

Life Sciences and Securities Litigation: Recurring Securities Fraud Risks in Garnering FDA Approval

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Summary

- Life sciences companies that depend on FDA approvals to produce and market their core products are frequently subject to securities lawsuits scrutinizing their disclosures during the approval processes.
- Recent securities cases analyzing these issues in detail highlight pitfalls and best practices for drafting accurate disclosures and defending any related securities litigation.



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Companies in the life sciences and other fields that regularly interact with the U.S. Food and Drug Administration (FDA) face a particular recurring risk of securities class action lawsuits. Any company seeking FDA approval for a new product, drug, medicine, or service should exercise care in its public statements and disclosures. If there are any setbacks in obtaining FDA approval, leading to an adverse impact on the company's stock, securities class action plaintiffs will be quick to scrutinize the company's past statements for accuracy regarding the development of its product. Although there is favorable precedent for defendants in these actions, particularly in the Second Circuit, several such cases have proceeded past the pleading stage this year. In-house and outside counsel advising life sciences companies on such disclosures should review these decisions carefully to ensure that they avoid the type of statements found actionable at the pleading stage, discussed below.

Recent Data

In recent years, plaintiffs have filed many complaints against life sciences companies based on setbacks in obtaining FDA approval, and courts have issued many relevant decisions. In 2023, plaintiffs filed at least 15 complaints alleging misstatements about clinical studies or the prospects for FDA approval, as well as many other complaints against life sciences companies related to COVID-19 vaccines or treatments or other regulatory issues with the FDA. The same year, federal courts issued over 20 decisions on those issues. Thus far in 2024, plaintiffs have filed at least 6 new complaints alleging misstatements regarding the prospects for FDA approval, and courts have issued at least 21 decisions related to these issues.

More often than not, defendants are successful in warding off these claims at the pleading stage. Of the 21 decisions issued by federal courts so far this year, 20 have addressed motions to dismiss. Each of those 20 decisions has granted the defendants' motion to dismiss at least in part: Seven have denied part of the motions, while 13 have granted the motions to dismiss in their entirety.

Favorable Law

Defendants' success at the pleading stage is due at least in part to favorable governing law regarding companies' public statements about their hopes for FDA approval. For example, in the Second Circuit, two court of appeals decisions affirming dismissals are instructive. In [Tongue v. Sanofi](#), the court of appeals held that companies making statements about their hopes for FDA approval are not required to "disclose[] FDA feedback merely because it tended to cut against their projections." 816 F.3d 199, 212 (2d Cir. 2016). In other words, "Plaintiffs were not entitled to so much information as might have been desired to make

their own determination about the likelihood of FDA approval by a particular date.” *Id.* [In re Philip Morris Int’l Inc. Securities Litigation](#) further confirmed that “defendants’ statements about the implications of their data cannot be misleading because a regulatory body,” like the FDA, “disagreed with the defendants’ conclusion; rather, so long as the defendants conducted a meaningful inquiry and in fact held the view they expressed, their statements will not be deemed to mislead in a manner that is actionable.” 89 F.4th 408, 421 (2d Cir. 2023).

Surviving the Pleading Stage

While companies seeking FDA approval can take comfort in this case law, they are still subject to scrutiny from securities plaintiffs and their counsel. As the six cases to partially survive motions to dismiss this year indicate, not all such lawsuits fizzle out at the pleading stage. Three of these recent district court decisions are particularly illustrative of how courts may view well-pleaded allegations of materially false and misleading statements regarding the FDA approval process. These cases arose in the District of New Jersey, the Central District of California, and the Southern District of New York—all common forums for such complaints, especially New Jersey, where many large pharmaceutical companies are located.

