SEC Charges Pharmaceutical Company for Violation of Regulation FD, Reinforcing Need to Establish Policies for Handling Material Non-Public Information

August 23, 2019

On August 20, 2019, pharmaceutical company TherapeuticsMD, Inc. ("TherapeuticsMD" or the "Company") settled charges by the U.S. Securities and Exchange Commission (the "SEC") that the Company had selectively disclosed market-moving information to sell-side analysts regarding potential approval of one of its drugs by the Food and Drug Administration (the "FDA").[1] This is the first stand-alone Regulation Fair Disclosure ("Regulation FD") action brought by the SEC in over five years.

The action underscores the importance of public companies maintaining policies and procedures for handling material non-public information ("MNPI") in a manner compliant with Regulation FD. Life sciences companies in particular are advised to develop standard operating procedures ("SOPs") based upon best practices governing the disclosure of MNPI arising from confidential FDA communications.[2]

TherapeuticsMD's disclosures to analysts. The settled order alleges that TherapeuticsMD made two selective disclosures concerning TX-004HR, a hormonal drug for the treatment of dyspareunia. The SEC alleged that these disclosures violated Regulation FD, which prohibits public companies from selectively disclosing MNPI to certain enumerated persons (in general, securities market professionals and holders of the issuer's securities who are likely to trade on the basis of the information) without concurrently making widespread public disclosure. Under Regulation FD, an intentional selective disclosure must be accompanied by a simultaneous public disclosure, while an unintentional selective disclosure must be followed "promptly" by a public disclosure.[3]

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1 *In the Matter of TherapeuticsMD, Inc.*, Admin. Proc. File No. 3-19362 (Aug. 20, 2019).

2 *See also* Andrew J. Ceresney et al., "Insight: The SEC/FDA Nexus: Best Practices for Publicly Traded Life Sciences Companies," *Bloomberg Law* (Nov. 19, 2018), https://news.bloomberglaw.com/securities-law/insight-the-sec-fda-nexus-best-practices-for-publicly-traded-life-sciences-companies.

3 Final Rule: Selective Disclosure and Insider Trading, 17 C.F.R. 240, 243, 249, Release No. 33-7881 (2000), https://www.sec.gov/rules/final/33-7881.htm.

June 2017 Disclosures. According to the SEC, TherapeuticsMD submitted TX-004HR's initial New Drug Application ("NDA") in July 2016 for approval by the FDA. The following May, however, the FDA expressed concerns regarding the NDA's lack of data on the drug's long-term safety. TherapeuticsMD arranged a meeting with the FDA on June 14, 2017, and filed a Form 8-K stating that the meeting would likely have one of two results: Either the FDA would permit TherapeuticsMD to restart the NDA approval process or TherapeuticsMD would resort to formal dispute resolution with the agency.

The June 14 meeting ended without the FDA providing a clear path forward for TX-004HR's approval. Following a meeting of TherapeuticsMD's executives on the next day, the Company sent a series of emails to sell-side research analysts characterizing the FDA meeting as "very positive and productive." TherapeuticsMD's stock price closed up 19.4% the following day, prompting the New York Stock Exchange to contact Company executives about the stock's activity. Instead of making a simultaneous public disclosure about the meeting's outcome, TherapeuticsMD filed a press release and Form 8-K over a month later, on July 17, 2017, after it received formal meeting minutes from the FDA.

July 2017 Disclosures. The Company's July 17, 2017 press release and Form 8-K stated that the FDA meeting had "enabled the company to present new information" to address the FDA's concerns, and disclosed that TX-004HR was not on a formal timeline for approval. In response to this disclosure, the Company's stock price fell 16% in pre-market and early trading.

On the same morning, during a pre-scheduled call with sell-side analysts, TherapeuticsMD executives described the "new information" submitted to the FDA as part of the NDA. Following the call, a Company employee emailed analysts three of the new studies submitted to the FDA as part of the NDA, and included a summary of the Company Chief Medical Officer's position on TX-004HR's safety. Each analyst promptly published research notes that detailed the more specific information about the FDA interactions, in several cases repeating the Company's positive conclusions about the studies' safety implications for TX-004HR. The stock rebounded, finishing down only 6.6% by market close. TherapeuticsMD did not publicly disclose the additional data it provided to the FDA for another two weeks.

Charges and Penalties. The SEC charged the Company with violations of Section 13(a) of the Exchange Act and Regulation FD thereunder and imposed a monetary penalty of $200,000. According to the SEC, the penalty took into account the Company's subsequent remedial action, including its implementation of policies and procedures that: (1) require public disclosure of MNPI in connection with Regulation FD, (2) provide "specific examples of types of [MNPI] that might arise in light of TherapeuticMD's business model," and (3) establish review protocols for "all external communications including earnings calls, analyst meetings, and press releases."

The SEC's Renewed Focus on Regulation FD. Following its adoption in 2000, the SEC's enforcement of Regulation FD appeared to reach a peak in 2009 and 2010 with cases brought in the direct aftermath of the financial crisis.[4] In recent years, however, the SEC has only rarely pursued stand-alone actions based on Regulation FD alone.[5] It is likely that the intentional nature of TherapeuticsMD's selective disclosures, as well as the Company's lack of policies and procedures relating to compliance with Regulation FD at the time of the events, influenced the SEC's decision to initiate the action. However, the settled order serves as a reminder that even simple descriptive language, such as characterizing a meeting as "positive" and "productive," can have material impacts in some circumstances.

The TherapeuticsMD action follows the SEC's dissemination last year of interpretive guidance on cybersecurity disclosure obligations. In that guidance, the SEC outlined its expectation that companies implement policies and procedures that ensure disclosures of MNPI related to cybersecurity risks and incidents are compliant with Regulation FD.[6] In light of the SEC's continued interest in enforcing Regulation FD, companies should apply appropriate care when handling MNPI and should ensure adequate policies and procedures are in place to govern disclosures.

Finally, this action reinforces the need for pharmaceutical and other FDA-regulated life sciences companies to develop best practices governing disclosure of confidential FDA-related information. As noted in prior Debevoise publications, the SEC/FDA nexus is rife with complexity as disclosure issues may arise in a variety of contexts, including confidential FDA feedback, inspectional findings, clinical trial developments, and post-approval developments.[7] The FDA meetings during the drug/device development process are particularly sensitive as they may provide key insights into a product's progression toward approval and such information may have the potential to move the market.

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4 *See, e.g.*, *SEC v. Christopher A. Black*, Litig. Rel. No. 21222 (Sept. 24, 2009), https://www.sec.gov/litigation/litreleases/2009/lr21222.htm ; *SEC v. Presstek*, No. 1:10-cv-10406 (D. Mass. Mar. 9, 2010); *In the Matter of Office Depot*, Rel. No. 34-63152 (Oct. 21, 2010), https://www.sec.gov/litigation/admin/2010/34-63152.pdf.

5 *See In the Matter of Lawrence D. Polizzotto*, Rel. No. 34-70337 (Sept. 6, 2013), https://www.sec.gov/litigation/admin/2013/34-70337.pdf.

6 *Commission Statement and guidance on Public Company Cybersecurity Disclosures*, 17 C.F.R. Parts 229 and 249, Release No. 33-10459 (Feb. 21, 2019), https://www.sec.gov/rules/interp/2018/33-10459.pdf.

7 *See* Ceresney, *supra* note 2.

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