



FCPA Compliance: An Ounce of Prevention....

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Webinar Overview

Today's Discussion

- FCPA Overview
- Recent Trends in FCPA Enforcement
- Specific Targeting of Pharmaceutical/Medical Device Sector
- FCPA Compliance Best Practices

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FCPA Overview

The FCPA is an anti-bribery statute that has two (2) main components:


- Anti-bribery provisions (prohibiting corrupt payments to foreign government officials and other designated persons and entities) ; and
- Accounting standards and internal controls (applicable to issuers as discussed below).

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FCPA Anti-Bribery Provisions


- The FCPA's anti-bribery provisions make it unlawful for a U.S. "domestic concern" (i.e., U.S. person or U.S. company) "issuer," or any other person in the United States (the jurisdictional reach of the FCPA will be discussed below):
 - with corrupt intent;
 - to offer, pay, promise to pay, or authorize payment;
 - directly or indirectly;
 - of anything of value;
 - to a "foreign official," foreign political party (or official thereof), or any candidate for foreign political office, or any person while;



FCPA Anti-Bribery Provisions (Cont'd)

- “knowing” that all or a portion of the payment or thing of value will be offered, given, or promised directly or indirectly to a “foreign official,” foreign political party (or official thereof), or any candidate political for foreign office;
- 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; and
- in order to assist in obtaining, retaining, or directing business to any person.


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FCPA's Jurisdictional Reach

- The FCPA's jurisdictional reach—the question of who is subject to its provisions—is a matter of some controversy.
- The anti-bribery provisions apply to:
 - individuals who are citizens, nationals, or residents of the United States, wherever they may be located;
 - any entity which is registered or organized under the laws of a state, territory, or possession of the United States;
 - entities or businesses located in the United States, or a territory or possession of the United States;


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FCPA's Jurisdictional Reach (Cont'd)

- The anti-bribery provisions also apply to:
 - individuals, entities, or businesses, wherever situated, which while in the United States engage in an act in furtherance of a bribe by using the mails or any other means or instrumentality of interstate commerce.
 - In recent years, the US Justice Department has expanded the scope of the FCPA's applicability through an aggressive interpretation of “using...any other means or instrumentality of interstate commerce.”


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Corrupt Payments

- The anti-bribery provisions of the FCPA prohibit corrupt payments to
 - A “foreign official,” which means:
 - any officer or employee of a foreign government or any department, agency, or instrumentality of a foreign government (including foreign militaries and government-owned companies);
 - any officer or employee of a public international organization (including the United Nations or the World Bank); or
 - any person acting in an official capacity for or on behalf of any foreign government or public international organization;

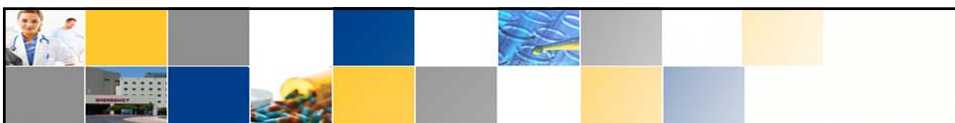
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Corrupt Payments (Cont'd)

- The anti-bribery provisions of the FCPA prohibit corrupt payments to
 - any foreign political party or official thereof or any candidate for foreign political office; or
 - any person, while knowing that all or a portion of such money or thing of value will be offered, given, or promised, directly or indirectly to any of the above persons.
 - The definition of foreign officials has been expanded recently to include high-ranking employees of state-owned enterprises, including hospitals and other medical facilities.


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“Knowledge”

- Under the FCPA, it is illegal to pay anyone (including third-party agents) when “knowing” that all or part of the payment will be passed to a covered official for purposes of obtaining or retaining business.
- “Knowledge” is defined broadly and includes:
 - Actual knowledge;
 - Awareness of a high probability of the existence of the circumstances; or
 - Willful blindness (consciously disregarding facts).


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Limited Exceptions/Defenses Under FCPA

- Exception for routine government action:
 - The anti-bribery provisions of the FCPA do not apply to facilitating or expediting payments;
 - Such payments may nevertheless violate (i) the accounting provisions of the FCPA if not accurately reported, and (ii) local law;
 - Anti-corruption laws in many countries (e.g., the UK, Germany, and Italy) do not have this exemption.
- Affirmative defenses:
 - A payment is lawful under the WRITTEN foreign law; and
 - Reasonable and bona fide expenditures for promotion/demonstration or contract performance.


