
Enforcement, Dealing with Inquiries and Investigations, Preventive Measures, Compliance Programs, Continuous Monitoring and Auditing

The International Pharmaceutical Regulatory & Compliance Congress

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June 6, 2007

What is the FCPA?

- An anti-bribery statute
- A “books and records” statute
- Federal statute passed by post-Watergate Congress in 1977 to prohibit bribery of foreign government officials for the purpose of obtaining or retaining business
- Enforceable by Department of Justice and SEC
 - Enforcement activity has dramatically increased in recent years

FCPA makes it unlawful to:

- Corruptly make a payment or gift (or offer or promise to pay or make gift) of money or anything of value
- Directly to:
 - Foreign government officials
 - Foreign political parties or officials
 - Officials of public international organizations, e.g., WHO
- Or indirectly to such persons through an intermediary while knowing that the payment or gift will be passed on

Unlawful (cont'd)

- If purpose is to obtain a quid pro quo, *i.e.*,
 - To influence official act or decision
 - To induce official to act or not act
- In order to:
 - Obtain or retain business; or
 - “Secure an improper advantage”
- Bottom line: avoid giving benefits that may have appearance of impropriety.

Who is Covered?

- U.S. citizens, nationals and residents, U.S.-based corporations/partnerships, wherever conduct occurs
- *Any* issuer under the federal securities laws
 - Any entity (whether U.S. or non-U.S.) that has a class of securities (including ADRs) registered pursuant to Section 12 of the 1934 Act or is required to file periodic reports pursuant to Section 15(b) thereof
 - Issuer can be liable for *any* subsidiary's bribery if issuer authorized, directed or was "willfully blind" to the activities of the subsidiary
 - Issuer can be liable for *any* subsidiary's inaccurate books and records if the subsidiary's books roll up
- Any person or entity committing an act in the U.S.

Who is a Foreign Official?

- Foreign government officials
 - Very broadly defined
 - Not limited to high level officials
 - Not limited to “federal” employees
 - Employees of government-owned or -controlled entities
 - Persons acting officially on behalf of government entity
 - Can include private persons who are “advisors”
 - Can include, as a practical matter, relatives of officials
 - *BellSouth* – wife of Nicaraguan legislator
- Includes employees of 75+ international organizations, including EU entities, UN entities, World Bank, Asian and African Development Banks, similar institutions

Foreign Official? (cont'd)

- Pharmaceutical Industry
 - Doctors employed by state owned hospitals and clinics
 - Pharmacists employed by state owned entities
 - Formulary boards
 - Safety inspectors

Retention of Third Parties

- Intermediaries
 - Agents
 - Consultants
 - Distributors
 - Pharmaceutical industry: event companies; companies that process studies
- Liability if covered person or entity “knows” improper payments are being made by third party to an official
- Knowledge includes:
 - “conscious avoidance”
 - “deliberate ignorance”

Third Parties (cont'd)

- Essential to perform due diligence on third parties
 - Document the due diligence steps
 - Retain investigative agency in appropriate cases
- Written contract with third party
 - Agreement to comply with FCPA
 - Agreement to disclose past or future affiliations with officials
 - Consider requiring annual certification of compliance
 - Require advance approval of travel/entertainment expenses
 - Consider requiring right to inspect third party's books
 - Prohibit assignment of duties
 - Provide for termination at will for violation of FCPA provisions
 - Permit disclosure of contract by issuer and its affiliates

Third Parties (cont'd)

- Payments to third party must be commensurate with services provided
- Payments should be through normal mechanisms and should not conceal the identity of the third-party payee
 - Utilize US banking system to facilitate tracing of payments; or
 - Pay at local bank where work is performed or agent resides;
 - Avoid any payments to Swiss, Liechtenstein or similar accounts
- Travel and entertainment expenses of third party
 - Require documentation
 - Consider requiring advance approval
- Obtain opinion from local counsel on legality of relationship

Joint Ventures

- Liability if greater than 50% control
 - Possible liability if found to be in “control” even if own less than 50%
- Even if minority interest, duty to take reasonable steps to try to prevent violations, such as by seeking to require:
 - Compliance programs
 - Investigations of potentially improper payments
 - Adequate financial systems and controls
- Significant issues raised by entering into JV’s with stated-owned or formerly state-owned companies, *e.g.*, Russia and China

Permitted Payments

- Facilitating payments
 - To secure routine governmental action to which the company is entitled
 - Examples
 - Customs clearance
 - Visas
 - Police protection
 - NOT to facilitate sales
 - Consult local law

Permitted Payments: Affirmative Defenses

- Expressly lawful under local law
 - Must be in written law
 - Custom and practice not enough
 - Silence in written law not enough
- Promotion/demonstration of products or performance of contract
 - Directly related to promotion/demonstration or fulfilling contract
 - Reasonable travel expenses
 - No sightseeing
 - No family members

FCPA's Second Prong: Accounting Obligations

- Books and Records
 - Duty to make and keep books and records which in reasonable detail, accurately and fairly reflect transactions
 - A bribe must be recorded as a bribe
- 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
 - Overlap with Sarbanes-Oxley § 404

