

Morgan Lewis

The FCPA and the Pharmaceutical Industry

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Today's Presenters



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Topics of Discussion

- Overview of the FCPA
- Overview of the 2010 U.K. Bribery Act
- Enforcement Trends
- The Pharmaceutical Industry
- Compliance Programs and Third-Party Due Diligence
- Responding to an Allegation
- Q&A

Overview of the FCPA

FCPA's Two Prongs

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

Anti-bribery 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

Books & Records Provisions

- Books and records
 - Must be in reasonable detail which 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

Exception to Anti-Bribery Provisions

- Facilitating or “grease” 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, mail services*

Affirmative Defenses

- 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
- Payments lawful under the written laws of the foreign country
 - Has never been recognized as a defense to a payment prohibited by the FCPA

PhRMA Code

- Applies to “relationships with U.S. healthcare professionals,” but may provide useful guidance for non-U.S. interactions
- Potentially relevant provisions
 - Informational presentations by pharmaceutical company representatives and accompanying meals (section 2)
 - Prohibition on entertainment and recreation (section 3)
 - Speaker programs and speaker training (section 7)

FCPA Violations – Potential Consequences

- Prison
- Criminal fines
- Civil penalties
- Disgorgement
- Collateral consequences

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”)
- Rescission of Contracts, Permits

Overview of the U.K. Bribery Act 2010

Overview of the U.K. Bribery Act 2010

- Sweeps away old law on bribery
- New offences
 - 2 “general” offences: bribery and taking a bribe
 - Bribery of foreign public official
 - Corporate offence: failure to prevent bribery
- Broad-brush, almost “principles-based” approach

General Offences

- Bribery: offering, etc. an **advantage** to another person
 - intending to induce or reward **improper performance** of a **relevant function**, or
 - knowing acceptance constitutes **improper performance**
- Taking a bribe:
 - requesting, accepting, etc. an **advantage**
 - intending, in consequence, or as a reward for, **improper performance** of a **relevant function**, or
 - where acceptance constitutes **improper performance**
 - **Performing improperly** (including procuring improper performance) in anticipation of an **advantage**

Bribery of Foreign Public Officials (s.6 Offence)

- Bribing a foreign public official (F) if intends to influence F in F's capacity as FPO, intending to obtain/retain business or business advantage
- Broadly overlaps with s.1 offence:
 - believed included to ensure OECD compliance
 - however, arguably even stricter: cf. “influence” to “improper performance”

Failure to Prevent Bribery (s.7 Offence)

- “Relevant commercial organisation” (C) commits an offence if person (A) “associated” with C bribes another person intending to obtain/retain business or a business advantage for C
- Strict liability offence
- Defence if C can prove it had in place “adequate procedures” designed to prevent persons associated with C from undertaking such conduct

s.7 Offence: Some Terms Explained

- “Relevant commercial organisation”:
 - UK body corporate or partnership which carries on business anywhere
 - Non-UK body corporate or partnership which carries on a business, or part of a business, in the UK
- “Associated”
 - A associated with C if A “performs services” for or on behalf of C, in whatever capacity
 - Non-exclusive examples: employee (presumed), agent, or subsidiary
 - May extend much further e.g. suppliers, joint ventures, advisers
 - Determined by all relevant circumstances, not just nature of relationship

s.7 Offence: Some Terms Explained (cont.)

- “Adequate Procedures”: no further explanation but “guidance” to be issued by UK government
 - Consultation in September; final guidance early 2011
 - Likely to be based on existing international guidelines, e.g. OECD, Transparency International, etc.
 - Likely to be principles-based: will need to tailor to specific circumstances, e.g. size, industry sector, geographic reach, transaction type, etc.
 - High-risk industries may have to be more robust

Penalties

- General offences and IPO offence
 - Individuals: 10 years imprisonment or unlimited fine
 - Other persons: unlimited fine
- Corporate offence: unlimited fine
- May trigger:
 - Automatic ban on tendering for public procurement contracts
 - Recovery/confiscation order: all proceeds of crime

Timing

- Act not yet in effect
 - Act will come into effect in April 2011
 - Consultation process on guidance on “adequate procedures” to commence in September
 - Guidance expected to be issued early in 2011
- Need to start preparing s.7 compliance programmes now to be ready for new regime

