry to date, and that legislation was supportive. At the federal level, the only significant government action has been a single hearing conducted by the Senate Special Committee on Aging in Summer 2006 that promised further investigation of the industry but so far has produced no report or other action.

Employer-Based Medical Tourism Insured Options

Many believe that medical tourism will experience significant growth when employers and other third party payors embrace it. Understandably, the economic burden of providing healthcare benefits is a major concern for American companies. Responding to this concern, private insurance companies are beginning to devise health plans that include a medical tourism option. This response to the interest of employers for a lower-cost option to domestic-based care is driving the transition of medical tourism to include an insurance-based model. However, certain critical issues need to be addressed if there is going to be large-scale adoption of medical tourism by third party payors.

Quality

While cost savings have been published widely, reliable evidence of quality is more elusive. Demonstrating and evaluating the quality of the provider of care is a liability and business issue crucial to the acceptance of those designing health benefit plans that will offer a travel benefit. Medical benefit plan developers must be able to identify foreign providers that deliver an acceptable level of care. Although there are a number of existing sources of quality indicators, the challenge today is translating these indicators into meaningful and actionable information

For example, one of the most trumpeted indicators of quality is Joint Commission International (JCI) accreditation. The JCI is an affiliate of The Joint Commission, the organization that accredits U.S. hospitals for a variety of purposes including eligibility for participation in Medicare and Medicaid. As of February 2009, JCI reports that over two hundred providers in thirty-five countries have received JCI accreditation. Instead of a single standard however, in addition to JCI accreditation, local and international licensure, certifications and accreditations may be available – including the International Organization for Standardization. Many foreign providers promote their association with

a respected U.S. provider or health system, such as Harvard Medical International, Johns Hopkins, Cleveland Clinic, Christus, or the University of Pittsburgh as yet more evidence of quality. Of course, the foreign hospital can produce its own data regarding morbidity and mortality, infection rates and outcomes, but because most of these data are self-reported, verification is difficult. Further, quality related data reporting requirements might be dictated by local law or regulation, making it difficult to reliably compare facilities from country to country or to compare foreign providers to U.S. providers.

With respect to physicians, U.S. board certification or comparable Western training may all be indicators of quality. A challenge confronting potential payors is to understand how to evaluate the credentials of physicians who have not trained in the West. In the United States, membership on the medical staff of a hospital gives rise to a presumption that the individual physician's credentials and performance have been reviewed and found acceptable. Although JCI accreditation may provide some degree of assurance, whether it is reasonable to rely on the review of others in a foreign country is another issue yet to be resolved.

Legal Issues

As noted above, the U.S. medical tourism industry is evolving as employers and other third parties investigate medical care abroad as an insured option. As this trend picks up steam, the legal and regulatory environment implicated by medical tourism will become more complicated.² But the legal issue most consistently cited as the threshold issue for foreign providers, insurers, and employers is medical liability and exposure to the U.S. court system.

Many are convinced that exposure to liability in U.S. courts is inevitable and that it is only a matter of time before an American patient looking for compensation for an injury caused by a foreign provider will retain legal counsel and be advised that recourse in

² Privacy, tax, licensure, The Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. §§ 1001, *et seq.*, state insurance regulation, the Foreign Corrupt Practices Act of 1977 (FCPA), 15 U.S.C. §§ 78 *et seq.*, and the Anti-Kickback Statute, 42 U.S.C. §§ 1320a-7b(b) are just a few of the many complex legal, regulatory, quality, and perception issues to be addressed in the future.

the foreign jurisdiction is inadequate by our standards. Aggressive attempts to file suit in the United States and receive compensation comparable to American jurisprudence are likely to follow. Clearly the stakes are high when the alternative is compensation from the legal system in another country.

While the incentive to get jurisdiction and recourse in the United States is obvious, plaintiffs will confront numerous barriers to obtaining compensation outside of the jurisdiction where the injury occurred. Vigorous and expensive litigation will ensue over issues relating to service of process, choice of law and conflicts of law, forum non conveniens, and enforcement of judgments. Each of these liability-related issues could be the subject of a lengthy analysis and review. But before a court addresses any of these complicated issues, the first issue to be resolved is whether the defendants will be subject to personal jurisdiction.

Personal Jurisdiction

A basic tenet of due process requires that a court have personal jurisdiction over a defendant before it can enter a valid judgment imposing a personal obligation on the defendant.³ However, a state court may properly acquire personal jurisdiction over a nonresident (long-arm jurisdiction) even though the defendant is not personally served within the forum state, provided that the defendant has certain “minimum contacts with the forum state such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice.”⁴

Long-arm personal jurisdiction may be either general or specific. A court can exercise general jurisdiction over a defendant even if the defendant’s forum-related activities do not serve as the basis of the lawsuit if the defendant’s conduct in the forum is “continuous and systematic.”⁵ If the foreign provider’s activities are extensive enough to be classified as continuous and systematic, it will be subject to the jurisdiction of that court generally for any lawsuit.

³ *Kulko v. Superior Court*, 436 U.S. 84 (1978).

