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Inside the Courts
An Update From Skadden Securities Litigators

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Ninth Circuit Holds That Courts Should Scrutinize Economic Plausibility of Securities Fraud Complaints in Evaluating Scienter

On June 10, 2020, the Ninth Circuit affirmed the dismissal of a putative securities fraud class action in a potentially significant decision for securities defendants, particularly those in the pharmaceutical, biotech and medical device space. The Ninth Circuit in *Nguyen v. Endologix, Inc*., No. 18-56322, 2020 WL 3069776 (9th Cir. June 10, 2020), held that the plaintiff's theory that a medical device manufacturer misled investors about its product's prospects for approval by the U.S. Food and Drug Administration (FDA) was too illogical to support the strong inference of scienter required to state a securities fraud claim. In doing so, the court held that lower courts should carefully scrutinize the economic plausibility of a securities plaintiff's fraud theory and reject allegations that do "not resonate in common experience," potentially giving securities defendants a powerful tool to resist meritless claims, particularly where the plaintiff fails to plead any motive to commit fraud.

Endologix is a publicly traded medical device manufacturer that focuses on treating disorders of the aorta. In 2013, the company obtained approval from European regulators to market a stent-like device called Nellix, which was used to treat aneurisms, and subsequently began seeking FDA approval to market Nellix in the United States. Over the next several years, Nellix allegedly encountered problems with "migration" (*i.e*., the device shifted its position within the body) in a subset of European patients with complex anatomies.

Throughout 2016, Endologix executives made a number of optimistic public statements predicting that the FDA would approve Nellix in a matter of months, allegedly in spite of knowing that Nellix's migration issues would likely pose an obstacle to approval. In late 2016, Endologix announced that the FDA had decided to require two years of additional clinical data before considering Nellix for approval, causing Endologix's stock price to drop. Several months later, Endologix decided to abandon its efforts to obtain FDA approval for Nellix altogether, resulting in another stock price drop. After this latter announcement, an Endologix investor brought suit in the Central District of California, alleging that the company and its executive officers had defrauded investors by representing that Nellix was likely to receive FDA approval while allegedly knowing all along that approval would be unlikely. The plaintiff buttressed her allegations

with confidential witness statements purportedly made by the company's former head of research and development. The district court dismissed the complaint with prejudice for failure to plead allegations creating a strong inference of scienter.

The Ninth Circuit affirmed. The court held that the "central theory of the complaint" — "that defendants knew the FDA would not approve Nellix, or at least that it would not do so on the timeline defendants were telling the market," but deliberately misled the market about Nellix's prospects for approval — did "not make a whole lot of sense." The court found it implausible that the "company would promise FDA approval that it knew would not materialize," particularly where the company had spent significant time and money to develop Nellix and secure its approval, and where there were no allegations that the defendants sold stock or otherwise capitalized on the alleged fraud before the "inevitable fallout." The Ninth Circuit held that the plaintiff's confidential witness allegations did not cure these deficiencies where the witness statements were long on "alarming adjectives" but lacked "any detail about the supposed device migration problems that Nellix encountered in the European channel." Taking the complaint's allegations holistically, the court held that the plaintiff's theory of fraud did "not resonate in common experience" and therefore did not satisfy the scienter requirement.

The court's decision is a potentially significant victory for pharmaceutical, biotechnology and medical device companies, which frequently face similar securities fraud allegations when a clinical trial is unsuccessful or when the company encounters problems obtaining FDA approval for its product. The court rejected a common (albeit illogical) securities fraud theory — that a company would lie to investors about an FDA approval process or clinical trial it knew was doomed to fail even though the company did not take advantage of the supposed lie in any tangible way. In so holding, the court's decision arguably provides greater protection for a class of companies frequently targeted by securities plaintiffs. More broadly, the court's holding that the Private Securities Litigation Reform Act "neither allows nor requires [courts] to check [their] disbelief at the door," and that courts should carefully scrutinize the economic plausibility of securities fraud theories where the plaintiff fails to plead any motive to commit fraud, is a potentially powerful weapon for securities defendants of all industries opposing specious allegations of fraud.

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