Comparison to FCPA

- Extends to private bribery
 - e.g. payment to an employee in procurement dept to favour bid
- No carve-out for facilitation payments
 - Likely to be a criminal offence; dependent on prosecutorial discretion
- Applies to bribe recipients
- No formal advisory service (cf. service provided by US A-G)
- Jurisdictional reach e.g. could catch US company with any business in the UK making facilitation payments in Indonesia
- No discretion on imposition of public procurement ban
- Current uncertainties in UK re plea bargaining

Practical Implications for Companies

- Identify whether a “relevant commercial organisation”
- Identify existing “associates”
- Put in place internal systems, policies and procedures, training programmes, etc.
- Consider how to deal with existing and future counterparties
- Consider insertion of clauses into employment contracts and terms of engagement with counterparties
- Consider due diligence issues on e.g. M&A: potential for inherited risk
- Even if not covered by the Act, companies may need similar anti-bribery policies to satisfy counterparties’ policies

Enforcement Trends

Enforcement Trends

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

DOJ: Continued Upward Enforcement Trend

- Increase in FCPA prosecutors and agents
 - In June 2010, the FBI announced increasing its FCPA enforcement unit by 33% (from 12 to 16)
- Use of traditional criminal law enforcement techniques
 - “From now on, would-be FCPA violators should stop and ponder whether the person they are trying to bribe might really be a federal agent.”
 - Lanny Breuer, Assistant Attorney General, Criminal Division

