February 16, 2016

SciClone Pharmaceuticals Settles FCPA Action Over China Business Practices

Executive Summary

On February 4, 2016, the U.S. Securities and Exchange Commission ("SEC") announced a settled enforcement action against U.S. pharmaceutical company SciClone Pharmaceuticals, Inc. ("SciClone"), alleging violations of the anti-bribery provisions and internal accounting controls and books and records provisions of the Foreign Corrupt Practices Act ("FCPA").[1] Specifically, the SEC alleged that, between at least 2007 and 2012, employees of SciClone subsidiaries, acting as SciClone's agents in China, provided money, gifts, travel, hospitality, and other benefits to Chinese foreign officials, particularly healthcare professionals ("HCPs") employed at Chinese state-owned hospitals, in order to increase sales of SciClone's pharmaceutical products. The related transactions were allegedly falsely recorded in SciClone's books and records as legitimate business expenses, such as sponsorships, travel and entertainment, conferences, honoraria, and promotion expenses. SciClone neither admitted nor denied the SEC's findings.

Under the SEC's Cease and Desist Order (the "Order"), SciClone agreed to pay disgorgement of $9.426 million, prejudgment interest of $900,000, and a civil penalty of $2.5 million, for a total of more than $12.8 million.[2] SciClone also agreed to provide reports to the SEC every nine months over a three-year period regarding the status of its remediation efforts and the implementation of various compliance measures.

According to a public statement issued by SciClone, the U.S. Department of Justice completed a related investigation and declined to take any further action.[3]

This settlement resolves long-running investigations of SciClone that began no later than August 2010 when SciClone disclosed that it had received an SEC subpoena regarding its business practices in China.[4]

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[1] *See* In the Matter of SciClone Pharmaceuticals, Inc., Exchange Act Release No. 77058 (February 4, 2016), *available at* http://www.sec.gov/litigation/admin/2016/34-77058.pdf.

[2] As is typically the case, the SEC did not explain the basis for the resolution amount in its Order or press release announcing the settlement.

[3] *See SciClone Announces Final Resolution with the Securities and Exchange Commission and the Department of Justice*, SciClone Pharmaceuticals Press Release (February 4, 2016), *available at* http://investor.sciclone.com/releasedetail.cfm?releaseid=953520.

[4] *See* SciClone Pharmaceuticals, Quarterly Report (Form 10-Q), at 13 (August 9, 2010).

By March 2014, SciClone had further disclosed that "a payment of $2.0 million to the government in penalties, fines and/or other remedies [was] probable."[5] It is not clear from the public record why the government investigations took more than five and a half years to reach resolution or why the company's 2014 projection of the settlement amount was so much lower than the final settlement amount.

In light of the SEC's persistence in continuing to sanction pervasive improper gifts and entertainment practices, especially in China, and even in the absence of any clear bribery, SciClone's settlement serves as an important reminder that companies should develop and implement appropriate internal controls, including well-designed approval processes and audit procedures, to ensure that gifts and entertainment to clients and foreign officials are provided for legitimate business purposes and not in exchange for obtaining or retaining business or to secure any improper advantage. In addition, the settlement underscores the importance of conducting a thorough internal review when compliance issues come to the company's attention.

Factual Allegations

According to the Order, from at least 2007 through 2012, SciClone's sales representatives openly sought to increase sales of SciClone pharmaceutical products in China by providing monetary gifts, travel, and other benefits to HCPs at Chinese state-owned or state-controlled health institutions in exchange for increased prescription orders.[6] The SEC alleged that SciClone directed, approved, and was generally aware of many aspects of the sales and marketing activities in China as conducted by the company's wholly-owned subsidiary, SciClone Pharmaceuticals International Ltd. ("SPIL").[7] SPIL's books and records were consolidated by SciClone and reported in the parent company's financial statements. SciClone sales representatives "regularly reported to senior management of SPIL on their efforts to increase sales."[8]

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[5] SciClone Pharmaceuticals, Annual Report (Form 10-K), at 23 (March 17, 2014).

[6] The SEC and Department of Justice have taken the position that HCPs at state-owned hospitals are foreign officials. *See* In the Matter of Mead Johnson Nutrition Co., Exchange Act Release No. 75532, 2015 WL 4538145, at *2 (July 28, 2015); Johnson & Johnson, Deferred Prosecution Agreement, App'x A ¶ 28 (Jan. 14, 2011).

