

Securities Regulation Daily Wrap Up, FRAUD AND MANIPULATION—D. Mass.: Macular degeneration drug trial info. in plain sight, so no fraud, (Mar. 19, 2025)

Securities Regulation Daily Wrap Up

By [Jay Fishman, J.D.](#)

Reasonable investors wouldn't have found the pharmaceutical omissions suspect or scienter-driven.

The Massachusetts District Court dismissed a class action fraud complaint with prejudice because: (1) the alleged omitted drug trial information was, in fact, publicly available to investors before and during the relevant period; and (2) reasonable investors would not have suspected that the company or its executive officers were deliberately hiding pertinent information. Furthermore, throughout the class period, the FDA never doubted the company's drug trial findings or asked for more information ([In re Apellis Pharmaceuticals, Inc. Securities Litigation](#), No. 1:24-cv-11470-JEK (D. Mass. Mar. 17, 2025)).

Macular degeneration drug trial. The plaintiff investors bought stock in the pharmaceutical company between January 28, 2021, and July 28, 2023 (the class period), the start of which saw the company begin patient trials on a drug to slow but not cure macular degeneration. The possible side effects from the drug included: (a) retinal or intraocular inflammation; (b) isochemic optic neuropathy; and (c) retinal vasculitis, the most serious of the three conditions because it could lead to blindness.

The complaint. Patients with conditions (a) or (b) could develop condition (c), and the investors' dispute principally concerned the company and its staff not disclosing how frequently they actually tested patients during the trial to see whether those patients developed any of the conditions or, if they had conditions (a) or (b), whether they developed condition (c). So the complaint was *not* about material misstatements made on SEC-filed Form 10Ks, 10Qs or press releases but solely about omissions.

The investors specifically claimed that throughout the class period, the executive officers repeatedly stated small percentages of improvement in patients taking the drug over the placebo, and that no patients ever developed retinal vasculitis. But what was materially omitted, the complaint alleged, was the fact that the defined protocol for conducting the trial did not require the company to perform the test commonly used to detect retinal vasculitis for patients who either left the trial early or who developed conditions (a) or (b). Disclosing these omissions, the plaintiffs proclaimed, would have been important to investors for determining whether there was a fair market for the drug. While the FDA approved the drug in February 2023, the American Society of Retina Specialists, by the end of the class period, reported six incidents of retinal vasculitis in patients treated with the drug and the stock price declined nearly 70 percent to the investors' detriment.

The defendants moved to dismiss the Exchange Act Section 10/Rule 10b-5 and Section 20(a) complaint, asserting that the pleadings were deficient under Federal Civil Procedure Rule 9(b) and the Private Securities Litigation Reform Act (PSLRA).

Court: omissions don't add up to fraud. The court based its decision on the proposition that "a material omission is actionable only if it 'renders affirmative statements made misleading.'" Thus, regarding the alleged omission, namely the omitted frequency of the test for determining retinal vasculitis, the court said this was not misleading as a matter of law because the frequency of testing under the trial protocol was actually "information [already] made available to investors" in 2020, well before the executives made the challenged statements during the class period. In

fact, the record revealed the parties agreeing to the protocol's fifth amended version dated August 12, 2020, which was immediately published on the ClinicalTrials.gov website.

The protocol disclosed that participants were given the test at the beginning of the trial, at approximately 12 and 24 months into the trial, and within 30 days of a patient's early termination from the trial. While the plaintiffs complained that the protocol did not require the test immediately after retinal vasculitis was detected, the court said "it is not a material omission to fail to point out information of which the market is already aware"; in other words, reasonable investors were aware of the protocol and would not, therefore, have been misled by the defendants' statements into believing that more testing was occurring than what was provided for in the protocol.

Additionally, because the FDA approved the drug, reasonable investors would have believed the company was conducting the tests at the frequency specified in the FDA-approved protocol. The court concluded that since the company employed the publicly available FDA-approved methodology for testing for retinal vasculitis, the plaintiffs could not plausibly allege that the defendants' statements about the absence of retinal vasculitis were materially misleading. As for scienter, the court remarked that "where a complaint is devoid of any direct-evidence allegations, the indirect-evidence allegations in the complaint will need to do more work to carry the burden of raising a strong inference of scienter on their own," which the investors have not done. And because their allegations for primary fraud under Section 10(b) and Rule 10b-5 failed, the plaintiff investors' secondary allegations for control person liability against the executive officers under Section 20(a) failed as well.

This case is No. 1:24-cv-11470-JEK.

Judge: Kobick, J.

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Companies: Michigan Laborers Pension Fund; Apellis Pharmaceuticals, Inc.

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