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Client Alert

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Court Dismisses Shareholder Suit Seeking To Recover Stock Drop from FDA Nonapproval of Experimental Drug

Companies that sell products or services that cannot be marketed without regulatory preclearance, and particularly companies that develop experimental drugs and medical devices, should take note of the recent opinion by Judge Sim Lake of the Southern District of Texas in *Callinan v. Lexicon Pharmaceuticals, Inc.*, No. H-19-0301, slip op. (S.D. Tex. Aug. 14, 2020). Judge Lake dismissed with prejudice a putative class action brought by investors seeking to recover losses arising from Lexicon's stock price dropping after a key drug in development did not receive FDA approval. The well-reasoned opinion should caution plaintiffs against bringing similar cases that seek to hold companies and executives accountable for the downside risks of seeking regulatory approval.

The allegations in *Lexicon* centered on sotagliflozin, an investigational drug developed to serve as an adjunct to insulin for type 1 diabetes patients that would potentially allow patients to achieve better clinical outcomes and a higher quality of life. However, like all drugs in its class, sotagliflozin's benefits came with a heightened risk of diabetic ketoacidosis, a sometimes-fatal complication of type 1 diabetes. Ultimately, the FDA's advisory committee voted 8-to-8 on the question of whether the benefits of the drug outweighed its risks, and the FDA did not approve the drug. The EU regulator later approved sotagliflozin for use in certain type 1 diabetes patients.

Plaintiffs were Lexicon shareholders that claimed losses based on the drop in the value of Lexicon's stock following the announcement of the advisory committee's tie vote. Plaintiffs claimed that Lexicon and its executives misled the market (and the FDA) about the increased DKA risk and the magnitude of the benefits offered by the drug. Plaintiffs also seized on the FDA's criticism of the endpoint used in one clinical study to suggest that Lexicon was warned not to proceed with the study as designed, yet failed to communicate that warning to the market.

In a systematic, 114-page opinion, Judge Lake dismantled plaintiffs' theory, explaining that none of the alleged misstatements were actionable. First, the Court found that the alleged warning about the study's endpoint was

insufficiently alleged: "Missing from the [complaint], however, are allegations of facts showing when, where, to whom, or how the FDA raised its concerns about the composite endpoint." Slip op. at 34. Second, the Court found that Lexicon accurately disclosed its trial data and therefore did not conceal the DKA risk. Third, the Court found the plaintiffs' allegations that Lexicon overstated sotagliflozin's benefits not credible when considering the full context of the advisory committee meeting transcript (which was partially quoted throughout the complaint). The Court dismissed other categories of alleged misstatements for similar reasons.

Judge Lake also dismissed the complaint for failing to allege scienter, finding allegations that sotagliflozin was "essential for Lexicon's survival" not to be credible when the very SEC filings partially quoted in the complaint revealed other late-stage drugs Lexicon had under development or in the market. *Id.* at 91–92. The Court dismissed allegations from confidential witnesses who were not alleged to have spoken to any of the individual defendants. Finally, the Court noted that motivation was not pleaded where the only motives pleaded were common to all corporate defendants.

The Court found loss causation inadequately pleaded because plaintiffs failed to allege "that the alleged misrepresentations caused inflation of the price of Lexicon's common stock." *Id.* at 109. The Court dismissed the complaint with prejudice, stating that "the court is persuaded that plaintiffs have pleaded their best case, and that any additional attempt to amend would be futile." *Id.* at 114.

Lexicon and recent opinions from other districts illustrate that plaintiffs must plead more than a stock drop to survive a motion to dismiss, and that realization of the foreseeable risk that a regulator will act against a company's interest does not, without more, indicate fraud.[1]

[1] Paul Bessette, Mike Biles, and Rebecca Matsumura from King & Spalding's Corporate and Securities Litigation team, along with Lisa Dwyer from the firm's FDA and Life Science's team, represented Lexicon Pharmaceuticals, Inc. in the above-described case.