

Morgan Lewis

2012 Update
FCPA Enforcement and Compliance
Medical Technology Learning Institute

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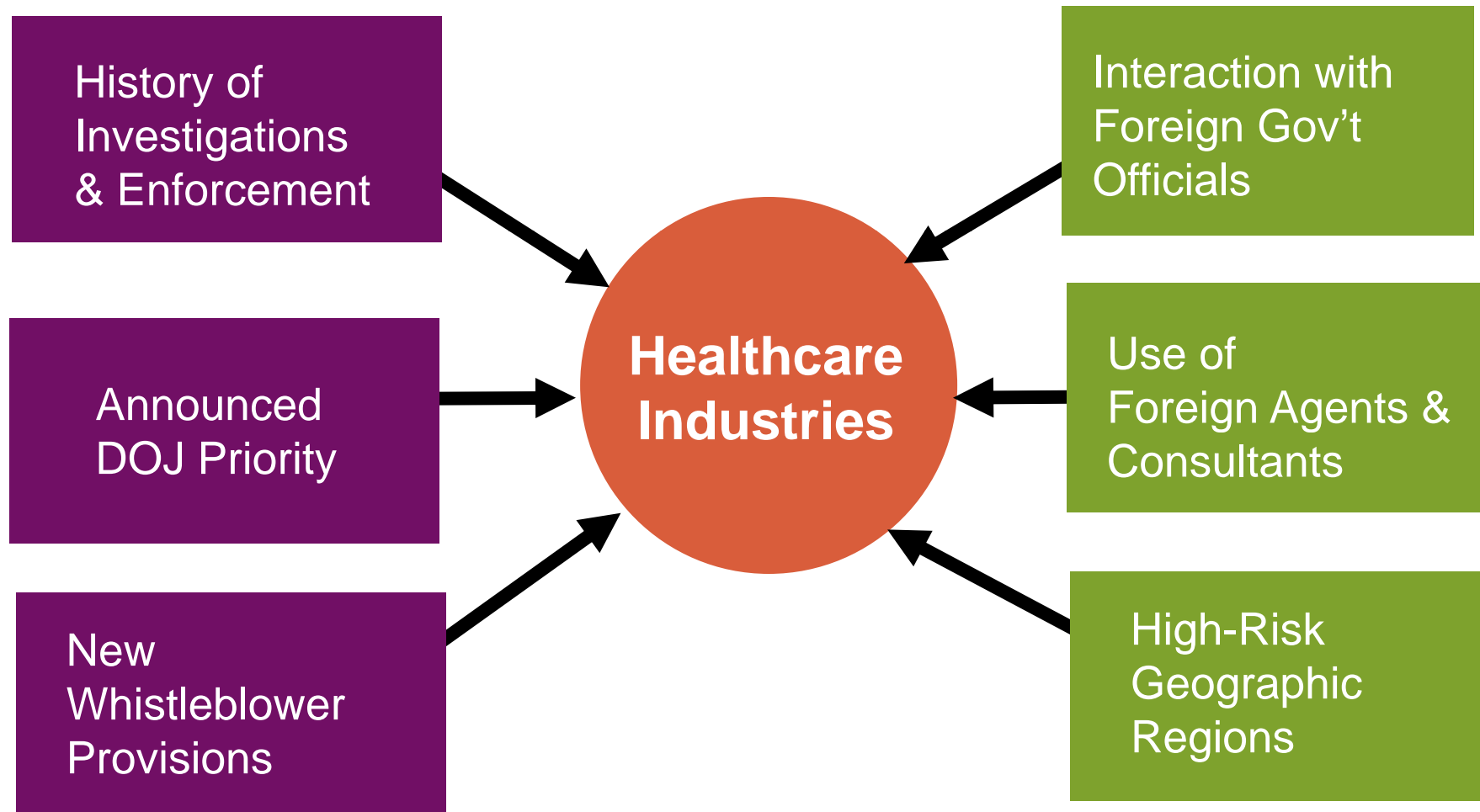


Speaker Information

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- Katie McDermott is a Partner in the Washington, D.C. office of Morgan, Lewis & Bockius LLP and has been involved in health industry enforcement and compliance matters for over 20 years. She has served as an Assistant U.S. Attorney and DOJ Health Care Fraud Coordinator, and is a recipient of the HHS-OIG Inspector General's Integrity Award for her work in government health care fraud matters.
- Ms. McDermott has a national corporate practice devoted exclusively to health industry corporate defense matters in a broad array of government investigation and litigation representations, including DOJ investigations and *qui tam* actions under the False Claims Act relating to allegations of off-label promotion, regulatory violations and anti-kickback violations. Katie has been designated as one of the top fraud and abuse compliance attorneys in the country by Nightingale's and as a *DC Super Lawyer* in white collar matters and top Washington attorney for handling government disclosures and whistleblower suits. In 2012, Katie was recognized as a *Life Sciences Star* in Fraud and Abuse by the Legal Media Group.
- Katie also represents various health industry sectors on government compliance and disclosure matters, compliance policy development, global fraud and abuse, transparency and codes of ethics counseling. She conducts training and internal reviews for corporate Boards and related corporate operations. Katie has been involved in FCPA and anti-bribery matters related to counseling, internal investigations, HCP interactions and industry codes of ethics implementation.
- Ms. McDermott currently serves as a Board Member for the BNA Medical Devices Law and Industry publication. She has served as faculty at the Seton Hall Health Care Compliance Certification Program for many years and as adjunct faculty at the Catholic University Columbia School of Law, teaching on health care compliance and enforcement. She is licensed to practice law in the District of Columbia, Massachusetts and Maryland and has been admitted in various federal and state court proceedings.

FCPA Enforcement Risk – Healthcare Industries



Medical Device FCPA Enforcement

2008	2011	2012
<p>AGA Medical Corp. (June 2008)</p> <ul style="list-style-type: none"> - China - \$2 million penalty 	<p>Johnson & Johnson and Dupuy Inc. (April 2011)</p> <ul style="list-style-type: none"> - Greece, Poland, Romania, Iraq - \$70 million penalty -voluntary self-disclosure -compliance program strength avoided independent monitor 	<p>Smith & Nephew (February 2012)</p> <ul style="list-style-type: none"> - Greece - \$22 million penalty <p>Biomet, Inc. (March 2012)</p> <ul style="list-style-type: none"> - Argentina, Brazil, China - \$23 million penalty <p>Orthofix International (October 2012)</p> <ul style="list-style-type: none"> -Mexico -\$7.44 million -No independent compliance monitor.