[7] In the Order, the SEC emphasized that SciClone "direct[ed] the relevant operations of SPIL and its subsidiaries" and oversaw SPIL's operations, including through "appointment of directors and officers of SPIL, review and approval of its annual budget, business and financial goals, and oversight of its legal, audit, and compliance functions." SciClone also reviewed and approved annual SPIL marketing and promotional budgets, and, during the relevant period, certain SciClone officers served as officers or directors of SPIL and traveled frequently to China to participate in the management of SPIL.

[8] Release No. 77058, at *3.

The SEC alleged that, in reports submitted to SPIL management, sales representatives routinely referred to HCPs with the greatest impact on sales volume as "VIP clients" and detailed "instances in which 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."[9] For example, a February 2007 sales report discussed providing VIP clients vacations to Anji, China. Likewise, a November 2007 sales report mentioned recruiting a VIP client by paying for the VIP client's family vacations and regular family dinners through an employee expense account. In that report, the sales representative attributed a nearly four-fold sales increase to that HCP as a result of providing travel and meals to the VIP client's family.[10] Other reports referenced inviting VIP clients to the annual Qingdao Beer Festival, which consisted "of golf in the morning and beer-drinking in the evening."[11] The SEC asserted that these sales practices were "known and encouraged by certain former SPIL managers at the time SPIL and SciClone had overlapping officers and/or directors."[12]

According to the SEC, in 2007, SciClone hired a "well-connected" regulatory affairs specialist (the "Specialist") to assist the company in its efforts to lobby China's State Food and Drug Administration to approve a license application for a new medical device product[13] as well as a license renewal application for Zadaxin, its most profitable pharmaceutical product in China.[14] At the time both applications were pending, the Specialist arranged for two foreign officials who had oversight authority over the license approval process to attend an academic conference in Greece, related to SciClone's new medical device, at SciClone's expense. When neither foreign official secured a travel visa in time to attend the conference, the Specialist "instead provided them at least $8,600 in lavish gifts."[15] The Specialist subsequently submitted two expense reimbursements for the gifts, the first of which was approved by the senior vice president of SPIL. After learning of the gifts, SciClone terminated the Specialist and "conducted an internal investigation related to the Specialist's conduct and practices in China."[16] The SEC noted,

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[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] *Id.*

[13] Though the Order does not specify the medical device product in question, on December 28, 2006, SciClone announced that it had submitted a regulatory application to the Chinese State Food and Drug Administration for approval to market the DC Bead, a product for the treatment of liver cancer. *See SciClone Submits Regulatory Application for DC Bead in China*, SciClone Pharmaceuticals Press Release (December 28, 2006), *available at* http://investor.sciclone.com/releasedetail.cfm?ReleaseID=420501.

[14] Release No. 77058, at *3.

[15] *Id.*

[16] *Id.* at *4.

however, that SciClone's review "did not look more broadly at sales and marketing practices in China," and "[n]o further action or remedial actions were taken by SciClone or SPIL after the conclusion of the internal investigation in 2008."[17]

Additionally, the SEC alleged that, prior to 2012, SciClone failed to perform adequate due diligence of its third-party vendors, including local Chinese companies that were hired to provide travel and entertainment services—including arranging transportation, accommodations, and meals for HCPs—in connection with conferences, seminars, and other events. SciClone also allegedly lacked effective controls for ensuring that the services provided by travel and entertainment vendors had an appropriate business purpose and actually occurred. As an example, the SEC alleged that between 2008 and 2010, SciClone sponsored dozens of Chinese HCPs to attend liver and oncology conferences in the United States, during which a significant portion of the travel expenses went towards sightseeing trips to Las Vegas and Los Angeles and tours of the Grand Canyon and Disneyland. Likewise, in April 2010, SPIL sponsored Chinese HCPs to attend a seminar in Japan regarding Zadaxin. The SEC asserted that "[w]hile a portion of the meeting appeared to involve a half a day of education activities, the remaining six days involved sightseeing and tourist locations such as Mt. Fuji."[18]

