

Fourth Circuit Holds that False Claims Act Requires Allegations of Specific False Claims Where a Scheme Merely Alleges that Such Claims Were Possible

Patterson Belknap Secures Win for Pharmaceutical Client

In a decision last week addressing the pleading demands for complaints filed under the False Claims Act ("FCA"), the U.S. Courts of Appeals for the Fourth Circuit rejected the relator's¹ request to apply a more lenient pleading requirement in cases in which a relator is unable to show that actual false claims were submitted for government reimbursement. This decision is likely to have a significant impact on FCA cases pending in the Fourth Circuit, and will give FCA defendants nationwide a clear, well-reasoned decision to cite in support of motions to dismiss claims for failure to plead actual false claims with particularity.

In *United States ex rel. Nathan v. Takeda Pharmaceuticals North America, Inc.*, -- F. 3d ----, 2013 U.S. App. LEXIS 765 (4th Cir. Jan. 11, 2013), the Court reviewed the dismissal of claims brought by a relator who alleged that his employer, Takeda Pharmaceuticals, engaged in off-label marketing in connection with the promotion of Kapidex,² a proton pump inhibitor approved to treat gastroesophageal reflux disease (GERD) and erosive esophagitis (EE). Declining to adopt a more lenient application of Rule 9(b), the Fourth Circuit set forth a strict pleading standard for FCA plaintiffs:

[W]hen a defendant's actions, as alleged and as reasonably inferred from the allegations *could* have led but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment. To the extent that other cases apply a more relaxed construction of Rule 9(b) in such circumstances, we disagree with that approach.

2013 U.S. App. LEXIS 765 at *14 (emphasis in original). The Court found that the particularity requirements of Rule 9(b) may apply with "particular force in the context of the Act, given the potential consequences flowing from allegations of fraud by companies who transact business with the government." *Id.* at *10.

In a unanimous published opinion, the Fourth Circuit affirmed the dismissal of Nathan's complaint, holding that Nathan's claims failed to meet the pleading requirements of Rule 9(b). The court noted that Nathan "fail[ed] to state any plausible allegation connecting [] general statistics" regarding prescription practices to off-label prescriptions submitted for government reimbursement. *Id.* at *19. Finally, Nathan's citation to prescriptions submitted to government reimbursement programs relied on "generalized statistics" and did not "constitute plausible allegations that Takeda caused presentment of a false claim to the government." *Id.* at *21-22.

¹ The plaintiff in FCA matters is referred to as a *qui tam* relator.

² Kapidex is now called Dexilant. The amended complaint and the Fourth Circuit's decision refers to the drug exclusively as Kapidex.

In its rejection of Nathan's arguments, the court articulated a clear, strict pleading standard for FCA plaintiffs who attempt to circumvent the pleading requirements of Rule 9(b). The court emphatically rejected Nathan's claim that a *qui tam* relator "need only allege the existence of a fraudulent scheme that supports the inference that false claims were presented to the government for payment." *Id.* at *9. Instead, the court adopted Takeda's position that "liability under the Act attaches only to false claims actually submitted to the government for reimbursement." *Id.* at *13. In the absence of specific false claims, the court may not "infer that a Medicare patient who has received a prescription for an off-label use actually filled the prescription and sought reimbursement from the government." *Id.* at *23.

Patterson Belknap represented Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America Inc. The Patterson Belknap team included William Cavanaugh, Daniel Ruzumna, Sean Murray, and Aileen McGill.

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