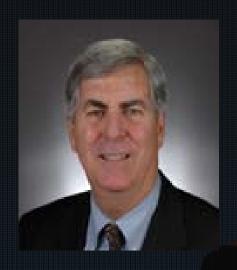
# Addressing Potential FCPA Risks in an Era of Heightened Enforcement

May 21, 2010 **E**pstein**B**ecker**G**reen



EpsteinBeckerGreen 1227 25<sup>th</sup> Street, NW Suite 700 Washington, DC 20037 Phone: 202-861-4180 sgerson@ebglaw.com

#### Stuart M. Gerson Member of the Firm

Stuart M. Gerson is Epstein Becker & Green's Senior Litigation Partner and is resident in the firm's Washington, DC and New York offices. He concentrates on the defense of complex civil and criminal fraud cases (including matters covered by the Foreign Corrupt Practices Act and other matters of extraterritorial concern), antitrust and securities cases, and class action litigation generally. Mr. Gerson has successfully tried many complex cases before judges and juries, and also has acted as settlement counsel, mediator, and arbitrator. He was an advisor to Republicans on the Senate Banking Committee during the Carter Administration with respect to the questionable payments investigations that led to the development of the FCPA in its current form.

Much of Mr. Gerson's practice is centered on representing companies involved in the health care industry, including insurers, hospitals, pharmaceutical manufacturers and managed care providers. Mr. Gerson is currently involved in the defense of several of the largest health care fraud cases brought by the federal government.

Mr. Gerson also has a substantial appellate practice and is an active and successful practitioner before the U.S. Supreme Court and the 13 United States Circuit Courts of Appeals. He has litigated over 2,500 reported cases.

Mr. Gerson was Acting Attorney General of the United States at the beginning of the Clinton Administration. And, as head of the Civil Division of the Department of Justice from 1989 to 1993, Mr. Gerson served as the federal government's chief litigator in all major matters, including those related to financial institution fraud, defense fraud, health care reimbursement, food and drug law, and health care fraud.

Mr. Gerson has served as an adjunct professor of law at Georgetown University Law Center. He is a frequent guest on CNBC, NBC, Fox News and other broadcast outlets, commenting on important business litigation, antitrust, health care and justice issues. Mr. Gerson's commentaries have been published in law journals and in newspapers, including *The Wall Street Journal*, and *The Los Angeles Times*.







EpsteinBeckerGreen 1227 25th Street, NW Suite 700 Washington, DC 20037 Phone: 202-861-4187 dvandemark@ebglaw.com

#### Dale C. Van Demark Member of the Firm

Dale C. Van Demark is a Member of the Firm in the Health Care and Life Sciences and Business Law Practices in the firm's Washington, DC office.

Mr. Van Demark represents clients in a broad array of business transactions in and outside of the health industry. Mr. Van Demark has extensive experience in mergers and acquisitions, with a particular emphasis on tax-exempt health system affiliation and restructuring transactions. He also frequently represents clients in a variety of other business transactions including debt and equity financing and joint venturing.

Mr. Van Demark has been at the forefront of advising clients with respect to the globalization of the U.S. healthcare industry. In this regard, Mr. Van Demark advises foreign and domestic enterprises with respect to the formation of medical centers in developing countries and the burgeoning medical tourism industry.

Mr. Van Demark also provides tax-exempt counseling to both tax-exempt organizations and those seeking business relationships with tax-exempt organizations. He regularly advises clients on matters related to tax-exemption qualification and compliance, including issues related to private inurement, intermediate sanctions and joint ventures. Mr. Van Demark also assists tax-exempt organizations develop, implement and evaluate governance and tax-exemption compliance "best practices."

Mr. Van Demark serves as the Vice Chair, Strategic Activities of the Business Law and Governance Section of the American Health Lawyers Association and speaks and writes regularly on matters related to his practice.







EpsteinBeckerGreen 1227 25<sup>th</sup> Street, NW Suite 700 Washington, DC 20037 Phone: 202-861-1869 jrush@ebglaw.com

#### Joel C. Rush Associate

Joel C. Rush is an Associate in the Business Law and Health Care and Life Sciences Practices in the firm's Washington, DC office.

Mr. Rush represents clients in a broad array of business transactions, in and outside of the health industry. He advises clients with regard to corporate structure, mergers and acquisitions, joint ventures, contracting, licensing requirements, and. federal and state regulatory compliance for transactions involving health-related industries.

