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Rise In Securities Class Action Filings In Life Sciences Sector

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LAST YEAR PROVED TO BE ANOTHER record period for securities class actions, with a 13% increase in cases filed compared with 2018, and a 24% increase in claims brought against life sciences companies compared with 2018, according to a report by Cornerstone Research*: Securities Class Action Filings: 2019 Year In Review*.

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There were more than three dozen court decisions involving life sciences companies in 2019, nine of which related to statements about clinical trial results. Courts dismissed six of these cases at the pleading stage based on the Private Securities Litigation Reform Act of 1995 (PSLRA), while the other three are ongoing.

The stakes associated with defending against litigation past the dismissal stage are high, as evidenced by *Hsu v. Puma Biotechnology, Inc*. (C.D. Cal.) – the first securities class action to reach a jury verdict in nearly a decade – in which the jury returned a unanimous defense verdict on the majority of the plaintiffs' claims attacking Puma's disclosures regarding its successful Phase III trial. An analysis of 2019 court decisions at the critical motion-to-dismiss stage provides useful guidance for public life sciences companies preparing to discuss or disclose clinical trial results.

Courts evaluated risk factors and other public information to assess statements about clinical trial results. In *Celgene Corp. Securities Litigation*, 2019 WL 6909463 (D.N.J. Dec. 19, 2019), the fact that the company had already publicly disclosed the allegedly concealed facts was sufficient to defeat a securities claim premised on that alleged omission. Celgene had publicly announced that its drug was "a potentially transformative therapy" that "offered a potential new path to break into the lucrative IBD [irritable bowel disease] market." The plaintiff alleged that these statements were materially misleading because they were unsupported by existing scientific data. But because the company had already disclosed that it lacked endoscopic data for its Phase II trial and a control group for its Phase Ib study, any reasonable investor would have already known about the lack of data.

Disclosures about the risk that interim data might change may not shield a company from liability, however. In *Khoja v. Orexigen Therapeutics, Inc*., 2019 WL 4599882 (S.D. Cal. Sept. 23, 2019), the company had warned investors about the preliminary nature of the interim results of a clinical trial. Nevertheless, the court permitted the case to proceed against two executives because, at the time they were touting the positive results of the interim data, they allegedly knew but failed to disclose that the Food & Drug Administration had informed them that the data had a "high degree of uncertainty and were likely to change with the accumulation of additional data." Taking this allegation as true (as required at the early dismissal stage of the case), the court concluded it would be misleading to discuss the

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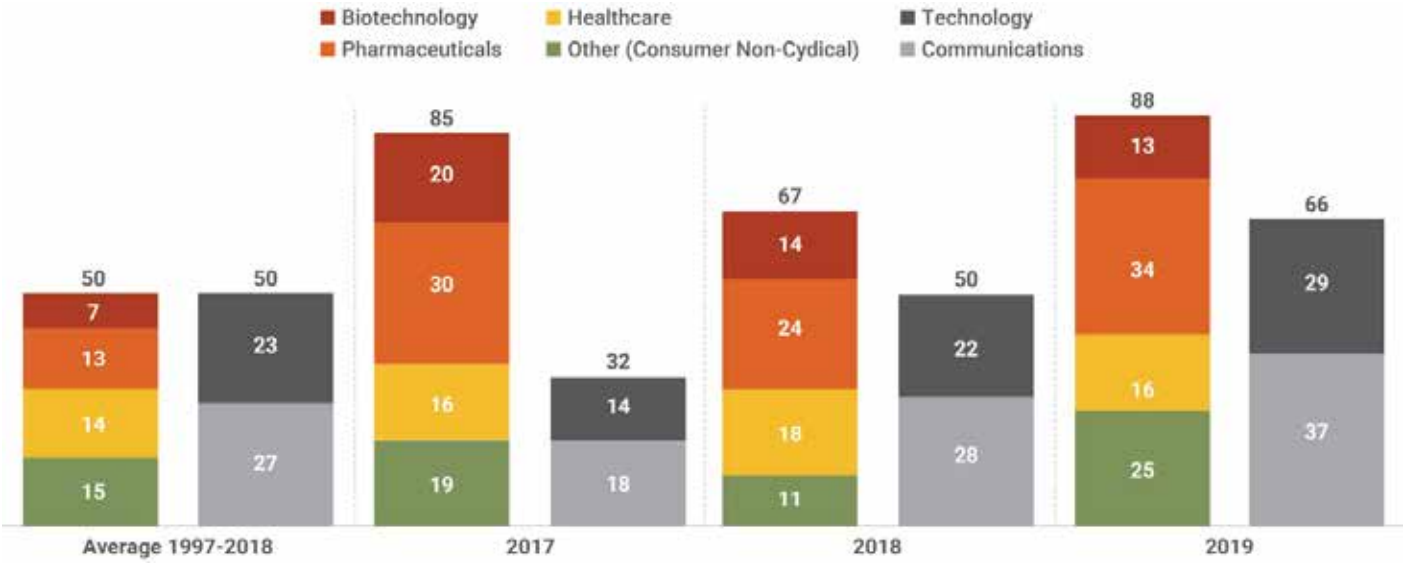