FCPA Settlement Points of Interest

- Voluntary Disclosures.
- Non-Prosecution v. Deferred Prosecution.
- Self-Monitoring v. Independent Monitor.
- Compliance Program *Bon Fides*.
- Multi-Jurisdictional Results-Global Parallel Proceedings.
- Individual Liability.
- Relevance of Industry Codes of Ethics
- Expansion of new anti-bribery provisions by other countries. E.g. Sweden Anti-Bribery Statute, July, 2012.

FCPA Issues

- New DOJ FCPA Guidance, Expected Nov. 2012. May include discussion on corporate compliance programs, including successor liability.
- Over 80 pending investigations.
- Decline in 2012 in FCPA enforcement actions from prior years. Triumph of compliance? Do not bet on it. 2011 (48) v. 2012 (15).
- SEC Whistleblower Provisions and Enforcement.
- Congressional Interest in FCPA enforcement and potential amendments.

FCPA Issues

- Shareholder Suits. There have been a few...
- Transactional Due Diligence. Orthofix-agrees to assure that “business entities are only acquired after a thorough FCPA and anti-corruption due diligence by legal, accounting and compliance personnel.” If that is not “practicable” such a FCPA due diligence review must be done subsequent to the transaction.
- Successor Liability. It’s complicated. Latent discovery or due diligence discovery?
- Disclosure Assessments. Decision tree analysis on mandatory and discretionary disclosure factors.
- Third Party Distributorships. Oversight is Company responsibility. Background Vetting, Red Flag assessment, Training, Certifications, Monitoring, Auditing. Orthofix Attachment C mandates documented risk-based due diligence of third parties.

FCPA Settlements and Attachment C: Mandated Compliance Terms-The DOJ Way

- Attachment C of the FCPA settlements contains compliance provisions that are a roadmap for FCPA compliance and due diligence activities. These provisions are not boilerplate.
- In 2012 Pfizer and Orthofix executed Attachment C obligations.
- Both settlements contain significant provisions related to anti-bribery compliance and monitoring.
- Orthofix FCPA Settlement contains similar but reduced compliance terms in Attachment C of its settlement. Less Directive.
- Orthofix Attachment C addresses transactional due diligence expectations and third party relationships for device company international operations.

Wal-Mart (2012)-Media Reports

- Media allegations only raise questions of process and policy. Companies want to be able to show:
- Timely investigation of allegations.
- Investigation undertaken by competent, qualified and independent personnel.
- Investigation should not be controlled or directed by business unit.
- Prompt assessment of merits and any corrective action.
- Careful assessment of disclosure obligations and strategic benefits.

U.S. Enforcement

- Expansion of investigative resources
- Increased SEC enforcement
- Collaboration with foreign authorities
- Focus on individual prosecutions
- More FCPA trials
- Use of traditional law enforcement techniques
- Industry-wide focus

U.S. Enforcement

Global Footprint of FCPA Enforcement			
Countries at Issue in Corporate FCPA Enforcement Allegations			
2011		2010	
Country	Combined Actions*	Country	Combined Actions*
China	4	Nigeria	10
Greece	2	China	4
Iraq	2	Iraq	4
Mexico	2	Indonesia	3
South Korea	2	Thailand	3
16 additional countries	1 (each)	Vietnam	3
		Angola	3
		Azerbaijan	2
		Greece	2
		Hungary	2
		Côte d'Ivoire	2
		Mexico	2
		Russia	2
		Saudi Arabia	2
		Turkmenistan	2
		35 additional countries	1 (each)

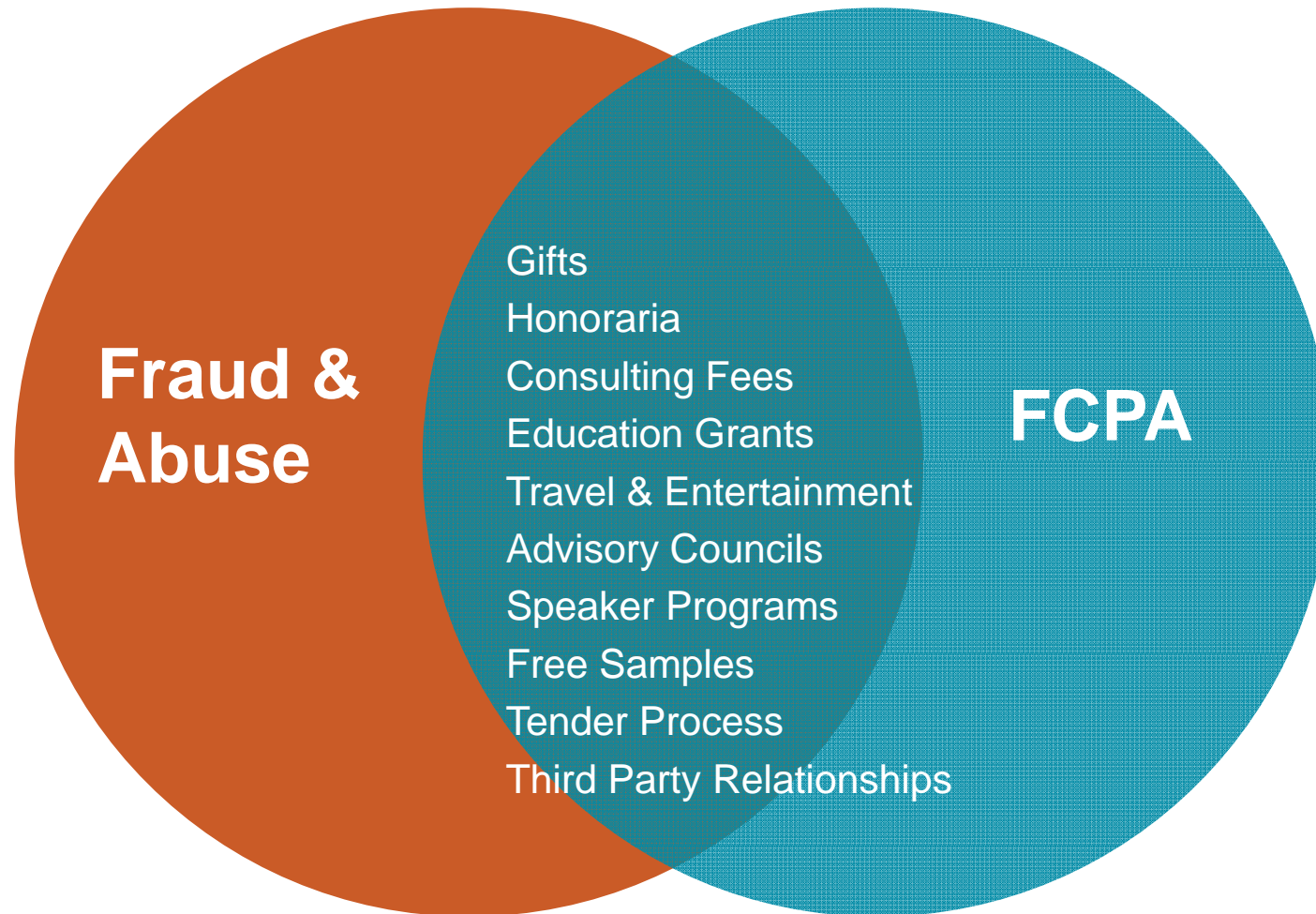
* These statistics combine related enforcement actions involving each company and its subsidiaries and affiliates.

