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Key Securities Litigation Issues For Life Science Cos.

Law360, New York (March 1, 2016, 12:14 PM ET) --


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The life sciences industry has become a priority target for shareholder plaintiff's lawyers. According to Cornerstone Research's 2015 annual study, securities class action filings against pharmaceutical and medical device companies have risen for three consecutive years and accounted for approximately 32 percent of all securities class action filings nationwide during 2015.[1] Many of these cases involve adverse U.S. Food and Drug Administration decisions, clinical holds, unfavorable study results and undisclosed safety or efficacy problems. Fortunately, pharmaceutical and medical device companies can mitigate the risk of securities litigation by implementing prudent disclosure practices and by proactively reviewing their disclosures with outside counsel.

The Duty to Disclose Unfavorable Facts and the Impact of Prudent Disclosure Practices

Many suits against life sciences companies follow a similar template: An unfavorable event — such as an FDA nonapproval or negative study outcome — causes a sudden drop in the stock price. Plaintiffs file suit and attack the company's disclosures in the months or years preceding the stock drop, arguing that the disclosures were overly optimistic and did not adequately warn about skeptical interim comments from the FDA or problems with the study. The company's ability to win a motion to dismiss turns on the divergence between what the company's executives allegedly knew at the time of the disclosures and what they told the market.

One of the core issues in this analysis is materiality: When is an unfavorable piece of news material and when is there a duty to disclose? The Supreme Court has clarified in two recent opinions that while companies do not have an affirmative duty to disclose all material information that an investor might want, a company can be liable for not disclosing material facts that are necessary to prevent the company's affirmative disclosures from being misleading. In Matrixx Initiatives Inc. v. Siracusano, 131 S. Ct. 1309, 1318 (2011), a pharmaceutical company publicly denied that its nasal gel caused users to lose

their sense of smell despite possessing a small number of adverse event reports and knowledge of research suggesting that such a link may exist. The court emphasized that the company did not have a freestanding duty to volunteer the existence of those reports, but undertook a duty to disclose the reports when it publicly stated that any reports of a link were "completely unfounded and misleading." Id. That the number of adverse event reports was arguably not statistically significant did not automatically relieve the company of a duty to disclose, as the company must weigh whether the omitted fact would significantly alter the "total mix" of information from a reasonable investor's perspective rather than from management's perspective. Id. Similarly, in Omnicare Inc. v. Laborers District Council Construction Industry Pension Fund, 135 S. Ct. 1318, 1326-29 (2015), the Supreme Court held that while a company generally cannot be liable for a pure statement of opinion that the company subjectively believes, a company could be liable if it is aware of material facts that would make the statement of opinion misleading. Id.

These opinions have significant consequences for life sciences companies, which frequently confront the ups and downs of the FDA approval process and issues about study design and execution. Many district courts have held that companies do not have a duty to disclose interim FDA communications as long as their public disclosures are sufficiently qualified. The Southern District of New York recently cited a line of cases where "courts have rejected claims of material omissions where pharmaceutical companies did not reveal procedural or methodological commentary, or interim status reports, received from the FDA as to drugs under review," so long as the company's affirmative disclosures do not guarantee success or factually contradict the adverse interim information. In re Sanofi Securities Litigation, 87 F. Supp. 3d 510 (S.D.N.Y. 2015). In the Sanofi case, the court granted the company's motion to dismiss even though the FDA had expressed "misgivings" about the company's reliance on a single-blind study and had advised the company that a "heavier burden of proof" would be required for approval. The court noted that the company never guaranteed approval and that these interim communications were insufficiently pessimistic to disabuse the company of a reasonable expectation that the drug could be approved. More recently, in Vallabhaneni v. Endocyte Inc., the Southern District of Indiana granted a motion to dismiss where the company failed to disclose interim FDA criticism of a Phase 2 study design, noting that "numerous courts have concluded that a defendant pharmaceutical company does not have a duty to reveal interim FDA criticism regarding study design or methodology." No. 1:14-cv-01048-TWP-MJD, (S.D. Ind. Jan. 4, 2016).

Indeed, the unnecessary disclosure of an unfavorable interim event can actually trigger litigation that might never have been filed had the company waited until the appropriate time to make its disclosure. Because many development stage life sciences companies lack significant revenues, the stock market may overreact to interim disclosures that lack sufficient context, thus causing a significant stock price decline and triggering securities class action litigation.

Courts will, however, deny dismissal when a company selectively discloses FDA communications or study results in a manner that is rendered misleading by the omission of material information that would significantly alter a reasonable investor's perception of the facts. For example, in the Delcath Systems Inc. Securities Litigation, the Southern District of New York denied dismissal where the company disclosed a seemingly favorable 7 percent mortality rate for the drug group arm of a Phase 3 study without disclosing that patients in the control group had zero deaths. 36 F. Supp. 3d 320, 332 (S.D.N.Y. 2014). The company also disclosed that the drug caused "similar" side effects as traditional treatment methods, but omitted that the rates of side effects were higher. Id. The court held that these omissions arguably created a more favorable impression regarding the drug's safety profile than the actual facts known to the company would indicate. See id. In KB Partners I LP v. Pain Therapeutics Inc., the FDA allegedly instructed the company that its stability data was insufficient, "required" the company to

submit a minimum of six months of stability data in its resubmitted new drug application (NDA) and directed the company to remove a variable "curing period"[2] before resubmitting the NDA. Case No. A-11-CA-1034-SS, (W.D. Tex. Dec. 1, 2015). The company allegedly resubmitted the NDA without including at least six months of stability data and without fully removing the variable curing period. In its public disclosures, the company stated that it resubmitted the NDA "in response to" the FDA's initial complete response letter, that "[t]he FDA has not requested or recommended additional clinical efficacy studies prior to approval" and that the FDA "did ask us for more detailed stability work, which was done in the interim between 2008 and 2010," but did not disclose that the resubmitted NDA allegedly failed to comply with the FDA's specific requests for six months of stability data and the elimination of the variable curing period. Id. at *9-10. The court held that these statements were potentially actionable given that the company allegedly knew it failed to comply with the FDA's instructions regarding the stability data before resubmitting the NDA.

Conclusion

Given the recent uptick in securities lawsuits against the life sciences industry, it is more important than ever for pharmaceutical, biotech and medical device companies to exercise caution in making disclosures regarding the progress of new products under development as well as potential risks associated with products currently on the market. Life sciences companies should be particularly wary of making selective disclosures of favorable information that omit negative details that would create a materially different impression for investors if those facts were included. Counsel should carefully read each proposed disclosure in the context of the company's prior statements to make sure that the total mix of information does not leave a misleading impression of the prospects for a successful outcome. The Securities and Exchange Commission and numerous courts have further emphasized that companies should provide specific risk disclosures rather than mere boilerplate disclosures about regulatory risk or safety issues. This includes an obligation for SEC registrants under Item 303 of Regulation S-K to disclose specific known trends or uncertainties that are reasonably expected to have a material impact on net sales, revenues or income. Avoiding selective disclosures and including more specific risk disclosures can increase a company's ability to defeat any shareholder suits that may be filed.

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[1] "Securities Class Action Filings: 2015 Year in Review," Cornerstone Research.

[2] The "curing period" was a three or six month block of time after bottling of the drug during which it would be held before stability testing would begin.