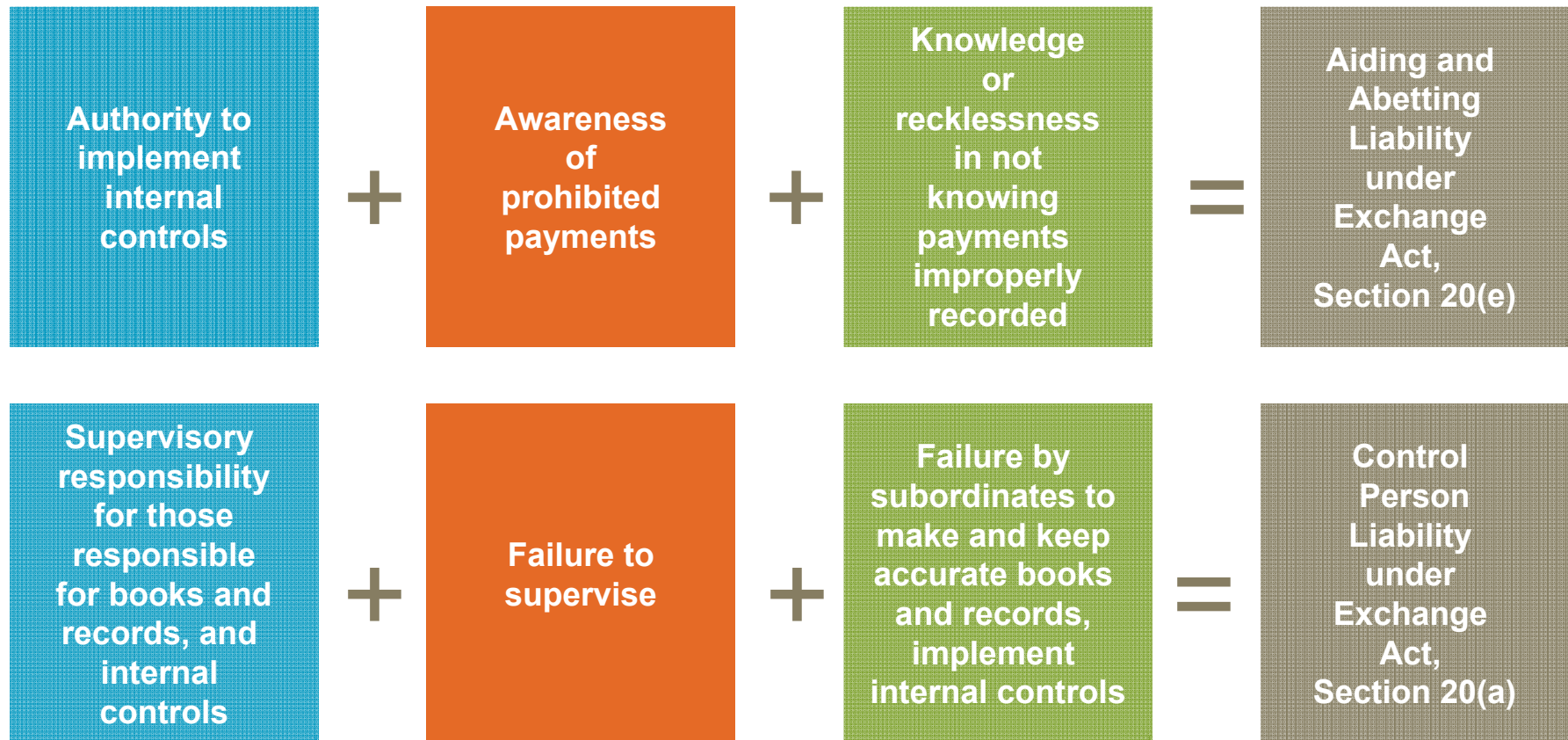
The Rise of SEC Enforcement

- Fundamental reorganization of the SEC Enforcement Division & expansion of investigative tools
 - National specialized enforcement units
 - *Asset management, Market abuse, Structured and new products, FCPA, Municipal securities and public pensions*
 - Increased focus on individual liability
 - New cooperation tools
 - Office of Market Intelligence
 - *Responsible for the collection, analysis, risk-weighting, triage, referral, and monitoring of tips, complaints, and referrals*