- 2010: 50 countries at issue
- 2011: 21 countries at issue
- Growing number of FCPA “hot spots”

Anti-Corruption Challenges for Healthcare Companies

- Expanding an international presence is a key long-term growth strategy for many leading healthcare companies
- Developing nations are spending more money on healthcare and driving the increase in global demand
- Foreign hospitals, clinics, laboratories, and medical providers frequently are state owned or state controlled
- Employees of state-owned or state-controlled entities are “foreign officials” under the FCPA
- Companies work through commercial agents and other third-party representatives.
- Enforcement agencies want similar FCPA recoveries.
Sweden Anti-Bribery Statute, July, 2012.

Healthcare Industries – Potential FCPA Issues



AdvaMed, EucoMed, Kuala Lumpur and the Codes of Ethics Harmonization Challenge

- AdvaMed Code is similar but also different from other international codes of ethics.
- Challenges to global risk management with different and competing statutes and codes of ethics.
- Definition of HCP-how broad must it be to manage global risk?
- How to structure global risk management operations to address difference in law and ethics?

U.S. Foreign Corrupt Practices Act

ANTIBRIBERY PROVISIONS

Prohibit bribery of foreign government or political officials for the purpose of obtaining or retaining business or securing any improper business advantage

BOOKS & RECORDS PROVISIONS

Require SEC-registered or reporting issuers to make and maintain accurate books and records and to implement adequate internal accounting controls

Antibribery Provisions

- It is unlawful for:
 - an issuer, domestic concern, or anyone acting within the jurisdiction of the United States
 - with “corrupt intent”
 - to directly or indirectly
 - offer, pay, promise to pay, or authorize payment
 - of “anything of value”
 - to a “foreign official”
 - for the purpose of obtaining or retaining business or securing any improper advantage

Exception to Anti-bribery Provisions

- Facilitating payments
 - Exception has limited application
 - Payment by a foreign official to expedite or secure the performance of routine governmental actions
 - Applies only to non-discretionary actions by a foreign official, such as processing government paperwork or providing routine government services
 - *e.g., police protection*

Books & Records Provisions

- Books and records
 - Must be in reasonable detail that accurately and fully reflect transactions
 - Payments, gifts, and entertainment
- Effective internal accounting controls
 - company policies and procedures
 - documentation (e.g., expense forms)
 - reporting
 - certifications
 - corrective actions

The FCPA's Third-Party Payment Provisions

- The FCPA's broad definition of knowledge means that a company can be liable for the actions of its agents and third-party representatives
 - Antibribery provisions cover improper payments made to “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 foreign official”
 - Knowledge is established “if a person is aware of a **high probability** of the existence of such circumstance, unless the person **actually believes that such circumstance does not exist**”
- More than 50% of FCPA prosecutions involve liability based on the use of agents and representatives
- Due diligence and monitoring of agents and third-party representatives is increasingly important

Device Company Product Training and Education-An Affirmative Defense

- Payments related to product demonstration or promotion
 - A reasonable and bona fide expenditure
 - Directly related to the promotion, demonstration, or explanation of products or services
 - Or the execution or performance of a contract

Potential FCPA Fines & Penalties

Business Organizations

- \$25 million criminal fine per violation (books and records and internal control violations)
- Up to \$2 million criminal fine per violation (antibribery violations)
- \$10,000 civil penalty or disgorgement of gross gain
- Alternative Fines Statute, 18 U.S.C. § 3571(d) (twice the gain or loss)

