SciClone Pharmaceuticals Pays More Than $12 Million to Settle FCPA Allegations Relating to Payments to Healthcare Professionals in China

February 9, 2016

Anti-Corruption

On February 4, 2016, SciClone Pharmaceuticals, Inc. ("SciClone") agreed to pay $12.8 million to settle allegations by the Securities and Exchange Commission ("SEC") that SciClone, through its subsidiaries in China, violated the US Foreign Corrupt Practices Act ("FCPA") by providing payments and other benefits to healthcare providers ("HCPs") at Chinese state-owned and state-controlled hospitals in an effort to increase pharmaceutical sales.

A. Alleged Misconduct

SciClone is a California-based pharmaceutical company that issued and maintains a class of publicly traded securities on NASDAQ. The company operates in China through SciClone Pharmaceuticals International Ltd. ("SPIL"), a wholly-owned foreign subsidiary of SciClone that has an affiliate in Hong Kong. As alleged by the SEC in its Cease and Desist Order, SciClone directs the relevant operations of SPIL and its subsidiaries and oversees SPIL's operations through various means, including through the appointment of directors and officers of SPIL, review and approval of its annual marketing and promotion budgets, and oversight of its legal, audit, and compliance functions. The SEC further alleged that some SciClone officers served as officers and directors of SPIL, traveled frequently to China to participate in SPIL's management, and negotiated contracts with Chinese distributors.

The statement of facts in the SEC Cease and Desist Order alleges that SPIL acted as an agent of SciClone when it gave money, gifts, sponsorships and other things of value to HCPs in order to obtain sales of SciClone's pharmaceutical products in China. Sales representatives regularly reported to the senior management of SPIL on their efforts to increase sales, and referred to those HCPs with the greatest impact on their sales volume as "VIP clients." In their reports to SPIL management, sales representatives openly referred to instances where they provided weekend trips, vacations, gifts, expensive meals, foreign language classes, and entertainment to HCPs in order to obtain an increase in prescriptions from those HCPs. The SEC highlighted an ongoing tradition, going back to August 2005, for SPIL to sponsor numerous VIP clients to attend the annual Qingdao Beer Festival, consisting of "golf in the morning and beer-drinking in the evening." The SEC highlighted another instance in November 2007 when a sales representative recounted the experience of recruiting a VIP client by paying for family vacations and regular family dinners through an employee expense account and attributed a nearly four-fold sales increase to that VIP as a result.

The SEC further alleged that, in 2007, SciClone had hired a "well-connected" regulatory affairs specialist ("Specialist") in China to facilitate licensing for an application for a new license and a renewal application that were both pending at the time. The Specialist arranged trips to Greece at SciClone's expense for two

State Food and Drug Administration officials who had oversight over new product approvals and renewals of licenses for existing products. When the officials were unable to obtain travel visas in time, the Specialist instead provided them at least $8,600 in lavish gifts. When SciClone learned of the gifts, it terminated the Specialist and conduct an internal investigation related to the Specialist's conduct and practices in China. But the SEC criticized SciClone for failing at that time to look more broadly into its sales and promotion activities in China.

The SEC emphasized that SciClone did not devise and maintain a sufficient system of internal accounting controls and lacked an effective anti-corruption compliance program. In particular, the SEC criticized SciClone's lack of due diligence over local Chinese travel companies, which SciClone and affiliates routinely hired to provide services in connection with conferences, seminars, and other events, many of which did not have a legitimate educational purpose or had a minimal amount of time spent on educational activities rather than sightseeing.

As part of its remedial efforts, SciClone conducted a detailed, comprehensive internal review of promotional expenses of employees from 2011 to early 2013 and found high exception rates indicating violations of corporate policy that ranged from fake *fapiaos*,[1] inconsistent amounts or dates on *fapiao*s, excessive gift or meal amounts, unverified events, doctored honoraria agreements, and duplicative meetings. On this basis, the SEC alleged that transactions were falsely recorded in SciClone's books and records as legitimate business expenses.

In its Cease and Desist Order, the SEC noted that SciClone had taken steps to improve its internal accounting controls and to create a robust compliance function. SciClone's cooperation and remediation efforts included: (1) hiring a compliance officer for its China operations; (2) undertaking an extensive review of the policies and procedures surrounding employee travel and entertainment reimbursements; (3) substantially reducing the number of suppliers providing third-party travel and event planning services; (4) improving its policies and procedures around third-party due diligence and payments; (5) incorporating anti-corruption provisions in its third-party contracts; (6) providing anti-corruption training to its third-party travel and event planning vendors; (7) disciplining employees and their managers who violate SciClone's policies; and (8) creating an internal audit department and compliance department.

B. Consequences

To settle the SEC's claims that SciClone violated the FCPA's bribery, internal controls, and books and records provisions, SciClone agreed to disgorge $9.4 million in profits, pay $900,000 in prejudgment interest, and pay a $2.5 million civil penalty. SciClone also agreed to report to the SEC for a three-year period regarding its remediation efforts and efforts to implement FCPA and anti-corruption compliance measures.

Like many recent SEC enforcement actions in the FCPA space, SciClone's resolution came in the form of a settled administrative proceeding. SciClone did not admit or deny the SEC's findings as part of the settlement.

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[1] See a detailed explanation of *fapiaos* here.

C. Implications

The SciClone settlement is the latest in a string of actions in which US enforcement agencies have taken the position that HCPs and pharmacists that are employees of state-owned hospitals or pharmacies are "foreign officials" under the FCPA,[2] and which remind life science companies of the need for robust compliance policies and controls for interacting with such officials. This settlement also reinforces lessons learned from other anti-corruption cases, including the need to:

- develop and implement effective internal controls designed to verify expense claims and ensure that reimbursed funds are used for appropriate purposes, including gifts, meals, entertainment, and travel;
- adopt robust controls over the use of travel agencies in China, which continues to be an area of focus for both US and Chinese regulators;
- provide adequate anti-corruption training to employees to ensure that they understand the corruption risks in dealing with HCPs and other government officials;
- timely investigate and remediate reports or findings of improper activity, broadening the scope of an internal investigation as necessary if signs show more systemic misconduct; and
- ensure that a company's compliance program extends to its foreign subsidiaries and joint ventures, with a focus on robust financial accounting controls, easy access by employees of foreign subsidiaries and joint ventures to company anti-corruption policies, requirements, and trainings, and the provision of on-the-ground compliance personnel for high- risk foreign jurisdictions.

The settlement also illustrates how regulators view historical conduct -- in some cases dating back more than a decade -- through the lens of present-day compliance expectations, rather than expectations at the time of the misconduct.

[2] US regulators have so asserted in recent enforcement actions involving Biomet, Tyco, Johnson & Johnson, Smith & Nephew, Pfizer, Eli Lilly, Stryker, BMS, and Mead Johnson, among others.

If you have any questions concerning the material discussed in this client alert, please contact the following China-focused members of our Global Anti-Corruption practice group:

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