In *Butala v. Owlet, Inc.*, a district court in the Central District of California addressed a motion to dismiss filed by defendant Owlet, Inc., and related individuals, in a lawsuit alleging that the defendants disseminated materially false and misleading statements about whether Owlet had the necessary FDA approval to market its new product, the “Smart Sock.” 2024 WL 3648141, at *1 (C.D. Cal. Aug. 5, 2024). Although the FDA regulates and requires approval for “medical devices,” in early 2015, the FDA issued guidance indicating that it may not require FDA approval for certain “general wellness products” that present a lower risk to users’ safety. Owlet’s Smart Sock was a type of baby monitor, intended to alert parents of their infant’s breathing, heart rate, and oxygen levels. First, Owlet released a version without “alarm and notification features,” which, in its view, meant that it would not be a “medical device” requiring FDA approval. However, it soon began incorporating those alarm features, which, in essence, constituted notifications to parents about their child’s health.

In 2016, the FDA sent letters to Owlet notifying it that the Smart Sock indeed met the definition of a “medical device.” Owlet did not disclose those notifications publicly; instead, it launched a new version of the Smart Sock that still contained the alarm feature, altered some of its promotional language, and added a disclaimer that the product was not intended to “cure, treat, or prevent any disease or health condition.” The FDA continued to warn Owlet that the Smart Sock was a medical device requiring FDA clearance, but Owlet continued to sell it without such clearance. In October 2021, the FDA issued a public

warning letter requesting that Owlet cease distribution of the Smart Sock, following which Owlet's stock price fell 23 percent. The plaintiffs' Rule 10b-5 lawsuit against Owlet followed, and Owlet moved to dismiss.

The district court denied Owlet's motion to dismiss. The court held that the plaintiffs had adequately alleged material misstatements, such as Owlet's statement in its Form S-4 filed with the Securities and Exchange Commission (SEC) in March 2021 that Owlet's products were being sold "in compliance in all material respects with applicable FDA laws." The Owlet defendants argued that the 2016 FDA letter was not definitive because it "invited Owlet to correspond with the FDA" regarding the classification, portraying Owlet's FDA correspondence as a good-faith dispute that it did not need to disclose. The court disagreed, however, noting that the FDA "[n]ever adopted Owlet's contrary position that the Smart Sock was a general wellness device," and thus Owlet had no good-faith basis for believing it was in compliance with FDA regulations. 2024 WL 3648141, at *5. The court noted that despite the company's subsequent statements that Owlet had communicated its belief to the FDA that the Smart Sock "is not a medical device" and that the FDA could require authorization later, those qualifications "did not accompany the misleading statements." *Id.* at *6.

The court also found a strong inference of scienter because the complaint adequately alleged that "Owlet was facing a 'quintessential Catch-22' between raising funds required to secure FDA approval of its 'flagship' product and selling the product without FDA regulation to raise the capital required to obtain FDA approval." *Id.* at *7. That catch-22 created the strong inference that the Owlet defendants, having been warned by the FDA, intended to mislead the public about the status of the FDA's approval of the Smart Sock. Accordingly, their motion to dismiss was denied.

In another case, a district court in the District of New Jersey granted in part and denied in part motions to dismiss filed by defendant RenovaCare, Inc., and related individuals and entities. *In re RenovaCare, Inc. Securities Litigation*, 2024 WL 2515034 (D.N.J. June 3, 2024). RenovaCare owned an experimental medical device, the SkinGun, used to treat burns. The plaintiffs alleged that the defendants made false and misleading statements and unlawfully manipulated RenovaCare's stock price in a "pump-and-dump" scheme. Central to the alleged scheme was the defendants' concealed use of a third party to run a promotional campaign touting RenovaCare as an investment. Among other things, the promotional campaign claimed "that the SkinGun would be approved by the [FDA] because RenovaCare had submitted a[n approval] application"—even though RenovaCare had submitted no such application. *Id.* at *3. After RenovaCare's involvement in the promotional campaign came to light and its operations came under scrutiny, the defendants doubled down, claiming that they "had no editorial control over the content" of the campaign and were unaffiliated with the campaign's publisher, and reiterating "the

upcoming ‘major milestone’ of an initial FDA filing.” *Id.* at *3, *4. The district court largely sustained the plaintiffs’ claims, holding that they had adequately alleged market manipulation, false statements, and a scheme by defendants to defraud investors.