Mr. Rush helps clients develop, implement, and evaluate corporate compliance programs, including compliance programs that address health care fraud and abuse and the Foreign Corrupt Practices Act. He provides due diligence advice related to a variety of corporate transactions, including private equity transactions, venture capital transactions and private placements.

Mr. Rush advises clients on matters related to tax-exemption qualification and compliance, including issues related to private inurement, intermediate sanctions, and joint ventures.

Prior to joining EpsteinBeckerGreen, Mr. Rush worked as a law clerk for a large pharmaceuticals company and an intern for the U.S. Navy Judge Advocate General in Washington, DC.







Navigant Consulting, Inc.

1 Rockefeller Plaza
New York, NY 10020
Phone: 212-554-2603
jspinelli@daylightforensic.com

#### Joseph A. Spinelli Managing Director

Joseph Spinelli is a leading authority on white-collar crime with more than 30 years of forensic experience. He joined a Big Four accounting firm as a principal in 1994, founding its forensic practice. During his 12-year tenure there, Joe was office-coordinating partner for the Northeast and public services industry leader.

Before his Big Four experience, he spent eight years as New York State's first inspector general, leading fraud, abuse, waste, and corruption investigations for all New York State agencies and authorities. Joe also served as assistant director of criminal justice for the state of New York, with responsibilities for the investigation of criminal complaints and fraud allegations throughout state government. His efforts resulted in a wide array of high-profile criminal convictions for fraud and corruption.

Prior to his appointment as Inspector General, Joe served as a Special Agent for the Federal Bureau of Investigation in both the New York and New Haven field offices. Joe also served as independent private sector inspector general for Miami-Dade County and was an independent fiscal monitor during the post-Sept. 11 recovery effort at the World Trade Center, with investigative, compliance and monitoring responsibilities.

Joe earned a bachelor's degree from Ricker College and a law degree at John Marshall Law School. In 2004, Joe was elected to the board of regents of the Association of Certified Fraud Examiners, an international professional association with 30,000 members.

In February 2010, Joe was appointed by Governor Paterson of New York to the New York State Commission on Public Integrity.







Navigant Consulting, Inc. 1155 Connecticut Avenue, NW 4th Floor Washington, D.C. 20036 Phone: 202-552-8407 jperlman@daylightforensic.com

#### Jay Perlman Director

Jay Perlman is a director with Navigant in its Washington office. He has almost twenty years of legal, regulatory compliance and investigative experience relating to the financial services sector. Jay concentrates on matters relating to securities, anti-money laundering and anti-bribery and corruption compliance, and conducts investigations and due diligence reviews, performs compliance program reviews and risk-assessments and develops and delivers training programs.

Jay was previously an attorney in the securities enforcement and regulatory group of a large law firm and prior to that was also Associate General Counsel for a broker-dealer/ investment adviser where he developed and implemented policies, procedures and training programs relating to SEC and FINRA regulatory requirements and coordinated the firm's responses to regulatory matters and litigation. Additionally, Jay also served as Associate General Counsel of The Motley Fool Inc. in Alexandria, Va. and frequently appeared in the media as a spokesman for the company and authored several articles about investor education and securities fraud.

Before entering the private sector, he held various positions in at the Securities and Exchange Commission and served as a Special Assistant United States attorney in the Eastern District of Virginia.

Jay has a bachelor's degree from Fordham University and earned his law degree from Albany Law School of Union University.







Robin Gazawi
Supervisory Special Agent
Federal Bureau of Investigation
International Corruption Unit





# Presentation Outline

- Overview of the FCPA and the Current Enforcement Environment
- » FCPA and the Healthcare Industry
- » Preventing an FCPA Violation
- » FCPA Case Studies



# Overview of the FCPA and the Current Enforcement Environment



# FCPA: The Basics

- » FCPA is comprised of two primary sets of provisions
  - Anti-Bribery Provisions
  - Accounting Provisions
    - Books and Records
    - Internal Controls



# FCPA: The Basics

- » Enforcement of the FCPA
  - Department of Justice (DOJ)
    - Criminal and civil enforcement of anti-bribery provisions
  - Securities & Exchange Commission (SEC)
    - Civil enforcement of accounting standards and internal controls
    - Civil injunctive authority, fines & disgorgement of profits





