

Foreign Corrupt Practices Act enforcement refocuses on life sciences

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Introduction

Takeaways

Recent life science settlements and investigations

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Life sciences companies should prepare for renewed Foreign Corrupt Practices Act enforcement by US authorities. This focus may be felt particularly acutely by mid-market and emerging companies with nascent compliance programmes. Likewise, the globalisation of healthcare is increasing the enforcement risks for companies outside of the pharmaceutical and medical device manufacturing space, including clinical research organisations, hospitals and providers.

On February 19 2016 Kara Brockmeyer, chief of the Foreign Corrupt Practices Act Unit of the Securities and Exchange Commission (SEC), announced that the SEC would be "going back to the pharma industry after a break for a period of years". Brockmeyer explained that the SEC was prioritising investigations involving pharma companies because the industry had historically been problematic and was "having a difficult time addressing [Foreign Corrupt Practices Act] risks". The US Department of Justice (DOJ) has never backed off its interest in the life sciences industry.

Takeaways

Life sciences companies should pay attention to the following key points:

- The DOJ and the SEC continue to exhibit a willingness to pursue prescription-level and doctor-level activities, particularly if they indicate broader control issues.
- China and Latin America remain focus areas for Foreign Corrupt Practices Act enforcement.
- The SEC continues to use books and records and internal controls provisions aggressively in order to avoid burden-of-proof issues associated with bribery charges.
- The DOJ and the SEC frequently seek to enforce traditional Anti-kickback Statute issues extraterritorially via the Foreign Corrupt Practices Act (as in *Olympus*); as a result, even more aggressive Foreign Corrupt Practices Act theories may be developed against the life sciences industry.
- The DOJ and the SEC are looking at all areas of life sciences companies, not just sales and marketing (eg, recent investigations such as *Optimer Pharmaceuticals Inc* have focused on grants and clinical research).
- Continued globalisation of healthcare is creating Foreign Corrupt Practices Act risks for providers, clinical research organisations and benefit managers – not just manufacturers.
- Mid-market and emerging companies operating in foreign jurisdictions are particularly at risk if they have not invested sufficiently in compliance programmes.
- With the DOJ's hiring of compliance counsel Hui Chen, a company's fundamental compliance programme deficiencies are likely to be readily apparent.
- Proactive compliance efforts that emphasise risk assessment, auditing and monitoring are critical to mitigating Foreign Corrupt Practices Act risk.
- Consolidation and M&A activity in the industry are presenting challenges and making compliance due diligence and rapid integration activities critical for acquirers.

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Alere

On March 15 2016 [Alere Inc](#) disclosed that it was under DOJ investigation for its sales practices and relationships with government officials and distributors in Africa and China. The company had disclosed in November 2015 that it was under investigation by the SEC for similar Foreign Corrupt Practices Act-related conduct. The investigation of Alere, a diagnostics service provider of point-of-care testing for infectious diseases, suggests that the DOJ and the SEC are expanding their Foreign Corrupt Practices Act focus on the life sciences industry beyond pharmaceutical and medical device companies.

Nordion

On March 3 2016 the SEC and [Nordion \(Canada\) Inc](#) resolved charges of Foreign Corrupt Practices Act books and records violations, with the company paying a \$375,000 civil penalty. In addition, the SEC charged former Nordion employee [Mikhail Gourevitch](#) with bribery and books and records violations under the Foreign Corrupt Practices Act. Gourevitch agreed to pay \$178,950 in disgorgement, interest and civil penalties to resolve the charges. The SEC order, which Nordion did not admit or deny, alleged that Nordion had:

- made improper payments to a third-party agent to obtain Russian government approval to distribute the company's liver cancer treatment and mischaracterised these payments as legitimate business expenses; and
- failed to conduct meaningful due diligence on the third-party agent and maintain an effective system of internal controls to prevent improper payments.

Olympus

On March 1 2016 [Olympus Latin America](#) entered into a deferred prosecution agreement with the DOJ and paid a criminal penalty of \$22.8 million to resolve bribery charges under the Foreign Corrupt Practices Act. The DOJ charged Olympus with making improper payments to healthcare providers to increase sales of its medical devices in Central and South America, including Brazil, Bolivia, Colombia, Argentina and Mexico. The alleged primary vehicle for delivering improper benefits was medical education 'training centres' that provided salaries and other personal benefits to healthcare providers. This agreement was announced in conjunction with a separate agreement resolving charges against Olympus for violations of the Anti-kickback Statute in the United States.

SciClone

On February 4 2016 the SEC announced the resolution of an enforcement action under the Foreign Corrupt Practices Act against [SciClone Pharmaceuticals](#). SciClone agreed to pay \$12.8 million to settle books and records charges. The SEC order, which SciClone did not admit or deny, alleged that:

- representatives in China provided improper benefits to healthcare providers and state regulatory officials to increase prescriptions and obtain favourable treatment of regulatory applications and recorded these expenditures as legitimate expenses; and
- SciClone failed more broadly to assess potential risks related to sales and marketing practices in China. The limited nature of SciClone's investigation resulted in a failure to maintain a sufficient system of internal accounting controls to detect and prevent improper payments to foreign officials.

Bristol-Myers Squibb

On October 5 2015 the SEC and [Bristol-Myers Squibb](#) (BMS) resolved charges of books and records violations under the Foreign Corrupt Practices Act, with BMS agreeing to pay \$14 million in disgorged profits and civil penalties. The SEC order, which BMS neither admitted nor denied, contained the following allegations:

- Between 2009 and 2014, BMS China's sales representatives provided health providers with cash, jewellery, meals, travel, entertainment and conference sponsorships in an effort to obtain and increase sales. These expenses were recorded as legitimate expenses;
- BMS failed to respond to, investigate and remediate red flags regarding sales personnel's interactions with these Chinese healthcare providers, which were identified in compliance

assessments and internal audits; and

- Compliance resources and attention dedicated to the company's China operations were insufficient. Indeed, the compliance officer for Asia-Pacific was rarely present in China and there was a poor record of on-time completion of anti-corruption training for sales representatives.

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