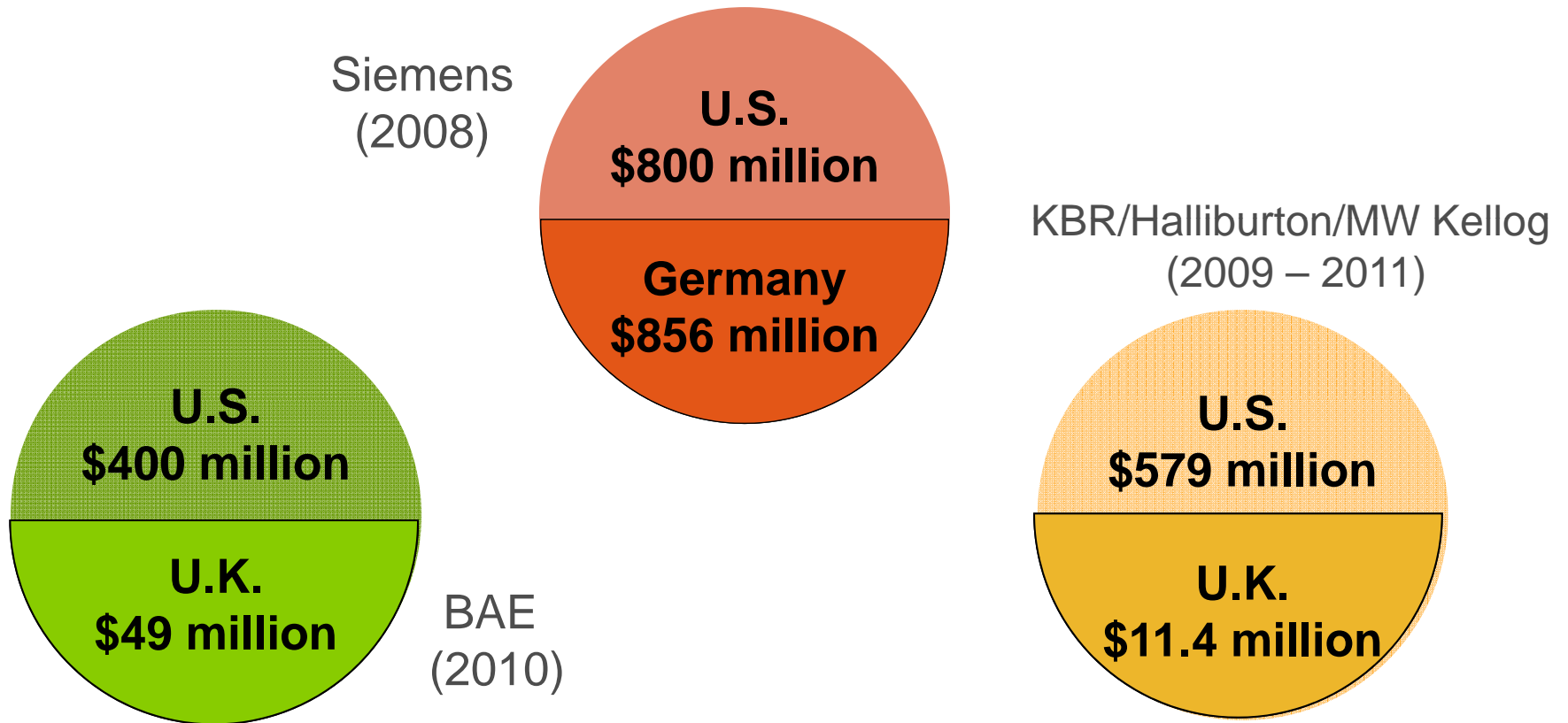
Individuals

- 20 years in prison and/or \$5 million per violation (books and records and internal control violations)
- 5 years in prison and/or \$250,000 fine per violation (antibribery violations)
- \$10,000 civil penalty or disgorgement of gross gain
- Alternative Fines Statute, 18 U.S.C. § 3571(d) (twice the gain or loss)

Potential FCPA Collateral Consequences

- Investigation Costs
- Business Disruption
- Foreign Enforcement Actions
- Reputational Harm
- Deferred Prosecution Agreements
- Independent Compliance Monitors
- Civil Litigation
- Exclusion from Government Contracting (“Corporate Death Penalty”)
- Recission of Contracts, Permits

