

**Advanced Issues in Promotion,
Inducements and Corrupt Practices,
including Foreign Corrupt Practices Act**

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Session Outline

- ▶ Environment and Pharma “Model”
- ▶ Nexus to government
- ▶ Industry practices most-scrutinized or implicated
- ▶ The Foreign Corrupt Practices Act
- ▶ Current trends in enforcement
- ▶ Thoughts on compliance

Environment

- ▶ Drugs save lives and drug companies want to succeed in business by saving lives and earning an honest profit
- ▶ Emerging markets play a big role in the growth of the top companies, and present a fertile ground for new companies
- ▶ A highly competitive market for products and relationships
- ▶ Strong dependability on business relationships
- ▶ Marketing and sales-driven cultures (after science)
- ▶ Employee compensation often largely based on sales targets
- ▶ Low salaries in public health care in many countries
- ▶ Underfunding of public institutions in many countries
- ▶ Low salaries across the board in some markets
- ▶ Not enough internal resources to monitor
- ▶ Attitudes about “how business is done in the market”

Environment (continued)

- ▶ Dispersed sales forces with available resources
- ▶ Growing resentment of the industry due to rising cost of products
- ▶ Media coverage of activities and political issues around “corruption”
- ▶ Attention by government authorities around the world
- ▶ Competitor complaints are a common enforcement tool
- ▶ Initiatives by top multinationals on “compliance”
- ▶ Multiple laws and practices across markets
- ▶ Industry association guidance (i.e., codes of conduct)
- ▶ Whistleblower proliferation
- ▶ Strong dependability on government persons (approvals, reimbursement, prescriptions)

Pharmaceutical and Medical Device Model

- ▶ Interactions with government agencies and officials
 - ▶ Research and manufacturing
 - ▶ Registration to approval
 - ▶ Importation and distribution
 - ▶ Promotion of products
 - ▶ Post-market safety and “pharmacovigilance”

Pharmaceutical and Medical Device Model (continued)

- ▶ Transacting with the government agencies and officials
 - ▶ Selling products
 - ▶ Samples
 - ▶ Tender bids
 - ▶ Pricing negotiations
 - ▶ Fee-for-service arrangements
 - ▶ Philanthropic and other funding
 - ▶ Value-added services

Nexus to Government “Employees” or “Officials”

- ▶ Physicians and other HCPs
- ▶ Hospital personnel
- ▶ Ministry of Health and regional officials: registration, tender, reimbursement, product surveillance
- ▶ Consultants, vendors
- ▶ Local definition of “civil servant”
- ▶ Public vs. private capacity
- ▶ Use of third parties
- ▶ Spouses and relatives
- ▶ Other government officials: political parties, customs, plants

Industry Practices Most Scrutinized or Implicated

- **Free value provided to customer/influencer individuals and entities**
 - Gifts
 - Cash
 - In-kind: equipment, supplies, products and merchandise, brand reminders, promotional items
 - Funding
 - Direct: philanthropic donations, grants, educational sponsorships (individual or entity), patient assistance programs, research (clinical, outcome studies)
 - Indirect: value-added (diagnostic services, nursing, patient education), professional advancement, business development, practice management, marketing/staffing support, reimbursement advice and assistance, speaking/writing skills training, formal education

Industry Practices Most Scrutinized or Implicated

- **Free value provided to customer/influencer individuals and entities (continued)**
 - Product samples
 - Registered and permitted
 - Distinguished from free products/merchandise
 - Business courtesies
 - Hospitality and meals
 - Entertainment
 - Travel and out-of-pocket expenses
 - Price Concessions
 - Discounts, rebates
 - Product returns and chargebacks

Industry Practices Most Scrutinized or Implicated

- **Fee-for-Service Arrangements**
 - Clinicians and influencers: Individual health care providers (HCPs), health care institution personnel (such as administrators), as well as individuals employed by government agencies and institutions or otherwise serving in a government official capacity
 - Speaker, including speaker training
 - Writer, including assistance
 - Preceptorship and O/R visit (i.e., sales agent education)
 - Consultant
 - Market research feedback
 - Clinical trial investigator

Industry Practices Most Scrutinized or Implicated

- **Fee-for-Service Arrangements (continued)**
 - Entities
 - Facilities fees, including use of space for training
 - Inventory management, market share analysis
 - Lease of space
 - Research site
 - Services rendered by employees (speaking, consulting, etc.)

