

Southern District of New York: Plaintiffs Must Allege That Failure to Disclose Form 483 Rendered Statements Actually Made Misleading

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On April 28, 2020, the Southern District of New York considered a question of first impression in the Second Circuit: whether a Form 483 from the FDA, which documents FDA concerns with manufacturing processes, is immaterial as a matter of law. *Schaeffer v. Nabriva Therapeutics*, No. 19-cv-4183 (VM), slip op. (S.D.N.Y. 2020) (Marrero, J.). The court determined that it could not “conclude that the Form 483 is so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of its importance.” However, the court held that the failure to disclose a Form 483 will usually be insufficient, standing alone, to raise a strong inference of scienter. The court granted defendants’ motion to dismiss because the plaintiff failed to allege facts demonstrating “that [d]efendants knew or recklessly disregarded that their statements were misleading in light of the Form 483.”

The court explained that “a Form 483 is a form of interim feedback rather than a final FDA decision on” a new drug application (“NDA”). A Form 483 “lists ‘significant conditions’ that may indicate a drug is being prepared in ways that do not comply with FDA regulations.” Once the FDA issues a Form 483, “the company is then responsible for taking corrective action to address any significant conditions identified.”

In the case before the court, plaintiffs alleged that defendants violated Section 10(b) and Rule 10b-5 by making several statements regarding an NDA without mentioning the company’s receipt of a Form 483. Plaintiffs alleged that the failure to disclose the Form 483 led investors to believe that the NDA would be approved within the year, “even though the Form 483 allegedly demonstrated that approval of the NDA would be delayed beyond that year.”

The court held that the Form 483 was not *per se* immaterial. The court noted that other courts have “reached conclusions covering the entire spectrum on” the materiality of Form 483s. The court found that at the circuit level, “[t]he Eighth Circuit has provided the only clear guidance so far.” The Eighth Circuit has instructed that “the issuance of Form 483s may render a defendant’s statement about its compliance with FDA regulations or [Current Good Manufacturing Practice regulations (“cGMP”)] false, or at least misleading . . . depending on a number of factors, including the number, severity, and pervasiveness of objectionable conditions noted, as well as whether a company has failed to address or correct the deficiencies noted by the FDA.” *Pub. Pension Fund Grp. v. KV Pharm. Co.*, 679 F.3d 972 (8th Cir. 2012). The court found it significant that “[t]he First Circuit has suggested its agreement with the Eighth Circuit’s conclusion.” *Nabriva* slip. op. (citing *In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31 (1st Cir. 2014)). The court further found that “[t]he large number of decisions denying motions to dismiss Section

10(b) claims involving Forms 483 bolsters the conclusion that Forms 483 may be material depending on the circumstances alleged.”

At the same time, the court found that “[b]ecause a Form 483 is interim FDA feedback, there is no standalone duty to disclose its existence.” The court held that defendants’ failure to disclose the Form 483 would “be actionable only if disclosure was necessary to render the statements [at issue] not misleading.” The court noted, for example, that “failing to disclose a recent Form 483 that lists numerous potential cGMP violations could potentially render misleading a company’s statements that is presently in compliance with cGMP violations.” The court found that two of the defendants’ statements at issue “could mislead a reasonable investor” because of the failure to disclose the Form 483.

But the court held that the plaintiff’s allegations were insufficient to raise a strong inference of scienter. The court noted that “knowledge of a Form 483 alone might be enough to render certain statements both misleading and made with scienter” if the “Form 483 . . . clearly contradicts the statement being made (for example, that the company is currently in substantial compliance with cGMP regulations).” But in “the majority of Form 483 cases,” plaintiffs must “rely on additional factual matter to corroborate the allegedly serious nature of the omitted Form 483.” The court explained that “[t]his is not an unduly high pleading requirement,” as there are “a wide variety of ways that a plaintiff might adequately allege a defendant’s failure to mention a Form 483 was reckless.” The court noted, for example, that plaintiffs could point to “a pattern of FDA feedback reflecting the same unresolved concerns,” or “statements by confidential former employees reflecting that the problems identified in the Forms 483 were pervasive enough that they could not be readily remedied.” The court found the “[p]laintiff here pleads no such additional facts, instead relying on the conclusory allegation that the Form 483’s observations alone rendered [d]efendants’ public statements knowingly or recklessly misleading.”

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