Multi-Jurisdiction Enforcement

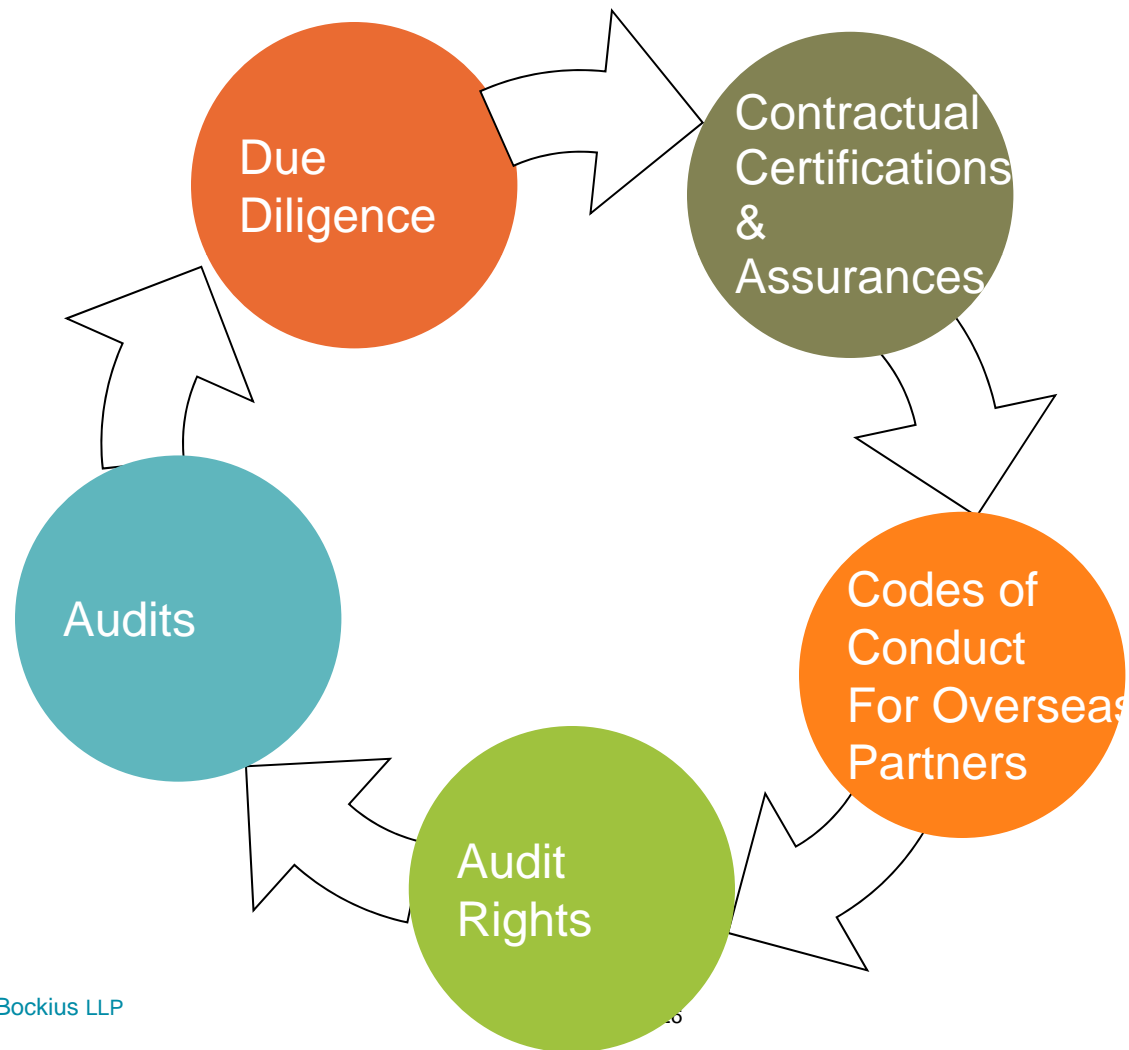


Increased International Enforcement

- *Ganswindt / Siemens AG* (May 2011)
 - German prosecution of former Siemens AG managing board member resulting in €175,000
- *Niko Resources Ltd.* (June 2011)
 - Niko pleaded guilty under Canada's foreign anti-bribery law resulting in C\$9.5 million and 3 years of probation
- *Alstom Group* (November 2011)
 - Swiss prosecution resulting \$2.7 million fine / \$38.8 million disgorgement
- *Ferrostaal AG* (December 2011)
 - Germany prosecution resulted in €140 million fine against company (~\$181 million USD)

Managing Global Risk

What Are The Government's Expectations?



Business Checklist

- Business Justification
 - Services to be provided
 - Qualifications
- Connections to government
 - Recommended by Government Official
 - Interaction with Government Officials.
- Legal under local law
- Red Flags
- Third Party Cooperation
 - Cooperation with due diligence
 - Agreement to comply with policies and anti-corruption laws

Anti-Bribery Compliance Program Components

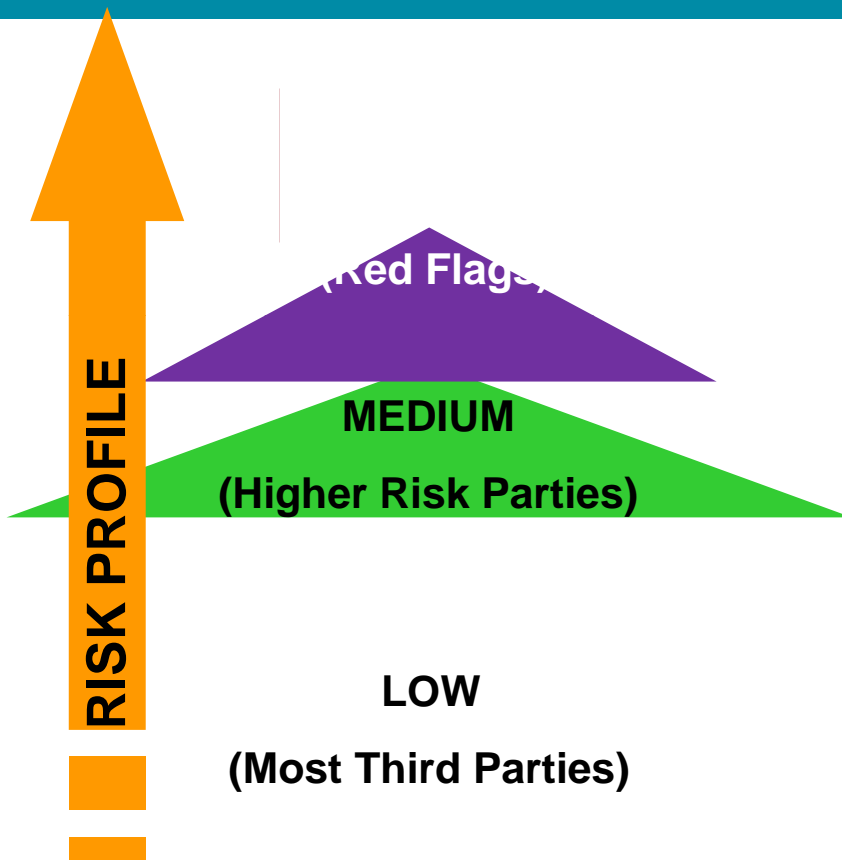
- Clearly articulated corporate policy and procedures
- Consistent and comprehensive training
- Oversight, monitoring and reporting system (e.g., hotline)
- Disciplinary procedures to address violations
- Due diligence and oversight of agents, business partners, vendors, joint ventures
- Financial and accounting procedures to ensure internal controls, and accurate books, records and accounts
- Periodic reviews of compliance program
- Documentation of compliance efforts

What Is Due Diligence?

- Essential part of an anti-corruption compliance program
- An investigation of risks across a number of regulatory and business issues
- Used to understand and evaluate initial and ongoing risk of doing business with a third party
- Used to evaluate options to limit risk
- Risk-based approach
- Use of questionnaires and checklists
- Verification
- Documentation of due diligence

Risk Tiering

Risk Based Protocol



Actual criteria/break points closely tailored to business; not “one size fits all”

Individualized Inquiry

- Red flags, e.g. government relative, unauthorized payment terms, party requested by customer
- Inquiry tailored to particular situation
- Senior management approval

Enhanced Procedures

- Parties interfacing with government or who represent the company
- More rigorous intake procedure (e.g. written business justification, questionnaire, site visit, anti-corruption contract terms, or investigative report)
- Periodic refreshing and monitoring

Basic Procedures

- Majority of low risk parties not interfacing with government (e.g. vendors selling goods)
- Basic know your customer procedure at initial intake only (e.g. use information from existing vendor intake process)