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Accounting and Internal Controls

- FCPA accounting and internal control accounting provisions only apply to “Issuers,” as well as individual officers, directors, and employees of Issuers
 - Issuers are public companies with registered securities in the United States or companies required to file reports under the Securities Exchange Act; and
 - FCPA accounting and internal control provisions apply not only to the Issuer itself, but also subsidiaries, joint ventures, and affiliates owned and controlled (i.e., more than 50% of the voting power) by the Issuer.
 - Provisions require that publicly traded companies keep sound accounting and internal controls.


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FCPA Penalties

- Criminal Penalties:
 - \$2 million per violation for business entities
 - Individuals may face criminal fines of up to \$250,000 and/or receive sentences of up to five years' imprisonment
 - To the extent a criminal offense causes a 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


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FCPA Penalties

- Civil Penalties:
 - The FCPA authorizes civil penalties of up to \$10,000 against enterprises and individuals for civil violations of the anti-bribery provisions
- In addition, in an SEC enforcement action, the court may impose an additional fine not to exceed the greater of (i) the gross amount of the pecuniary gain to the defendant as a result of the violation, or (ii) a specified dollar limitation. The specified dollar limitations are based on the egregiousness of the violation, ranging from \$5,000 to \$100,000 for a natural person and \$50,000 to \$500,000 for any other person


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Related Violations

- Violations of the FCPA may involve violations of other U.S. and foreign laws
 - Money laundering;
 - Fraud (mail and wire);
 - Conspiracy;
 - Antitrust violations;
 - Obstruction/false statements;
- FCPA investigations may trigger follow-on civil litigation (e.g., securities fraud actions, lawsuits brought by competitors and foreign governments)
- Criminal violations of the FCPA may trigger other collateral consequences, including:
 - Debarment from contracting with the U.S. Government;
 - Loss of certain U.S. export privileges; and
 - Cancelled contracts.


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Pharma Initiative

- In November of 2009, the Department of Justice announced that it planned to investigate the pharmaceutical and medical device industries for suspected violations of the FCPA.
- On August 13, 2010 the New York Times reported that the Pharma Initiative has expanded to include at least a dozen major drug and medical device companies that are under investigation by federal prosecutors and securities regulators for possible FCPA violations.
- The focus of these inquiries appears to include concerns whether these companies have made payments or other improper inducements to non-U.S. physicians to influence the results of clinical trials of drugs and devices that might find their way into the U.S. market.

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Pharma Initiative (Cont'd)

- GlaxoSmithKline, Bristol Myers Squibb, Eli Lilly, and Merck, among others, have disclosed that they had been contacted by the DOJ and SEC with regard to their obligations under anti-corruption laws.
 - The investigation appears to focus on various aspects of the pharmaceutical industry's dealings in foreign countries, including the recruitment of physicians for clinical trials.
 - As many countries have state-run medical systems, drug companies conducting business overseas often deal with state officials, as well as health sector employees who have previously been considered government officials for FCPA purposes.
- The United Kingdom has followed the United States in focusing attention on the pharmaceutical industry.


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Perceptions of Corruption

- US Government expects a reasonable due diligence inquiry of prospective representatives and partners:
 - An inquiry that is sufficient to establish bona fides of the foreign party, to identify and resolve any foreign government official issue;
 - It also should reflect the US entity's communication that it expects compliance with the FCPA; and
 - Should consider greater due diligence in high risk jurisdictions


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Perceptions of Corruption

- In December, Transparency International released the results of its 2010 Global Corruption Barometer, a world-wide public opinion survey on perceptions of corruption in countries around the world. The survey concluded that perceptions of corruption around the world have increased over the last three years.
- Specific findings include: (1) one in four respondents reported paying a bribe over the past year in interacting with basic service providers (e.g., customs, education, and/or tax authorities); (2) six out of ten respondents reported that corruption in his or her country had increased over time; (3) political parties were identified as the most corrupt institutions around the world; (4) the police are cited as being the most frequent recipient of bribes; and (5) Sub-Saharan Africa had the highest bribery rate in the world.


