Anti-Corruption Risks for Pharmaceutical and Medical Device Companies

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Overview

- Anti-Corruption Enforcement Trends
- Significant Cases
- Risk Factors for Pharmaceutical and Medical Device Companies
- Compliance Strategies
Numbers Thru 2011

- **DOJ**
- **SEC**

Year: 2004 2005 2006 2007 2008 2009 2010 2011

- **DOJ**:
  - 2004: 2
  - 2005: 3
  - 2006: 7
  - 2007: 8
  - 2008: 13
  - 2009: 14
  - 2010: 48
  - 2011: 23

- **SEC**:
  - 2004: 5
  - 2005: 7
  - 2006: 7
  - 2007: 20
  - 2008: 20
  - 2009: 26
  - 2010: 26
  - 2011: 25
FCPA Enforcement Trends

- Corporate settlements on slower pace than 2011, and well below 2010.

- Justice Department and SEC are devoting time to settlement and investigation of big cases – News Corp, Weatherford, Avon and more

- DOJ seeking to prosecute more individuals in FCPA cases

- Pharma and medical device industries continue to be focus

- 20 pharma and medical device companies still under investigation.
Foreign Country Focus

- China and Europe continue to be focus of health industry corruption investigations
- Conduct in China has been prosecuted in at least 33 percent of all FCPA prosecutions.
- Greece and Eastern European countries have been focus of FCPA prosecutions involving pharmaceutical and medical device companies
FCPA Enforcement in Healthcare: We Mean What We Say

- Healthcare industry was target of industry sweep.
- In November 2009, Lanny Breuer, Criminal Division AAG, announced FCPA enforcement against pharmaceutical industry would be “a focus for the Criminal Division in the months and years ahead.”
- DOJ and SEC have made good on this promise. Other than oil and gas industry, DOJ and SEC have racked up most enforcement actions against pharmaceutical and medical device industries.
Pharmaceutical Industry Sweep

- At least 9 companies under recent or current investigation
  - Baxter – Pending investigation.
  - Eli Lilly – Pending investigation.
  - SciClone – Pending investigation.
- Both brand and generic pharmaceutical companies in the mix
Medical Device Industry Sweep

- Biomet 2012 -- $22.8 million
- Covidien – pending
- Immucor – pending
- AGA Medical 2008 -- $2 million
- Smith and Nephew 2012 -- $22 million
- Zimmer Holdings -- pending
FCPA Enforcement Risk Factors

- International nature of healthcare means FCPA risk is inherent to the industry.
- International sales for pharmaceuticals total more than $100 billion annually.
- AAG Breuer stated in 2009, “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.”
State-Owned Enterprises

- DOJ/SEC enforcement program against pharma and medical device companies rests on interpretation that “foreign official” includes doctors, nurses and other health care professionals employed by public hospitals and other government organizations.

- DOJ interpretation of “foreign official” is now on appeal by 11th Circuit in Haiti Telco prosecution.

- Since 2002, eleven companies have settled cases based on this theory including: Syncor 2002; Schering-Plough 2002; Diagnostic Products Corp. 2005; Micrus Corp. 2005; Immucor 2007; AGA Medical 2008; Smith & Nephew 2012; Biomet 2012 and more.
Foreign Clinical Trials

- 65% of clinical trials investigating FDA-regulated products are conducted overseas.
- 78% of participants in all clinical trials were enrolled at foreign sites, typically foreign medical institutions which often are government-owned and/or controlled.
- Companies use Clinical Research Organizations and International Review Boards to manage clinical trials with foreign medical institutions.
- Payments of “anything of value” by CRO or IRB to foreign medical institution may violate FCPA.
Conferences, Sponsorship and Continuing Medical Education

- Sponsoring travel, meals, lodging and attendance of foreign healthcare professionals creates significant risks
- One “big pharma” settlement is replete with instances where sponsorship was exchanged for commitments by foreign health officials to purchase sponsor companies products
- Detailed protocol and compliance procedures needed in this area to protect against violations
Third-Party Agents & Distributors