Sample Risk Categories

Category A

- Do not represent Company
- Do not act on Company's behalf
- Third Parties with Business Certification
- No government customers; do not interface with government officials
- No government affiliation
- No Red Flags

Category B

- All Third Party Representatives

Category C

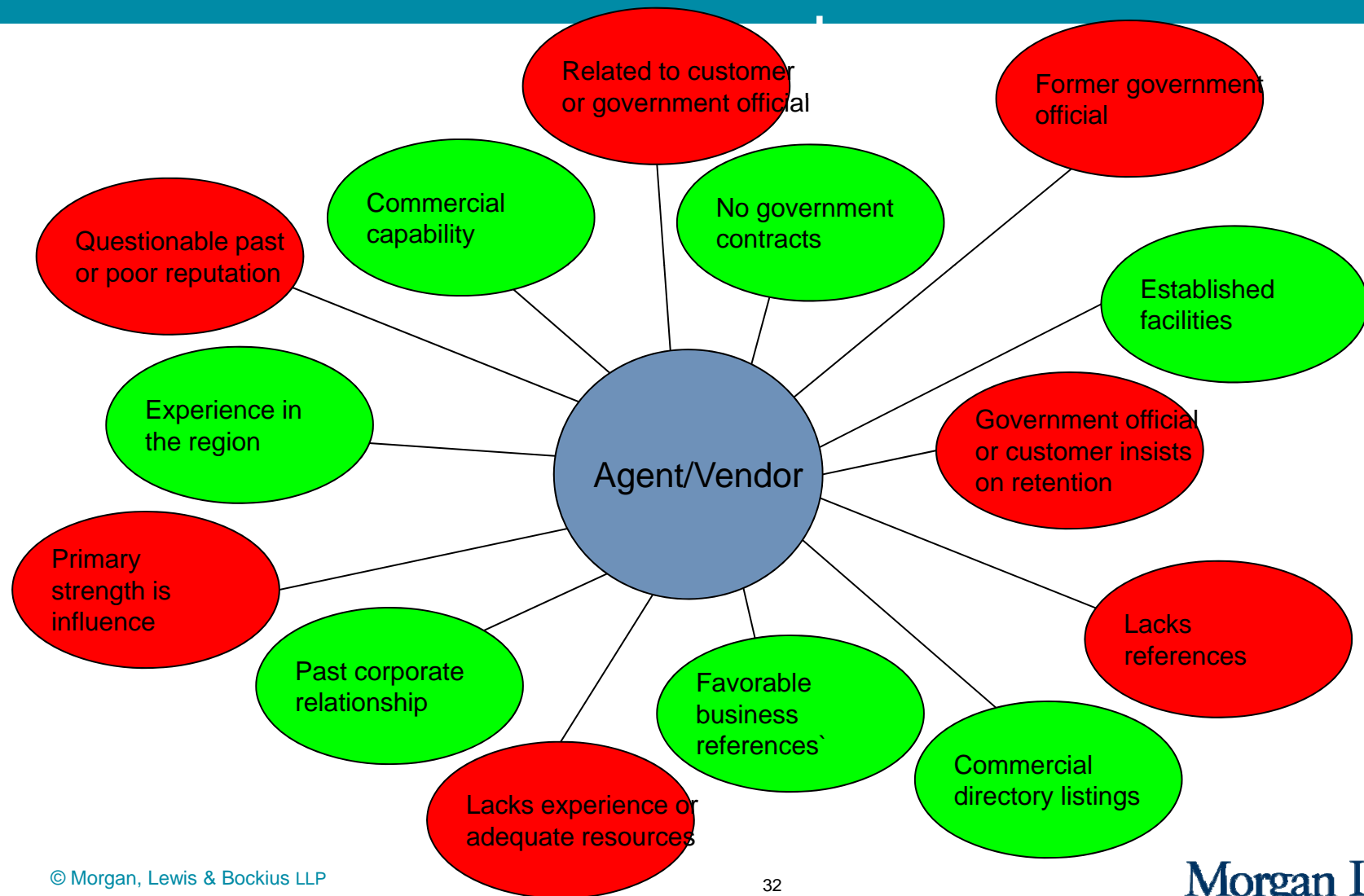
- Third Party Representatives that have government customers or interface with government officials
- or
- Third Party Representatives that have sales or distribution in, located in, or have bank accounts in high risk jurisdictions