# **Anti-Bribery Provisions**

## Key Elements – It is unlawful for:

- 1. a U.S. person, U.S. company, or any other person in the U.S.
- 2. with corrupt intent, to offer, pay, promise to pay, or authorize payment of, directly or indirectly, anything of value
- 3. to a "foreign official," foreign political party (or official thereof), or any candidate for foreign political office (each a "covered official"), or any person while "knowing" that all or a portion of the payment or thing of value will be offered, given, or promised directly or indirectly to a covered official
- 4. for the purpose of influencing any official act or decision, inducing any act or omission in violation of a lawful official duty, or securing an improper advantage
- 5. in order to assist in obtaining, retaining, or directing business to any person





# Anti-Bribery Provisions: "Foreign Officials"

- » "Foreign Officials" include:
  - Any officer or employee of a foreign government or any department, agency, or instrumentality of a foreign government
- » 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
  - Doctors/nurses/technicians employed by state owned hospitals and clinics
  - Pharmacists employed by state owned entities



# Anti-Bribery Provisions: "Knowledge"

- » A person's state of mind is "knowing" with respect to conduct, a circumstance, or a result if such person:
  - has actual knowledge
  - has a firm belief that such circumstance exists or that such result is substantially certain to occur
  - has awareness of a high probability of the existence of the circumstance
  - is willfully blind or consciously disregards the facts





# Anti-Bribery Provisions: Penalties

#### » Criminal Penalties

- \$2 Million per violation for business entities
- Individuals face a fine up to \$100,000 and/or up to 5 years in prison
- To the extent the violation causes pecuniary gain or loss, U.S. law authorizes alternative maximum fines equal to the greater of twice the gross gain or twice the gross loss

#### » Civil Penalties

- Civil penalties up to \$10,000 for violations of anti-bribery provisions
- » Debarment from contracting with U.S. government



# Accounting and Internal Control Provisions

- » Apply to "Issuers," as well as individual officers, directors and employees of Issuers
- "Issuers" are public companies with registered securities in the U.S. or companies required to file reports under the Securities Exchange Act
  - > Includes foreign companies with American Depository Receipts (ADRs)
- » Apply to subsidiaries, joint ventures and affiliates owned and controlled (more than 50% voting power) by the Issuer
  - Control can also be a facts and circumstances test (i.e., board seats, management control)





# Accounting and Internal Control Provisions

#### » Issuers must:

- Maintain books, records and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the issuer; an
- Devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that:
  - (i) transactions are executed in accordance with management's general or specific authorization;
  - transactions are recorded as necessary (I) to permit preparation of financial statements in conformity with GAAP or any other criteria applicable to such statements, and (II) to maintain accountability for assets;
  - access to assets is permitted only in accordance with management's general or specific authorization; and
  - the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences (audits).
- » Issuers are required to make a good faith effort to cause non-U.S. affiliates in which a U.S. Issuer owns 50% or less of the voting power to maintain internal accounting controls





# Accounting and Internal Control Provisions: Penalties

#### » Criminal Penalties

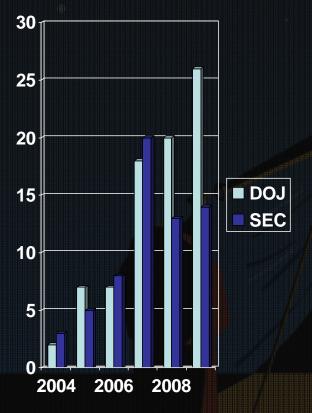
- Fines up to \$25 Million per willful violation for business entities
- Individuals facts criminal fines up to \$5 Million and/or prison sentences up to 20 years for willful violations

#### » Civil Penalties

- Fines up to \$500,000 for business entities and up to \$50,000 for individuals
- Additional penalties may be imposed



# Era of Heightened FCPA Enforcement



- 2009 continued the annual trend of record levels of FCPA enforcement brought by DOJ and SEC
- Since 2005, DOJ has brought more prosecutions than in the almost 30 years between the enactment of the FCPA in 1977 and 2005
- Criminal fines over the past 5 years have exceeded \$1 Billion
- DOJ has disclosed that it currently has at least 140 open FCPA investigations, indicating that aggressive FCPA enforcement can be expected for the foreseeable future





# Era of Heightened FCPA Enforcement

"We must vigorously enforce our own laws that prohibit bribery of foreign officials, such as,...the Foreign Corrupt Practices Act. And we must work together to support our partners in anti-corruption enforcement, and expose all efforts to undermine the effectiveness of anti-corruption initiatives."

