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Regulation FD Compliance Requires Continued Vigilance

Yesterday, the SEC announced charges and an associated cease-and-desist order against a public pharmaceutical company for violating Section 13(a) of the Exchange Act and Regulation FD. The violations involved communications with sell-side research analysts regarding potential approvals from the U.S. Food and Drug Administration (FDA). Regulation FD generally prohibits an issuer's selective disclosure of material nonpublic information and requires prompt corrective action and disclosures when a violation has occurred. According to the order, at the time of the problematic conduct, the company did not have policies or procedures relating to compliance with Regulation FD and did not require Regulation FD training for employees but subsequently implemented these protections.

This case sends two important messages to public companies: the SEC continues to focus on Regulation FD; and a robust compliance program remains critically important both to avoid Regulation FD violations and to minimize the consequences of regulatory scrutiny in the face of a violation.

The SEC found that in mid-June of 2017, the company sent private messages to sell-side analysts describing as "very positive and productive" a publicly-announced meeting it had with the FDA regarding a new drug approval, and that the FDA officials had been surprisingly "accommodating." The company's stock price jumped nearly 20% on heavy trading volume the next day. The company did not issue a Regulation FD-compliant announcement regarding the FDA meeting. A month later in mid-July, the company issued a press release announcing that, while it had submitted additional information to the FDA to address FDA "concerns," it did not have a clear timeline and path forward for approval of the new drug application. The stock dropped 16% in pre-market trading, and analysts began e-mailing the company for clarity regarding the press release's contents. Prior to the market opening, the company held a pre-scheduled call with analysts and sent follow-up emails to them providing undisclosed details about the prior FDA meeting, the information subsequently submitted to the FDA and specific reassurances regarding the prospects for approval. After analysts published research notes containing these additional details, the stock rebounded by the end of the day's trading to close down only 6.6%. During the company's early August 2017 earnings call, the company provided broader public disclosures for the first time concerning the information submitted to the FDA and related drug approval matters.

Public companies would be well advised to review their Regulation FD compliance and control systems and training programs to ensure that these systems and programs are up to date, state-of-the-art and take into account the specifics of a company's business model.

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