Enhanced Due Diligence

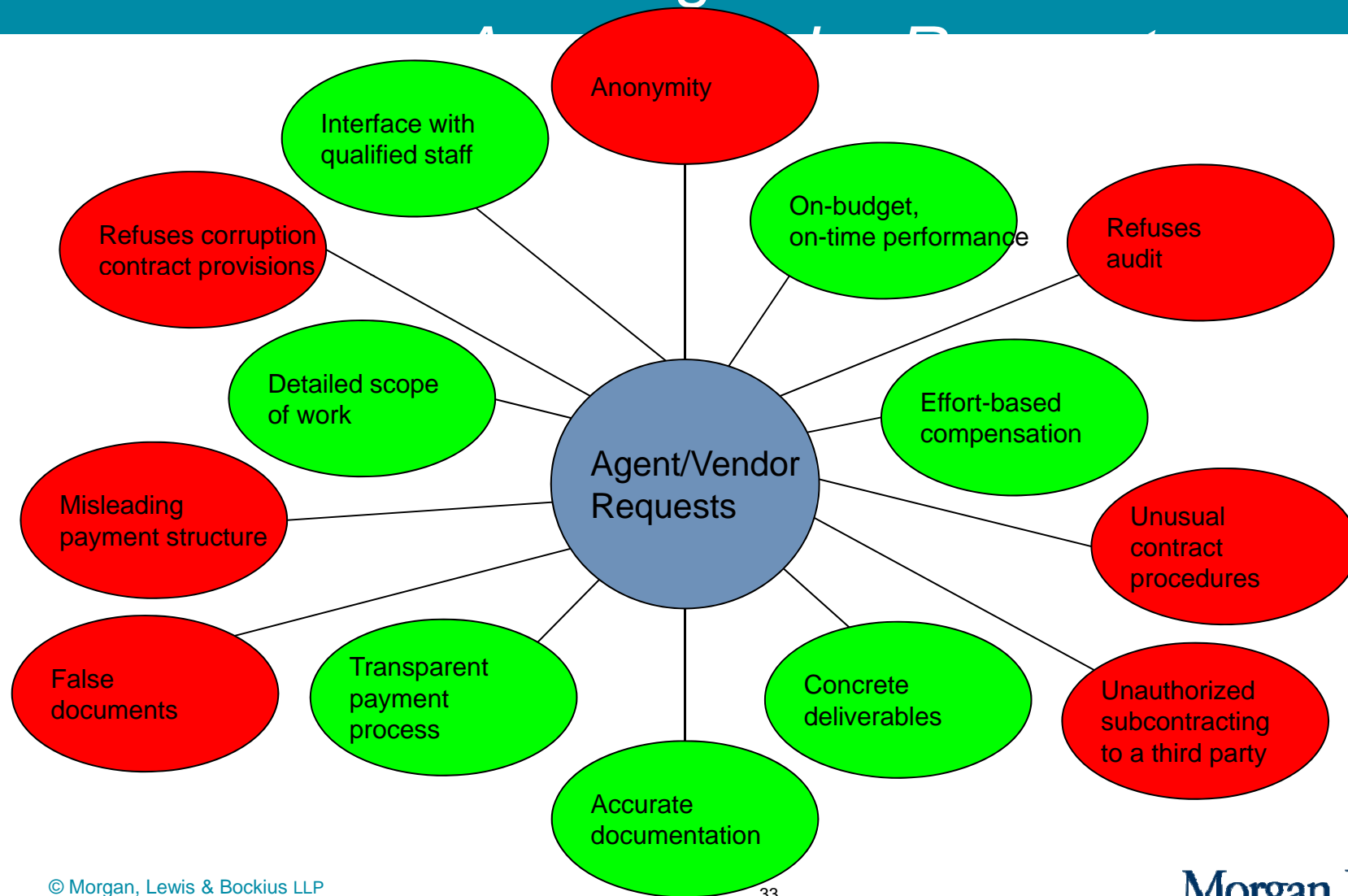
- Any Third Party for whom Red Flags have been identified during due diligence

RISK

Red Flags

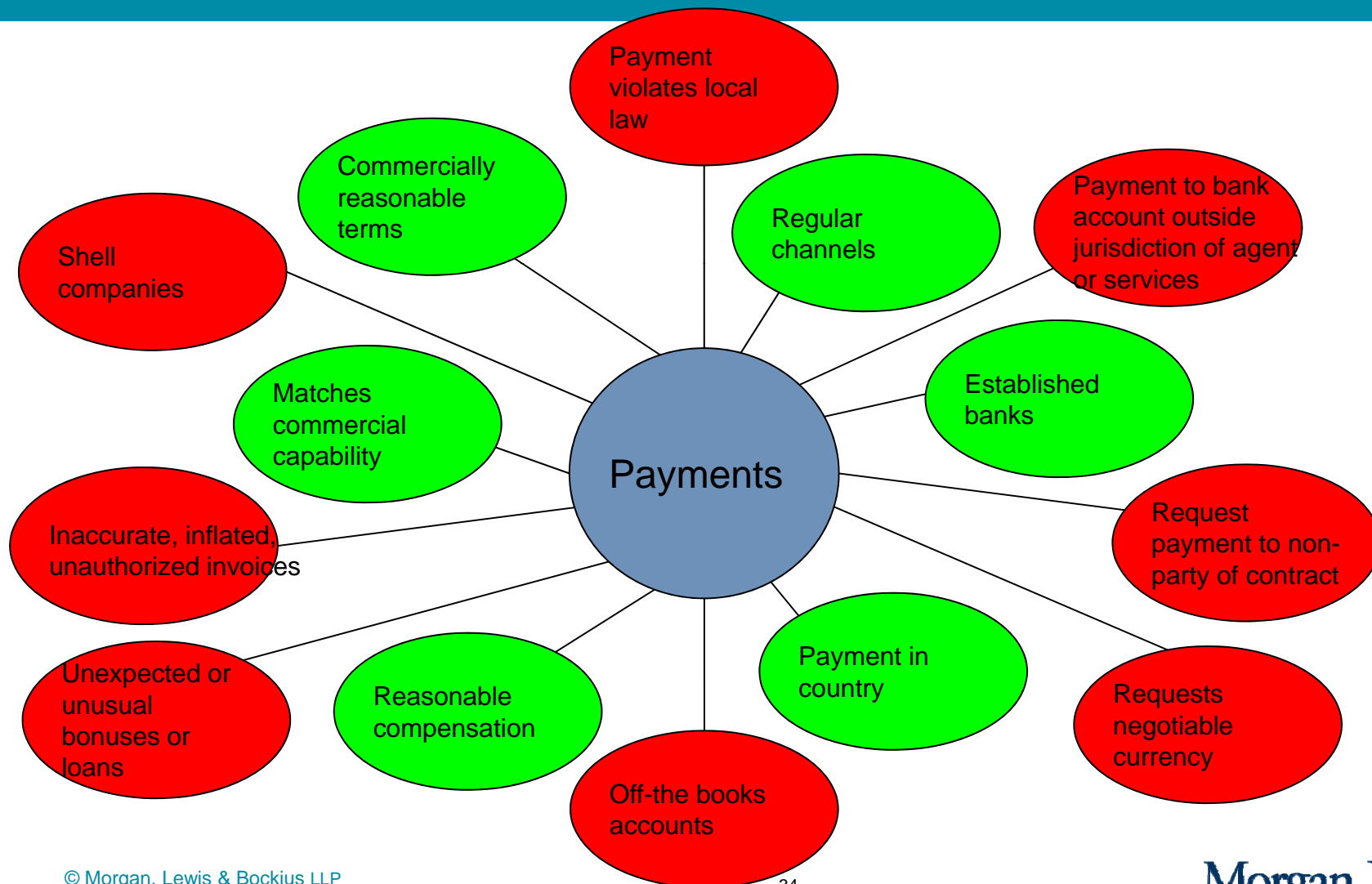


Red Flags



Red Flags

Payments



Components Similar Under U.S.S.G. and UKBA

U.S. Sentencing Guidelines

- Code of Ethics
- Effective response to allegations
- Remediation and corrective action
- Management oversight
- Compliance officer
- Reports to the board
- Communication and training
- Monitoring, auditing, and reporting