 - *Responsible for harvesting that intelligence to better inform the SEC's investigative focus and priorities*
- Financial Reform Act Whistleblower Provisions

More Criminal Prosecutions of Individuals

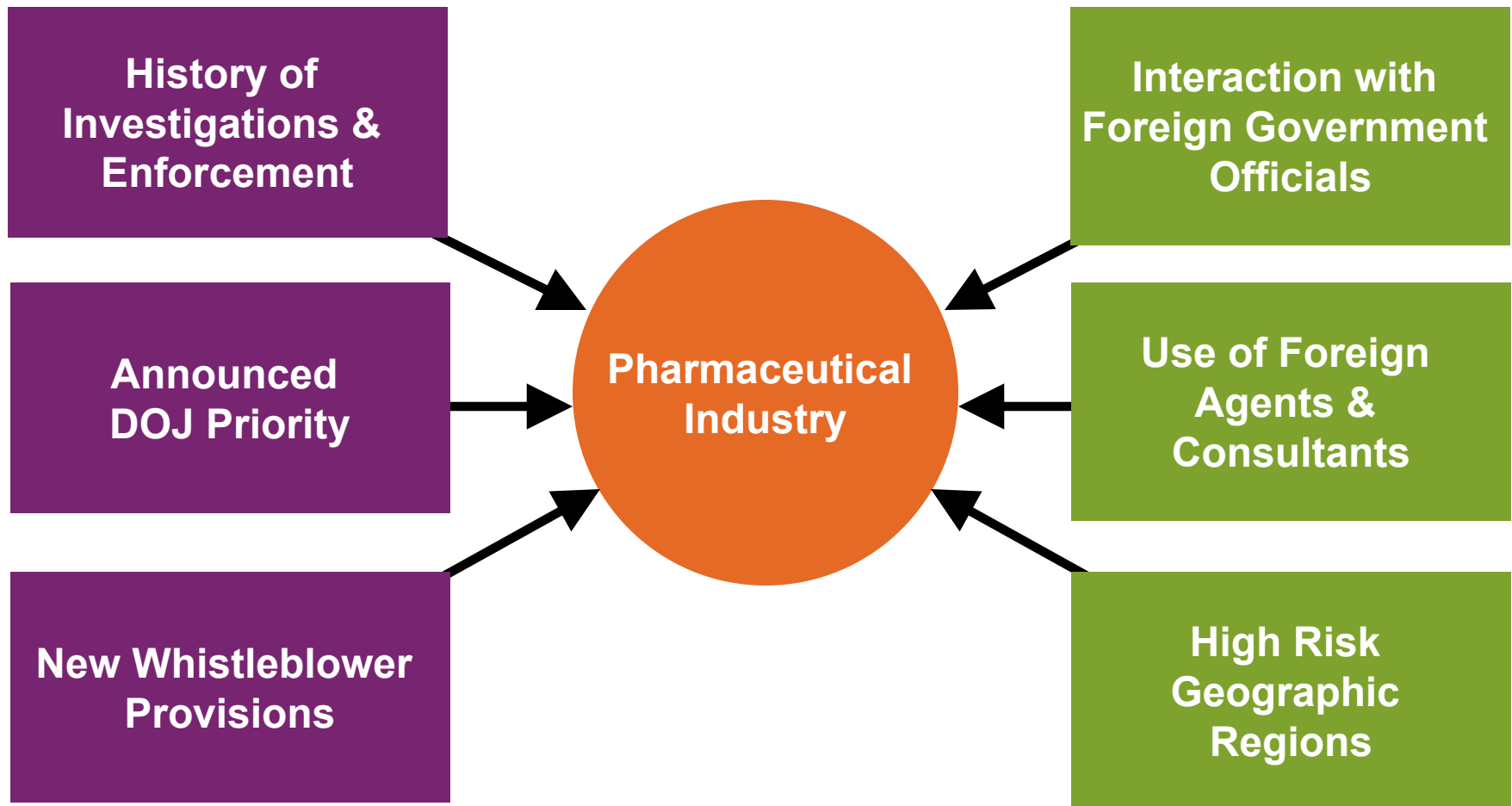
- More criminal prosecutions of and enforcement actions against individuals
 - 75% of DOJ prosecutions during 2009
 - 3 SEC enforcement actions during 2009
 - 3 FCPA trials during 2009
 - 22 individuals arrested on January 19, 2010
- Bases for Liability
 - Direct Liability
 - Aiding and Abetting Liability
 - Control Person Liability

