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Ninth Circuit Affirms Dismissal of Securities Fraud Case Where Pharmaceutical Company Had No Motive to Lie About Likelihood of FDA Approval

Last week, the Court of Appeals for the Ninth Circuit issued a ruling that offers a strong defense to pharmaceutical companies that face securities fraud lawsuits after experiencing setbacks in the FDA approval process. In *Nguyen* v. *Endologix, Inc.*,[1] the Ninth Circuit affirmed the dismissal of a putative securities class action in which the plaintiff alleged that a medical device manufacturer fraudulently expressed optimism that a product would receive FDA approval when, in fact, the company and its executives knew that the FDA would not approve the product. The Ninth Circuit rejected plaintiff's theory because, even assuming defendants had access to negative information, the complaint failed to identify any *motive* for the alleged fraud, such as an allegation that defendants stood to personally profit from concealing the information. The decision reaffirms that courts are likely to find allegations of scienter implausible if the person alleged to have lied had no apparent reason to do so.

Background

Endologix manufactures and sells medical devices to treat abdominal aortic aneurysms. In May 2016, Endologix released positive data after the first year of its FDA clinical trial for a new medical device called Nellix, and expressed optimism that Nellix would be approved by the FDA. In November 2016, however, Endologix disclosed that the FDA would not approve Nellix within the original timeframe, citing increases in "migration" issues—*i.e.*, a positional shift in location after implantation—during the second year of the clinical trial. In May 2017, the company announced that it would not seek FDA approval of Nellix at all and would instead focus on developing a second-generation device.

In January 2017, a putative class of shareholders sued Endologix and its CEO and CFO for securities fraud. The complaint alleged that defendants knew Nellix had experienced migration issues in European patients in 2015 and early 2016, and therefore that "defendants knew the FDA would not approve Nellix."[2] Plaintiff relied primarily on a former employee who purportedly recalled a "stream of complaints and incident reports" about Nellix migration issues beginning in 2015, and two European reports that identified Nellix

1 2020 WL 3069776 (9th Cir. June 10, 2020).

2 *Id.* at *8.

migration issues in 2016.[3] The district court ruled that plaintiff failed to plead a strong inference of scienter and dismissed the complaint. Plaintiff appealed.

The *Nguyen* Decision

The Ninth Circuit panel unanimously affirmed the district court's order and ruled that plaintiff failed to adequately allege scienter. Rejecting the allegations that defendants knew about the past history of migration problems, the Ninth Circuit explained that, absent any allegations that defendants sought to personally profit from concealing the "migration" issues from investors, such as by selling stock, plaintiff's theory had "no basis in logic or common experience" and could not create a strong inference of scienter.[4] The Ninth Circuit relied heavily on a Fourth Circuit decision in which that court similarly found it "improbable that [a company] would stake its existence on a drug and a clinical trial that the company thought was doomed to failure."[5]

The Ninth Circuit also found that the complaint lacked the particularity necessary to demonstrate scienter under the PSLRA's heightened pleading standard. For example, although the complaint relied heavily on anecdotes from a confidential witness, the witness did not provide *specific facts* about the purported device migration issues in Europe, such as how many patients were affected, how far the device was migrating, and whether device migration led to other medical issues. Nor did the two European reports cited in the complaint support an inference of fraudulent intent; one report was explicitly acknowledged and discussed by defendants during an investor call, and the other concerned only a single patient.

Ultimately, the Ninth Circuit determined that "[t]he more plausible inference to be drawn from the allegations in the complaint is that defendants made promising statements about the timing of FDA approval based on the initial results of the U.S. clinical trial, but then modulated their optimism when the results began to raise more questions."[6]

Implications of the *Nguyen* Decision

The Ninth Circuit's decision reaffirms that scienter is a high bar to satisfy in lawsuits alleging setbacks in the FDA approval process, particularly where no motive to defraud shareholders has been identified. The decision correctly recognizes that pharmaceutical companies and their executives, like investors and the general public, *want* new drugs and medical devices to receive FDA approval and to become available for the successful treatment of patients on the fastest practicable timeline. Undue optimism cannot be conflated

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3 *Id.* at *10.

4 *Id.* at *1.

5 *Cozzarelli* v. *Inspire Pharmaceuticals Inc.*, 549 F.3d 618, 627 (4th Cir. 2008).

6 *Nguyen*, 2020 WL 3069776, at *11.

with intent to defraud. The Ninth Circuit's decision also reinforces the "exacting" requirement that securities fraud be pleaded with particularity.[7] Complaints that rely on confidential witness statements and reports must provide *specific details* showing that the allegedly adverse information was known to the individual defendants who made the allegedly false and inconsistent public statements. In that sense, the *Nguyen* decision echoes the Second Circuit's recent decision in *Jackson* v. *Abernathy*, which significantly heightened the pleading burden for plaintiffs attempting to plead scienter through low-level employees who are not alleged to have information about the intent of senior management or any role in preparing public disclosures.

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[7] *Id.* at *8 (citing *Zucco Partners, LLC* v. *Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009)).

This memorandum is not intended to provide legal advice, and no legal or business decision should be based on its content. Questions concerning issues addressed in this memorandum should be directed to:

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