Pharmaceutical Company Reaches Preliminary Agreement in Principle to Resolve DOJ and SEC Investigations

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On May 12, 2016, Aegerion Pharmaceuticals, Inc., announced that it has reached "preliminary agreements in principle" with the Department of Justice (DOJ) and the Securities and Exchange Commission (SEC) to resolve the agencies' investigations into its sales activities and public statements regarding Juxtapid, a drug in capsule form, which is used to treat a rare form of high cholesterol and costs about $250,000 a year.[1]

The company's announcement is especially notable for the statements that, under the agreement with DOJ, Aegerion will plead guilty to two misdemeanor misbranding violations of the Food, Drug, and Cosmetic Act (FDCA), and enter into a five year deferred prosecution agreement regarding charges that the company violated the Health Insurance Portability and Accountability Act and obstructed justice relating to the Risk Evaluation and Mitigation Strategies (REMS) program. The expected misdemeanor violations include one count for marketing Juxtapid with inadequate directions for use and another for the failure to comply with the REMS for the drug. Aegerion also will enter into a civil settlement agreement to resolve alleged False Claims Act (FCA) violations and will enter into a consent decree with the Food and Drug Administration (FDA) prohibiting future violations of law. The question of whether Aegerion will be required to enter into a corporate integrity agreement with the Department of Health and Human Services (HHS) apparently has not been decided.[2]

Based on the language in the company's statement, it appears that the preliminary agreement in principle with SEC has been reached with SEC staff and is not as advanced as the proposed settlement with DOJ. Thus, "the SEC's Division of Enforcement will recommend that the SEC accept a settlement offer from the company on a neither-admit-nor-deny basis" regarding alleged negligent violations of the Securities Act relating to certain statements made by the company in 2013. The proposed resolution will include a civil penalty, censure, and an order prohibiting future violations of the securities laws.[3]

Under the proposed consolidated settlement, Aegerion will pay $40 million to resolve the claims against the company. The proposed agreement is further notable, however, for the fact that it will allow Aegerion to pay the sum over five years, with an initial payment of approximately $3 million upon finalization of the agreement, quarterly payments totaling approximately $3.7 million per year for the first three years, and quarterly payments totaling approximately $13 million per year for the final two years, with the outstanding amounts accruing interest at 1.75% per year.[4]

The company's statement also makes clear that the preliminary agreement in principle does not address the DOJ and SEC inquiries into the company's operations in Brazil, referring to an investigation by Brazilian authorities into whether Aegerion violated local anti-corruption laws.[5]

1 Aegerion Pharmaceuticals, Inc. (2016, May 12). *Form* 8-K. Retrieved from http://ir.aegerion.com/sec.cfm (last accessed May 15, 2016).
2 *Id.*
3 *Id.*
4 *Id.*
5 *Id.*

Although Aegerion's press release does not describe the circumstance underlying the DOJ and SEC investigations, the company received an FDA Warning Letter in November 2013 regarding statements that Aegerion's then-CEO Marc Beer made in two appearances on CNBC's "Fast Money" program in June and October 2013.[6] Following his second appearance on the program, in which he stated that "patients are going to die of a cardiac event, either a stroke or a heart attack, if we don't have them on therapy," Beer resigned as CEO. In the Warning Letter, the FDA objected that his comments "misleadingly suggest[ed] that Juxtapid is safe and effective as a monotherapy," while it is approved only for use as an adjunct to other therapies, and failed to communicate its significant risks or that Juxtapid is "only available through a restricted program under a [REMS], where healthcare providers and pharmacies must be certified in order to prescribe and distribute Juxtapid."[7] Both Beer and Aegerion are currently defending a class action lawsuit in which shareholders claim that his remarks damaged the value of the company's stock.

AGG's Observations

- These settlements serve as another cautionary tale and provide insight into the types of communications that can land companies and their executives in the government's crosshairs.
- Communications that promote unproven and off-label benefits of an approved drug—particularly while omitting or downplaying significant risks—can draw the attention not only of FDA, but also of DOJ and SEC.
- We have previously written and advised on recent developments involving company discussions about product and potential FDA-related implications and have cautioned clients that other regulatory bodies, distinct from FDA, may take an interest as well. This case serves as yet another reminder of these risks.

6 FDA, Office of Prescription Drug Promotion, Juxtapid NDA 203858 Warning Letter, Nov. 8, 2013. Retrieved from http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/UCM374338.pdf (last accessed May 15, 2016).

7 *Id.*

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