SEC Enforcement



The Pharmaceutical Industry

FCPA Enforcement Risk – The Pharmaceutical Industry



Pharma Industry – A History of Enforcement

2009

— **Pfizer:** \$2.3 billion civil / criminal fines

2008

— **Cephalon:** \$435 million civil / criminal fines and forfeiture

2007

— **BMS:** \$499 million civil fines and disgorgement

2003

— **AstraZeneca:** \$354 million civil / criminal fines

2001

— **TAP:** \$875 million civil / criminal fines

Pharmaceutical Industry Targeted

- The application of the FCPA to the pharmaceutical industry **“will be a focus for the Criminal Division in the months and years ahead.”**
 - Lanny A. Breuer, Assistant Attorney General, Criminal Division
Address to the Pharmaceutical Regulatory and Compliance Congress (November 12, 2009)

Pharmaceutical Industry Targeted

- “The depth of **government involvement** in foreign health systems, combined with **fierce industry competition** and the **closed nature of many public formularies**, creates a significant risk that corrupt payments will infect the process. **The Criminal Division stands ready to ferret out this illegal conduct and we are uniquely situated to do so.**”
 - Lanny A. Breuer, Assistant Attorney General, Criminal Division (November 12, 2009)

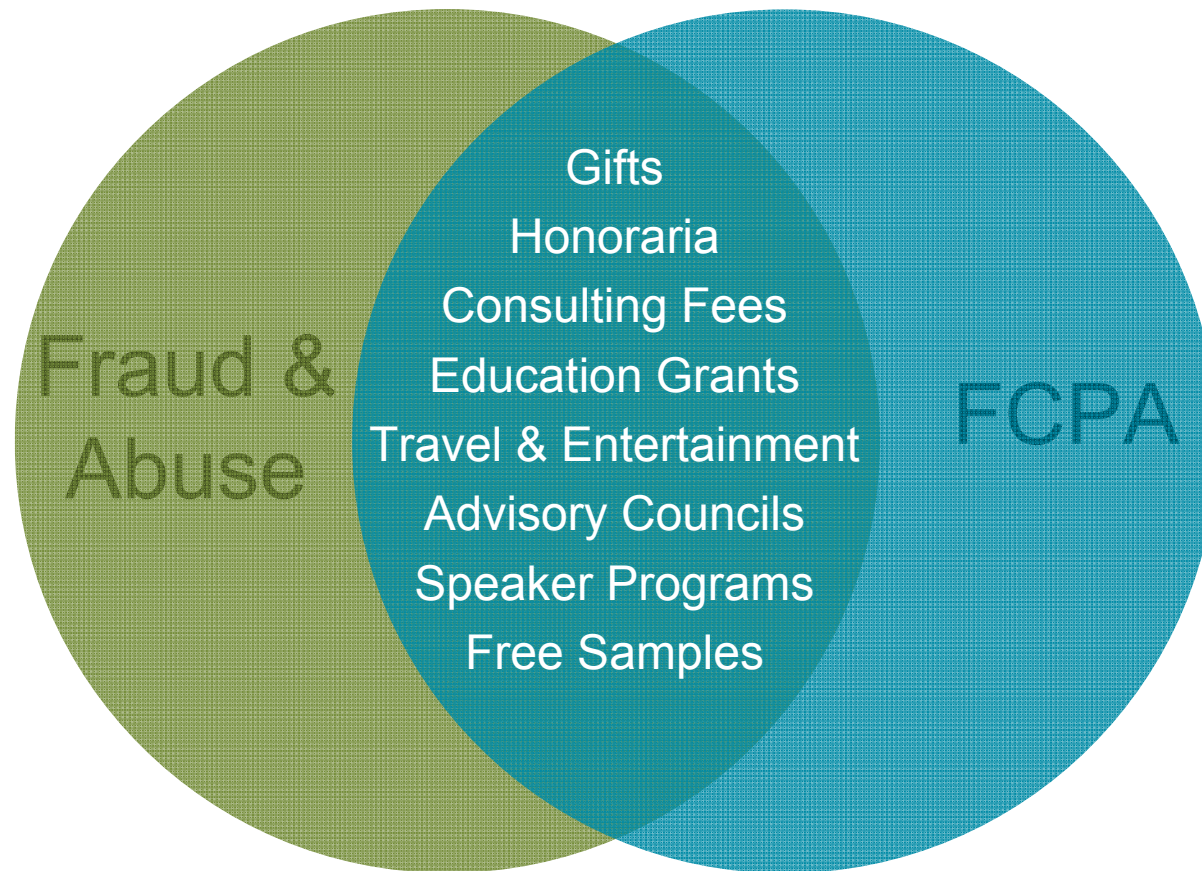
Pharmaceutical Industry Targeted

- “Our remarkable **FCPA unit** and our terrific **health care fraud unit** will be working together to investigate FCPA violations in the pharmaceutical industry in an effort to maximize our ability to effectively enforce the law in this **high risk area**.”
 - Lanny A. Breuer, Assistant Attorney General, Criminal Division, Address to the 22nd National Forum on the Foreign Corrupt Practices Act (November 17, 2009)