⁴ *International Shoe Co. v. Washington*, 326 U.S. 310 (1945).

⁵ *Gorman v. Ameritrade Holding Corp.*, 293 F. 3d 506, 509-10 (D.C. Cir. 2002).

Specific personal jurisdiction more narrowly permits a court to exercise personal jurisdiction over a non-resident defendant when the defendant's forum-related activities serve as or are related to the basis of the lawsuit.⁶ Specific jurisdiction is dependant on facts specific to the individual case before the court. The fact that a court finds specific personal jurisdiction in one case has no bearing on any subsequent case. A plaintiff faces a significantly higher burden in proving general jurisdiction as opposed to specific jurisdiction. Accordingly, for purposes of this discussion we will assume that general personal jurisdiction is unlikely.

The Current Model and Personal Jurisdiction

With the few exceptions where the medical tourist is insured, most patients find out that there are available choices when they need a procedure that they cannot afford in the United States from the websites of medical tourism facilitators or the providers.

Assuming the foreign provider's contacts with the forum state are limited to the Internet, there is guidance from a number of cases that have considered whether Internet activity could establish the minimum contacts to assert jurisdiction over the foreign person.

Zippo Mfg. Co. v. Zippo Dot Com, Inc.,⁷ is a widely cited case discussing whether Internet contacts are sufficient to base personal jurisdiction. The court in *Zippo* applied a sliding scale that found personal jurisdiction "directly proportionate to the nature and quality of commercial activity that an entity conducts over the Internet." On one end of the scale are passive sites that merely provide information. On the other end are those sites where the "defendant clearly does business, such as the knowing and repeated transmission of computer files over the Internet."⁸ At this stage of the industry's development, most foreign provider Internet sites and those of travel facilitators fall somewhere in the middle of the *Zippo* sliding scale—arguably short of the nature and quality of commercial activity or minimum contacts that would allow a court to assert personal jurisdiction over the defendant. Not all courts follow *Zippo*.⁹

⁶ *ALS Scan, Inc. v. Digital Serv. Consultants, Inc.*, 293 F. 3d 707, 712 (4th Cir. 2002).

⁷ 952 F.Supp. 1119 (W.D. Pa. 1997).

⁸ *Id.* at 1124.

⁹ See, *Howard v. Missouri Bone and Joint Center*, 373 Ill App 3d 738 (2007).

The Insured Model, Additional Contacts, and Personal Jurisdiction

Once medical tourism evolves to an insured option model, competition for and service to patients is certain to require more business activity than the current patient-to-provider cash model. To effectively attract and compete for patients, providers may decide it is necessary to employ U.S.-based sales or marketing staff, have offices physically in the United States, or make direct solicitations to American payors and patients. Foreign providers may deem it necessary to have contractual or agency arrangements with American physicians to examine and counsel patients before they travel and to provide follow-up care.

Each business decision foreign providers make adds weight to arguments that a plaintiff's lawyer will make in favor of jurisdiction. For example, an employee of the foreign provider may record erroneous clinical information from the patient in an office in the United States leading to an allegation by the patient that the erroneous information is the proximate cause of an injury abroad. It is also likely that counsel for an injured patient will cite necessary but negligent follow-up care arranged by the foreign provider in the United States as a basis for jurisdiction. As these new clinical and business-driven relationships and activities proliferate, a court may find it more difficult to dismiss a case based on the absence of minimum contacts with the state.

Will Courts Treat Medical Negligence Cases Differently?

However, other important policy considerations may affect whether a court will be as willing to assert personal jurisdiction over a foreign defendant accused of medical malpractice as it would over defendants engaged in other forms of commerce.

Although we can find no reported cases in which personal jurisdiction has been asserted against a foreign provider by a court in the United States, judges have often dealt with jurisdictional arguments in medical malpractice cases involving patients and physicians from different states.

A review of intrastate cases indicates that judges take note of the special nature of healthcare and tend to approach medical malpractice cases with a special

measure of deference. “The nature of the activity in which the defendant is engaged is important.”¹⁰ As providers and their facilitator agents do what is necessary to compete for American patients and establish a physical presence in a state, they will be deliberately engaging in more contacts with the state. In other forms of commerce similar contacts may be sufficient for a court to assert personal jurisdiction, but public policy considerations in a medical malpractice case may result in a different outcome. Judges in medical malpractice cases have found the idea that “tortious rendition of medical services is a portable tort,” which can be deemed to have been committed “wherever the consequences foreseeably were felt is wholly inconsistent with the public interest in having services of this sort generally available.”¹¹

Courts have also been mindful of the related issue of fair treatment of medical care providers. While all long-arm analyses must consider the fairness as a matter of due process, the analysis is slightly modified in medical malpractice cases. In *Gelineau v. New York University Hospital*,¹² a New Jersey resident voluntarily traveled to New York for treatment of an aneurism. While in New York, the patient received a blood transfusion. Shortly after returning home, he was diagnosed as having hepatitis and brought suit against the hospital in a New Jersey court for damages related to the disease. The court in *Gelineau* held that the issue is “whether or not a physician, a hospital, or such, licensed only to practice in New York, having been sought out by a resident of the State of New Jersey, or even perhaps a resident of a foreign nation, should be required to defend a malpractice action in those respective forums based upon the standards of care and the substantive laws of those foreign forums. We think not.”¹³

In general, long-arm jurisdiction concerns itself with whether the defendant purposefully availed himself of the forum in question. Long-arm jurisdiction in medical malpractice cases will also take into consideration whether the plaintiff purposefully availed himself of services outside the forum. In *Gelineau*, the court found that the exercise

¹⁰ *Harlow v. Children’s Hosp.*, 432 F.3d 50, 63 (1st Cir. 2005).