US Jurisdiction

- Primary Violations: US nexus
 - US companies
 - US persons
 - US acts
- Books and Records or Internal Controls Violations
 - US issuers liable for books and controls of subsidiaries and controlled affiliates
 - Scinter not required
 - Does NOT need to relate to bribery of foreign officials; any books and records or internal control violation can qualify
 - Improper payments to foreign private doctors could be covered

US Jurisdiction (cont'd)

- SEC uses books and records / internal controls authority to reach bribery of foreign officials where there is no primary jurisdiction
 - Failure to record bribes as bribes
 - Internal controls inadequate because the bribes occurred

Issues Confronting the Industry

- Congresses and Company Sponsored Events
 - Doctors invited based on prescriptions?
 - Who selects the doctors: Medical or Marketing?
 - Doctors expected or asked to increase future prescriptions?
 - Ratio of science to entertainment?
 - Location of event?
 - Reasonableness of entertainment?

Issues (cont'd)

- Studies
 - Medical purpose?
 - Results obtained from doctor?
 - Results utilized and/or published?
 - Payments commensurate with work?
 - Initiated by Company or doctor?
 - Product supplied by company?

Issues (cont'd)

- Consultants / Advisory Boards
 - Actual work performed?
 - Work reasonably necessary or useful?
 - Compensation commensurate?
- Speeches and articles
- Gifts
- Donations
 - Purpose?
 - Who requested it?
 - Any connections to government officials?

Issues To Look For

- Local law complied with?
 - Approvals of relevant hospital officials?
 - Restrictions on amounts of payments?
 - Results of studies provided to regulatory bodies where required?
- Payments under multiple names or to associations?
- Written contract entered into with clear obligations by the official?
- Work product (where applicable) actually delivered to company?
- Expenses supported and documented?
- Appropriate management authorization?
- Legal approval?

Insights From Recent FCPA Cases

- Must focus on anti-bribery *and* records/controls issues
- Jurisdiction and *scienter* limits on anti-bribery provisions – they are important, but . . .
- Limits are not very meaningful for complex multinationals
 - U.S. persons often involved in cross-border projects
 - Communications and payments route through U.S.
 - Books and records violations do not require *scienter*
 - DOJ/SEC are aggressive in pursuing “willful blindness”
- Bottom line: If a bribe is paid overseas, it is going to be very expensive – at a minimum, a costly investigation is required

Insights (cont'd)

- Government is pursuing ever more aggressive theories
 - *Schering-Plough* – charitable contributions as benefits
 - *Kozeny/Pinkerton* – alleged knowledge of bribes paid in the past and continued participation seen as *scienter*
- Government is seeking more intrusive remedies
 - Government-imposed monitors are standard (*Monsanto, Titan, Diagnostic Products, Schering, In-Vision*), though DOJ has stated they are not mandatory in every case
 - Monitors will likely be given generally unreviewable:
 - access to records, including real-time access to calendars of top officials
 - ability to impose changes to FCPA-related compliance processes
 - DOJ prior approval of key executives and compliance personnel (*Aibel Group Ltd.*)

Insights (cont'd)

- Fines and disgorgement payments are increasing
 - *Titan* – more than \$28 million in fines/disgorgement
 - *Vetco Gray* - \$26 million total criminal penalty for 3 subs (\$12 million for 1 sub with prior FCPA conviction)
- FCPA increasingly intruding into M&A deals
 - FCPA issue caused Titan/Lockheed merger to fail
 - FCPA issues arising in midst of InVision merger with GE led government to require burdensome consent agreements from both companies
 - Issuer liability for incorrect representations and warranties contained in merger agreement filed as an exhibit to a merger proxy statement

Insights (cont'd)

- Foreign Issuers subject to enforcement actions
 - *ABB Ltd.* – first case brought by the SEC against a foreign issuer
 - *Statoil* – first case brought by DOJ against a foreign issuer
 - Norwegian government brought case as well
- Voluntary Disclosure
 - *Schnitzer Steel* – deferred prosecution for parent, guilty plea by subsidiary, and \$7.5M fine

More Aggressive European Enforcement of Domestic Laws?

- Public reports of investigations, dawn raids, and prosecutions in
 - Italy
 - Germany
 - Others?
- Likely impact on US FCPA enforcement

Annex:

Summary of Recent FCPA Cases

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Recent Cases: Dow Chemical (2007)

- Fifth-tier sub allegedly paid \$200,000 in bribes to India's Central Insecticides Board and state officials to get approval of and right to distribute products
- Books and records and internal controls violations alleged
- No anti-bribery charge
- SEC found that no Dow employee knew or approved of improper payments – strict liability
- Parent settled with SEC: \$325,000 civil penalty

Recent Cases: El Paso (2007)

