

## U.S. District Court for the District of Massachusetts Holds Pharmaceutical Companies Not Required to Disclose FDA Inspectional Observations Made on Form 483

In an important ruling dismissing a comprehensive securities class action complaint against Genzyme Corporation, the U.S. District Court for the District of Massachusetts held last week that regulatory comments and inspectional observations provided by the FDA to pharmaceutical companies like Genzyme – including commentary supplied on FDA Form 483 – are of “questionable materiality” and are not automatically required to be disclosed by regulated issuers. The decision means that the plaintiffs’ bar will not be able to leverage critical comments delivered in the day-to-day give-and-take between the agency and a pharmaceutical company into a securities lawsuit.

Multiple securities class actions were filed against Genzyme in 2009 in the wake of a series of manufacturing and regulatory setbacks. Two Genzyme facilities experienced failures at a key stage in the manufacturing process, ultimately determined to have been caused by a rare virus. Separately, FDA inspections at the Company’s Allston, Massachusetts facility resulted in issuance of a Form 483 and, ultimately, warnings concerning Genzyme’s compliance with the FDA’s current Good Manufacturing Practices (“cGMPs”). Finally, the FDA delayed approval of an important new biologic product, Lumizyme, beyond the date publicly anticipated by Genzyme. The plaintiffs’ 141 page, 364 paragraph consolidated complaint alleged that Genzyme committed securities fraud by making a “daunting number” of purportedly fraudulent statements about these events in order to keep Genzyme’s stock price artificially high. According to the investors, Genzyme deliberately withheld information from the market about the state of its manufacturing facilities, its knowledge of the FDA’s concerns, the likely delayed approval for Lumizyme in light of these issues, and the predicted effect of all of them on production, revenue and net profit. The complaint asserted that the market price for Genzyme stock fell only when Genzyme signed a consent decree with the FDA that disclosed the scope of the problems and the depth of the FDA’s concerns. Among other things, the pleading contended that Genzyme omitted to disclose adverse information about these events that it “knew” based upon correspondence and communications with the FDA, including inspectional observations made on a Form 483.

The Court rejected all of the plaintiffs’ theories of liability. According to the Court, the plaintiffs’ “speculative” effort to tie multiple different events together could not support the required “strong inference” that Genzyme intentionally or recklessly acted to deceive the markets. The Court took note of the fact that throughout the class period, Genzyme disclosed considerable adverse information of the very sort the plaintiffs claimed was concealed. Genzyme’s extensive disclosure of its manufacturing and regulatory problems supported the more plausible inference that Genzyme disclosed what it knew when it knew it, and that was inconsistent with a fraudulent motive to withhold information from investors.

In reaching this conclusion, the Court also held that FDA Forms 483 – common forms expressing FDA inspectional observations of possible regulatory non-compliance – were of “questionable materiality” such that their nondisclosure alone is unlikely to raise an inference of a fraudulent or reckless intent to deceive the market. Judge O’Toole specifically rejected the plaintiffs’ contention that Form 483 observations are required to be disclosed as a matter of law. Instead, the Court noted that the forms are not a “final agency determination,” are subject to change, and are thus of only “questionable materiality.” Importantly, according to the Court, “it simply cannot be that every critical comment by a regulatory agency – even about matters as important as good manufacturing practices – has to be seen as material for securities law reporting purposes . . . .”

The *Genzyme* ruling affirms that the Company's robust disclosures throughout its manufacturing problems and the negotiations that led to its execution of a consent decree with the FDA could not amount to an actionable securities claim, and confirms that securities plaintiffs cannot just string together unrelated and temporally disconnected facts in order to build an inference of fraud. In that respect, the opinion holds plaintiffs to the tough standards of the PSLRA, which requires securities complaints to plead a "strong inference" of fraud with great particularity.

The opinion also has important implications for the life sciences industry. Judge O'Toole's conclusion that FDA observations on Forms 483 were not required to be disclosed as a matter of law strengthens a growing judicial consensus that critical regulatory comments are not necessarily disclosure events. That holding should give comfort to pharmaceutical companies and other issuers regulated by the FDA that their constant give-and-take with the agency will not permit plaintiffs to leverage some criticism into a securities case.

The Ropes & Gray litigation team representing Genzyme in this case was led by partners [John Donovan](#) and [Rob Jones](#).