NOTES: 1. SECTORS AND SUBSECTORS ARE BASED ON THE BLOOMBERG INDUSTRY CLASSIFICATION SYSTEM. 2. THE "OTHER" CATEGORY IS A GROUPING PRIMARILY ENCOMPASSING THE AGRICULTURE, BEVERAGE, COMMERCIAL SERVICES AND FOOD SUBSECTORS. 3. AVERAGE FIGURES MAY NOT SUM DUE TO ROUNDING.

SOURCE: CORNERSTONE RESEARCH

positive results without also disclosing their unreliability. Orexigen's risk factors were not sufficient because telling investors the interim data might change with additional results was not the same as telling them that the data were highly uncertain and likely to change.

The court in *Micholle v. Ophthotech Corp.*, 2019 WL 4464802 (S.D.N.Y. Sept. 18, 2019), also allowed the case to proceed notwithstanding the company's disclosure that it had modified the methodology for determining enrollment eligibility for its Phase III trial. The court accepted the plaintiff's allegation that the disclosure failed to reveal that this change significantly affected the enrollment criteria by including a patient population that was excluded in Phase II. Particularly given other statements by the company and its executives that there were "no meaningful changes" to the enrollment criteria and that the changes were not "material or significant in any way."

Opinion Versus Fact

Some courts construed statements interpreting clinical trial results as non-actionable opinion statements. In *Lehmann v. Ohr Pharmaceutical Inc.*, 2019 WL 4572765 (S.D.N.Y. Sept. 20, 2019), the court held that a dispute about the proper interpretation of clinical trial results as compared to prior comparable studies did not state a claim for securities fraud. In this case, the plaintiffs complained that the defendants' positive statements about the interim and final results of a Phase II clinical trial – which later failed in Phase III – were materially misleading because the defendants failed to disclose that the trial had not performed consistently with prior comparable studies. The court cautioned against the "Monday morning quarterback[ing]" inherent in interpreting the Phase III trial's ultimate failure as evidence that the company's prior opinion statements were false or misleading. Notwithstanding the plaintiffs' view that the company should not have proceeded with the Phase III trial given the aberrant Phase II results, the court declined to "adopt a rule that discourages free scientific inquiry in the name of shielding investors from risks of failure."

The court in *Nguyen v. New Link Genetics Corp.*, 2019 WL 591556 (S.D.N.Y. Feb. 13, 2019), rejected claims that a company's statements characterizing prior clinical trials

as a basis for its own study design and results were misleading. The court emphasized that the statements referred only to results of "major studies," and that, generally speaking, "interpretations of the results of various clinical studies" are a matter of opinion.