¹¹ *Coggeshall v. Reproductive Endocrine Associates of Charlotte*, 376 S.C. 12, 18 (2007), (citing *Wright v. Yackley*, 459 F.2d 287, 289-90 (9th Cir. 1972)).

¹² 375 F. Supp. 661(DNJ 1974).

¹³ *Id.* at 669 (emphasis added).

of specific jurisdiction would be fundamentally unfair, and would negatively affect the practice of medicine. “Any other rule would seem to be not only fundamentally unfair, but would inflict upon the professions the obligation of traveling to defend suits brought in foreign jurisdictions, sometimes very distant jurisdictions, there brought solely because the patient or client upon his return to his own home decided to sue at home for services sought by himself abroad.”¹⁴ The court reasoned that such a liberal application of personal jurisdiction would ultimately harm persons such as the plaintiff as doctors would be less inclined—or altogether disinclined—to treat non-resident patients.

Conclusion

The number of Americans seeking access to care outside of the U.S. is growing and most predict that the numbers will accelerate significantly once such care is available as an insured option. Many issues need to be more fully addressed before the expected flood of Americans is realized. As has been discussed, concerns about quality must be resolved and third party payors must fully embrace the option to travel for care. The legal and regulatory environment in which medical tourism will be delivered will be complicated. Foremost among the legal issues is medical liability and whether the business and clinical infrastructure for a viable medical tourism option in a medical benefit plan will give rise to personal jurisdiction in American courts.

Convincing a court that it has personal jurisdiction over a defendant thousands of miles away is difficult if the only contact with the plaintiff’s state of residence is the Internet. However as foreign providers step up their efforts to attract patients and payors, those very same efforts will be the basis upon which personal jurisdiction will be argued. Opening offices, clinics, having employees in the United States, and engaging American physicians to deliver post-treatment care will certainly represent minimum contacts that will affect a court’s consideration of whether to assert personal jurisdiction. Even with the special treatment courts have historically given to intrastate disputes of this type in medical malpractice cases, there is no precedent for cases arising from medical tourism. Given the differences in substantive law and the significant disparity in

¹⁴ *Id.* at 667.

compensation available in foreign judicial systems, vigorous litigation in American courts is predictable. A judge responding to perceived unfairness may be more inclined to give one of the residents of their state a day in the local courts if there are minimum contacts with his state. Even if plaintiffs will rarely succeed, the cost of defending these actions—even at the jurisdictional level—will be hard-fought and expensive.

Opportunities for U.S. Academic Medical Centers in the Persian Gulf

Michael B. Lampert, Esquire
Ropes & Gray LLP
Boston, MA

Relationships have blossomed in recent years between leading academic medical centers (AMCs) in the United States and hospitals, governments, and private foundations in the Persian Gulf. This article briefly discusses trends in the Gulf Cooperation Council (GCC)¹ that have converged to present opportunities for these relationships; the nature of the opportunities that are available; and the legal considerations that AMCs evaluating these opportunities should assess.

Trends in Healthcare in the Persian Gulf

Current opportunities for AMCs in the Persian Gulf have arisen largely from shifting demographics and governmental responses to them.

The average life expectancy in many Persian Gulf countries has increased dramatically in recent decades. For example, since 1970 life expectancy in Qatar and the United Arab Emirates has increased from sixty to seventy-six years and from sixty-one to seventy-nine years, respectively. These numbers can be compared to an increase from seventy-one to seventy-eight years in the United States over the same period.² As in other countries with comparable demographics, the longer-lived populations have increased the need for long-term and complex acute care, as more people survive to experience later-life chronic illness. For example, in the United Arab Emirates, coronary heart disease now is the leading cause of death and 25% of the population now is living with diabetes.³ These changes have significantly increased demand for healthcare.

¹ GCC countries are Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates.

² UN data, Life expectancy at birth (The State of the World's Children 2009, United Nations Children's Fund), <http://data.un.org/Data.aspx?q=life+expectancy+at+birth+state&d=SOWC&f=inID%3a97> (visited Feb. 25, 2009).

³ Dr. Javid Hamid Farooqi, *An Audit for Cardiovascular Disease Risk Assessment and Management in a Rural Primary Health Center in Abu Dhabi*, 4 MIDDLE EAST J. OF FAM. MED. 8, 8 (2006), available at www.mejfm.com/journal/March2006/MEJFM_March_06.pdf (visited Feb. 19, 2009); Lara Setrakian, *UAE and Diabetes: One in Four Has It*, ABC NEWS, Dec. 23, 2007, <http://abcnews.go.com/Health/Diabetes/Story?id=4044952&page=1> (visited Feb. 19, 2009).