Attorney General Eric Holder (November 7, 2009)

"FCPA violations have been and will continue to be dealt with severely by the SEC and other law enforcement agencies. Any company that seeks to put greed ahead of the law by making illegal payments to win business should beware that we are working vigorously across borders to detect and punish such illicit conduct."

Mary Schapiro, SEC Chairman (Feb. 11, 2009)





# Increased Focus on Individual Prosecutions

"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**."

Mark Mendelsohn, Former Deputy Chief – DOJ Fraud Section, ABA Conference, Sept. 11, 2008

"We firmly believe that for our enforcement efforts to have real deterrent effect, culpable individuals must be prosecuted and go to jail where the facts and the law warrant."

Assistant Attorney General Lanny A. Breuer, Keynote Address at the Tenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum (November 12, 2009)





# Increased Focus on Individual Prosecutions

Lanny Breuer: "Put simply, the prospect of significant prison sentences for individuals should make clear to every corporate executive, every board member, and every sales agent that we will seek to hold you personally accountable for FCPA violations. As we focus on the prosecution of individuals, we will not shy away from tough prosecutions, and we will not shy away from trials."





# **Industry Wide Investigations**

» DOJ and SEC officials consider it is possible that, in response to market pressures and demands, competitors may adopt similar, but improper, practices and strategies to enhance their competitive positions





# Big Penalties

- » Huge Financial Penalties, Fines and Disgorgement of Profits
- » Jail Time for Corporate Executives
- » Loss of Reputation
- » Criminal and Civil Litigation
- » Potential Debarment From Government Contracting
- » Massive Attorneys' Fees
- » Disruption of Business
- » Diversion of Corporate Focus





# FCPA and the Healthcare Industry



# Heightened Focus on Pharmaceutical and Medical Device Industries: The Unique Nature of the Industry

- » Speaking at the Pharmaceutical Regulatory and Compliance Congress, Assistant Attorney General Breuer said that DOJ "will be intensely focused on rooting out foreign bribery" in the pharmaceutical industry
  - pharmaceutical companies generate approximately one-third of their total revenue, about \$100 billion dollars, from sales outside the U.S.
  - because many health systems outside the U.S. are regulated, operated and financed by foreign governments "...it is entirely possible...that nearly every aspect of the approval, manufacture, import, export, pricing, sale and marketing of a drug product in a foreign country will involve a 'foreign official' within the meaning of the FCPA."
  - companies should carefully reconsider the range of individuals who could be deemed "foreign officials" under the FCPA—from the health minister to a lab technician at a government-owned hospital. "The depth of government involvement in foreign health systems, combined with fierce industry competition...creates a significant risk that corrupt payments will infect the process."





# Heightened Focus on Pharmaceutical and Medical Device Industries: DOJ's Response

- » AAG Breuer confirmed that DOJ's FCPA unit and health care fraud unit have already begun to work together to investigate FCPA violations in the pharmaceutical and device industries
- » DOJ has been able to leverage the expertise of analysts with extensive industry knowledge in its health care fraud group in connection with FCPA investigations to significantly improve its ability to identify corrupt practices and investigate and prosecute complex FCPA cases in the pharmaceutical and medical device industries

# Heightened Focus on Pharmaceutical and Medical Device Industries: Industry Wide Investigations

## » Medical Device/Orthopedic Implant Industry

- DOJ FCPA investigation followed domestic investigation of violations of the anti-kickback statute
- Multiple companies have made public disclosures of ongoing FCPA investigations

### » Pharmaceutical Industry on Notice

"First, in the months ahead, you can expect to see the department increasingly using the Foreign Corrupt Practices Act to prosecute kickbacks and bribes paid to foreign government officials by pharmaceutical companies. As the drug companies do more and more of their business overseas where so much of the health care business is government run, we unfortunately see the opportunities for FCPA violations proliferating. In some foreign countries, nearly every aspect of the approval, manufacture, import, export, pricing, sale and marketing of a drug product may involve a "foreign official" within the meaning of the FCPA ... The department will not hesitate to charge pharmaceutical companies and their senior executives under the FCPA if warranted to root out foreign bribery in the industry."