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Perceptions of Corruption

- Transparency International Survey
 - Least corrupt: Denmark, Singapore, New Zealand
 - Most corrupt: Somalia, Myanmar, Afghanistan
 - Others: United States (22); Israel (30); Korea (39); South Africa (54); Thailand (78); China (78); India (87); Indonesia (110); Vietnam (116); Philippines (134); and Pakistan (143). The higher the number, the higher the perception that corruption is an issue is the specific jurisdiction.


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Recent Trends in FCPA Enforcement

- 2010 and 2011 have provided clear evidence that law enforcement and other government agencies, both in the United States and around the world, continue to tenaciously pursue anti-corruption enforcement, and they are acquiring ever-increasing resources to support their efforts.
- 2010 was another record-breaking year for enforcement of the FCPA. The US Justice Department charged 17 companies and 33 individuals with FCPA-related violations, and the US Securities and Exchange Commission (“SEC”) charged 20 companies and seven individuals with violations. This represents a marked increase from the number of DOJ and SEC FCPA enforcement actions in 2009. And 2011 is on pace to meet or exceed 2010’s performance.

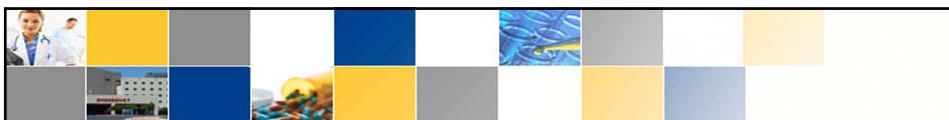
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Recent Trends in FCPA Enforcement (Cont’d)

- The number of enforcement actions is on the rise as is the magnitude of the settlements.
- 2010 saw eight of the ten largest FCPA settlements in history, accounting for over \$1 billion in criminal penalties alone.
- In 2010, the SEC launched its FCPA Unit, one of five new specialized units, in part to increase its ability to investigate FCPA violations on an industry-wide basis. The DOJ and Federal Bureau of Investigation (“FBI”) increased their FCPA resources as well.
- The DOJ and SEC have made the prosecution of individuals for FCPA violations an enforcement goal.


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Recent Trends in FCPA Enforcement (Cont'd)

- In 2010, 55% of FCPA enforcement actions targeted non-U.S. companies. In contrast, thus far in 2011, the authorities have charged only two non-U.S. companies.
- The U.S. government has explicitly targeted companies in countries that are not perceived as being sufficiently rigorous in enforcing their transnational bribery.
- On June 22, 2011, the SEC released the final version of the Dodd-Frank whistleblower regulations, that went into effect on August 12, 2011.
- Under Dodd-Frank, whistleblowers can receive between 10%-30% of monetary sanctions imposed in *all* resulting enforcement actions *worldwide*. Not all whistleblowers will qualify for an award, however.


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Recent Trends in FCPA Enforcement (Cont'd)

- The US government has in its general anti-corruption enforcement efforts shown willingness in the past year to pursue targets beyond companies that pay bribes. Notably, the DOJ has taken aim at recipients of bribes by seeking to punish the foreign officials and/or to recover bribes.
- Compliance monitors continue to feature prominently in FCPA settlements.
- In a related trend, the practice of requiring self-assessment and reporting in lieu of compliance monitors has gained momentum.
- While there is no private right of action under the FCPA, the past year has seen a number of shareholder derivative lawsuits brought against companies alleging losses due to violations of the FCPA.


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Recent Trends in FCPA Enforcement (Cont'd)

- Expanding the FCPA's jurisdictional reach :
 - *Tenaris* (a company based in Luxembourg), was alleged by the US Government to have “made use of the means and instrumentalities of interstate commerce” in making a “same day transfer of approximately \$32,140.67 through an intermediary bank” in New York to an agent acting on *Tenaris*'s behalf.
 - Expansion on the theory that a foreign transaction in U.S. currency is sufficient to establish U.S. territorial jurisdiction.