The SEC acknowledged that SciClone subsequently conducted "a detailed, comprehensive internal review" of its promotional expenses from 2011 to early 2013, but emphasized that the review ultimately identified several violations of corporate policy, including "fake fapiao,[19] inconsistent amounts or dates with fapiao, excessive gift or meal amounts, unverified events, doctored honoraria agreements, and duplicative meetings."[20]

The Anti-Bribery, Books and Records, and Internal Accounting Controls Charges

The SEC alleged that SciClone violated Section 30A(g) of the Exchange Act, 15 U.S.C. § 78dd-1, by "providing things of value to foreign officials, including healthcare professionals ("HCPs") who were employed by state-owned hospitals in China, in order to obtain sales of SciClone pharmaceutical products."[21] The SEC cited to the fact that in reports submitted to SPIL management, China-based sales representatives routinely referred to HCPs with the greatest impact on sales volume as "VIP clients" and detailed "instances in which they provided weekend trips, vacations, gifts, expensive meals, foreign

[17] *Id.*

[18] *Id.*

[19] "Fapiao" refers to official Chinese invoices used to demonstrate receipt of payment. In addition to serving as a legal receipt, fapiao are also used by the Chinese government to monitor the tax paid on any transaction.

[20] *Id.*

[21] *Id.* at *5.

language classes, and entertainment to HCPs in order to obtain an increase in prescriptions from those HCPs."[22] In addition, one sales manager described this as "luring them with the promise of profit."[23]

The SEC also alleged that SciClone violated Section 13(b)(2)(A) of the Exchange Act, 15 U.S.C. § 78m(b)(2)(A), by "improperly recording the payments to health care providers as sales, marketing, and promotion expenses."[24] The SEC noted that the false entries were initially recorded by SPIL and then consolidated and reported by SciClone in its consolidated financial statements.

Finally, the SEC alleged that SciClone violated Section 13(b)(2)(B) of the Exchange Act, 15 U.S.C. § 78m(b)(2)(B), by "failing to devise and maintain a sufficient system of internal accounting controls to detect and prevent the making of improper payments to foreign officials."[25] The SEC did not specify the particular ways in which SciClone's internal accounting controls were deficient.

SciClone's Remedial Efforts

The SEC credited SciClone with taking steps to improve its internal accounting controls and to create a dedicated compliance function. These steps 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 anticorruption 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.[26]

[22] *Id.* at *3.

[23] *Id.*

[24] *Id.* at *5.

[25] *Id.* at *5, 6.

[26] *Id.* at *6.

Key Takeaways and Analysis

As noted above, given the SEC's determination to continue sanctioning improper gift and entertainment practices in China, even in the absence of proof of an improper *quid pro quo*, [27] this resolution serves as yet another reminder regarding the critical importance of designing and implementing appropriate gifts, travel, and entertainment policies and procedures.

The facts alleged by the SEC provide several examples of gifts, travel, and entertainment to foreign officials that appear to have lacked a bona fide or legitimate business purpose and were found to be improper: vacations to exotic resorts and popular tourist destinations; sightseeing side-trips during business conferences and seminars; all-day golf and "beer-drinking" outings; pre-paid family vacations and family dinners; and "lavish" gifts valued at several thousand dollars. While the FCPA does not prohibit gift-giving *per se*, the SEC and DOJ have made clear that "[t]he larger or more extravagant the gift, . . . the more likely it was given with an improper purpose."[28] Conversely, "items of nominal value, such as a cab fare, reasonable meals and entertainment expenses, or company promotional items, are unlikely to improperly influence a government official, and as a result, are not, without more, items that have resulted in enforcement action by DOJ or SEC."[29] It is not surprising that this case caught the attention of the SEC, given the high volume and dollar value of gifts, travel, and entertainment provided to Chinese officials coupled with the fact that the gift-giving allegedly lacked any "legitimate educational purpose" and appears, instead, to have been done for the express purpose of "obtain[ing] an increase in prescriptions" for SciClone in China.[30] It is also not surprising, however, that the DOJ declined to prosecute in this matter given that, at least according to the SEC's allegations, the gifts and entertainment, while plainly excessive, do not appear to have "occurred in conjunction with other conduct reflecting systemic bribery or other clear indicia of corrupt intent."[31]

As the DOJ and SEC made clear in the FCPA Resource Guide, establishing comprehensive guidelines and approval processes for gifts, travel, and entertainment remains the most "effective and efficient means for controlling gift-giving, deterring improper gifts, and protecting corporate assets."[32] In particular, best

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[27] *See, e.g.*, In the Matter of Bristol-Myers Squibb Co., Exchange Act Release No. 76073, 2015 WL 5782426 (Oct. 5, 2015); In the Matter of Mead Johnson Nutrition Co., Exchange Act Release No. 75532, 2015 WL 4538145 (July 28, 2015).