Acting Deputy Attorney General Gary G. Grindler speaking to the National Institute on Healthcare Fraud on May 13, 2010





# Global Health Care Delivery

- Variety of activities. . .
  - US health systems developing abroad
  - Affiliations and research
  - Inbound and outbound "Medical Tourism"
- ... in the developing world ...
  - China and southeast Asia
  - Middle-east
  - South and Central America





# Global Health Care Delivery (Cont.)

- ... and aggravating factors
  - Government agent partners
  - Entrepreneurial industry participants (medical tourism)
  - Non profit culture / charitable mission
- But:
  - Culture of compliance
  - Below the radar?



# Preventing and Responding to an FCPA Violation



# Preventing and Responding to an FCPA Violation

# Elements of An Effective FCPA Compliance Program





- 1. Standards, policies and procedures to prevent and detect criminal conduct;
- 2. Responsibility at all levels of the program, together with adequate program resources and authority for its managers;
- 3. Communicating standards and procedures, including a specific requirement for training at all levels;
- 4. Monitoring, auditing, and non-retaliatory internal guidance/reporting systems, including periodic evaluation of program effectiveness;
- 5. Due diligence in hiring and assigning personnel to positions with substantial authority;
- 6. Promotion and enforcement of compliance and ethical conduct through incentives and discipline; and
- 7. Response and Prevention Taking reasonable steps to respond appropriately and prevent further misconduct upon detecting a violation.





Both DOJ and the SEC have stated that an Anti-Bribery and Corruption Compliance Program should be "risk based". An effective Anti-Bribery and Corruption Compliance Program should include the following:

#### A. Bribery and Corruption Risk Assessment

- Conduct a comprehensive review of the organization and assess the potential bribery and corruption risks associated with its products and services, customers, third-party business partners and geographic locations in which it operates.
- The risk assessment can serve as the documented rationale for the compliance program.

#### B. System of Policies and Procedures

- Develop and document a clearly articulated policy against bribery and corruption that enforces a tone of compliance from the board and management.
- Develop a system of procedures and processes that address permitted and prohibited conduct, supervisory
  and compliance approvals for certain conduct and documentation of such approvals.





#### C. Internal Financial Controls System

- Develop, document and maintain a system of internal financial controls to ensure that all payments are accurately recorded in the organization's books and records in accordance with applicable regulatory requirements.
- Special attention should be paid to those areas which may directly affect the anti-bribery and corruption
  compliance program such as procurement, onboarding of vendors, agents, consultants and other third-party
  business payees and gifts and entertainment.

#### D. Risk Based Third-Party Due Diligence

- Develop and document an investigative due diligence protocol that will assess the potential bribery and corruption risks associated with third-parties such as vendors, consultants, suppliers, agents and joint venture partners.
- The nature and extent of the investigative due diligence should be based on the third-party's risk profile.
- The protocol should set forth the remedial steps that may be taken for those parties that represent an elevated risk of bribery and corruption, including, but not limited to escalated due diligence or the termination of the relationship.





#### E. Compliance Monitoring Program

- Develop and document processes and/or controls to periodically assess the effectiveness of the compliance program and potential vulnerabilities and monitor for employee compliance.
- Such processes may include periodic testing and validation, review of available metrics and design of self-assessment forms and exercises.

#### F. Training

- Develop training materials that clearly and concisely interpret applicable legal, regulatory, policy and procedural requirements as well as the possible ramifications associated with non-compliance. The training materials should be reviewed periodically to ensure their continued adequacy.
- Training should be provided regularly to senior management and key compliance and business personnel.





### Key Elements of an Effective FCPA Compliance Program

### G. Whistleblower Allegations and Investigations

Develop and maintain a system for receiving complaints containing allegations of bribery and corruption as well as a system to investigate such allegations and document the actions taken with respect to such complaints and investigations.

### H. Compliance with Local Regulatory Requirements

Multi-national organizations should be aware of local anti-bribery and corruption regulations in the various jurisdictions in which it operates and ensure that its compliance program addresses such requirements.





### Key Elements of an Effective FCPA Compliance Program

### G. Whistleblower Allegations and Investigations

Develop and maintain a system for receiving complaints containing allegations of bribery and corruption as well as a system to investigate such allegations and document the actions taken with respect to such complaints and investigations.

### H. Compliance with Local Regulatory Requirements

Multi-national organizations should be aware of local anti-bribery and corruption regulations in the various jurisdictions in which it operates and ensure that its compliance program addresses such requirements.









#### The Issues to Consider

- A. Multinational companies make payments and maintain relationships with many thousands of business partners and intermediaries all over the world.
- B Certain customers, vendors, intermediaries and other third-parties, however represent higher potential risk than others.
- Investigating all of an organization's vendors, intermediaries and other third party business partners would likely be logistically overwhelming and enormously expensive.