Indeed, McKinsey & Company has projected demand for overall healthcare in GCC countries to grow 240% by 2025.⁴

Fortunately, as demand for advanced healthcare has increased, so too have resources available to meet the demand. Over the same period since 1970, while life expectancies were increasing over 25%, per capita gross domestic product in Qatar and the United Arab Emirates increased from \$4,841 to \$75,978 and from \$3,173 to \$43,709, respectively.⁵ Available resources for healthcare therefore have expanded significantly.

Recognizing this increased need and capacity, governments and non-governmental organizations in the Persian Gulf have provided incentives to encourage the development of private healthcare facilities.⁶ For example, in Dubai the government provided land and funding for the fifteen million square foot Dubai Health Care City Campus (DHCC) which, when complete, will encompass clinical services for disease treatment and prevention, and a “wellness community” with outpatient clinics, luxury spa resorts, alternative medical services, hotels, and residences.⁷ Further hoping to incentivize development, the government exempted the DHCC from all taxes and regulations, allowing DHCC (which has received guidance from Harvard Medical International) to create its own regulatory structure.⁸

Similarly, on the non-governmental side, the Qatar Foundation, a private, nonprofit organization founded by His Highness Sheikh Hamad Bin Khalifa Al-Thani, committed \$7.9 billion to operate the Sidra Medical and Research Center (Sidra) in Qatar, scheduled to open its doors in 2012.⁹ Sidra will serve as the primary teaching hospital of

⁴ Viktor Hediger, *et al.*, PRIVATE SOLUTIONS FOR HEALTH CARE IN THE GULF 52 (McKinsey & Company) (2007), available at www.mckinseyquarterly.com/PDFDownload.aspx?L2=12&L3=63&ar=1947 (visited Feb. 19, 2009).

⁵ UN data, Per capita GDP at current prices - US Dollars (National Accounts Estimates of Main Aggregates, United Nations Statistics Division), <http://data.un.org/Browse.aspx?d=SNAAMA> (visited Feb. 25, 2009).

⁶ See Hediger, *supra* note 4, at 51.

⁷ Robert K. Crone, *Flat Medicine? Exploring Trends in the Globalization of Health Care*, 83 ACAD. MED. 117, 119 (2008); Dubai Healthcare City, Medical Community, www.dhcc.ae/EN/AboutDHCC/Pages/MedicalCommunity.aspx (visited Feb. 26, 2009); Dubai Healthcare City, Wellness Community, www.dhcc.ae/EN/AboutDHCC/Pages/WellnessCommunity.aspx (visited Feb. 26, 2009).

⁸ See Crone, *supra* note 7, at 119.

⁹ Qatar Foundation, Vision and Mission, www.qf.org.qa/output/page77.asp (visited Feb. 25, 2009); *State-of-the-art building planned*, 2 QATAR CHRONICLE 3(2007), available at http://qatar-weill.cornell.edu/media/chronicle/pdfs/qatarChronicle_v2_n5_low.pdf (visited Feb. 26, 2009); *\$7.9bn endowment fund set up for*

Weill Cornell Medical College in Qatar and will provide specialty care services for women and children and some medical and surgical services for all adults.¹⁰

Biomedical research, focused on women's and children's health, will be conducted in partnership with Weill Cornell.¹¹

The aggregate result of these demographic shifts and the economic incentives provided by governments and non-governmental organizations is a greater need for advanced care, greater resources for it, reduced costs associated with developing private healthcare facilities, and thus a greater opportunity for providers, including AMCs.

Nature of Opportunities

From the perspective of hospitals, academic institutions, and governments in the Persian Gulf, AMCs can offer expertise, experience, and instant international recognition—all key components in accelerating ground-up development of world-class healthcare and cutting-edge facilities. From the perspective of AMCs, participation in new ventures in the Gulf can support mission goals of improving access to quality medical care around the world and decreasing health inequalities; enhance the institution's international reputation; and generate revenue through payments for advisory and management services, clinical care, name licensing, and licensing of intellectual property developed from research conducted abroad.¹²

Several top AMCs have already formed relationships with hospitals, governments, or private foundations in the Persian Gulf, with the AMCs' involvement generally falling in three categories.¹³ First, some AMCs have provided advisory or consulting services to existing or newly formed healthcare facilities, using their institutional experience to

Sidra medical facility, THE PENINSULA, Mar. 8, 2007, available at www.sidra.org/files/pdf/August%2007.pdf (visited Feb. 25, 2009); Sidra Medical and Research Center, Project Updates, www.sidra.org/output/page1721.asp (visited Feb. 23, 2009).

¹⁰ Qatar Foundation, Weill Cornell Medical College in Qatar, www.qf.org.qa/output/page552.asp (visited Feb. 23, 2009); Qatar Foundation, Sidra Medical and Research Center, www.qf.org.qa/output/page85.asp (visited Feb. 25, 2009).