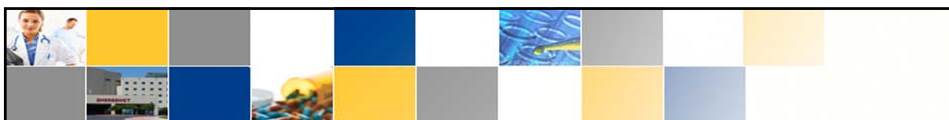
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Recent Trends in FCPA Enforcement (Cont'd)

- There is also some indications that the FCPA may be growing beyond its original focus on bribery of foreign officials by U.S. companies and, after the U.S. signed the OECD Convention in 1997, by their overseas competitors.
- Over the past year, and even more so in the first part of 2011, the agencies have focused on Chinese companies who have listed in the U.S. and are alleged to have made fraudulent disclosures concerning their financial results. In some cases, it appears that the government has expanded its investigation to include allegations that these companies may have engaged in improper transactions with Chinese officials. If so, this would represent an expansion of the FCPA's traditional focus in that it appears to involve what would be, to the company and its home country, *domestic* corruption.


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FCPA Compliance Programs

- The single most effective step a company can take is to develop an effective FCPA compliance program which includes the following elements:
 - Internal Compliance Program
 - Due Diligence on Third Parties/Transactions
 - Prompt Response to Possible Violations
- U.S. Government will consider each of these elements in evaluating whether to bring enforcement action.
 - Clearly written company-wide FCPA compliance code and policies (in the case of “issuers,” they must create and maintain a system of internal controls)
 - Appointment of a compliance officer
 - Communication from upper management, setting tone from top
 - Performance of due diligence of agents, potential joint venture partners, and potential targets for M&A
 - Inclusion of FCPA compliance provisions in certain international contracts
 - Hotline or other means for internal disclosures
 - Employee training, especially for those individuals involved with international agents and customers


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Highlights of an FCPA Compliance Program

- Clearly written company-wide FCPA compliance code that:
 - Explains key provisions and risk areas;
 - Provides guidance on permissible behavior; and
 - Tailors guidance to specific operating risks.
- Appointment of a compliance officer;
- Communication from upper management, setting tone from top;
- Performance of due diligence of agents, potential joint venture partners, and potential targets for M&A;
- Inclusion of FCPA compliance provisions in certain international contracts;
- Hotline or other means for internal disclosures;
- Employee training, especially for those individuals involved with international agents and customers


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Highlights of an FCPA Compliance Program

- An effective compliance program will start with the statement: “No corrupt payments. No exceptions. Even if everyone else is doing it”
- It will also cover consequences for noncompliance (company-specific sanctions as well as legal sanctions) and touch on the following items:
 - Grease/Facilitation Payments
 - Interactions with Government-Owned Businesses
 - Agent Due Diligence
 - Interactions and Meals & Entertainment
 - Gifts & Hospitalities
 - Foreign Charitable Contributions


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Highlights of an FCPA Compliance Program

- An effective compliance program should include:
 - Compliance monitoring;
 - Training completion certification;
 - Annual compliance certification;
 - Audit testing of high-risk areas;
 - Internal/External compliance audits;
 - Confidential reporting system; and
 - “Tone at the Top”

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“Grease Payments”

- General rule: No “grease” or facilitating payments:
 - Almost always violates local law;
 - Difficult for employees to determine what are routine or nonroutine decisions;
 - Could violate FCPA accounting provisions in case of issuer) if not accurately reported (and if reported, could constitute an admission of a local law violation).
- Consider exceptions for payments which are:
 - minor in value (and clearly for non-discretionary matters);
 - necessary if one’s life is at stake;
 - thoroughly vetted by the company’s compliance administrator; and
 - if made, must be accurately recorded in the books of an issuer.


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Meals and Entertainment

- Company personnel may provide meals and entertainment in good faith and not with any corrupt intent or expectation of a favor:
 - Meals and entertainment should be directly related to a bona fide and legitimate business purpose;
 - The value of the meal or entertainment should be reasonable;
 - The meal or entertainment should comply with local law;
 - The venue should be tasteful and comply with generally accepted business and professional standards;
 - Company personnel should be in attendance; and
 - Regular meals or entertainment to the same official or group of officials may create an appearance of impropriety.


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Gift Giving

- Gift-giving is very important in some cultures and absolutely prohibited in others
 - Gift guidelines – no cash; nominal value;
 - Company personnel must only provide gifts in good faith and not with any corrupt intent or expectation of a favor;
 - The value of the gift should be reasonable;
 - Gifts should be embossed with the Company's logo to extent possible;
 - Regular gifts to the same official or group of officials may create an appearance of impropriety; and
 - The issuer's books and records must accurately reflect the value and nature of all gifts.