In another case, *In re Regulus Therapeutics Inc. Securities Litigation*, 406 F. Supp. 3d 845 (S.D. Cal. 2019), the plaintiffs complained that the company downplayed a potential link between its drug and liver toxicity, by claiming it had not seen any such link in its chronic toxicity studies, without disclosing that it had not adequately investigated existing preclinical and nonclinical data to assess the validity of those statements. The court held the plaintiff to a high burden of identifying particularized facts establishing what the supposedly omitted data were and how the data contradicted the company's statements. Absent those allegations, the court could not evaluate "how and to what extent these purported preclinical and nonclinical results 'suggested a link between [the drug] and liver toxicity,'" and could not conclude the statements were sufficiently alleged to be false.

The plaintiff's insufficient pleading likewise resulted in dismissal of claims regarding the interpretation of clinical trial results in *Biondolillo v. Roche Holding AG*, 2019 WL 1468140 (D.N.J. Apr. 3, 2019). In this case, the plaintiff asserted that the company's executives falsely described the results of a Phase III clinical trial as "showing a significant increase in the standard of care." The court reasoned that because the statements were interpretations of clinical trial results, they were statements of opinion, not fact. No allegations established that the executives did not honestly believe what they were saying or that they lacked a reasonable basis for these statements.

The court also dismissed opinion statement claims in *Bailey v. Esperion Therapeutics, Inc.*, 2019 WL 3296235 (E.D. Mich. Feb. 19, 2019). There, the plaintiffs alleged that the company's opinion statements about its drug candidate's safety and tolerability were false or misleading because the company knew that some patients participating in ongoing Phase II and Phase III trials had suffered fatal adverse events. Yet Esperion had access only to blinded data and did not know whether adverse events were experienced in the control or treatment groups. The court thus held that without specific alleged details regarding known adverse events in the treatment group, the plaintiffs had failed to allege that the defendants intentionally or recklessly misled investors.

What Is Meaningful?

Some courts concluded that nonspecific descriptive statements about clinical trial results were not misleading. Statements characterizing the results of a clinical trial using terms that have no established usage in the industry may be so subjective that they cannot be misleading statements of fact, as required by the securities laws. This inquiry is fact-specific, however, and companies should not assume that using such terms will evade liability. In *Tung v. [C#198601245:Bristol-Myers Squibb Co.]*, 412 F. Supp. 3d 453 (S.D.N.Y. 2019), the court dismissed the plaintiffs' claims challenging the company's statements that a 5% cut-off could be used to define a "strong" expression of PD-L1 (a protein that can prevent the immune system from attacking healthy cells) for its anticancer drug. Even though the company had used a 5% cut-off to define only a "positive" expression in prior studies, the company had never taken the categorical position that the term "strong" required a cut-off of more than 5%, and there was no basis to rely on a competitor's definition of "strong" expression as the industry standard.

Similarly, in *Ohr Pharmaceutical Inc.*, the plaintiffs alleged that the company's description of interim results

ABOUT THE AUTHORS

About the authors: **Michele Johnson** is a partner in the Litigation and Trial Department at Latham & Watkins LLP, specializing in representing public companies, officers and directors, and financial institutions in complex civil litigation matters. **Colleen Smith** is also a partner in the Litigation and Trial Department. She specializes in representing life sciences companies in complex civil litigation matters. And **Amanda Betsch** is an associate in the Litigation and Trial Department, specializing in representing public companies in complex civil litigation matters.

as “clinically meaningful” was misleading because the control arm performed worse compared to prior trials, causing the treatment arm results to appear better than they otherwise would have been. The plaintiffs argued that the defendants should have disclosed that had the control arm results been in line with prior trials, the difference in outcomes between the control and treatment arms would not have been clinically meaningful. The court disagreed, concluding that the term “clinically meaningful” was “legally meaningless” because it had no established definition in the industry.

Given the natural volatility in the life sciences sector, particularly for emerging companies, it is anticipated that plaintiffs will continue to file securities class actions and aggressively pursue claims against life sciences companies. The sector, however, is beginning to see a positive trend in early dismissals of securities class actions as courts acknowledge companies’ robust risk disclosures in connection with key life cycle events.

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