¹¹ Sidra Medical and Research Center, Biomedical Research, www.sidra.org/output/page1724.asp (visited Feb. 23, 2009).

¹² See Allison Van Dusen, *America's Top Hospitals Go Global*, FORBES, Aug. 25, 2008, available at www.forbes.com/2008/08/25/american-hospitals-expand-forbeslife-cx_avd_0825health.html (visited Feb. 19, 2009); Michael G. Merritt, *et al.*, *Involvement Abroad of U.S. Academic Health Centers and Major Teaching Hospitals: The Developing Landscape*, 83 ACAD. MED. 541, 545 (2008).

¹³ See Merritt, *supra* note 12, at 542–44.

assist by establishing standards of practice, training clinicians, and developing educational programs focused on addressing the region's healthcare needs.¹⁴ Second, other AMC's have entered into full-scale management agreements, appointing personnel from their home institution to serve in executive leadership roles, and tailoring guidelines, standards, and procedures to the local facility and population.¹⁵ Finally, a few AMC's both operate and own their own facilities in the Gulf.¹⁶

Legal Considerations

It is not possible in this article to provide a detailed analysis of all legal issues that AMC's should consider when undertaking some form of venture in the Persian Gulf. The following discussion therefore briefly describes the most pertinent threshold considerations that AMC's should address before embarking on a new opportunity.

Counterparty

Most AMC's' participation in the Gulf will include one or more local counterparties. As in any transaction, diligence into potential counterparties is key. Initial questions and considerations should include general business and legal compliance, and the counterparty's long-term commitment, as would be done in the context of any affiliation.¹⁷ However, diligence also should review in somewhat more detail the identity of each counterparty's officers, directors, and equity owners, including their relationships in the host country; the reputation of each counterparty as a business entity in the community; and, depending on the nature of the anticipated relationship, each counterparty's current capital and debt structure in order to assess the impact of

¹⁴ See *id.* at 543–44.

¹⁵ See *e.g.*, Cleveland Clinic, Cleveland Clinic Appoints Kenneth Ouriel, M.D., to Lead Sheikh Khalifa Medical City in Abu Dhabi; Tommaso Falcone, M.D. Named Interim Chairman, Division of Surgery, http://my.clevelandclinic.org/media_relations/library/2007/822.aspx (visited Feb. 19, 2009); Johns Hopkins Medicine International, Tawam Medical Center, www.jhintl.org/for-health-care-systems/hospital-management/tawam-hospital (visited Feb. 19, 2009).

¹⁶ Merritt, *supra* note 12, at 543.

¹⁷ Illustrating the importance of ensuring long-term counterparty support, George Mason University recently announced that, due to reduced financial support from its counterparty, it will close its branch campus in Ras al Khaymah, one of the United Arab Emirates. See Tamar Lewin, *George Mason University, Among First with an Emirates Branch, Is Pulling Out*, N.Y. TIMES, February 28, 2009, available at www.nytimes.com/2009/03/01/education/01campus.html?scp=1&sq=%20George%20Mason%20U%0biversity,%20Among%20First%20with%20an%20Emirates%20Branch,%20Is%20Pulling%20Out&st=cse.

Shari'ah law's prohibition on debt financing. AMCs should ensure that counterparties demonstrate long-term commitment to the proposed project.

Legal Form

For limitation of liability, tax, accounting, and operational reasons, AMCs should consider legal form carefully. Options generally include “virtual” association through contract, foreign registration of the AMC, foreign registration of a separate subsidiary of the AMC, and foreign incorporation of a new entity. The process and time involved in foreign registration and foreign association, will vary by country, but can provide operational and legal advantages. As in other contexts, *bona fide* operation through a subsidiary can help to isolate risk.

U.S. and Foreign Tax Consequences

AMCs should be aware of potential tax consequences that may arise from operations abroad. First, AMCs should be aware that foreign activities can, depending on their nature, generate unrelated business income that is taxable in the United States against the AMC. Second, AMCs should consider the tax treatment of compensation and other benefits paid to U.S. citizens posted in the Gulf, as U.S. income tax frequently will apply. Third, AMCs should be cognizant that tax-exempt status is not necessarily cross-jurisdictional. However, local law may allow an AMC to apply for tax-exempt status, and, if a general exemption is not available, an AMC nonetheless may be able to negotiate a special agreement exempting its earnings. Additionally, some Gulf countries have created tax-free zones to encourage development.¹⁸

Personnel

Most AMCs' activities will necessitate at least some on-the-ground staffing and leadership in the host country. Some issues that AMCs must consider when sending personnel abroad include logistics of immigration and employment authorization; restrictions on work visas; and potential application of the host country's labor and

¹⁸ For example, extensive information regarding tax-free zones in the United Arab Emirates is *available at* www.uaefreezones.com/. For an overview of tax-free zones and other tax issues in Qatar and selected other Persian Gulf countries, see Ernst & Young, MIDDLE EAST TAX REVIEW 12 (2008), *available at* [www.ey.hu/Global/assets.nsf/Middle_East/Middle_East_Tax_Review_08/\\$file/METR%20-%20March%202008.pdf](http://www.ey.hu/Global/assets.nsf/Middle_East/Middle_East_Tax_Review_08/$file/METR%20-%20March%202008.pdf).

employment laws, which may affect an AMC's relationship with its transported U.S. employees, and almost certainly would affect an AMC's relationship with any local hires.