[28] *A Resource Guide to the U.S. Foreign Corrupt Practice Act*, Criminal Division of the U.S. Department of Justice and the U.S. Securities and Exchange Commission, at *15 (November 14, 2012), *available at* http://www.sec.gov/spotlight/fcpa.shtml.

[29] *Id.*

[30] Release No. 77058, at *3, 4.

[31] FCPA Resource Guide, at *15.

[32] FCPA Resource Guide, at *16.

practices suggest that companies should implement approval procedures that include a comprehensive screening mechanism to confirm a proposed gift, travel, or entertainment expenditure has a legitimate business purpose and is not being given in order to secure any improper advantage or in exchange for obtaining or retaining business.[33] Among the procedures that companies can consider are transparency letters with the employer of the gift, travel or entertainment recipient; consideration of local law and employer restrictions on receipt of things of value; careful scrutiny of the business, promotional and/or marketing portion of any travel or conference, including how it compares to the entertainment portion; employee attestation regarding the relevant circumstances; analysis of patterns of approval requests, including attention to frequency and aggregate value; and periodic audit of gift, travel and entertainment requests, approvals, and documentation.

Additionally, it is important to note that the SEC viewed as inadequate the internal review initially conducted by SciClone in 2008—which was narrowly focused on the conduct of a single employee—when the company first discovered that certain gifts were improperly provided at its foreign subsidiary. Indeed, SciClone appears to have received little credit for identifying some of the illicit activity and proactively conducting a voluntary internal review; it was instead criticized for "not look[ing] more broadly" at its sales and marketing practices in China.[34] While the SEC did not articulate what factors it considered in reaching a resolution in this case, it is likely that SciClone's inadequate initial response to a potential violation, which resulted in certain misconduct continuing through 2012, was considered by the SEC in fashioning the appropriate remedy in this matter.

Though regulators have recently emphasized that companies are not required to "boil the ocean" when investigating a potential FCPA violation, there is still an expectation that an internal investigation will be "thorough."[35] Thus, the scope of any internal investigation should be carefully designed based on the facts and circumstances developed during the course of a review, and should take into account any compliance

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[33] For more information on best practices for designing and implementing gift, travel, and entertainment policies and procedures, *see SEC FCPA Action Against Bristol-Myers Squibb Highlights Importance of Addressing Red Flags and Compliance Gaps*, Paul, Weiss, Rifkind, Wharton & Garrison LLP – Anti-Corruption & FCPA Practice Group Client Alert (October 8, 2015), *available at* http://www.paulweiss.com/practices/litigation/anti-corruption-fcpa/publications/sec-fcpa-action-against-bristol-myers-squibb-highlights-importance-of-addressing-red-flags-and-compliance-gaps.aspx?id=21012.

[34] Release No. 77058, at *4.

[35] *See, e.g.*, Remarks of Assistant Attorney General Leslie R. Caldwell at New York University Law School's Program on Corporate Compliance and Enforcement, United States Department of Justice (April 17, 2015), *available at* http://www.justice.gov/opa/speech/assistant-attorney-general-leslie-r-caldwell-delivers-remarks-new-york-university-law ("Although we expect internal investigations to be thorough, we do not expect companies to aimlessly boil the ocean. Indeed, there have been some instances in which companies have, in our view, conducted overly broad and needlessly costly investigations, in some cases delaying our ability to resolve matters in a timely fashion.").

breakdowns that may have contributed to the alleged misconduct at issue. The scope of any review should flow logically from the circumstances of the misconduct identified, taking into account the company's business and compliance environments.

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This memorandum is not intended to provide legal advice, and no legal or business decision should be based on its content. Questions concerning issues addressed in this memorandum should be directed to:

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