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Travel Expenses

- Company personnel must provide travel for business purposes in good faith and not with any corrupt intent or expectation of a favor:
 - Legitimate business purpose, no cash and not excessive;
 - Travel and accommodations should be reasonable and directly related to a bona fide and legitimate business purpose;
 - Tourist and entertainment excursions should generally not be paid for by the Company;
 - Money (compensation or per diem) should generally not be given to individuals unless required by the agreement with the government customer;


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Travel Expenses (Cont'd)

- The FCPA compliance officer should approve travel expenses;
- Foreign counsel should be consulted to ensure compliance with local law;
- Prior written notification, itinerary, and budget of the trip should be given to the government organization that employs the recipient; and
- The issuer's books and records must accurately reflect the value and purpose of travel.


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Charities

- Corruption issues may be present if a government official responsible for a transaction has an interest or position with a foreign charity
 - Due diligence should be performed before making charitable contributions
 - Following a donation, confirmation that such donation has been used for its intended purpose should be obtained
- Schering-Plough case:
 - Total of \$76 000 was over 4 to a charity operated by a government official
 - Payments were broken into small amounts to avoid detection


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Liability Caused by Third Parties

- The actions of a third party acting as an agent, representative, or consultant can expose companies to FCPA liability under the “knowing” standard.
 - Care must be taken in the retention of such persons;
 - Establish business justification for hiring of such person
 - Provide FCPA briefing;
 - Perform due diligence; and
 - Ensure that all agreements are written and include appropriate FCPA representations and warranties.
- Careful and thorough due diligence, as well as continuing oversight, helps to establish the defense that any improper or questionable payments were made without the company’s (or any individual officer’s or employee’s) knowledge


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Business Justification Under FCPA

- Business Justification
 - Work to be performed;
 - Economics of appointment;
 - Other options for reaching customer, if any, such as more qualified intermediaries.
- Interview Requirement
 - All potential agents should have a face-to-face interview with the key account manager, business unit manager, or regional manager; and
 - Should receive FCPA briefing.


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Due Diligence on Third Parties

- Focus on reputation, corrupt history, qualifications, and red flags.
- Sample list of due diligence materials:
 - Agents questionnaire;
 - Commercial and special registrations under local law;
 - Business references;
 - Database searches, including U.S. restricted parties lists;
 - FCPA certification;
 - U.S. embassy reference (ICP) or local counsel report;
 - Due diligence materials should be gathered by a business division other than the division which intends to retain the third party.
- Due diligence materials should be reviewed by legal counsel, which can then address/resolve “red flags”

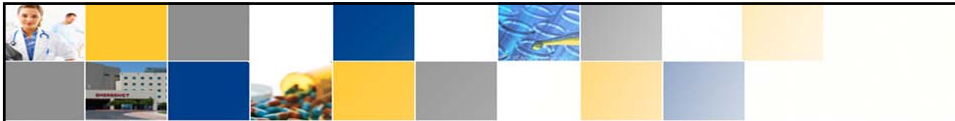
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Due Diligence on Third Parties

- Due diligence materials should be reviewed by legal counsel, which can then address/resolve “red flags”
- Caution: carefully scrutinize “success fees”
- Maintain records of due diligence
- **Bottom line: the FCPA knowledge standard imposes an affirmative duty to determine reputation of agents, commissioned sales representatives, and certain other third-party intermediaries or contractors that have any interaction with foreign officials**

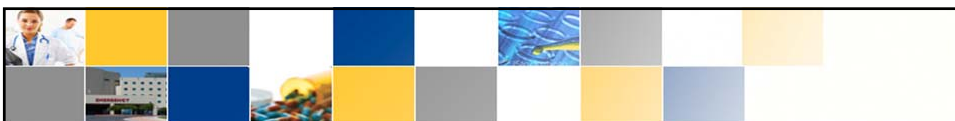
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FCPA Red Flags

- Red flags include:
 - Failure to comply with local law;
 - Refusal to execute FCPA compliance representations or warranties or cooperate with FCPA due diligence information;
 - Party has a bad reputation or is the subject of allegations of corrupt, unethical, and/or criminal activity;
 - Agent or joint venture partner has been previously convicted of a corruption offense or other crime;
 - Party is a current government official, political candidate, or royal family member candidate;


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FCPA Red Flags (Cont'd)

