COVINGTON

Bristol-Myers Squibb Pays More Than \$14 Million to Settle FCPA Allegations Relating to Payments to Healthcare Providers in China

October 9, 2015

Anti-Corruption

On October 5, 2015, Bristol-Myers Squibb Company ("BMS") agreed to pay more than \$14 million to settle allegations by the US Securities and Exchange Commission ("SEC") that BMS, through its joint venture 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 and pharmacists at state-owned pharmacies in an effort to increase pharmaceutical sales.

A. Alleged Misconduct

BMS is a New York-based pharmaceutical company listed on the New York Stock Exchange. The company operates in China through Bristol-Myers Squibb (China) Investment Co. Limited ("BMS China"). BMS China in turn operates through Sino-American Shanghai Squibb Pharmaceuticals Limited ("SASS"), a joint venture 60% owned by BMS and over which BMS has operational control, including the ability since 2009 to name SASS's president and the majority of its board of directors.

The statement of facts in the SEC <u>Cease and Desist Order</u> alleges a series of failures by BMS from 2009 to 2014 to respond to and remediate a pattern of conduct in which BMS China employees achieved their sales, in part, by providing HCPs and pharmacists at state-owned pharmacies with cash and other inducements in exchange for prescriptions and drug listings. These failures, as alleged by the SEC, included:

- Improper expense reimbursements and inaccurate recording. In 2009, BMS China began reviewing certain travel and entertainment expenses for sales employees and discovered "non-compliant claims, fake and altered invoices and receipts, and consecutively numbered receipts." BMS China then began post-payment reviews of all travel, entertainment, and meeting expense claims. Between mid-2009 and late 2013, BMS China identified numerous false, improperly documented, and unsubstantiated claims, including claims based on fake purchase orders and meetings that had not occurred. These improper claims were inaccurately recorded in BMS China's books and records as legitimate business expenses; BMS China's books and records were then consolidated into those of BMS.
- Failure to investigate employee disclosures. Certain BMS China employees also admitted to having submitted false reimbursement claims and having used the funds to benefit HCPs, including by paying rebates, providing entertainment, and funding gift cards for HCPs as a way to help reach sales targets; employees also told BMS China management that this was a widespread practice in response to HCP demands. BMS China did not investigate these claims.

- Failure to remediate audit findings. Internal compliance audits conducted in 2006 also revealed "weaknesses" in BMS China's processes for monitoring payments to HCPs, the "lack of formal processes around the selection and compensation of HCPs as speakers, deficiencies in obtaining and documenting the approval of donations, sponsorships, and consulting arrangements with HCPs,", as well as a "failure to conduct post-event verification" of conferences and meetings sponsored by sales representatives. Despite knowledge by BMS China management and members of BMS's compliance department, these deficiencies were not timely remediated. Annual internal audits between 2009 and 2013 again detected a lack of effective controls and documentation related to payments to and interactions with HCPs, including that BMS China "failed to track payments to HCPs, including high-risk payments, in its quarterly review of potential inappropriate payments," and failed also "to enforce controls relating to the documentation, approval, and payment of distributor rebates," as well as a "lack of due diligence assessments of distributor compliance," the "failure to properly document and approve agreements with HCPs who served as speakers," and the "lack of a mechanism to ensure that services were received in exchange for sponsorships."
- Lack of compliance resources. The SEC also noted the company's tardiness in providing compliance personnel specific to BMS China and/or on the ground in China, and pointed out that the majority of China employees failed to complete BMS anti-bribery training by the due date (in part because much of the training was "inaccessible to a large number of sales representatives who worked in remote locations").

In sum, the SEC alleged that BMS failed to respond appropriately to red flags and to maintain an adequately robust internal controls environment. To the contrary, BMS China documents cited by the SEC purportedly referenced and tracked "investments" made in HCPs and pharmacists working for government-controlled pharmacies -- such as cash payments, gifts, meals, entertainment, travel, speaking engagements, subsidized conference and meeting attendance, and promotional prizes -- in order to obtain prescription sales and maintain drug listings.

The SEC did note, however, that BMS has since adopted a number of remediation and compliance measures to address HCP-related corruption risks, including conducting pre-reimbursement review of all expense claims; using a third-party vendor to verify events; reducing incentive-based compensation for sales and distribution employees at BMS China; and terminating or disciplining certain employees.

B. Consequences

To settle the SEC's claims that BMS violated the FCPA's internal controls and books and records provisions, BMS agreed to disgorge \$11.4 million in profits, pay \$500,000 in prejudgment interest, and pay a \$2.75 million civil penalty. BMS also agreed to report to the SEC for a two-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, BMS's resolution came in the form of a settled administrative proceeding. BMS was not required to admit or deny the SEC's findings as part of the settlement.

C. Implications

The BMS 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,¹ 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;
- 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; 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.

If you have any questions concerning the material discussed in this client alert, please contact the following attorneys:

Eric Carlson	+86 21 6036 2503	ecarlson@cov.com
Hui Xu	+86 21 6036 2508	hxu@cov.com
Victor Wu	+86 10 5910 0507	vwu@cov.com
Ping An	+86 21 6036 2512	pan@cov.com
Ashley Nyquist	+1 202 662 5893	anyquist@cov.com

This information is not intended as legal advice. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

In an increasingly regulated world, Covington & Burling LLP provides corporate, litigation, and regulatory expertise to help clients navigate through their most complex business problems, deals and disputes. Founded in 1919, the firm has more than 800 lawyers in offices in Beijing, Brussels, London, Los Angeles, New York, San Francisco, Seoul, Shanghai, Silicon Valley, and Washington.

This communication is intended to bring relevant developments to our clients and other interested colleagues. Please send an email to unsubscribe@cov.com if you do not wish to receive future emails or electronic alerts.

© 2015 Covington & Burling LLP. All rights reserved.

¹ US regulators have so asserted in recent enforcement actions involving Biomet, Tyco, Johnson & Johnson, Smith & Nephew, Pfizer, Eli Lilly, Stryker, and Mead Johnson, among others.