

SEC Files First Reg FD Action In Years

Regulation Fair Disclosure was passed in 2002 to fill what many saw as a regulatory gap – the selective disclosure of material non-public information by issuers. Essentially the Regulation – now known as Reg FD – requires a company to either not disclose the information or make it available to all.

Following the passage of Reg FD the Commission brought enforcement actions with mixed results. Perhaps the best known action was brought against Netflix in 2013. Since that date, however, the Commission has not brought a Reg FD action – until now. Last week the Commission filed a settled administrative proceeding based on the regulation -- *In the Matter of TherapeuticsMD, Inc.*, Civil Action No. 3-19362 (August 20, 2019).

The Proceeding

The Florida based firm conducts research and develops and commercializes pharmaceutical drugs for women's health issues. In the last several years the company has been developing TX-004HR, a hormone drug therapy. A new drug application was submitted to the FDA in early July 2016. The agency notified *TherapeuticsMD* that it would complete a review by early May 2017. While the firm was developing two products in this area, only TX- 004HR had progressed to this stage.

The company expected to begin communicating with the FDA on proposed labeling and post-marketing requirements shortly before the review was completed. The FDA, however, sent the firm a letter noting that unspecified deficiencies precluded conversations.

In early May the FDA sent *TherapeuticsMD* a second letter that identified one deficiency: the lack of long-term safety data. After disclosing the contents of the letter in a press release and Form 8-K filing, the company requested and received a meeting date with the FDA. *TherapeuticsMD* also disclosed the meeting, noting possible outcomes.

On June 14, 2017 the firm met with the FDA and reviewed the pertinent data. The

Related Capabilities

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meeting ended with a clear path forward identified by the agency. Subsequent emails described the meeting as very positive, noting that the firm was waiting for the meeting minutes to assess the path forward. Three analysts followed-up on an offer in the email to discuss the matter further. Following the discussions, the firm's share price increased significantly. There were no public disclosures about the meeting.

When the meeting notes were received in early July 2017, *TherapeuticsMD* filed a Form 8-K and press release updating the public. Later that day, firm executives conducted a pre-scheduled conference call with analysts during which the meeting with the FDA was reviewed. New information that had been submitted to the agency was identified. During the call three studies that had been submitted to the agency were emailed to the analysts on the phone along with other information from the company about TX-004HR. Following the publication of reports by certain analysts the stock price, which had declined, rebounded. During these events *TherapeuticsMD* did not have policies or procedures relating to compliance with Regulation FD. The Order alleges violations of Exchange Act Section 13(a) and Regulation FD.

To resolve the proceedings Respondent consented to the entry of a cease and desist order based on the section and regulation cited in the Order. The firm also agreed to pay a penalty of \$200,000.

Comment

TherapeuticsMD is not remarkable for its facts – it is standard fare Reg FD. It is remarkable since the case is the first in years, perhaps signaling a renewed focus on the area. Nevertheless, the Regulation remains an important safeguard against selective disclosures, ensuring that if material non-public information is disclosed to persons outside the company it become available not just to the few but to the public, echoing the main street investor focus of the enforcement division. Companies would be well advised in the wake of *TherapeuticsMD* to carefully revisit their compliance programs in this key area.