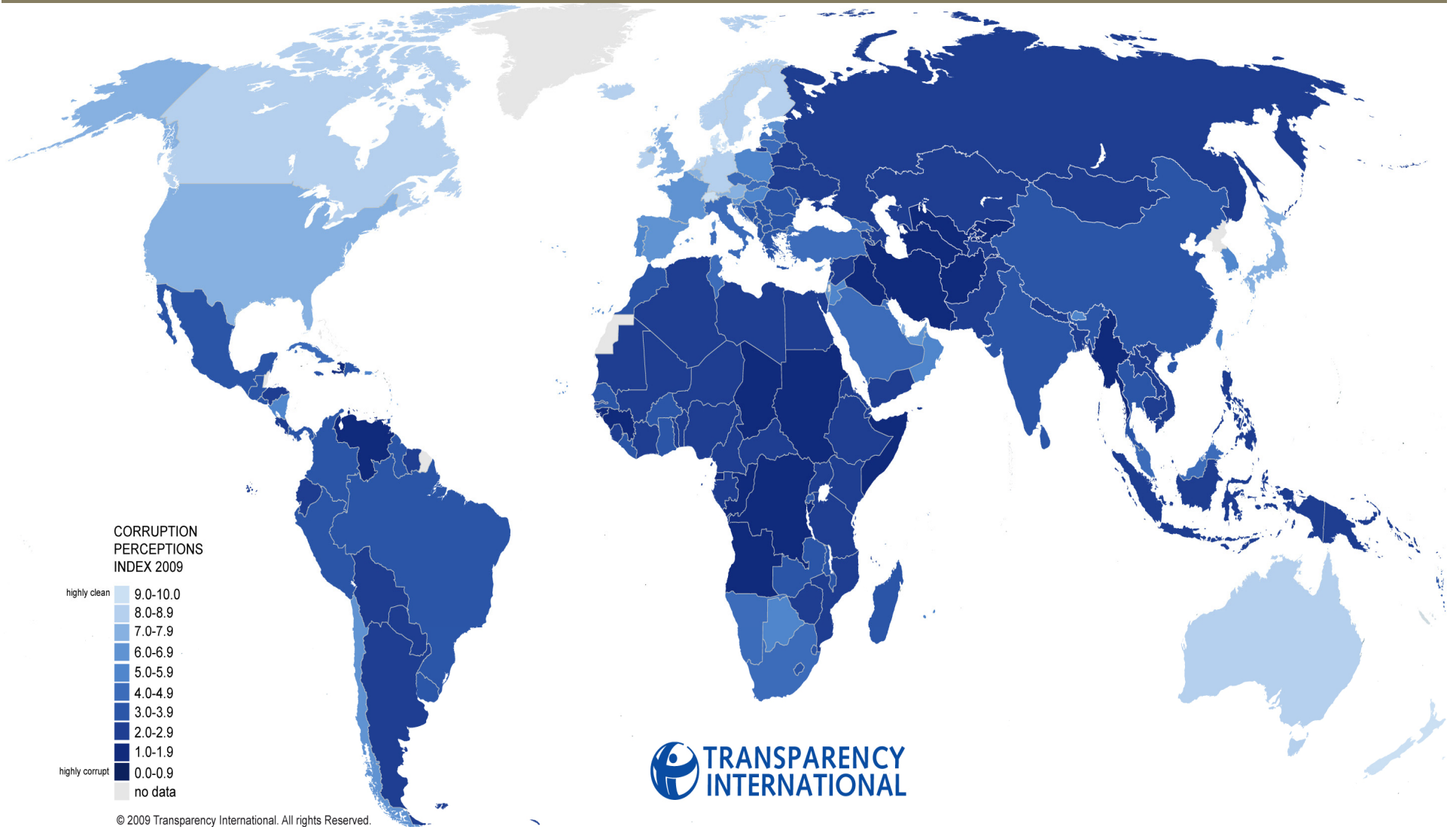
Anti-Corruption Challenges for Healthcare Companies

- Expanding an international presence is a key long-term growth strategy for many leading health-care companies
- Developing nations are spending more money on health-care 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

Pharma Industry – Potential FCPA Issues



How The DOJ, SEC & SFO See The World



Compliance Programs and Third-Party Due Diligence: Practical Responses in a Dynamic Enforcement Environment

Components of an “Effective” Compliance Program

- Compliance program components include:
 - Clearly articulated corporate policies 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, and 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