Licensure and Reimbursement

Depending on the activities contemplated, an AMC may need to satisfy licensing and credentialing requirements for healthcare professionals and facilities. Also, depending on the activities contemplated and no different than in U.S. ventures, an understanding of the system of healthcare finance is crucial. Many GCC countries have both public and private payor systems, with varying limitations on reimbursement for services provided in certain settings or by certain providers, sometimes resulting in coverage for care provided in public facilities but not private hospitals.¹⁹

Intellectual Property and Research

Available research opportunities may be a significant factor driving an AMC's decision to pursue a venture in the Gulf. Initial considerations for conducting research include required government approvals; additional ethical restrictions; in-country oversight; and coordination of in-country oversight with oversight of U.S. research. Depending on its federal-wide assurance, an institution's foreign research activities may also be subject to the Common Rule. The AMC's own intellectual property and commercialization policies should also be considered in the context of the host country's intellectual property laws, including ownership, trade secret protection, and licensing.

U.S. Compliance

Issues of U.S. law and oversight also must be part of an AMC's considerations. For example, the Foreign Corrupt Practices Act (FCPA) broadly prohibits bribery of foreign officials to obtain or retain business, often deeming an employee of a government-owned facility to be a foreign official within the scope of the law.²⁰ Thus, an AMC must be aware of the official status of any people with whom it works, among other safeguards. Other U.S. legal issues include import and export limitations. In addition, any AMC considering clinical or educational programs to be located in the Gulf must consider questions of accreditation.

¹⁹ See Hediger, *supra* note 4, at 51, 57.

²⁰ 15 U.S.C. §§ 78dd-1 *et seq.*

Conclusion

Numerous and exciting opportunities exist for AMCs in the Persian Gulf. While successfully seized by a number of institutions, the opportunities are by no means exhausted, and will continue to evolve as the sophistication of early ventures grows.

While all business development can benefit from early consideration of legal issues, working in an unfamiliar legal system makes the need for such consideration particularly acute. Careful and early analysis of the novel legal issues can greatly increase the likelihood that an AMC's aspirations for activities in the Persian Gulf will be met with success.

Arbitration Clauses in International Agreements: Why and How?

Jean Engelmayer Kalicki, Esquire
Bonard I. Molina García, Esquire
Arnold & Porter LLP
Washington, DC

In our global economy, transactional attorneys in the health industry can expect to be involved increasingly in deals involving international parties. Because a contract is only as good as the parties' ability to enforce it, however, it is essential that deal lawyers understand the issues specific to the resolution of international commercial disputes. In particular, we address below two threshold questions: why is arbitration often preferable to court litigation in the international context, and how should arbitration be structured in international deals?

Why Arbitrate Rather Than Litigate?

Historically, arbitration was viewed as preferable over litigation primarily for reasons of efficiency and costs. These traditional justifications did not always prove true in domestic cases, where arbitration came more and more to resemble litigation as practiced in U.S. courts. In the *international* context, however, there are two entirely different reasons for favoring arbitration: neutrality of the decision maker and enforceability of the final award.

No party is keen to subject itself to a foreign jurisdiction, particularly when its contract counter-party would have the “home court advantage” and may have the political or economic influence to affect outcomes in its local courts. Arbitration addresses this issue by permitting the parties to select a neutral decision maker that is largely insulated from interference by the courts.

Even where judges are considered neutral, their judgments may prove not worth the paper they are written on. To date, there is no international convention requiring the courts of one country to honor a court judgment issued in another country. By contrast, some 144 countries have ratified the New York Convention,¹ which requires courts in

¹ Convention on the Recognition and Enforcement of Foreign Arbitral Awards, 1958 (New York Convention), available at www.uncitral.org/pdf/english/texts/arbitration/NY-conv/XXII_1_e.pdf.

any of those countries to recognize and enforce arbitration awards issued in any of the other signatory countries.

How Should Arbitration Be Structured in International Deals?

There is an old adage that arbitration is a procedure that has too few lawyers in the beginning and too many in the end. At the time important business transactions are being finalized, the parties are usually reluctant to focus on the possibility that one or the other might not honor its commitments. The arbitration clause is usually one of the last items drafted and often with little care—copied from a prior transaction and not tailored to the particular deal. This can lead to numerous problems later, ranging from difficulty even getting a dispute resolution procedure underway to problems enforcing the award. Poor drafting of the arbitration clause inevitably increases the length and expense of the arbitral proceedings. Yet as discussed below, many of these problems can be avoided by care at the outset.

Institutional or Ad Hoc?

Arbitrations may be administered by an organizational body (*institutional arbitration*) or directly by the parties and the tribunal (*ad hoc arbitration*). While the cost of institutional arbitration may at first blush appear higher, *ad hoc* proceedings frequently require the arbitrators (or a tribunal “secretary,” often a less experienced lawyer) to handle procedural or logistical matters more efficiently delegated to an experienced case administrator. In any event, in the context of an international dispute, institutional arbitration has several key advantages that more than justify any ostensible cost differential.

