

The Ninth Annual Pharmaceutical Regulatory Compliance Congress and Best Practices Forum

Foreign Corrupt Practices Act Update

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RECENT TRENDS IN FCPA ENFORCEMENT ACTIVITY

- **Clear Trend Toward Increased FCPA Enforcement**
 - 2007 was a record year for FCPA enforcement actions
 - 38 enforcement actions were brought by DOJ/SEC
 - Previous record was 15 enforcement actions in 2006
 - The pace of enforcement actions has thus more than doubled
 - M & A enforcement activity on the rise as well
 - No sign of this trend slowing down; FCPA remains a high priority for the Government

Pharmaceutical and Medical Device Industries Are in the Cross-hairs

- Recent DOJ/SEC enforcement actions show a focus on the industry
- February 2007: Johnson & Johnson announcement of voluntary disclosure of potential improper payments under the FCPA in connection with medical device sales
 - Company's worldwide chairman forced to resign
- December 2007: Akzo Nobel settlement for “after-sales service fees” made to facilitate sales of pharmaceuticals in Iraq. Over \$3.4 million in fines and penalties assessed
- July 2008: AGA Medical settlement for various “discounts, commissions and rewards” paid to Chinese physicians who purchased the company's products. \$2 million criminal penalty and various compliance measures – including a compliance monitor
- Stryker, Zimmer, Biomet, Smith & Nephew and Medtronic investigations
 - Begun with a simple letter from the SEC

Clear Trend Toward Increased Enforcement Against Individuals

- Historically, corporations have been the primary focus of FCPA enforcement
- October 2007: Mark Mendelsohn of DOJ publicly discussed “a very concerted effort to supplement our prosecution of corporations . . . with our prosecution of natural persons”
- In a later speech, Mendelson described “prosecution of individuals” as one of the top trends in FCPA enforcement activity
- Associate Directors in the Enforcement Division of the SEC have spoken similarly
- Coordinated investigation and prosecution of corporate executives for FCPA violations will be the rule, rather than the exception, going forward

The New Stakes Are High For Corporate Executives

- The potential statutory criminal penalties for FCPA violations are severe
 - Incarceration for up to 20 years and/or fines up to \$5 million
 - Employees may not be indemnified
 - Alternative Fines Act – twice the benefit sought to be gained
- Statutory application is modified somewhat by the Sentencing Guidelines
- But most individual defendants are still sentenced to a term of imprisonment

Trends in Interaction Between DOJ and Foreign Enforcement Authorities

- Increased Collaboration Between DOJ and Foreign Enforcement Authorities
 - Akzo Nobel Non-Prosecution Agreement: DOJ acknowledges cooperation from Dutch Public Prosecutor.
 - Stanley Jackson, former Chairman and CEO of KBR, Plea: DOJ assisted by authorities in Italy, France, Switzerland and United Kingdom.
 - Increased collaboration will certainly lead to increased prosecutions in US and abroad.
- Increased Willingness to Give "Credit" for Fines Paid to Foreign Enforcement Authorities
 - Statoil (2006): Deferred Prosecution Agreement imposed \$10.5 million fine payable to US authorities on Norway-based Statoil subject to offset for \$3 million fine paid to Norwegian authorities.
 - Akzo Nobel (2007): Non-Prosecution Agreement provided that within 180 days, Dutch-based Akzo Nobel had to reach resolution with Dutch authorities and pay 381,000 Euros or Akzo Nobel required to pay fine of \$800,000 to US authorities.

Trends in Imposition of Independent Monitors

Morford Memo Imposes Heightened Scrutiny on Imposition of Monitors.

- Prosecutors must notify the appropriate United States Attorney or Component Head prior to the execution of an agreement that includes a corporate monitor.
- Corporation may select the monitor candidate but the Government reserves the right to veto the candidate.
- Office of the Deputy Attorney General must approve the monitor.
- Monitor is an independent third-party, not an employee or agent of the corporation or the Government.
- Monitor's primary responsibility is "to assess and monitor a corporation's compliance" with the deferred or non-prosecution agreement, and "not to further punitive goals."
- If a corporation chooses not to adopt a recommendation of a monitor, the corporation or monitor should report that fact to the Government; Government may consider this conduct in determining compliance with the agreement.

Be Careful Out There

- As a result of these trends, please be careful out there
- Do not lightly dismiss any FCPA allegation that crosses your desk
- Some level of investigation/due diligence always required
- The degree of investigation turns on the facts and the context
- Doing nothing is not a viable option; someone is – or will be – looking over your shoulder