

Return of Regulation FD Enforcement

November 5, 2019 Matthew Fry, Kayla Cristales

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On August 20, 2019, the Securities and Exchange Commission (SEC) charged TherapeuticsMD, Inc., a publicly traded pharmaceutical company, with violations of Regulation FD for the selective disclosure of material nonpublic information. This matter represents the first case focused on Regulation FD that the SEC has brought in considerable time and suggests that the SEC may have a renewed focus on Regulation FD compliance.

Regulation FD generally prohibits issuers and their representatives from making selective disclosures of material nonpublic information to their stockholders and securities industry professionals. Public disclosures of material nonpublic information may be made through a Form 8-K or through any other method or methods designed to provide broad, non-exclusionary distribution to the public, which methods have grown and evolved with technological developments since Regulation FD's adoption in 2000.

In its cease-and-desist order, the SEC found that TherapeuticsMD selectively disclosed material nonpublic information to analysts on two occasions relating to interactions with the Food and Drug Administration (FDA). By way of background, in July 2016, TherapeuticsMD submitted an initial New Drug Application (NDA) to the FDA for approval of a drug candidate in development. On May 5, 2017, the company received a Complete Response Letter from the FDA citing a lack of long-term safety data as the single deficiency in the NDA. On the following day, TherapeuticsMD disclosed the letter and its contents before trading opened, and the company's stock price fell 10.5%.

Selective Disclosures Concerning Results of FDA Meeting. Following a request from TherapeuticsMD, the FDA agreed to meet with the company on June 14, 2017 to discuss the letter, and TherapeuticsMD publicly announced the meeting date in the Form 8-K describing the Complete Response Letter. The day after the meeting, a TherapeuticsMD executive sent e-mails to six sell-side analysts indicating that the meeting was "very positive and productive" and offered to have follow-up phone calls with several of the analysts. The company's stock price rose significantly the day after the e-mails were sent to the analysts, and one analyst later published a research report using the same terminology the executive had privately used to describe the meeting. The company did not make any public disclosures concerning the FDA meeting until July 17, 2017.

Selective Disclosures Concerning Receipt of FDA Minutes. On July 5, 2017, TherapeuticsMD received formal minutes concerning the meeting from the FDA. On July 17, 2017, TherapeuticsMD issued a press release and filed a Form 8-K announcing that it had met with the FDA and had provided the FDA new information that could "address concerns raised by the FDA" but offering few other details about the new information provided. The price of TherapeuticsMD stock fell approximately 16% in early trading. TherapeuticsMD executives held a conference call with analysts early that morning, disclosing details about the new information provided to the FDA that had not been disclosed publicly, and a company employee sent a summary from the company's Chief Medical Officer to the analysts describing why the new information supported the drug's safety. Shortly thereafter, each of the analysts published reports containing details from the call and the favorable new information provided to the FDA. The price of TherapeuticsMD stock significantly

rebounded by market close. TherapeuticsMD did not publicly disclose the details it had given the analysts until its earnings call in August 2017.

TherapeuticsMD did not have Regulation FD policies or procedures during the time period at-issue.

Without admitting or denying the SEC's allegations, TherapeuticsMD agreed to pay a civil money penalty of \$200,000 to the SEC and to not violate Regulation FD or Section 13(a) of the Securities Exchange Act of 1934 in the future.

This matter highlights some of the Regulation FD perils for issuers and the importance for issuers to adopt and maintain Regulation FD policies and procedures. Even though the staff of the SEC has indicated in speeches that it does not intend to second guess close materiality calls, it is more difficult to defend against Regulation FD claims if an issuer has not institutionalized Regulation FD policies and procedures. Stocks prone to high volatility also pose a challenge as the SEC could infer materiality based upon market fluctuations. Further, holding private meetings with analysts can be perilous due to the appearance of impropriety even if issuers are careful to only disclose publicly available or immaterial information. As an alternative, issuers may consider publicly announcing analyst calls and permitting all investors to attend the call by webcast. Early stage issuers whose stock price is largely driven by material news announcements rather than quarterly earnings reports may need to be extra vigilant in their Regulation FD compliance efforts and would be wise to engage in regular Regulation FD training of their directors, officers and employees.

In the words of Carolyn M. Welshhans, Associate Director of the SEC's Division of Enforcement, "Information about a pharmaceutical company's interactions with the FDA can be critical to investors. It is essential that when companies disseminate material, nonpublic information, they do so fairly and appropriately to all investors and not just a select few analysts."

For additional information please contact any member of Haynes Boone's [Capital Markets and Securities](#) practice group.