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ENFORCEMENT ACTIONS

Lessons on Honoraria and Research Grants From the Alexion Settlement

By Lori Tripoli, *Anti-Corruption Report*

The SEC's July 2, 2020, announcement that Boston-based Alexion Pharmaceuticals Inc. agreed to settle FCPA charges for some $21 million over inappropriate payments two subsidiaries made to healthcare providers in Russia and to government officials in Turkey is another resolution of corruption in the pharmaceuticals industry in less than two weeks.

Coming on the heels of the U.S. government's $346-million settlement of FCPA cases with Swiss pharmaceutical and healthcare company Novartis AG and a current and former subsidiary, the SEC's $21-million deal with Alexion demonstrates that, while much of the business world might still be on pause, the "SEC continues to move cases along despite the global pandemic and shutdown," observed Martin Bloor, a member at Cozen O'Connor.

The settlement, in which Alexion resolves charges it violated the books and records and internal accounting provisions of the FCPA without admitting or denying the SEC's findings, is noteworthy, in part, because it puts the pharmaceutical industry back in the spotlight. "It is clear from the settlements reached thus far in 2020 that the pharmaceutical industry remains very much a focus of regulators," said Palmina Fava, a partner at Vinson & Elkins.

The prescription drug business and, indeed, the healthcare industry in its entirety need to get used to being in the U.S. government's field of vision. "The funds distributed to the healthcare industry amidst the COVID-19 pandemic likely will generate additional inquiries in the years ahead to ensure they were used as intended and did not involve fraudulent activity," Fava noted.

See "Novartis and Subsidiaries Settle FCPA Cases for $346M, Avoiding a Monitor Despite Recidivism" (Jul. 8, 2020).

A Problem That Can Plague Successful Startups

The SEC maintained that Alexion subsidiaries in Turkey and in Russia made inappropriate payments to government officials to obtain favorable treatment for Soliris, a drug used to treat rare blood disorders that the company began selling commercially in 2007.

"This fact pattern is typical of young and successful pharmaceutical and medical device companies three to five years post commercialization," said David Resnicoff, a partner at Riley Safer. "Their business and geographic footprints tend to grow faster than their internal financial controls and compliance

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infrastructure," Resnicoff explained, noting that Alexion's "product was commercialized in 2007, and the corrupt activity began in 2010."

Sham Consultant in Turkey

Between 2010 and 2015, Alexion's subsidiary in Turkey paid a consultant more than $1.3 million disguised as consulting fees and expense reimbursements. The consultant, hired because of connections to Ministry of Health officials in Turkey, used some of the money to give those officials gifts, meals and cash to obtain favorable treatment for Soliris.

The program through which Alexion sold Soliris in Turkey required healthcare providers appointed to serve on commissions by that nation's Ministry of Health to: review and approve each patient's application to start Soliris therapy; provide separate approvals to pay for prescriptions; and provide recurring approvals to continue the Soliris therapy.

Following payments by the consultant to Turkish government officials, patient prescriptions for Soliris were approved and Alexion Turkey received confidential information from government officials.

According to the SEC's cease and desist order, two Alexion managers in Turkey asked a third-party vendor to pay the consultant and provide falsified invoices for reimbursement to Alexion Turkey. Employees then recorded payments inaccurately – in fact, an Alexion Turkey manager directed expenses claimed by the consultant to be written in pencil so they could be revised or concealed.

Although the consultant submitted expense documentation that was vague, with large expenses merely described as "other expense," some of the original documentation actually indicated that the money was for the benefit of government officials, the SEC maintained.

Alexion Turkey employees had not received much training on anti-bribery compliance during this time period, the SEC alleged, and did not have sufficient internal accounting controls, a deficiency especially acute for a company in frequent contact with foreign officials.

This is not that surprising, however, given the growth stage of the company, Resnicoff said. "It is the rare small company that is building its compliance architecture in tandem with its commercial operations," he remarked.

See "Facilitation Payments, Foreign Officials, Bona Fide Expenditures and More: Actionable Insight From the Authors of 'Defending Clients in FCPA Investigations'" (Mar. 6, 2013).

Creative Bribes in Russia

According to the SEC, Alexion Russia senior managers believed that certain HCPs at state-owned healthcare institutions had decision-making authority regarding regional healthcare budgets and regulatory decisions. Between 2011 and 2015, Alexion Russia paid more than $1 million to these HCPs. This sum included money to persuade healthcare providers to boost the number of Soliris prescriptions that were approved through Russia's sales program and to influence the regulation of the drug.