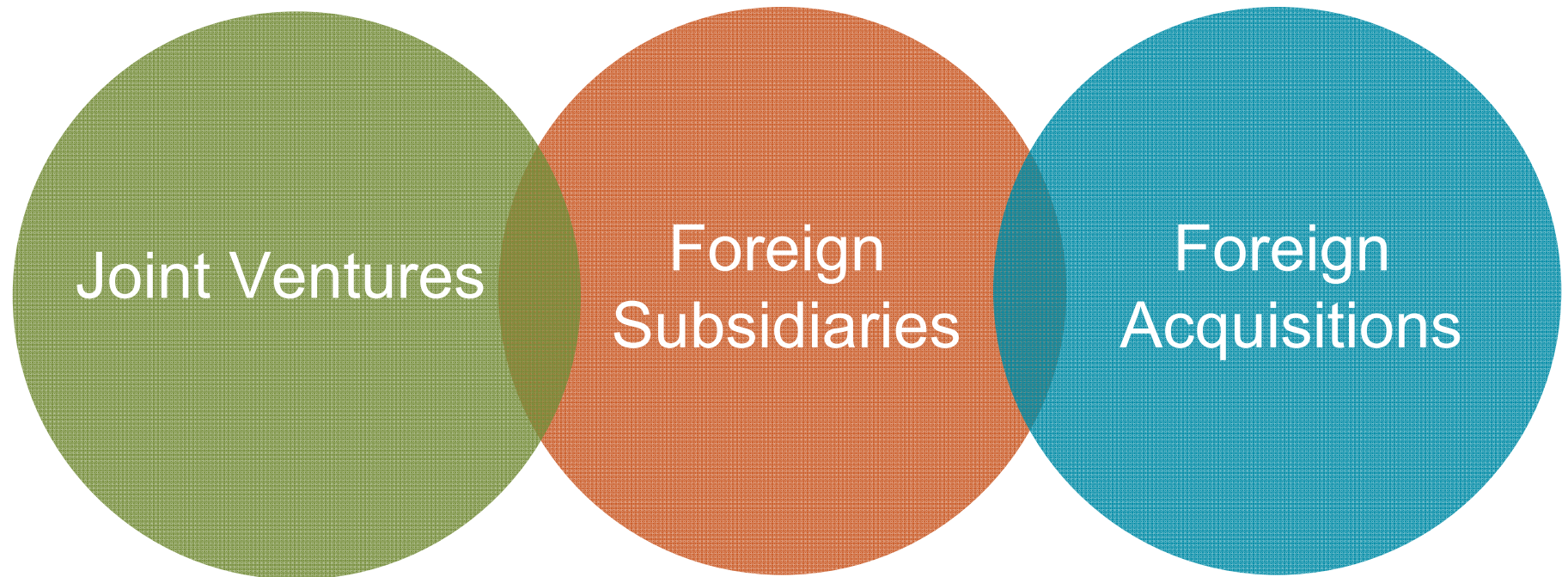
Evaluating Effectiveness of Controls: Where to Start

- 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?

Third-Party Representatives

- Foreign Affiliates
- Distributors
- Sales Agents
- Joint Ventures
- Foreign Medical Providers

Other Business Partners



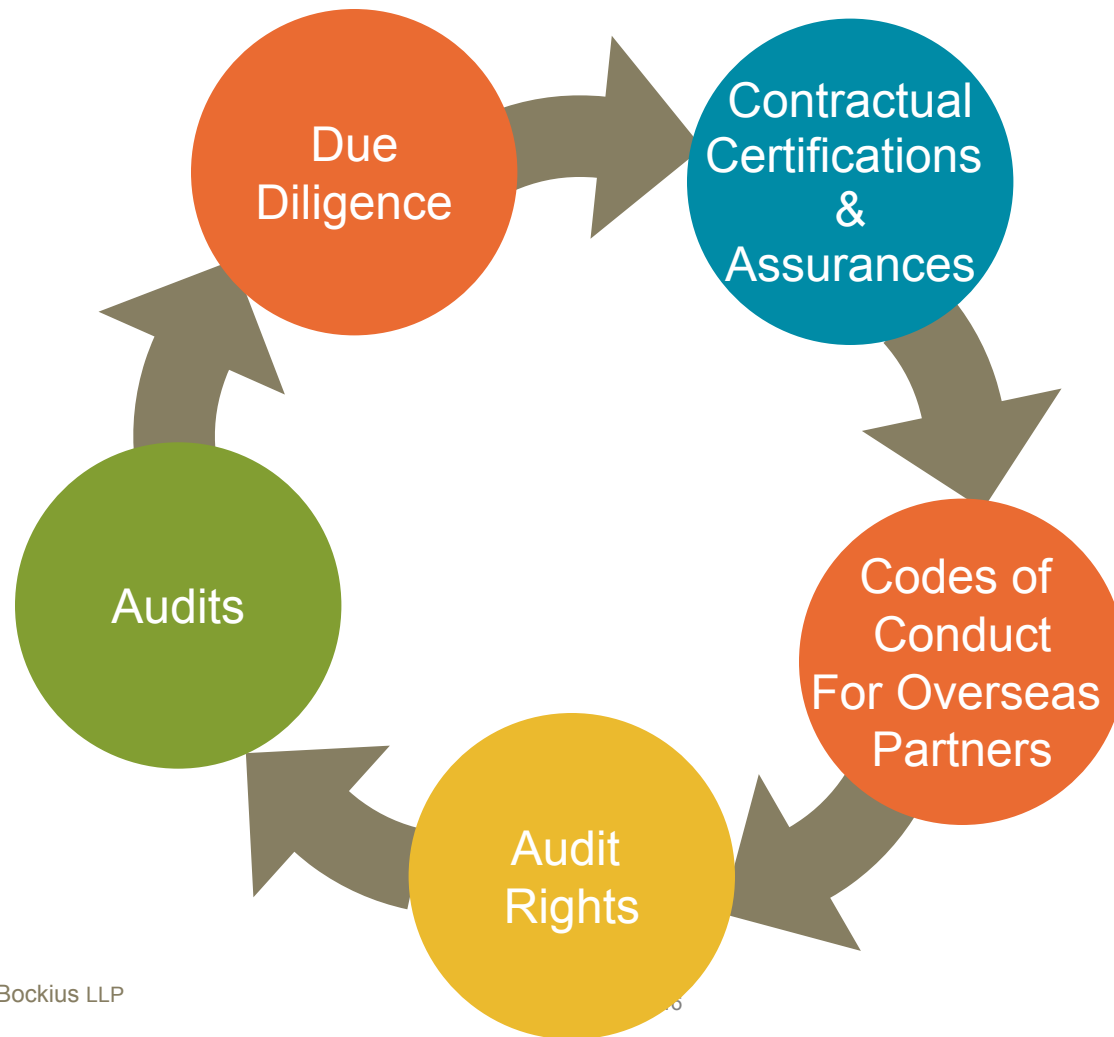
What Are The FCPA's Third-Party Payment Provisions?

