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## PERSPECTIVE

## Life sciences companies under attack by plaintiffs' bar

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**L**ife sciences companies remain under attack by the class action securities plaintiffs' bar. According to Cornerstone Research, at midyear the number of filings against pharmaceutical companies already had eclipsed the 2016 total. A similar trend was observed at other life sciences companies. Given the number of biotechnology and other life sciences companies located in California, securities claims relating to their disclosures are frequently litigated in California federal courts.

A common trigger for significant stock movements regarding pharmaceutical, medical device and other life sciences companies is release of information regarding clinical trials or discussions regarding product clearance with the Food and Drug Administration. Several courts recently have addressed allegations that a company's statements about ongoing trials were false or misleading because they did not accurately report information about the design of the trials or the results of the studies, including interim results reported before the studies concluded. In these cases, a number of defendants have been able to prevail on motions to dismiss where the plaintiffs have not adequately pleaded either that (1) the statements actually were false or misleading at the time that the defendants made them, or (2) there was a strong inference of the defendants' scienter (or both).

On Aug. 18, the 9th U.S. Circuit Court of Appeals issued an opinion in *In re Atossa Genetics Inc. Securities Litigation*, 2017 DJDAR 7966. In an opinion authored by Judge Ronald Gould, the court affirmed in part, reversed in part, and vacated in part the district court's dismissal of a class action complaint alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act.

The decision turned on factual and opinion statements by the company and its chairman and chief executive officer regarding a cancer screening system. The FDA had cleared a sample collection device in a premarket notification procedure. But the plaintiffs alleged that the company then marketed the device as part of a diagnostic cancer-detection system, and in conjunction with other, unapproved diagnostic tools. The panel found that a number of the defendants' statements about FDA approval — as well as later statements about concerns that the FDA had expressed regarding the company's marketing — were misstated or omitted material information that a typical investor would have wanted to know.

In June, Central District of California Judge James Otero found that statements by biopharmaceutical company CytRx Corporation and its executives about the effect of an FDA-mandated partial clinical hold on a Phase 3 trial were not actionable because the statements were compatible with the defendants' alleged knowledge at

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the time they made them. Additionally, the court concluded that a number of forward-looking statements about the timeline for completing the trial were protected by the safe-harbor provisions of the Private Securities Litigation Reform Act, because the statements were accompanied by cautionary statements directly related to risks that allegedly materialized.

These are just two recent examples of a flurry of litigation nationwide dealing with similar issues. The most common fact pattern involves claims that companies misled investors by omitting or misrepresenting critical feedback received from the FDA. Courts continue to make clear that companies need not disclose every detail of their communications with or interim feedback from the FDA. But when a company chooses to make positive statements about a product, the regulatory process, or its communications with the FDA, those statements will be scrutinized, both for accuracy and completeness. Disclosing the FDA's most positive comments while omitting its more negative ones is perilous.

Even opinion statements are not always insulated from attack. To be clear, a number of companies and executives have prevailed on motions to dismiss claims that they were overly optimistic in public statements regarding the likelihood of securing regulatory approval for a product. Courts have continued to hold that optimistic statements about the prospects for obtaining FDA approval are not actionable where they are based on an honest belief with a reasonable basis (i.e., are not knowingly false or misleading) or qualify as forward-looking statements accompanied by cautionary statements about the specific risks related to the reported prospects.

But executives should understand that while opinion statements are necessarily harder to chal-

lenger than factual ones, the protection afforded to opinions is not unlimited. Those involved in formulating corporate disclosures should ask themselves what a "typical investor" would want to know about information that the FDA has conveyed. Although a company may need to provide context to help investors understand an FDA-imposed setback, the company and its counsel need to be vigilant to ensure that disclosures provide a fair summary of all available facts. Subjective optimism, even when the speaker truly believes that the setback is manageable, may not be sufficient to defeat a motion to dismiss subsequent securities fraud claims. The goal is to avoid a later accusation that the company engaged in strategic, selective disclosures.

Because it is often easier for companies to defend opinions than assertions of fact, companies should take care to make clear when they are offering one versus the other. Indeed, companies should try to avoid combining factual assertions with statements of opinion, wherever possible.

Finally, executives should understand that while general corporate risk factors that appear in disclosure documents matter, they are not a get-out-of-jail-free card. Where possible, risk factors should be tailored to actual facts, and should be reviewed and updated over time for changing circumstances. Moreover, a general risk factor will not shield a speaker or company from liability where they have specific information that creates a particular, undisclosed risk. For instance, a simple disclosure that the FDA may not approve a drug, or that the government may conduct an investigation, could be construed to be misleading where the company already possesses concrete information about the approval process or the existence of an ongoing inquiry.

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