For example, Physician A was the chair of a committee that made recommendations concerning the allocation of rare disease funds in one region of Russia. "Alexion Russia made honoraria and research payments to Physician A in significant part to influence

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the regional budget and standards in favor of Soliris," the SEC said, adding that the doctor "provided Alexion Russia with a copy of draft diagnostic standards and the ability to comment and revise the standards before they were submitted to the Ministry of Health." As a result, the SEC said, patients "requiring Soliris treatment were allocated 52 percent of the regional Ministry of Health budget in Physician A's region in 2013." Alexion paid Physician A approximately $100,000 from Alexion Russia from 2012 to 2015.

Payments were recorded inappropriately in Alexion Russia's books and records as honoraria, scientific research, educational expenses and business meeting expenses.

"This case is another example of different and creative ways in which companies can, allegedly, provide things of value" to healthcare providers and foreign officials, said John Kelly, a member at Bass Berry. "A lack of effective internal controls and compliance processes is consistently an area of weakness that allows bad actors to engage in bribery," he noted.

See "An In-House Perspective on Tackling the Challenges of Compliance in Russia and the CIS" (Oct. 2, 2019).

Books and Records Violations for Commercial Bribery in Brazil and Colombia

The SEC also alleged that employees at Alexion Brazil and Alexion Colombia created inaccurate financial records concerning payments to patient advocacy organizations or directed third parties to create the inaccurate records. Some of the inappropriate behavior included submittal of grant requests by an Alexion Brazil manager and an employee to the company's global grant review committee that misstated how the requested funds would be allocated to activities addressed in the grant request.

These allegations reveal the SEC's focus "on inaccurate books and records and corresponding insufficient internal controls concerning payments to patient advocacy programs, which are private, not governmental entities," Resnicoff said. "It is an example of the SEC's willingness to factor commercial bribery into a books and records/internal controls enforcement action that is largely focused on bribery of government officials, something they have been signaling for some time," he continued.

See "Commercial Bribery: The FCPA's Forgotten Counterpart" (Jul. 8, 2020).

Closure for $21 Million

To resolve the SEC's charges, Alexion agreed to pay more than $14.2 million in disgorgement, more than $3.7 million in prejudgment interest and a $3.5-million penalty, the SEC announced. The deal "marks the conclusion of investigations related to the previously disclosed May 2015 subpoena from the SEC and an October 2015 voluntary request for information from the DOJ focused on the company's operations and compliance with the FCPA in various countries including Brazil, Colombia, Japan, Russia and Turkey, and other applicable laws," Alexion announced in a July 2 statement. The DOJ has closed its inquiry, the statement noted.

Cooperation and Remediation

The company had both cooperated with the government and remediated, the SEC noted

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in its order. The "steps taken by Alexion" are best practices, Kelly maintained. "Alexion's cooperation included regular briefings to SEC staff regarding the facts developed in its internal investigation in multiple countries and the findings from its forensic accounting review," he observed. Alexion also provided translations of key documents, he noted.

Interestingly, "what Alexion does not appear to have done as part of its cooperation is to provide summaries of witness interviews or assist in making current and former employees available for interviews," said Jaime Guerrero, a partner at Foley & Lardner. In addition, the company "did not self-disclose the misconduct and, instead, it began its internal investigation after receiving a subpoena from the SEC," he noted.

Remedial activity undertaken by the company did include "enhancing its policies and procedures regarding payments to third parties, including the implementation of a centralized system to track and monitor third-party payments, improving its internal audit function, revising its healthcare provider engagement process and oversight, performing proactive compliance market reviews, and enhancing compliance training," Kelly said.

Alexion ultimately received a civil monetary penalty amounting to just 25 percent of the amount of unjust enrichment and that "sends a strong message to companies involved in future FCPA investigations that following best practices, fully cooperating, and taking appropriate remedial steps can result in a more favorable resolution," Kelly said.

"A company can negotiate a reasonable civil penalty even when it does not self-disclose its misconduct to the SEC," Guerrero said. In this case, "Alexion was able to convince the SEC that its cooperation and remediation efforts warranted a significant discount from the amount of its unjust enrichment," he continued.

See "What to Consider When Deciding Whether to Self-Disclose: An Interview With Steptoe's Lucinda Low" (Apr. 4, 2018).

A Spotlight on Auditing

Among Alexion's remediation efforts was enhancing its internal audit function. "Often companies in the throes of an enforcement proceeding focus primarily on the compliance program elements – policies, procedures, training, etc.," Resnicoff observed. "Alexion's enhancement of audit, along with compliance, speaks to a real priority for SEC and for DOJ, namely, effective auditing and data mining," he said.