- Pharma and medical device companies rely on foreign networks of third-party agents, sub-agents and distributors.
- Smith and Nephew held liable for bribes paid by its distributors to government doctors in Greece.
- Due diligence procedures are critical for agents and distributors.
- Contractual protections through representations and warranties, and monitoring of third-party activities.
Regulatory Risks

- Foreign licensing and permit requirements for pharma and medical device companies.
- Customs regulations.
- Freight forwarders.
- Patent applications.
- Charitable donations to affiliated entities.
“Anything of Value” in Foreign Healthcare Markets

- FCPA covers payments of money or “anything of value” to foreign officials
- Product samples.
- Gifts and discounts.
- Entertainment, flights and lodging.
- Event attendance and related expenses.
- Contributions to charities.
International Application of Healthcare Anti-Kickback Statute

- Focus is on same items as AKB – cash, gifts, charitable donations, travel, meals, entertainment, grants, speaking fees, honoraria, and consultant arrangements.

- DOJ coordinating Healthcare Fraud and FCPA staff to focus on pharma and medical device companies.
Whistleblower Risks

- Healthcare industry has history with False Claims Act relators.
- False Claims bar will add SEC whistleblower expertise and seek to bring FCPA claims.
- SEC whistleblower program gives whistleblowers 10 to 30% compensation of fines and penalties greater than $1 million.
- Companies need to establish whistleblower “triage” programs.
- Voluntary disclosures may be needed to “beat” whistleblowers to SEC and DOJ.
Physician Payments Sunshine Act

- January 2013 new rules kick in requiring to record and disclose any payments or benefits to physicians.

- Congress believes drug and device companies are flouting anti-kickback laws by enriching physicians and creating detrimental conflicts of interest.

- Prosecutors will comb this data for investigative leads and initiate FCPA and AKB investigations.
HHS-OIG Exclusion Authority

- Under federal law, mandatory and permissive exclusion authority can be death knell for pharma and medical device companies.

- Felony criminal convictions related to healthcare programs result in mandatory exclusion for minimum of five years under 42 U.S.C. § 1320a-7(a). HHS-OIOG is seeking longer exclusion periods, some to life.

- HHS-OIG also uses permissive exclusion authority for felony convictions “related to fraud.”

- One reason one of the biggest pharma/device company was cited for FCPA settlement was fear of HHS-OIG exclusion authority.
Compliance Programs
Healthcare Companies – Take These Steps

- Healthcare companies have experience and history with compliance.

- Pharmaceutical and medical device industries have strengthened compliance programs over past decade.

- Companies need to build off established codes of conduct to avoid unlawful inducement and ensure appropriate marketing of medication and devices to healthcare professionals.

- Build specific compliance controls and programs tied to specific risks outlined above: state-owned healthcare workers; sponsorships; third party agents/distributors; foreign clinical trials.
Compliance Program Basic Elements

- Compliance policy and tone at top.
- Anti-corruption policies and procedures: (gifts; hospitality, entertainment, expenses; customer travel; political contributions; charitable donations, sponsorships; facilitation payments; solicitation, extortion).
- Risk assessment.
- Annual review and ongoing assessment.
- Senior management oversight of compliance program and reporting access and obligation to board.
Compliance Program Basic Elements (cont.)

- Training program for anti-corruption compliance, including:
  - Training directors and officers, and where necessary and appropriate, employees, agents, and business partners.
  - Annual certifications to ensure compliance with training requirements.

- Internal controls to identify and prevent bribery:
  - Internal audits must be supplemented with forensic audits, since internal audits hinge on “materiality” and may not catch bribery schemes.
  - Every expenditure of money where bribery may occur should have specific controls and management procedures to prevent bribery (e.g., gifts and hospitality, review form for certain amounts, and review by compliance and legal offices).
Compliance Program Basic Elements (Cont.)

- Ongoing advice and internal reporting system:
  - Internet-based guidance and reporting systems.
  - Hotline reporting system for employees to make anonymous reports.

- Disciplinary procedures to address violations of anti-corruption policies and procedures.

- Due diligence procedures to review third-party agents:
  - Inform foreign business partners of its anti-corruption compliance program.
  - Seek reciprocal written anti-corruption and anti-bribery commitments from its foreign business partners.
Questions
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