Finally, in *In re Y-mAbs Therapeutics, Inc. Securities Litigation*, a district court in the Southern District of New York addressed a motion to dismiss a lawsuit alleging that clinical-stage biopharmaceutical company Y-mAbs and its executives made misleading statements about the approval prospects of one of the company’s cancer drug candidates, “Omburtamab.” 2024 WL 451691 (S.D.N.Y. Feb. 5, 2024). In repeated meetings with Y-mAbs before the company submitted its biologics license application (BLA) to distribute the drug, the FDA expressed concern about the usefulness of two studies Y-mAbs conducted without a control group. Despite these concerns, Y-mAbs submitted an initial BLA for Omburtamab in August 2020. The FDA rejected the BLA for failing to “contain substantial evidence consisting of adequate and well-controlled investigations that [O]mburtamab is safe and effective” for its proposed treatment. *Id.* at *2. Subsequently, the FDA continued to inform Y-mAbs that the data were insufficient to support a renewed BLA. In March 2022, Y-mAbs resubmitted its BLA—without FDA approval. In October 2022, the FDA released a document publicly identifying issues with the renewed BLA submission and “highlight[ing] the fact that FDA had repeatedly warned Y-mAbs over the course of years’ about some of these issues.” *Id.* at *4.

Following the rejection of its initial BLA, Y-mAbs made numerous statements about Omburtamab’s progress toward approval that the plaintiffs alleged were misleading in light of the FDA’s repeated warnings. Specifically, Y-mAbs (i) provided several rosy estimates of the timing of the BLA resubmission; (ii) expressed optimism about Omburtamab’s progress toward resubmission; (iii) made numerous statements interpreting the FDA’s feedback and guidance, including that the revised BLA “should satisfy the concerns the FDA” raised and that the FDA “confirmed our path towards our March BLA resubmission” (*id.* at *10); and (iv) made statements regarding clinical trial data relevant to its BLA.

The district court granted Y-mAbs’s motion in part and denied it in part. The court held that categories (i), (ii), and (iv) above were *not* actionable because they were forward-looking statements, mere opinions and statements of optimism, or were *disclosed* disagreements with the FDA about data interpretation. By contrast, the court held that various statements to the effect “that Defendants had in their possession all the information the FDA requested or had resolved all concerns raised by the FDA” were actionable. *Id.* These statements went beyond puffery and were plausibly read to conflict with contemporaneous feedback from the FDA. These conflicts rendered the defendants’ statements materially misleading. Notably, the court reached this conclusion despite the favorable *Tongue* decision from the Second Circuit, which suggested that interim FDA

feedback will often not be material. The district court reasoned that the defendants' public disclosures about their back-and-forth with the FDA showed "that *Defendants* themselves understood that the FDA's feedback was material. Having done this, Defendants were not permitted to disclose this interim feedback in a partial and misleading manner." *Id.* at *11. The conflicts between the FDA's feedback and the defendants' public statements about that feedback were also sufficient to allege scienter.

Conclusion

In sum, while life sciences companies can take some comfort in favorable case law regarding securities fraud allegations arising from FDA-related disclosures, they must exercise care in their public disclosures about FDA interactions, including adding sufficient cautionary language and identifying instances where statements are forward-looking. In particular, companies should avoid disclosures that could plausibly be read to contradict warnings or feedback previously received from the FDA, which may give rise to allegations sufficient to survive a motion to dismiss. In-house and outside counsel advising life sciences companies on these issues and assisting with drafting SEC filings and related disclosures should carefully review any prior FDA correspondence about key products to ensure that disclosures accurately represent the full scope of any related regulatory developments.

Endnotes

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