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Avoiding Shareholder Class Actions After FDA Drug Denials

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According to the U.S. Court of Appeals for the First Circuit's opinion in In re: Ariad Pharmaceuticals Inc. Securities Litigation, "When a company's stock declines, a shareholder lawsuit often follows."[1] That maxim rings particularly true for pharmaceutical companies seeking approval from the U.S. Food and Drug Administration for experimental drugs, who often see putative securities class actions filed following an adverse FDA decision.

By searching Westlaw, we found that in the first three quarters of 2020, out of 10 such cases, eight class actions were dismissed on a motion to dismiss or had such a dismissal upheld on appeal, while only two were allowed to proceed.

However, while the majority of such class actions are unsuccessful, it's still useful to understand why pharmaceutical companies are targeted and how executives can manage this risk when discussing the FDA approval process.

Why Plaintiffs Target Pharmaceutical Companies

When the FDA declines to approve an experimental drug, the sponsoring company becomes a tempting target for shareholder plaintiffs for several reasons.

First, the alleged damages, which are measured based on the amount or percentage of the stock price decline following the release of information that cures the alleged fraud, can be substantial.

An unexpected adverse decision by the FDA typically results in an immediate and precipitous price decline because the value of the company, especially smaller companies, is largely or entirely dependent on the chance that an experimental drug will gain FDA approval for marketing and sale in the U.S.

Further, the process of seeking FDA approval involves multiple public disclosures about the drug development and safety testing process. For example, clinical trial results are often published in medical journals; an advisory committee may meet, resulting in a public transcript; and the FDA may publish its reasons for delaying, disputing and ultimately denying approval.

These disclosures provide plaintiffs with many opportunities to take phrases out of context, which they can use to try to overcome the heightened pleading requirements of the Private Securities Litigation Reform Act and Federal Rule of Civil Procedure 9(b).

The good news for pharmaceutical companies is that federal courts are increasingly seeing through plaintiffs' attempts to plead fraud by hindsight. Because the PSLRA imposes a heightened pleading standard on securities fraud plaintiffs, the motion to dismiss is the first major point of inflection for these cases. Cases that survive a motion to dismiss are permitted to proceed to discovery, imposing significant costs on defendant companies.

Managing Litigation Risk When Discussing FDA Approval Process

Pharmaceutical companies must carefully consider public statements about ongoing clinical trials or the FDA approval process. Based on our analysis of recent FDA nonapproval cases that have survived a motion to dismiss, we recommend the following considerations to mitigate this risk.

Avoid statements that can be interpreted as a guarantee of FDA approval.

Statements that downplay the risk that the FDA will not approve a drug expose the speaker and the company to increased liability from shareholder plaintiffs. Companies should be cautioned not to imply to investors that the drug has a clear path for regulatory approval, that approval is a question "not of if, but when," or make similar statements that could be understood as a guarantee of approval.

Avoid providing a firm timeline for FDA approval.

Companies also increase their risk by reporting positive progress toward FDA approval while failing to disclose negative feedback from the FDA, such as an indication that the FDA will require additional clinical data before approval. Notably, in these cases, courts generally find that a duty to disclose the FDA's criticism would not have arisen if the company had not made affirmative representations about the timeline for approval.

Disclose all data contradicting positive statements.

Similarly, courts find fault where pharmaceutical companies fail to disclose underlying data from a trial that contradicts statements about the study's results or the likelihood of FDA approval. A safer course is to not discuss results from studies that have not been reported publicly in press releases or medical journals.

Update generic risk factors regarding FDA approval after receiving negative feedback from the FDA.

Shareholders may successfully argue that a company's generic risk disclosure indicating that FDA approval may not be granted is misleading once the company has access to data indicating that FDA approval is unlikely.

Executives and board members should have Rule 10b5-1 trading plans.

The Private Securities Litigation Reform Act requires plaintiffs to plead a strong inference of scienter, or fraudulent intent. If an insider sells stock shortly before an adverse decision by the FDA, then a plaintiff

will try to use the timing of the sale as evidence of the insider's scienter. But if the insider's stock sales were made pursuant to a trading plan that complies with the requirements under Rule 10b5-1, that strongly cuts against an inference that the sales were made on the basis of inside, adverse information.

Conclusion

While pharmaceutical companies likely cannot avoid shareholder lawsuits seeking to recover from a stock drop following the FDA's decision not to approve a drug, carefully monitoring company statements discussing an experimental drug can reduce the likelihood that this type of lawsuit will present anything more than a nuisance to the company.

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[1] In re Ariad Pharmas., Inc. Secs. Litig., 842 F.3d 744, 748 (1st Cir. 2016).