- Party is an immediate family relative or business associate of a government official or political candidate;
- Party is recommended by a government official or political ;
- Unusually high commission rate, or demands for excessive compensation (obtain comparables);
- Requests cash payment, payment to offshore accounts, requests for or payment to an account in a different name;
- Party has undisclosed owners;
- Party has undisclosed subagents or subcontractors that assist with the representation;
- Agent requests cooperation in tax avoidance or other illegal conduct


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FCPA Red Flags (Cont'd)

- Agent lacks the organizational resources to undertake the proposed activities;
- Country has a reputation for government corruption;
- Lack of transparency in financial records;
- Lack of internal controls;
- Statements such as:
 - “My Close Relative Is A Government Official, and You Don’t Have A Chance Unless You Deal With Me”
 - “I Have Never Worked In Your Industry Before, But I Know The Right People”


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FCPA Red Flags (Cont'd)

- What to do when you encounter red flags?
 - Increase level of due diligence investigation;
 - Require investigation by M&A target;
 - Conduct joint investigation;
 - Evaluate potential successor liability; and
 - Weigh business risks of transaction.


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FCPA Compliance Training

- Compliance efforts should include regular anticorruption training
- All employees whose activities could raise FCPA or anti-corruption concerns, or who supervise such persons, are required to regularly attend training seminars
- Training seminars may be tailored to the issues and challenges presented in individual markets


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FCPA Violation Notification

- Compliance programs should include procedures for reporting and responding to problems or possible violations, including:
 - Notification of appropriate compliance personnel and members of management;
 - Transaction holds;
 - Document preservation; and
 - A mechanism should also be in place to permit anonymous reporting.


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UK Bribery Act

- The Bribery Act 2010 (Act), which creates a new and consolidated scheme of bribery offenses came into effect in April 2011.
- The Act replaces bribery offenses formerly in effect in the UK. Sections 1 and 2 of the Act contain two general offenses that prohibit the giving and taking of bribes in the public and private sectors. Section 6 creates a discrete offense that prohibits bribery of a foreign public official.
- When an offense under Section 1, 2, or 6 is committed by a corporate entity, any senior officer of the entity with whose "consent or connivance" the offense was committed is also liable.

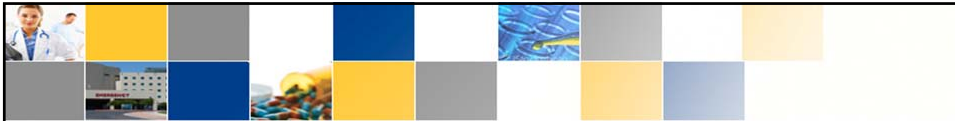
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UK Bribery Act

- Section 7 creates liability for "commercial organizations" that fail to prevent bribery. This occurs when a person associated with a commercial organization commits bribery intending to obtain or retain business or a business advantage for the organization. An organization can avoid liability under Section 7 if it can prove that it had adequate procedures in place to prevent bribery.
- The jurisdictional reach of the Act extends beyond the UK, and Serious Fraud Office (SFO) officials who will be prosecuting violations of the Act have signaled their intention to assert broad jurisdiction under the Act.

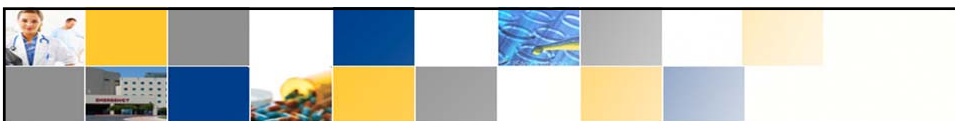
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UK Bribery Act

- Unlike the FCPA, the Act does not provide any exception for facilitation or expediting payments—small payments to induce routine government action. The Act's treatment of facilitation payments supports the Organization for Economic Co-operation and Development's (OECD) efforts to encourage countries to eliminate solicitation and facilitation payments.
- The Act does not specifically address hospitality, gifts, travel, or other promotional expenses. Therefore, these expenditures will be subject to the main provisions of the Act, including the adequate procedures defense, and prosecutorial discretion will likely dictate what is a reasonable expenditure. UK officials have stated that expenses that are both reasonable and proportionate to the nature of the organization's business may not require prosecution.
- Because commercial organizations may be liable under Section 7 of the Act, it is important for organizations to consider how to effectively demonstrate the right "tone at the top" as part of their "adequate procedures."

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Conclusion

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