First, disputing parties obtain the benefits of established procedural rules, administrative capacities, and in some cases formal review, to shepherd the proceedings from the filing of a claim on to a properly formed award.² If the parties disagree about the scope or conduct of the arbitration, institutional rules provide a framework for resolution, by the

² See, e.g., the Rules of Arbitration of the International Chamber of Commerce’s International Court of Arbitration (ICC), January 1, 1998, available at www.iccwbo.org/uploadedFiles/Court/Arbitration/other/rules_arb_english.pdf; the International Dispute Resolution Procedures of the American Arbitration Association’s International Center for Dispute Resolution (ICDR), available at www.adr.org/sp.asp?id=33994.

tribunal or by the administering institution before the tribunal is constituted. The availability of experienced administrators can also streamline the proceedings and avoid uncertainties and additional costs. In the absence of such a structure, parties to an *ad hoc* arbitration have to themselves address and agree (hopefully *before* the dispute arises) on the various components of their arbitral mechanism. In the absence of agreement, the lack of an institution to resolve disputed issues can result in an impasse, even regarding threshold issues like constitution of the tribunal.

The choice between institutional and *ad hoc* arbitration also can have substantive implications for enforceability. Practice has shown that reviewing courts are more likely to defer to judgments of arbitrators if the process has been overseen by a well-recognized institution administering widely accepted rules. In some jurisdictions such as China, courts will *only* enforce awards issued through institutional arbitrations. The threshold decision of how to structure the arbitration should therefore include an analysis of the various *fora* where an award may have to be enforced, including the location of relevant assets.

Critical Provisions

Attorneys drafting arbitral clauses for international agreements should carefully consider three fundamental issues: the seat of the arbitration, rules for tribunal selection, and possible differences between the legal systems of the parties.

Seat of Arbitration

The seat is not simply the physical location where hearings are held, which may turn on issues of convenience. It is the formal forum for the proceedings that can have tremendous substantive significance for the outcome of the case. Generally, the law of the forum—and not the law governing the contract—will determine a host of important foundational and procedural issues. This includes whether and how the national courts can become involved in the arbitral process (in support or interference), and what the likelihood is that the ultimate award will be enforced. The law of the forum can also influence the available means of challenging arbitrators, seeking emergency relief, and

other vitally important issues in a case.³ This will be of special significance to attorneys in the health products field, for example, where the possibility of intellectual property disputes could make the availability of preliminary injunctions particularly important.

For this reason, parties are advised to choose a formal seat in a country that is a signatory to the New York Convention, and where international arbitration is widely accepted and court jurisdiction favors expeditious enforcement of awards.⁴ As a recent U.S. decision illustrates, parties can face serious difficulties when trying to enforce an award issued from a non-New York Convention country.⁵ Even in certain Convention countries courts are unfamiliar with international arbitration and wrongly apply national rules to issues of challenge and enforcement.

Clear Rules for Tribunal Selection

The best way to destroy an arbitration is to prevent it from ever starting. Establishing a procedure for selecting the tribunal is thus critical. In institutional arbitration, the institution's rules will include a mechanism for constituting the tribunal in the event that the parties do not agree or one party declines to participate. In *ad hoc* arbitration, the absence of such rules can enable recalcitrant parties to thwart the proceedings at the outset. To prevent this, it is essential that agreements for *ad hoc* arbitration provide not only for a clear process of selecting arbitrators, but also for an appointing authority to make default appointments if needed. The appointing authority can be a court, an arbitral institution acting for that limited purpose, or the holder of a particular office.

Arbitrations are usually conducted either by a sole arbitrator who is agreed upon by the parties or appointed by a governing authority, or by a panel of three. Three-arbitrator panels are more expensive and more apt to take a longer time to hear evidence, consider arguments, and reach a final award. However, these panels frequently

³ For example, in one case in the early 1980s between Finnish and Australian companies, where Finnish law was applicable to their contract and the forum was England, it was deemed that English procedural law should apply. This included the English Limitations Act. Under the English limitations period, however, the claims were completely time-barred, even though Finnish law had no comparable statute of limitations. In other words, the choice of the place of arbitration decided the outcome of the case, notwithstanding the different substantive law of the contract.

⁴ The parties and the Tribunal can still agree to hold hearings in another location if more convenient; the procedural law that governs will remain that of the formal seat.

⁵ See *In re Int'l Bechtel Co. Ltd. & Dep't of Civil Aviation of the Gov't of Dubai*, 360 F. Supp. 2d 136, n. 3 (D.D.C. 2005).

engender more confidence from the parties than would a single-arbitrator proceeding, if only because the greater number of decision makers reduces the likelihood of undue bias or inappropriate decision making. If the parties nonetheless agree to have a single arbitrator, they may consider specifying that he or she should not share the nationality of either party.

