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

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.
**FCPA Enforcement Trends**

Number of FCPA Enforcement Actions from 2007 - 2016

![Graph showing FCPA Enforcement Trends from 2007 to 2016 with bars for DOJ and SEC actions.]

Source: Gibson Dunn 2016 Year-End FCPA Update

**FCPA Enforcement - Healthcare**

Healthcare FCPA Fines (Millions of US dollars)

<table>
<thead>
<tr>
<th>Company</th>
<th>Fines (Millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Devices (UK)</td>
<td>$19</td>
</tr>
<tr>
<td>Pharmaceuticals (UK)</td>
<td>$36</td>
</tr>
<tr>
<td>Medical Devices (UK)</td>
<td>$39</td>
</tr>
<tr>
<td>Pharmaceuticals (UK, Netherlands)</td>
<td>$96</td>
</tr>
<tr>
<td>Pharmaceuticals (UK)</td>
<td>$97</td>
</tr>
<tr>
<td>Medical Devices (US)</td>
<td>$98</td>
</tr>
<tr>
<td>Pharmaceuticals (US)</td>
<td>$99</td>
</tr>
<tr>
<td>Pharma (UK)</td>
<td>$100</td>
</tr>
<tr>
<td>Pharmaceuticals (Switzerland)</td>
<td>$101</td>
</tr>
</tbody>
</table>

**Countries involved in FCPA enforcement actions from 2005 to 2016**

[Map of countries involved in FCPA enforcement actions from 2005 to 2016 with numbers indicating the number of enforcement actions.]

Note: This chart includes combined corporate enforcement actions.

Source: Miller & Chevalier FCPA Summer Review 2016
FCPA Enforcement Actions - Country Breakdown

<table>
<thead>
<tr>
<th>Countries Involved in FCPA Enforcement Actions from 2005 to 2016 (to date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
</tr>
<tr>
<td>17</td>
</tr>
</tbody>
</table>

Source: Miller & Chevalier FCPA Summer Review 2016

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 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.

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.

Lesson Learned:
Inadequate due diligence and inadequate response plan.
Delegate Travel

Case Facts: Between 2007 – 2013, a large pharmaceutical company engaged a network of 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

Corporate Responsibility for Subsidiary Actions

Case Facts: The SEC brought claims against the former CEO and CFO of a large herbal vitamin supplement 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 mischievous 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

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 operations in China.

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

Lessons Learned: Inappropriate payments could take several forms
Hallmark Components of an Effective Compliance Program

1. Commitment from Senior Management
2. Clearly Articulated Policy Against Corruption
3. Oversight, Autonomy, and Resources
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

Q&A...

Presenters

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