

Securities Regulation Daily Wrap Up, FRAUD AND MANIPULATION— W.D.N.C.: Drug company may have been overly optimistic, but did not act recklessly, (Oct. 11, 2013)

[Click to open document in a browser](#)

By Rodney F. Tonkovic, J.D.

A securities fraud case was dismissed with prejudice after a district court concluded that the plaintiff failed to allege a strong inference of scienter. According to the court, the complaint's allegation that the defendants misled investors in order to stave off bankruptcy and to fund further clinical trials failed to satisfy the PSLRA pleading requirements when weighed against opposing inferences. Having found no primary violation of the Exchange Act, the court also dismissed the plaintiff's controlling person claims (*McIntyre v. Chelsea Therapeutics International, Ltd.* October 9, 2013, Cogburn, M.).

Background. The plaintiffs alleged that Chelsea Therapeutics International (Chelsea) omitted critical information regarding the development and approval of the drug Northera. Northera, generically known as droxidopa, is used to treat a disorder causing a sudden drop in blood pressure. Beginning in early 2008, Chelsea conducted two studies of Northera, the goal of which was to reach a specific measure of the patients' dizziness or lightheadedness.

One of the studies failed to demonstrate a statistically significant effect on the assessment scale used to measure dizziness. Chelsea then petitioned the FDA to modify the other, still ongoing study, to change its endpoint to one on a different scale. Chelsea later announced that this study had achieved a statistical improvement on the second scale.

The FDA accepted Chelsea's application for Northera. The briefing committee recommended that Northera not be approved, but the Advisory committee went against this recommendation. At the time, Chelsea was hopeful, but warned investors that the FDA was not bound by the Advisory Committee's recommendation. The FDA eventually denied the application.

Scienter. The court found that the complaint failed to allege facts giving rise to a strong inference of scienter. The plaintiff's theory, the court stated was that Chelsea intentionally misled investors to believe that the FDA would approve Northera based on the results of only one successful study. Chelsea was allegedly motivated to artificially inflate its stock price in order to stave off bankruptcy and to fund additional clinical trials.

Regarding motivation, the court found that the 4th Circuit has rejected similar arguments based on a company's alleged motivation to fund its operations. The court in that case held that the motivation to raise capital is common to any company and adds little support to an inference of fraud.

The plaintiff also argued that Chelsea's communications with the FDA showed recklessness, claiming that there was only one successful study on Northera, while the FDA requires two. The court, looking at the briefing transcript and statutory authority, determined that one successful study could, in fact, be sufficient. While Chelsea may have been overly optimistic, the court said, this optimism did not rise to the level of recklessness, especially in light of the numerous explicit warnings investors received from Chelsea. Finally, further tipping the scales in favor of the defendants was the fact that none of the individual defendants sold stock during the class period.

The court then found that amendments to the complaint would be futile. The plaintiff gave no indication how any of the noted deficiencies would be cured and had proffered no second amended complaint. The case was accordingly dismissed with prejudice.

The case is No. 3:12-cv-213-MOC-DCK.

Attorneys: Jeremy Allan Lieberman (Pomerantz Haudek Grossman & Gross LLP) for Cameron McIntyre. Francis P. McConville (Faruqi & Faruqi, LLP) and Paul Anthony Daniels (Ward Black Law) for Roman Zak. Lee M. Whitman (Wyrick Robbins Yates & Ponton LLP) for Chelsea Therapeutics International, LTD.

Companies: Chelsea Therapeutics International, LTD.

LitigationEnforcement: FraudManipulation NorthCarolinaNews