Three-member tribunals may be constituted in a variety of ways. Most commonly, each party will nominate an arbitrator, and then the two party-appointed arbitrators will agree on a presiding arbitrator. Alternatively, the parties or the administering institution may exchange lists of potential candidates and thereafter cross out unacceptable candidates and rank the remaining candidates. Whichever process the parties prefer, they should specify it in advance because this can be quite difficult to negotiate after a particular dispute has arisen. In international arbitration, *all* arbitrators (including party-appointed arbitrators) are required to be independent and impartial.

Treatment of Parties from Different Legal Systems

Disputes related to international agreements may well involve a party from a common law country and a party from a civil law country. The differences in these systems and the expectations each party may have regarding the conduct of the arbitration should be considered in crafting the arbitration clause.

For example, discovery as it is known in common law countries is foreign to most civil law countries. Parties in such countries are required to disclose the documents on which they rely but may not have to disclose adverse documents, much less respond to broad document requests common in U.S. litigation. Interrogatories and depositions play no role in civil law countries. Rules regarding privilege are different as well. When drafting arbitral clauses, parties should anticipate possible disputes about these issues, and either address them specifically in advance or more realistically select a framework for resolving such disputes. One common framework is the International Bar Association's Rules on Taking of Evidence in International Commercial Arbitration that establish a reasonable middle ground between legal systems.⁶

⁶ International Bar Association, Rules on the Taking of Evidence www.int-bar.org/images/downloads/IBA%20rules%20on%20the%20taking%20of%20Evidence.pdf International

There Is No “One Size Fits All” Clause

There is no “one size fits all” clause that can anticipate and solve all problems for all cases. Some clauses will work well for one jurisdiction but not for another,⁷ and some clauses may make sense in the context of certain types of disputes, but not in others.⁸

For this reason, *arbitration agreements should always be prepared on a case-by-case basis*. There is no substitute for carefully considering, for any particular transaction, (a) what types of disputes are most likely to arise; (b) where those disputes might arise or where an award might be enforced; and (c) what type of dispute resolution procedures will be most appropriate in that context. While a number of institutions offer “standard” clauses for consideration, these should be the starting point, not the end of the analysis.

When drafting a clause, clarity and forethought are essential. Ambiguity can arise from imperfect drafting, such as designating the governing institution by the wrong name. Even worse, ambiguity can arise from the parties trying to avoid difficult questions at the time of their contract.⁹ A clause need not be long or eloquent to avoid these pitfalls.¹⁰ But because a poorly drafted clause can defeat some of the very reasons that led the parties to select arbitration in the first place, transactional attorneys should seek advice from arbitration experts when drafting clauses for particular deals. The better the clause is at the outset, the more predictable the procedure later on and the less room for creative maneuvering when disputes arise.

Commercial Arbitration, June 1, 1999, available at www.int-bar.org/images/downloads/IBA%20rules%20on%20the%20taking%20of%20Evidence.pdf.

⁷ A clause providing for prejudgment interest, for example, could be held unenforceable in Saudi Arabia because it violates mandatory public policy in the form of Sharia law.

⁸ For example, a provision for “fast-track” arbitration, requiring resolution in a few months, could be disastrous to a party needing discovery to address complex factual determinations.

⁹ For example, in one case known to the authors, U.S. and Russian business negotiators proposed to “avoid” unpleasant arguments at the time of the transaction by ducking questions of governing law and selecting a neutral seat, and instead agreeing on “binding arbitration in Stockholm, under the laws of the Russian Federation and the State of New York.” This clause was a recipe for disaster. Absent selection either of a governing institution or procedural rules to organize an *ad hoc* arbitration, simply starting an arbitration could have been very difficult. Absent a clear selection of governing law, the clause would have guaranteed a long, costly, and complicated procedure in which the parties would have to brief both Russian and New York law, then argue which should prevail in the event of inconsistencies. The goal of “avoiding” disputes at the time of transaction thus would simply have multiplied disputes at the time of arbitration.

¹⁰ One classic clause had only nine words, simply reading “English law—arbitration, if any London according ICC Rules.” The UK courts held this to be a valid arbitration agreement, providing all the essential elements—seat, institution and procedural rules, and governing law.

DOING BUSINESS IN THE GLOBAL HEALTHCARE SECTOR Member Briefing: Special Edition

© 2009 is published by the American Health Lawyers Association. All rights reserved. No part of this publication may be reproduced in any form except by prior written permission from the publisher. Printed in the United States of America.

Any views or advice offered in this publication are those of its authors and should not be construed as the position of the American Health Lawyers Association.

“This publication is designed to provide accurate and authoritative information in regard to the subject matter covered. It is provided with the understanding that the publisher is not engaged in rendering legal or other professional services. If legal advice or other expert assistance is required, the services of a competent professional person should be sought.”—*from a declaration of the American Bar Association*



Copyright 2009 American Health Lawyers Association, Washington, DC
Reprint permission granted.

Further reprint requests should be directed to
American Health Lawyers Association
1025 Connecticut Avenue, NW, Suite 600
Washington, DC 20036
(202) 833-1100

For more information on Health Lawyers content, visit us at www.healthlawyers.org.