SEC Charges Biotech Company and Its Officers with Misleading Investors by Failing to Disclose FDA Concerns and Recommendations

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Background

On March 29, 2016, the Securities and Exchange Commission (SEC) announced charges against a biotech company and three of its officers for securities fraud. The company has agreed to pay $4 million to resolve the charges without admitting or denying the allegations. The SEC is proceeding against the officers of the company and seeking disgorgement, permanent injunctions, and officer-and-director bars.[1] Paul G. Levenson, Director of the SEC's Boston Regional Office, summed up the crux of the case as follows: "Companies must be forthcoming about their communications with regulators so investors can make informed investment decisions while knowing what challenges may lay ahead."[2]

Specifically, the SEC's Complaint alleges:

- The Food and Drug Administration (FDA) advised the biotech company in May 2012 that it had concerns regarding the overall survival rate of patients taking the experimental drug in the company's first study and recommended a second, larger randomized clinical trial.
- While the company disclosed FDA's concerns regarding the overall survival rate, it misled investors by failing to disclose FDA's recommendation for a second clinical trial or the company's plans with respect to that recommendation.
- In January 2013, after learning of FDA's concerns and recommendations, after making numerous statements omitting FDA's recommendations, and prior to any public disclosure of FDA's recommendations, the company raised approximately $53.8 million through a stock offering.
- On April 30, 2013, the day that FDA publicly disclosed its earlier recommendation for a second clinical trial, the company's stock price dropped 31%.

AGG's Observations

- The SEC's Complaint serves as a cautionary tale and provides insight into the types of communications that can land companies and their executives in the government's crosshairs.
- Communications that may be technically honest in what they say, but materially misleading in what they fail to say, carry substantial risk of SEC enforcement action.

1 SEC: Biotech Company Misled Investors About New Drug's Status With FDA, SEC Press Release No. 2016-59 (March 29, 2016), https://www.sec.gov/news/pressrelease/2016-59.html (last accessed April 7, 2016) ("Press Release"). The Press Release contains a link to the Complaint filed by the SEC on March 29, 2016 at https://www.sec.gov/litigation/complaints/2016/comp-pr2016-59.pdf (last accessed April 7, 2016) ("Complaint").

2 Press Release at 1.

- While we are unaware of any FDA action against the company to date, the agency has issued enforcement letters to companies for investor-related materials that are false and misleading or otherwise unlawful. Similarly, FDA prohibits pre-approval discussions that suggest an investigational product's safety, efficacy, or approval.

- We have 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.

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