

Mitigating the Growing Risk Posed by the FCPA and Global Anti-Bribery Regulations

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FCPA: A Quick Overview

Basics of the Act and Enforcement



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FCPA: Who?

- Issuers
- Domestic Concerns
 - U.S. citizens, residents or business entities.
- Other persons who take any act in furtherance of a corrupt payment within U.S. territory (added in 1998 to track OCED Convention).

FCPA: What?

- *Payment*, offer, or promise of payment of money or anything of value directly or through a third party.
- To a *foreign official* or official of a public international organization or knowing the payment will be passed on to such a person.
- With use of instrumentality of *interstate commerce*.
- For the *corrupt purpose* of influencing that person.
- To *obtain or retain* business.

FCPA: Books and Records

- Books and records provisions of the FCPA require issuers to keep accurate books and records.
- Reaches payments disguised as other expenses.

FCPA: Exceptions & Defenses

- Exception: Allows routine facilitating or grease payments.
- Affirmative Defense: Allowed by local written law.
- Affirmative Defense: Reasonable and bona fide expenditures under contract.

Early Traps

- Payments need not be direct.
- No requirement of actual knowledge.
- Responsible for actions of agents and employees.
- Business need not be with the foreign government. e.g., Payments to speed approval for private use or to allow quick customs clearance are also covered.

Global Enforcement

- Its not just for the U.S. anymore.
- Siemens
- European Statutes and emphasis.

Recent FCPA Cases: A Health Care Focus

What Can We Learn From the Past?



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Syncor International (2002)

- In 2002 Cardinal Health was acquiring Syncor International Corp., a California based radiopharma company.
- Due diligence revealed that from 1997 to 2002, the company's chairman authorized over \$340,000 in "commissions" to doctors who were employees of state owned hospitals.
- Over \$600,000 in additional payments were found on the books of foreign subsidiaries.

Syncor International (2002)

- DOJ: U.S. v. Syncor Taiwan Inc. The DOJ required this wholly owned Taiwanese subsidiary to plead to substantive and books and records charges. Imposition of \$2,000,000 fine and supervised probation.
- SEC: SEC v. Syncor International Corp. The parent company entered into a cease and desist order with the SEC. Record penalty of \$500,000. Retention of Independent Monitor required by the SEC.

Syncor International (2002): Take-Aways

- Be careful of who you consider a foreign official. Syncor shows that employees of state-owned entities will be considered to be within the scope of the FCPA. In countries where all or mostly all medical care is delivered through the states, almost anything you do will be covered.

Syncor International (2002): Take-Aways

- Foreign subsidiaries are a potential source of trouble:
 - The DOJ charged the foreign subsidiary based on the fact that the U.S. based chairman approved the payments.
 - The U.S. parent was held responsible for acts of foreign subsidiary.
 - Cardinal was able to negotiate who was held criminally liable.

Syncor International (2002): Take-Aways

- M&A
 - **DUE DILIGENCE.** Every merger or acquisition is a potential death trap for your company.
 - By reacting quickly to the discoveries, Cardinal was able to gain some assurances about later discovered conduct.
 - Transactional delays.
 - Question entries in books. Be wary of “commissions.”

Schering-Plough (2004)

- From 1999 to 2002 Schering-Plough's Polish subsidiary paid over \$75,000 to a foundation headed by the director of the Regional Health Authority.
 - The founder and president of Chudow Castle Foundation was also director of the Silesian Health Fund responsible for local health care.
- Local managers structured the payments to limit the need for approval and keep them from being passed up the finance department.

Schering-Plough (2004)

- The SEC imposed a civil penalty of \$500,000 on Schering-Plough even though it was clear no one at parent knew what was going on.
- The SEC required hiring of an independent monitor to review FCPA compliance.
- Individual prosecutions.

Schering-Plough (2004): Take-Aways

- Appears donation was to real charity.
- Parallels to Anti-Kickback Act (AKA) cases. Question “charitable” donations/grants.
- Finance controls need to be able to detect structuring; it’s not just for money laundering anymore.
- Parent liability without knowledge.

Diagnosics Products Corp. (2005)

- SPC (Taiwan) prosecuted by DOJ as an agent of DPC, a U.S. company. Pled guilty to bribery charge. Fine of \$2,000,000 and imposition of Independent Monitor.
- SEC fined DPC for violating anti-bribery, books and records and internal controls provisions of FCPA. Fine of \$2,800,000, plus disgorgement of \$2,000,000.
- Mandated disclosure to Chinese government.

Diagnosics Products Corp. (2005)

- DPC (Taiwan) voluntarily disclosed payment to doctors and hospital employees of commissions constituting 3 to 20 percent of sales to state-owned Chinese hospitals.
- Approved by local GM.
- Recorded as selling expenses.

