Lessons Learned from FCPA Cases in Healthcare

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What is the FCPA?

The Foreign Corrupt Practices Act ("FCPA") is violated when:

- An **issuer** or any of its officers, **directors, employees, agents** or shareholders, a domestic concern, or foreign national pays, offers, **promises to pay, or authorizes/approves** the payment of money or anything of value:
  - To a **foreign official**, foreign political party, candidate for political office, or official of a public international organization
  - In a corrupt effort to obtain, retain, or direct business to any person or obtain an **improper advantage**

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FCPA components

Anti-Bribery provisions

- It is a crime for any US person or company to directly or indirectly pay or promise anything of value to any foreign official to obtain or retain any improper advantage.

Accounting requirements

- Section 13 (b) (2) (A) of the Exchange Act
- "Make and keep books, records and accounts, which in reasonable detail, accurately reflect the transactions and dispositions of assets"
- Reasonable – such level of detail that would satisfy prudent officials in the conduct of their affairs.

Internal controls

- Section 13 (b) (2) (B) of the Exchange Act
- Devise and maintain a system of internal accounting controls sufficient to provide reasonable assurance that transactions are recorded appropriately and in accordance with rules and regulations.

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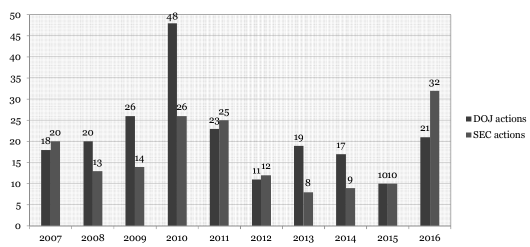
Source: Gibson Dunn 2016 Year-End FCPA Update

FCPA Enforcement Trends



Source: Gibson Dunn 2016 Year-End FCPA Update

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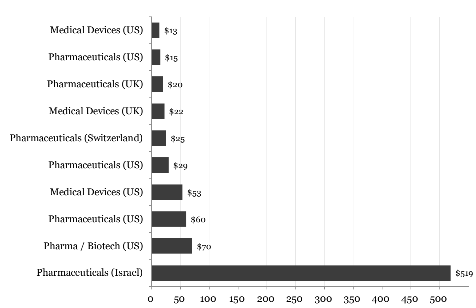
FCPA Enforcement - Healthcare



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Countries involved in FCPA enforcement actions from 2005 to 2016

Note: This chart includes combined corporate enforcement actions.

Source: Miller & Chevalier FCPA Summer Review 2016

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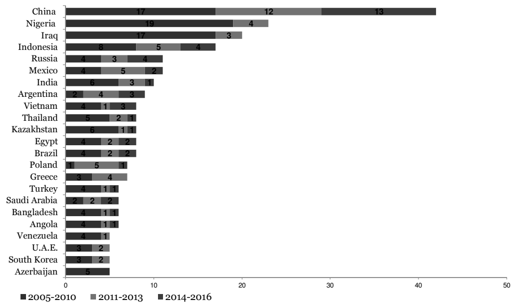
FCPA Enforcement Actions - Country Breakdown

Countries Involved in FCPA Enforcement Actions from 2005 to 2016 (to date)



Source: Miller & Chevalier FCPA Summer Review 2016

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Pay to Play

Case Facts: A manufacturer of generic pharmaceutical products allegedly made corrupt payments to government officials in Russia and Ukraine as well as state-employed physicians in Mexico.

- The company's Russian **distributor was owned by a government official**, who allegedly used his authority to increase the company's sales. The official earned about $65 million.
- In Ukraine, the company **hired a government official as a consultant** and paid him $200K through monthly fees and travel to influence the government's approval of the company's drug registrations.
- In Mexico, the company made alleged corrupt **payments to state-employed physicians** to influence the prescription of products.

The company **failed to devise and maintain proper internal accounting controls** to prevent the payments of bribes to win business. The company's **executives approved policies that wouldn't detect or stop the bribery**. Also, the executives apparently employed **compliance managers who were "unable or unwilling"** to enforce the company's anti-corruption program.

Penalty: Paid over **$500 million** to the DOJ and SEC and retained a corporate compliance monitor with a three-year term.

Lesson Learned: Inadequate corporate oversight

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Incentives to Health Care Providers

Case Facts: A pharmaceutical company's foreign subsidiaries allegedly made **corrupt payments to influence pharmaceutical sales**.