- No immunity by doing business through foreign affiliates or third parties
- Anti-bribery 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 believes that such circumstance does not exist”

What are the Risks of Working With Third Party Representatives?

- Third-Party Representatives can create liability for company
- Over 50% of FCPA prosecutions involve liability based on the use of agents and representatives
- Due diligence and monitoring agents and third-party representatives is increasingly important

What Are The Government's Expectations?



What Is Due Diligence?

- An essential part of an FCPA 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








What Factors Should be Considered in Evaluating Third-Party Representative Anti-Corruption Risk?

- Reasonableness and method of payment
- Size and structure of commissions and expenses
- Compliance with local law
- Competence of business partner
- Integrity of business partner
- Business partner's relationship to foreign government officials
- Business partner's past history
- Territory's reputation for corruption
- Conduciveness of the transaction to corruption







What Factors Should be Considered in Evaluating Third-Party Representative Anti-Corruption Risk? (cont.)

- Maintenance of accurate books and records
- Business partner's transparency in record-keeping
- Consistent standards
- Business partner's qualifications and resources
- Continuing oversight of business partner's activities
- FCPA safeguards in the contracts
- Certification of compliance

Third-Party Representatives: What are Examples of **Red Flags**?

-  Large commission, retainer or fee requests
-  Premiums added to contract
-  Unusually high service-related fees
-  Requests for cash
-  Customer or agent is owned or controlled by government official
-  Customer or agent is owned or controlled by relative of government official
-  Agent refuses to confirm he understands FCPA and will comply

Third-Party Representative Payments: What are Examples of **Red Flags**?

-  Large and numerous end-of-year adjustments
-  Request that payment be paid in third country or to third party
-  Foreign operations managers received unusual bonuses
-  Inconsistent invoicing or over-invoicing
-  Transactions are recorded as “cash” or checks are drawn to cash
-  New customers granted unusual credits

Responding to an Allegation

Responding to an Allegation

- Conduct a prompt and effective internal investigation
- Remediate
 - Make sure the prohibited activity is stopped
 - Address lapses, if any, in controls and implement improvements
 - Consider appropriate disciplinary measures
 - Terminate business relationships with relevant vendors, consultants, or partners
 - Conduct corrective training
- Consider Disclosure
 - Outside auditors
 - Financial statements/regulatory filings
 - U.S. or foreign authorities
- Effectively use outside and external resources

Going Forward

- Continued vigilance
 - Standards of conduct
 - Systems and controls
 - Compliance programs
 - Training
- Risk assessment
- Focus on third-party relationships

Q & A



international presence

Beijing Boston Brussels Chicago Dallas Frankfurt Harrisburg Houston Irvine
London Los Angeles Miami Minneapolis New York Palo Alto Paris Philadelphia
Pittsburgh Princeton San Francisco Tokyo Washington Wilmington