"Most sophisticated compliance programs piggyback on existing audit capacity to help perform their auditing and monitoring roles," Resnicoff explained. "Auditors are in the field every week of every year," he continued. "Why not take advantage of their presence when they are in far-flung operations?"

See "Experts from PwC Discuss Compliance Audits and Common Missteps" (Sep. 28, 2016).

The Way Forward on Honoraria and Grants

Alexion's experience provides a cautionary tale for honoraria and grants, two mechanisms through which money was transferred inappropriately to government healthcare providers. "The use of honoraria programs has become an increasingly common way to

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disguise improper payments to government officials," Bloor said.

Still, honoraria remain "a perfectly lawful way for pharma and medical device companies to pay HCPs for services rendered, such as consulting, product insight and speaking engagements," Resnicoff said. "Note that several of the Turkish and Russian physicians in the Alexion matter presented a heightened risk because they seem to have had dual roles: one as practicing government-employed healthcare providers, and one as members or agents of government agencies responsible for issues important to Alexion, such as diagnostic protocols, prescription approval, reimbursement, and approval of continued therapy," he continued. The lesson here, he said, is that healthcare providers should be screened upfront for dual roles during due diligence. "They are a significant red flag," he cautioned.

"The keys to ensuring legitimacy are transparency and checks and balances," Fava said, mentioning the following:

- transparency about the reasons for selecting the particular HCPs who receive honoraria or who lead research;
- transparency in evaluating whether those HCPs are key decision makers or high prescribers of the company's products;
- approval by the legal or compliance department of payments to the HCPs based on complete information about the HCPs' influence or contributions to the company;
- itemization of the costs expected in the research and either a fair market value analysis of those costs or a description of similar research and the costs attendant to it;
- proof that the honoraria and research grants are being used in the manner intended and approved by the company;
- publication – where appropriate – of the honoraria and research grants (or, at a minimum, disclosure to the HCPs' employer of the HCPs' receipt of such funds and participation in the company's research or other programs); and
- regular internal audits or other monitoring of a sample selection of these expenses.

See "Managing Corruption Risks Facing Healthcare Companies in Eastern Europe" (Jun. 12, 2019).

Establish an HCP Selection Committee

When establishing controls around honoraria programs, companies "should establish an HCP selection committee, independent from the companies' sales division, to select HCP for honoraria based on specific criteria," Guerrero suggested. "To the extent the sales division makes recommendations to the honoraria programs for the selection of certain HCPs, the selection committee should review those recommendations to determine if the recommendation could be viewed as for the purpose of influencing the HCP to favor the company," he continued.

HCP selection committees, in turn, "should implement controls to determine if the proposed HCP is a foreign official," Guerrero said. If that provider is a foreign official, the company should consider corruption risk associated with that person, he continued.

For instance, "if the HCP can make purchasing, prescription or regulatory decisions that

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could benefit the company, that HCP poses a higher risk than an HCP with no such power," Guerrero said. When a healthcare provider is a foreign official, either "the HCP selection committee or the company's compliance officer should conduct due diligence on the HCP," Guerrero said.

Companies with honoraria programs "should have risk-based policies and procedures to address payments of honoraria to HCPs," Guerrero said. Those include "maintaining documentation related to the rationale for selection of the HCP, the services that the HCP will be rendering for the honoraria, evidence that the services were ultimately rendered, and an evaluation of the services rendered," he said.

See "Internal Investigations in the Life Sciences Industry" (Jul. 8, 2020).

Safeguards for Research Grants

In the same vein, companies with a grants program should also establish a committee, one that consists of "uninterested company personnel to make decisions on grant requests," Bloor said. "Sales and marketing personnel should receive training to ensure that they remain separate and apart from the research grant award process," he continued. Decisions on grants "should be thoroughly documented and have a valid basis for the award," he said.

Research grants "are an important part of funding that advances research in the underlying market and community" that businesses in the pharmaceutical industry serve, Bloor said. Grants "absolutely can be awarded legitimately," he continued, cautioning that "it is important that companies are transparent in the process of awarding grants."

"Unlike honoraria for individual HCPs, research grants to HCPs/organizations are more likely to face increased anticorruption risk because of the presence of foreign officials at nearly every stage of the research," Guerrero explained. "For example, corruption risks exist at the regulatory approval stage as well as for payments made in connection with clinical trials and possible distribution of product," he said. To that end, "companies and HCP selection committees must establish effective due diligence and oversight of the HCPs/organizations as well as any third parties involved in the research or clinical trial process," Guerrero suggested.

See "Guarding Against Bribery When Conducting Clinical Trials Overseas" (Aug. 19, 2015).

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