DPC: Take-Aways

- Who is a foreign-official? Again, state-owned health care entities are a big concern.
- DPC (Taiwan) prosecuted as an Agent of DPC. Could have easily indicted the company. Voluntary disclosure helped.
- Danger of further prosecution by foreign government.

Micrus Corp. (2005)

- Maker of emboli coils for treatment of aneurysms accused of paying doctors at state-owned hospitals in France, Germany, Spain, and Turkey in exchange for purchase orders.
- Payments totaling \$105,000 disguised as stock options, honorariums, and commissions. Also made additional payments (\$250,000) without disclosures and approvals required by local law.

Micrus Corp. (2005)

- Company made voluntary disclosure after internal investigation.
- Two year deferred prosecution of company.
- \$450,000 penalty.
- Compliance program and independent expert required.

Micrus Corp.: Take-Aways

- Dealings with employees of state-owned entities will get you in trouble.
- Apply same standards to honorarium and consulting contracts abroad that you would to domestic agreements under AKA.
- Swift internal investigation and a voluntary disclosure benefits company.

Effective Compliance

Applications to Clinical Trials



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Broad Reading of Applicability

- “Obtain or Retain Business”
- *U.S. v. Kay*, 359 F.3d 738 (5th Cir. 2004)
 - Payments made to customs officials to reduce taxes.
 - Court said FCPA to be read broadly.
 - Reducing taxes means money could be spent differently.
- Clinical Trials: Can’t market product unless approvals are given.

Independent Contractors in Clinical Investigations

- Who carries out the trial?
 - CRO
 - PI
 - Reliance on IRB
- You have responsibility for these individuals and entities from an FCPA perspective even if you view them as Independent Contractors.

Dealing with Independent Contractors

- Before you hire a contractor ask:
 - Is anyone in your organization a foreign official or related to a foreign official?
 - Have you ever been accused of bribery or fraud?
 - Have you ever been barred from dealing with any government agency in the U.S. or abroad?
 - Have you ever made a payment to anyone to get their business?
 - Do you have anyone you have agreed to pay for helping you in your sales efforts? What is their relationship to you? How would they answer these questions?

Dealing with Independent Contractors

- Make them agree:
 - That they will not provide anything to a foreign official or a relative or designee of a foreign official to obtain or retain business for your company.
 - That they will not allow others to do so on your behalf.
 - That they will inform you if anyone seeks such a payment.

Dealing with Independent Contractors

- Before you pay them, make them certify that they have not broken any laws in obtaining the business including, specifically, payments to foreign officials.
- Repeat these questions every year.
- Know where your payments go.
 - One bank account.
 - No cash.
 - No dividing payments.

Potential Problem Areas: Joint Ventures & Business Combinations

- In the health care field there is often a trend towards joint ventures or other combinations with foreign companies. The fact that the action is taken through a joint venture or similar entity will not protect you. This can be a particular problem with local companies not subject to the FCPA or an equivalent local or international law.
 - Make your expectations known early on.
 - Diligence is key.
 - Same issues present when acquiring a company.

What to Look for: Transactional Issues (Joint Ventures or Acquisitions)

- Who are you dealing with? What is their reputation?
- What is in their contracts with vendors, sales reps, agents and consultants?
- What anti-bribery training or guidance have they given their people?
- Who are the sales people? What are their connection to your target/JV partner? To their customers?

Worst Case Scenario: What to do if a problem arises

- Freeze all the documentary evidence as soon as possible.
- Prepare for possibility of search warrants.
- Get investigators on the ground in foreign country ASAP. Interview everyone quickly. Consider need for outside counsel.
- Consider local law enforcement action and protection of employees.
- Evaluate voluntary disclosure.

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Stuart Altman's practice includes white collar criminal investigations and defense, including the representation of clients in securities enforcement proceedings and conducting internal investigations, corporate governance, and complex civil litigation.

Stuart has extensive experience representing business entities and individuals in criminal investigations and prosecutions, both as targets and witnesses. He has conducted numerous internal investigations for companies facing potential criminal and civil liability, and has advised clients on how to minimize the risk of such liability. Stuart has represented a variety of public companies, financial institutions and individuals in investigations and proceedings before the U.S. Securities and Exchange Commission (SEC), other agencies, and self-regulating organizations. He has represented and counseled companies and individuals in matters involving the Foreign Corrupt Practices Act. Stuart also has represented a major medical device manufacturer and several health care providers in connection with government investigations under the False Claims Act.

He was recently named by *Ethisphere Magazine* as one of a small group of "Attorneys Who Matter" in the Compliance field.

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