

Fourth Circuit Sustains Securities Fraud Claim Against Drug Manufacturer

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On March 6, the US Court of Appeals for the **Fourth Circuit** found that the United States District Court for the Western District of North Carolina had erred in dismissing a class action lawsuit filed under Section 10(b) of the **Securities Exchange Act of 1934** (Exchange Act) because the lower court had inappropriately relied on regulatory filings provided to the Securities and Exchange Commission and had incorrectly applied case law precedent. The plaintiff class contended that the defendants, Chelsea International, Ltd. and several of its corporate officers, materially misled investors over the risk associated with securing **Food and Drug Administration (FDA)** approval for a blood pressure medication that Chelsea was developing. Notably, the plaintiffs alleged that defendants had misled investors to believe that the FDA would approve the drug at issue based on the results of only one successful efficacy study, even though the FDA repeatedly had warned Chelsea that two successful studies and evidence of “duration of effect” would be necessary for approval of the new drug. The Fourth Circuit first held that the District Court erred in finding that Chelsea had failed to demonstrate the scienter necessary to sustain a securities fraud claim under the Exchange Act. The Fourth Circuit found that the District Court erred in its scienter analysis by considering SEC documents submitted by the defendants that were not integral to the complaint. The documents purportedly showed that the defendants did not sell any Chelsea stock during the class period. However, stock sales were never a part of the plaintiffs’ complaint and thus, the Fourth Circuit reasoned that the lower court should not have considered these SEC documents as evidence of the defendants’ intentions. Further, the Fourth Circuit held that material, non-public information known to the defendants about the status of the drug application conflicted with the defendants’ public statements on those subjects, which was an inconsistency the Fourth Circuit deemed sufficient to establish the severe reckless conduct necessary to establish an inference of scienter in securities fraud cases.

Zak v. Chelsea Therapeutics No. 13-2370 (4th Cir. Mar. 16, 2015)

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