Department of Justice – Opinion Procedure Release 08-02 required Halliburton to develop and implement:

"a comprehensive, risk-based FCPA and anti-corruption due diligence work plan which will address, among other things, the use of agents and other third parties; commercial dealings with state-owned customers; any joint venture, teaming or consortium arrangements; customs and immigration matters; tax matters; and any government licenses and permits. Such work plan will organize the due diligence effort into high risk, medium risk, and lowest risk elements."

The FSA fined Aon, Ltd £5.25 million for failing to establish and maintain adequate anti-bribery systems noting that Aon:

"did not take reasonable care to establish and maintain effective systems and controls for countering risks of bribery and corruption associated with making payments to...third-parties who assisted Aon in winning business from overseas clients, particularly in high risk jurisdictions."





#### A. Categorize third party relationships and risks

- 1. The labels used to describe these various relationships should be based on how they interact with your company rather than the standard industry code.
- 2. Arriving at these labels should take some time, and the process should include input from members of finance, procurement and individual business units.

#### B. Common relationship types

- 1. reseller (sometimes referred to as channel partners)
- 2. distributors
- 3. joint venture partners
- 4. agents (or sales agents)
- 5. freight forwarder
- 6. customs broker
- 7. lobbyist
- 8. firms (law, accounting, consultants, etc.)

Once the universe of relationship types is established, the types need to be sorted by risk and assigned an appropriate point value as a precursor to the risk scoring process. The numeric value assigned to a given relationship type should be based largely on the risk that this category of relationship represents to your organization.





#### A. De-dupe master vendor files

- 1. Experience tells us that most master vendor files contain large numbers of entries that are no longer active, or are duplicates or otherwise aren't worth the trouble. At the same time that you develop your relationship types and apply some form of risk scoring, it would be prudent to de-dupe your master vendor files and combine any duplicates into single entries.
- 2. Any inactive entities with which your organization hasn't transacted in two years or more should be deactivated on the system.

#### B. Perform second round of thinning out third party ranks

- 1. Any third party that has been designated as high risk but isn't worth the trouble and is either redundant or easily replaced with a less risky alternative should likewise be deactivated.
- 2. If after due diligence investigations are performed, serious red flags are raised that cannot be resolved to your satisfaction; it may be prudent to exit some of those relationships as well





#### A. Implement third party FCPA compliance program

- 1. It allows business people to recognize the causal factors of what makes for a high risk relationship and to pay more attention to those relationships. Of course, this type of awareness doesn't come easily.
- 2. Most often, it comes as a result of driving accountability by compelling business units to make a case to retain a high risk third party despite the risk factors that have been identified and making them accept responsibility for any liability that follows.
- B. No system or process is going to eliminate the risk of corruption
  - 1. Global organizations need not be overwhelmed by the challenge of applying a risk-based approach to their third party due diligence.
  - 2. The first step is to understand where risk comes from and how to respond to identified risk. It is critically important to recognize that certain activities with certain high risk third parties presents the greatest risk to your organization.

Compliance officers and C-level executives will sleep better at night once they can answer this question: Who are your highest risk third parties and what are you doing about them?





## FCPA Case Studies



NAVIGANT

### Individual Prosecutions Off to a Fast Start in 2010

### Shot Show/FBI Sting Case

- » DOJ recently announced the indictment of 22 executives and employees of companies in the military and law enforcement products industry on charges that they engaged in schemes to bribe foreign government officials to obtain and retain business
  - Assistant Attorney General Lanny A. Breuer of the Criminal Division proclaimed that this case marks "the first large-scale use of undercover law enforcement techniques to uncover FCPA violations and the largest action ever undertaken by the Justice Department against individuals for FCPA violations."
  - In addition to making 22 arrests, approximately 150 FBI agents executed 14 search warrants in locations across the country





### Enforcement in the Health Care Industry

### AGA Medical Corp

»Privately held Minnesota-based manufacturer of cardiac medical devices

»Agreed to pay a \$2 million criminal penalty and enter a three (3) year Deferred Prosecution Agreement (DPA)

»AGA was alleged to have authorized its independent Chinese distributor to pay kickbacks or rewards to physicians employed by government owned hospitals to encourage the purchase of AGA devices

»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

»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





# QUESTIONS?

**E**pstein**B**ecker**G**reen

VAVIGANT