- The company's Russian subsidiary used offshore **"marketing agreements" (which provided no real services)** to funnel millions of dollars to third parties chosen by government customers or distributors. The payments were often made to win business.
- In China, the company's subsidiary **falsified expense reports** to provide improper gifts (e.g. spa treatments, jewelry) and cash payments to government-employed physicians.
- Subsidiaries in Brazil and Poland also allegedly made improper payments to government officials or government-associated third parties through **charitable contributions** and **unusually large discounts** to government-affiliated distributors.

When company management learned of the possible FCPA violations, the allegedly improper payments **continued for more than five years**.

Penalty: Paid the SEC **$29.4 million**, which comprised disgorgement of $14 million, prejudgment interest of $6.7 million and an $8.7 million penalty

Lessons Learned: Inadequate due diligence and inadequate response plan.

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Delegate Travel

Case Facts: Between 2007 – 2013, a large pharmaceutical company engaged a network of **700+ travel agents to deliver $225 million in inappropriate payments** to health officials and doctors in China in order to boost sales.

- Examples of the inappropriate payments include the following:
  - Improper travel and entertainment with **no or little educational purpose**
  - Business class airfare that could be **exchanged by health officials** into two economy tickets
  - **Shopping** excursions
  - Family and **home visits**
- These payments were **recorded as legitimate expenses**, such as medical association sponsorships, employee expenses, conferences, speaker fees, and marketing costs.

The company was aware of these payments and **did not take action to stop them**. As a result, the company faced severe fines from both the US and Chinese governments.

Penalty: **$490 million fine** to the Ministry of Public Security in China, **$20 million** to the SEC, and **various prison sentences** ranging from 2-4 years for individuals

Lessons Learned: Inadequate compliance program

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Corporate Responsibility for Subsidiary Actions

Case Facts: The SEC brought claims against the former CEO and CFO of a large herbal vitamin supplements company for violations of the books and records provision of the FCPA. The executives were held accountable as **"control persons" for failing to adequately supervise** the miscreant employees of a Brazilian subsidiary.

- The subsidiary allegedly made payments to **third-party customs brokers who passed on portions of the payments to customs officials** to allow the import and sale of unregistered products in Brazil.
- The payments were recorded as legitimate importation expenses but **lacked supporting documentation**. They were accounted as import expenses in consolidated financial statements.

Given the executives' **supervisory roles in the preparation of financial statements** and maintenance of the company's internal controls, as well as **unresponsiveness to apparent red flags**, the SEC found the executives **liable for the violations**.

Penalty: Each paid a **$25K civil penalty** and agreed to a court order enjoining them from future violations

Lessons Learned: **Corporates** may be liable for subsidiaries' actions

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Charitable Contributions to Influence Foreign Officials

Case Facts: In 2013, the Chinese subsidiary of a personal care products company allegedly made an **improper payment to a government official in response to an investigation** by the Chinese Administration of Industry and Commerce ("AIC").

- The AIC was investigating the company for non-compliance with laws and local rules.
- In response, the company **asked a government official to intervene** with the AIC in exchange for a $150K contribution to a charity identified by the official.
- **Anti-corruption clauses** were **not included** in the executed contribution agreement.
- The connection between the AIC investigation and the charitable contribution was **not disclosed**.

The company was ultimately penalized for **inaccurately and/or unfairly describing the payment** as a contribution rather than a payment to influence the government official to favorably impact the outcome of the AIC investigation. The company also **failed to devise** and maintain a reasonable **system of internal accounting controls** over its subsidiary's operations in China.

Penalty: Paid the SEC **$766K**, which comprised $431K in disgorgement, $35K in prejudgment interest and a $300K civil penalty

Lesson Learned: Inappropriate payments could take several forms

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Source: Gibson Dunn 2016 Year-End FCPA Update

Hallmark Components of an Effective Compliance Program

1. *Commitment from Senior Management*
2. *Clearly Articulated Policy Against Corruption*
3. *Oversight, Autonomy, and Resources*
4. *Code of Conduct and Compliance Policies and Procedures*
5. *Risk Assessment*
6. *Training and Continuing Advice*
7. *Incentives and Disciplinary Measures*
8. *Third-Party Due Diligence and Payments*
9. *Confidential Reporting and Internal Investigation*
10. *Continuous Improvement: Periodic Testing and Review*
11. *Mergers and Acquisitions: Pre-Acquisition Due Diligence and Post-Acquisition Integration*

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Q&A…

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Presenters

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