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Client Alert

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Dismissal of Securities Claims Against Utah Biotech Company Provides Guidance in Securities Cases Involving Food & Drug Administration Form 483 Inspections

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A district court in Utah recently dismissed claims brought against a biotechnology company and its officers under Section 10(b) of the Securities Exchange Act and Rule 10b-5 adopted thereunder. The order in *Richfield v. PolarityTE, Inc.*, No. 2:21-cv-00561-BSJ provides helpful guidance on liability under the federal securities laws in cases involving a Form 483 inspection by the Food & Drug Administration ("FDA").[1]

BACKGROUND

PolarityTE, Inc. ("PolarityTE") is a biotechnology company headquartered in Salt Lake City, Utah that develops regenerative tissue products.[2] PolarityTE's flagship product is a tissue product called SkinTE® that is designed to repair and reconstruct skin in patients with chronic wounds, burns, surgical reconstruction events, scars, or who have had dysfunctional skin grafts removed.[3] The company submitted a biologics license application ("BLA") and an investigational new drug ("IND") application for SkinTE in July 2021.[4] In August 2021, the FDA placed a clinical hold on the IND application until PolarityTE resolved certain chemistry, manufacturing, and control ("CMC") items.[5] The FDA lifted the clinical hold in January 2022.

The clinical hold prompted interest from plaintiffs-side firms, and on September 24, 2021, a class action complaint alleging violations of the Federal securities laws was filed in the United States District Court for the District of Utah against PolarityTE and present and former officers of the company. Plaintiffs alleged that the August 2021 clinical hold on PolarityTE's IND application was related to unresolved issues identified as

observations on a Form 483 report prepared by an FDA inspection following an inspection of PolarityTE's manufacturing facilities in July 2018.

Defendants filed a motion to dismiss on various grounds, including that the plaintiffs had not sufficiently alleged that unresolved Form 483 observations from the July 2018 inspection caused the August 2021 clinical hold, and argued that the court should dismiss the complaint for failure to adequately plead a materially misleading statement or omission of fact. United States District Court Judge Bruce S. Jenkins agreed and dismissed the complaint with prejudice.

THE COURT'S RULING

The keystone of plaintiffs' allegations with respect to the July Form 483 report was that the FDA inspector observed that PolarityTE did not have a "potency assay" for its SkinTE product.[6] A potency assay is a measure of the biological activity of a product, and it is a necessary component of an IND application.[7] Plaintiffs argued that the Form 483 and the clinical hold letter from the FDA showed that PolarityTE did not have a potency assay for SkinTE when it submitted its IND application, which in turn caused the FDA to place a clinical hold on the application.

The Court held that the plaintiffs had not met their burden to plead specific facts showing that PolarityTE did not have a potency assay at the time it submitted its IND application in 2021. Regarding the clinical hold letter, the Court agreed with the defendants that the letter did not state that PolarityTE failed to provide a potency assay with its IND application, but instead expressed the FDA's disagreement with PolarityTE's proposed potency assay. For this reason, the Court concluded that the plaintiffs did not plausibly allege that the statements were false or misleading at the time they were made.[8]

The order also noted that one of the challenged statements regarding PolarityTE's work on the dosing for SkinTE specifically notified investors that the company's work on its dosing procedures was ongoing.[9] Since the challenged statement disclosed to investors that risk that plaintiffs claimed was concealed from the market, the Court found it implausible that it was materially misleading my omission of information about the July 2018 Form 483 observations.[10]

Concluding that the plaintiffs had not sufficiently alleged a connection between the July 2018 Form 483 observations and the August 2021 clinical hold, the Court dismissed the complaint.

KEY TAKEAWAYS

The PolarityTE lawsuit continues a trend of securities litigation against life sciences companies following disappointing news related to Form 483 inspections and submissions to the FDA for regulatory approvals. But the order confirms that dismissal is appropriate where there are no facts to show that a company failed to address FDA feedback. The order also shows the importance of specific risk disclosures and warnings to investors in connection with statements about regulatory compliance or submissions to federal regulators.

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[1] *See* Mem. Decision and Order Granting Defs.' Mot. to Dismiss the Second Am. Compl., *Richfield v. PolarityTE, Inc.*, No. 2:21-cv-00561-BSJ (D. Utah Apr. 19, 2023), ECF No. 99.
[2] *Id.* at 1.
[3] *Id.*
[4] *Id.* at 5.
[5] *Id.*
[6] *Id.* at 13–14.
[7] *Id.* at 14, n.5.
[8] *Id.* at 14–15.
[9] *Id.* at 15–16.
[10] *Id.* at 16.