Industry Practices Most Scrutinized or Implicated

- **Tender process**
 - ▶ Keeping track of tenders
 - ▶ Nature of “ancillary” transactions (e.g., donations)
 - ▶ Timing in relation to a tender decision
 - ▶ Totality of transactions involving the tendering entity
 - ▶ Totality of spend on such transactions
 - ▶ Bid tampering
 - ▶ Distributor involvement in tender process
 - ▶ Dealings with persons from the tendering entity
 - ▶ Involvement from the tendering entity

Industry Practices Most Scrutinized or Implicated

- **Third-party: distributors**
 - ▶ Do you know your third-parties?
 - ▶ Reputation, background, financials, policies, training
 - ▶ Who within the company deals with the third parties?
 - ▶ Do you know exactly what they do for your company?
 - ▶ Distribution, other services
 - ▶ Do you have contracts for ALL of these services?
 - ▶ How do you monitor transactions?
 - ▶ Is there a true right to audit?
 - ▶ How much does the business “depend” on the third party?
 - ▶ What requirements do you place on compliance training?
 - ▶ Bringing distributors to in-house training

Industry Practices Most Scrutinized or Implicated

- **Employee travel and entertainment (“T&E”) reimbursement**
 - ▶ Occupational fraud theme: Use of reimbursement for questionable purposes
 - ▶ Home made or purchased receipts and invoices
 - ▶ Altered or irrelevant receipts and invoices
 - ▶ Arrangements with vendors for fraudulent
 - ▶ Passing through of customer expenses

Industry Practices Most Scrutinized or Implicated

- **Congresses and meetings (particularly “non-local”)**
 - ▶ What is the event? Who sponsors it? Where is it?
 - ▶ Who decides to sponsor physicians? Why?
 - ▶ Who selects the physicians sponsored? How and how many?
 - ▶ How is this discussed with the physician?
 - ▶ Who pays for what and how?
 - ▶ Who approves these transactions? Level of documentation?
 - ▶ Who examines the program as against “purpose of sponsorship.” length of stay, number of physicians?
 - ▶ What if third-parties are involved: hospital employer, government agency, travel agent
 - ▶ How do you verify compliance with rules: before and after?

Industry Practices Most Scrutinized or Implicated

- **Vendors (any entity or individual)**
 - ▶ Who are they? If an entity, who are the principals?
 - ▶ What do they do? Is there a written agreement?
 - ▶ Who selected them?
 - ▶ Who approved them?
 - ▶ What kind of due diligence exists for becoming a vendor?
 - ▶ Are payments and contracted items/services examined, monitored, audited?

Industry Practices Most Scrutinized or Implicated

- **Value-added services**
 - Point of view: Bringing value to customers
 - ▶ Diagnostic equipment
 - ▶ Nurses services
 - ▶ Professional development
 - ▶ Patient education
 - ▶ Patient information
 - ▶ Reimbursement services and advice

What is the Foreign Corrupt Practice Act (FCPA)?

- ▶ United States law that prohibits attempts to gain a foreign business advantage in through bribery or other improper inducements

What is the FCPA?

- ▶ Two prongs to the statute:
 - ▶ Anti-Bribery
 - ▶ Books and Records

FCPA as an Anti-Bribery Statute: What is Prohibited?

- ▶ FCPA makes it unlawful to
 - ▶ provide a payment or gift
 - ▶ offer or promise to pay or make gift
- ▶ Directly or indirectly to
 - ▶ Foreign government officials
 - ▶ Foreign political parties or officials

FCPA as an Anti-Bribery Statute: What is Prohibited?

- ▶ Or through an intermediary knowing that the payment or gift will be passed on

FCPA as an Anti-Bribery Statute: What is Prohibited?

- ▶ If the purpose of payment or gift is to
 - ▶ Influence official act or decision
 - ▶ Induce official to act or not act
- ▶ In order to
 - ▶ Obtain or retain business
 - ▶ Secure an improper advantage over the competition
 - ▶ Obtain favorable or preferential treatment from the government

FCPA as an Anti-Bribery Statute: Who is a Foreign Official?

- ▶ Foreign government officials are broadly defined:
 - ▶ Not limited to high level officials
 - ▶ Not limited to what are commonly considered “government” employees

FCPA as an Anti-Bribery Statute: Who is a Foreign Official?

- ▶ Foreign government officials:
 - ▶ Traditional government employees
 - ▶ Employees of government-owned or government-controlled entities
 - ▶ Persons acting officially on behalf of a government
 - ▶ Private persons who are “advisors”
 - ▶ Relatives of officials (indirect payments)

FCPA: Liability Through Third Parties

- ▶ Liable if covered entity or person knows or should know improper payments are being made by third parties
- ▶ “Willful blindness” is not a defense
- ▶ Third parties include
 - ▶ Agents
 - ▶ Consultants
 - ▶ Distributors
 - ▶ Lobbyists
 - ▶ Joint venture partners

FCPA as a Books and Records Statute: Accounting Obligations

- ▶ Books and Records

- ▶ Duty to make and keep books and records which in reasonable detail, accurately and fairly reflect transactions

FCPA as a Books and Records Statute: Accounting Obligations

▶ Internal Controls

- ▶ Duty to devise and maintain system of accounting controls sufficient to provide reasonable assurance that all transactions are authorized and consistent with GAAP

FCPA as a Books and Records Statute: Accounting Obligations

- ▶ Liability for Books and Records Violations
 - ▶ U.S. companies are liable for books and controls of subsidiaries and controlled affiliates
 - ▶ Does not necessarily need to relate to bribery of foreign officials--any books and records or internal control violation can qualify
 - ▶ Substantial criminal sanctions
 - ▶ Individuals may face \$5 million fine and 20 years imprisonment