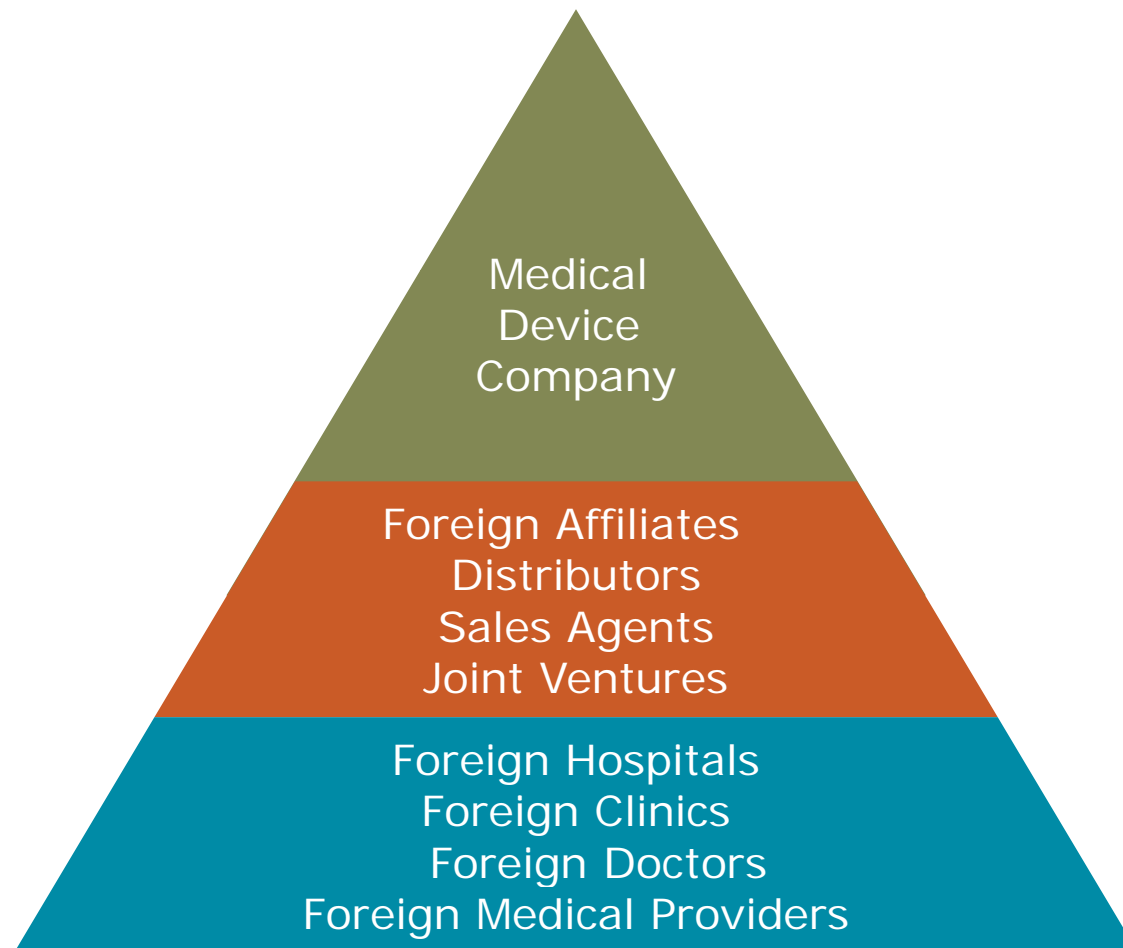
UK Bribery Act Principles

- Proportionate procedures
- Top-level commitment
- Communication and training
- Risk assessment
- Due diligence
- Monitoring and review

Evaluating Effectiveness of Controls: Where to Start

- Understand existing policies, procedures, and controls through review of key documents, interviews and field visits
 - Are employees sufficiently aware of policies and procedures?
 - Is there appropriate training?
 - Are the policies and procedures appropriately tailored for the business today (i.e., are they outdated or too broad)?
 - Does the company require compliance certifications? What do they cover?
 - How is compliance documented by the program? Are the requisite approvals being obtained?
 - Have there been prior audits of the anti-corruption program and financial controls?

Doing Business Through Third Parties



Third Party Due Diligence: Sample Roles & Responsibilities

Business

- Identify need for Third Party
- Initiate due diligence
- Coordinate with Third Party during diligence
- Decision-maker whether to retain Third Party or not

Business and Legal Affairs

- Conduct and oversee initial intake procedure for all Third Parties
- Classify Third Parties as Category A, B, or C
- Maintain “do not use” lists

Business & Legal Affairs

- Conduct and oversee Due Diligence
- Review for Red Flags and approve retention or route for individualized diligence
- Oversee training program for third parties and

Everyone Checks for Red Flags

Sample Vendor/Customer Questionnaire

EXHIBIT A

VENDOR/CUSTOMER: BASIC QUESTIONNAIRE (To Be Completed Prior To Entry Into Contract)

Name: _____

Address (including country): _____

Brief description of the business you will do with Viacom: _____

Country(ies) in which you will do business with Viacom: _____

Bank Name and Country of Payment: _____

Method of Payment (wire transfer, check, cash, etc): _____

Government ownership or affiliation: Yes _____ No _____
(Check the correct answer if your company is owned by or affiliated with a government official or foreign government)

If yes, please explain.

Government interaction: Yes _____ No _____

Practical Tips: Third-Party Due Diligence

- **Understand** how the third party was identified or recommended
- **Know** your business partners, agents and consultants
- **Know** your exposure to, or contacts with, foreign government officials (including employees of state-owned businesses)
- **Understand** the services to be provided and how the payment will be made
- **Conduct** a “red-flag” analysis