- Alleged purchases of crude oil from third parties through UN Oil-for-Food program while knowing/recklessly not knowing third parties passed on \$5.5M in illegal surcharges to Iraq
- Third party representations that not paying surcharges not enough – El Paso failed to conduct due diligence to confirm
- Charged with FCPA books and records and internal controls violations
- SEC settlement: \$5.5 million disgorgement; \$2.25 million civil penalty
- DOJ non-prosecution agreement settled OFAC and wire fraud charges (guided by new McNulty Memo)

Recent Cases: Vetco Gray (2007)

- 4 Vetco International Ltd. subs authorized agent to make about 378 corrupt payments (totaling \$2.1M) to Nigerian Customs Service
- Payments to procure preferential customs treatment for deepwater oil drilling equipment
- 3 of the subs pleaded guilty to anti-bribery violation and conspiracy: \$26M total fine (largest to date in DOJ prosecution)
 - \$12M paid by 1 sub with prior FCPA conviction
- Deferred prosecution agreement for 1 sub: consented to DOJ prior approval of appointments of
 - Executive Chairperson
 - Majority members of Compliance Committee (including chair)
 - Compliance Counsel

Recent Cases: Statoil (2006)

- Largest case brought to date against non-U.S. issuer
- Anti-bribery, books and records, and internal controls violations arising out of bribes paid to Iranian oil official via “consulting” agreement
- Deferred prosecution agreement – \$10.5 million fine
- SEC consent order – \$10.5 million disgorgement order
- Requires compliance consultant for three years

Recent Cases: AIG (2005)

- Managing Director of AIG Global Investment Corp. in US indicted by SDNY in 2005 for conspiracy, FCPA, Travel Act and money laundering violations
- Employee of Omega Advisors pleaded guilty, is cooperating
- Alleged payments of cash/gifts and promise of profits made to officials in Azerbaijan by co-defendant in unsuccessful effort to obtain control of to-be-privatized state oil company
- Indictment alleges AIG MD caused AIG to invest in consortium knowing that bribes had been and would be paid – knowledge of past bribes deemed sufficient

Recent Cases: Titan Corp. (2005)

- Paid \$3.5 million over 3 years to its agent in Africa, a business advisor to country's president, to support president's election, in effort to secure telecom contract
- Payments recorded as consulting services
- Titan pled to 3 felonies; paid \$13 million fine; entered into SEC consent; disgorged \$15.5 million; retained a monitor
- SEC noted in its Section 21(a) Report potential liability for false statements in publicly filed merger documents
- Lockheed ultimately terminated its merger with Titan

Recent Cases: Diagnostic Products Corp. (2005)

- Payments by Chinese subsidiary of US company to doctors at state-owned hospitals to secure business
- Recorded in books as routine business expenses
- Parent company halted the practice when it learned
- Sub pled guilty to FCPA bribery violation and paid \$2 million; jurisdiction based on a single fax sent to California
- Parent settled with SEC: disgorgement of \$2.7 million in profits from sub and compliance monitor for 3 years

Recent Cases: Monsanto (2005)

- Officer in US authorized Indonesian consulting firm to pay cash to Environment Minister in unsuccessful effort to persuade him to drop required environmental impact statement
- Recorded in books as consulting payment
- Separately, Indonesian affiliate companies made \$700,000 in improper payments over 6 years to 140 Indonesian officials, including house for wife of senior Agriculture Ministry official
- Deferred Prosecution agreement: 3 years; paid \$1 million
- SEC consent: payment of \$500,000 and compliance monitor

Recent Cases: InVision/GE (2004)

- Case involved sales of airline baggage screening devices for airports in Thailand, Philippines and China and evidence of third-party payments to foreign officials
- FCPA issues arose before closing of InVision merger with GE; GE and InVision both agreed to consent orders; InVision voluntarily disclosed FCPA violations to DOJ; consent agreement delayed InVision's incorporation into GE unit
- Failure to conduct due diligence and lack of an FCPA compliance program led to stipulated findings that InVision lacked internal controls as required by FCPA
- InVision agreed to pay 800K fine and hire monitor

Recent Cases: Schering-Plough (2004)

- Officer of sub in Poland made donations to Polish charitable foundation established to restore castles
- Foundation's president was also head of a government pharmaceutical board
- Donations recorded with false purposes (*e.g.*, disease prevention) and officer structured payments to stay within his grant of authority
- S-P settled with the SEC for books and records and internal controls violations; paid \$500,000 and agreed to appointment of an FCPA compliance monitor

Recent Cases: Syncor Int'l Corp. (2002)

- Foreign subs paid \$600k in bribes to doctors in state-controlled hospitals in Taiwan, Mexico, Belgium, Luxembourg and France
- Bribes to induce doctor referrals to Syncor-owned/operated medical centers and hospital purchases of radiopharmaceuticals
- Illicit payments discovered during due diligence related to merger with Cardinal Health; self-reported
- Parent: \$500k civil penalty; compliance consultant
 - Anti-bribery, books and records and internal controls violations alleged
- Taiwan sub: \$2M criminal fine
 - Board chairman of sub authorized payments while in CA

THE END