Defenses to the FCPA

- ▶ Two affirmative defenses:
 - ▶ Alleged bribery scheme was lawful under written laws of the recipient's country
 - ▶ Alleged bribery scheme was a reasonable and bona fide expenditure related to promotion, demonstration, or explanation of products or services, or related to the execution or performance of a contract
 - ▶ These affirmative defenses are narrowly construed

Defenses to the FCPA

- ▶ One exception for facilitating or expediting payments:
 - ▶ Such “grease” payments are permissible if the purpose is to expedite or secure the performance of a routine, non-discretionary governmental action by the payee
 - ▶ Should be of limited value
 - ▶ Governmental action includes
 - ▶ issuing licenses and permits
 - ▶ processing customs paperwork
 - ▶ providing police protection

FCPA Penalties

- ▶ Criminal penalties
 - ▶ Maximum \$2 million fine for companies
 - ▶ Maximum \$100,000 fine and five years imprisonment for individuals
 - ▶ Companies may not indemnify convicted officers, directors, employees, agents, or stockholders for payment of any fine

FCPA and Its Impact on the Pharmaceutical and Medical Device Industry

▶ Red Flags

- ▶ Inflated or unusually large commissions or bonus payments to employees or third party representatives who interact with government officials
- ▶ Requests for large amounts of payments in cash or in bearer instruments
- ▶ Payments through a third party or to an account in an offshore or unrelated third country
- ▶ False invoices or over-invoicing
- ▶ Lack of transparency in expenses and accounting records
- ▶ A consultant, agent, or business partner whose qualification includes a personal relationship with government officials
- ▶ Apparent lack of qualifications or resources, on the part of the consultant, distributor, representative, or joint venture partner, to perform the services offered

Current Trends

- ▶ Enforcement of the FCPA has dramatically increased in recent years
- ▶ 38 enforcement actions in 2007
- ▶ 15 enforcement actions in 2006
- ▶ Increased number of voluntary disclosures
- ▶ Increased cooperation among multi-national prosecutors
- ▶ Recent FCPA enforcement actions show that companies without effective compliance programs incur the highest penalties

Current Trends

- ▶ U.S. Government is seeking more intrusive remedies:
 - ▶ Government-imposed monitors
 - ▶ Monitors may be given
 - ▶ access to records, including real-time access to calendars of top officials
 - ▶ ability to impose changes to FCPA-related compliance processes

Current Trends

- ▶ Fines and disgorgement payments are increasing
 - ▶ Titan (2005) – more than \$28 million in fines/disgorgement
 - ▶ Vetco International (2007)- \$26 million total criminal penalty for 3 subsidiaries (\$12 million for one subsidiary with a prior FCPA conviction)

Current Trends

- ▶ Titan Corp. (2005)
 - Paid \$3.5 million over 3 years to its agent in Africa, a business advisor to country's president, in effort to secure telecom contract
 - Payments recorded as consulting services
 - Titan pled guilty to 3 felonies; paid \$13 million fine; entered into SEC consent; disgorged \$15.5 million; retained a monitor

Current Trends

▶ Vetco International (2007)

- Four Vetco subsidiaries authorized agent to make multiple payments (totaling \$2.1 million) to Nigerian Customs Service to procure preferential customs treatment for deepwater oil drilling equipment
- Three of the subsidiaries pleaded guilty to anti-bribery violation and conspiracy: \$26 million total fine (largest to date in DOJ prosecution)
 - ▶ \$12 million paid by one subsidiary with prior FCPA conviction
- Deferred prosecution agreement for one subsidiary: consented to DOJ prior approval of appointments of
 - ▶ Executive Chairperson
 - ▶ Majority members of Compliance Committee (including chair)
 - ▶ Compliance Counsel

Thoughts on Compliance

Compliance: Know the business

▶ Profiling

- ▶ Country indices/scores/reputation
- ▶ Business culture of the market; political and economic environment
- ▶ History of the operations; past audits
- ▶ Local business model and drivers
- ▶ Involvement of the government (regulator, customer, interested party)
- ▶ Local efforts by industry associations
- ▶ Local enforcement efforts
- ▶ Overall sales goals; strategy and tactics
- ▶ Knowing management
- ▶ Linking to region: issues and resources

Compliance: Know the product

- ▶ The label (and its local restrictions) and registration
- ▶ The influencer, decision-maker, buyer, user, recipient
- ▶ The brand plan and sales tactics
- ▶ The reimbursement scheme
- ▶ The sales channel (tenders, formularies, distribution, pricing and discounting)
- ▶ The horizon: new indications; known other uses; timeline-launch to patent expiry
- ▶ The medical affairs piece: post-market, scientific exchanges
- ▶ Congresses
- ▶ Programs: consignment; rotations
- ▶ Competitive products

Compliance: Transparency

- ▶ Transparency of transactions and accounting formalities
 - ▶ Supporting documentation
 - ▶ Specificity required
 - ▶ Knowing the local practices and vulnerabilities
 - ▶ Reliable approvals
 - ▶ Trending and monitoring
 - ▶ Price concessions
 - ▶ Off-invoice, non-trade discounts
 - ▶ Petty cash

QUESTIONS

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