

Southern District of New York: The “Mere Existence” of Reports of Adverse Pharmaceutical Events Is Not Material, Standing Alone

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On March 26, 2020, the Southern District of New York dismissed a securities fraud action alleging that a pharmaceutical company failed to disclose certain serious adverse events (“SAEs”) experienced by patients using the company’s liver disease drug. [Liu v. Intercept Pharms., 2020 WL 1489831 \(S.D.N.Y. 2020\) \(Kaplan, J.\)](#). The court recognized that “[a]dverse events are material when there is a scientifically reliable basis for inferring a potential causal link between the drug and the adverse event.” But the court emphasized that “[t]he mere existence of reports of adverse events is not material.” Rather, “[s]omething more is needed.”

At issue in the case before it were reports that 27 out of 3,000 patients—or less than 1% of users—experienced one or more SAEs during the one-year long class period. The SAEs consisted of “nineteen deaths and eleven cases of serious liver injury.”^[1] Plaintiffs argued that they “sufficiently [had] pled ‘something more’” by pointing to factors such as “the FDA’s historic concern with liver injuries”; an FDA investigation into the SAEs commenced after the company announced that a patient in its Phase 2 trial had died; and “the FDA’s concerns about the ‘vulnerabilities’” of certain very sick patients and “the known need for these patients to receive a lower dose” of the drug.

The court found these factors insufficient to demonstrate the materiality of the SAEs. The court explained that liver damage “is a known complication of most prescribed drugs.” The court also found that FDA actions taken after the disclosure of an SAE did not demonstrate the materiality of the SAEs that were not previously disclosed. The court reasoned that plaintiffs “falsely equate[d] FDA action taken *after* the statements at issue were made with whether adverse events were material under the securities laws *at the time* the statements were made.” The court also found that “[t]o the extent that there were concerns about the vulnerabilities of late-stage patients,” these concerns did not support a finding of materiality because “these patients ha[d] compromised livers and already were quite sick.” The court emphasized that “some adverse events may be expected to occur randomly, especially with a drug designed to treat people that are already ill.”

The court observed that “[w]hen plaintiffs’ argument is stripped of its allegations of ‘something more,’ they are left only with the occurrence of serious liver injury or death in fewer than 1 percent” of patients. The court found that these allegations “[fell] short” of adequately pleading that a “reasonable investor would have viewed the thirty reported SAEs as significantly altering the total mix of information available.”

[1] Three patients suffered liver injuries prior to their deaths.

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