Fourth Circuit Rejects Inferential Pleading in False Claims Act *Qui Tam* Suit Regarding Off Label Marketing

Last month the Fourth Circuit issued a decision that alters the landscape of rulings regarding pleading requirements for an off label promotion claim under the Federal False Claims Act (FCA). In *US ex rel. Nathan v. Takeda Pharmaceuticals North America, Inc.*, No. 11-2077, 2013 WL 136030 (4th Cir. Jan. 11, 2013), the Fourth Circuit affirmed the district court's dismissal of a relator's *qui tam* complaint alleging that the pharmaceutical manufacturer engaged in off label marketing of its heartburn medication Kapidex, resulting in the submission of false claims for reimbursement in violation of the FCA. In dismissing relator's claim, the Court rejected the notion that relator could satisfy Rule 9(b)'s heightened standard by pleading only the existence of an off label promotion scheme without plausibly alleging that particular, identifiable false claims were actually presented to the government.

The Decision

A former Takeda sales manager filed a *qui tam* complaint alleging that Takeda engaged in off label marketing by: (1) promoting Kapidex to rheumatologists, who typically do not treat patients with the two conditions for which the FDA has approved the drug; and (2) providing doctors with samples of only a high Kapidex dose leading doctors to prescribe the high dosage for unapproved conditions. Judge Trenga from the Eastern District of Virginia dismissed the complaint because it failed to allege the "presentment" of a false or fraudulent claim to the federal government for payment under 31 U.S.C. § 3729(a)(1)(A) of the FCA and failed to adequately allege that Takeda caused doctors to write off label prescriptions. On appeal, the Fourth Circuit affirmed primarily on the presentment question, finding that the complaint's "inherently speculative" allegations failed under Rule 9(b)'s specificity requirement to demonstrate that false claims were actually presented to the government.

The Fourth Circuit explained that to satisfy Rule 9(b) "a relator must allege with particularity that specific false claims actually were presented to the government for payment." Without injecting "some indicia of reliability" into the complaint by tying the alleged off label marketing practices to claims that were "actually" presented, relator's complaint "could have led, but need not necessarily have led, to the submission of false claims." The court rejected relator's argument that he need only plead the existence of a fraudulent off label promotion scheme rather than plausibly allege that particular identifiable false claims were actually presented.

Applying this standard, and distinguishing cases in which the alleged fraud "necessarily" led to the submission of false claims, the court rejected the four categories of allegations in relator's amended complaint. First, allegations of off label promotion of Kapidex to rheumatologists fell "far short" because relator did not allege that the targeted rheumatologists wrote any off label prescriptions that were submitted to the government for payment, "a critical omission" in an FCA case. Second, the court rejected relator's allegation that false claims must have been presented because 16 doctors who received only high dosage samples of Kapidex wrote 98 prescriptions that were submitted to the government. The court rejected this "implausible inference linking general statistics to the 98 prescriptions for Kapidex," because relator did not allege directly that any of the 98 prescriptions were for off label uses. The court found that relator's third set of allegations—that about 9,000 prescriptions were submitted to the government for reimbursement in two sales districts—failed because they did not include the dosages of the prescriptions, the types of doctors issuing them, the types of illnesses for which the prescriptions were issued, or whether these doctors had received samples from defendants. Finally, the court analyzed the affidavits submitted by relator of doctors who claimed that they prescribed high dosage Kapidex to treat an unapproved condition in Medicare patients. The doctors averred that they were unaware that the drug was available in lower doses because of defendants' sampling practices. The court rejected these allegations because they did not include the approximate dates on which the prescriptions were written,

the patients for whom they were written, whether patients ever filled them, and whether the prescriptions resulted in reimbursement requests to the government.

Conclusion

The Fourth Circuit's decision adds to the debate among circuits as to what level of specificity Rule 9(b) requires in the FCA context. Recent decisions indicate a spectrum of views: from strictly requiring a claim in hand; to requiring relator to plead representative examples of the claims; to requiring relator to plead an underlying fraudulent scheme in a way that leads to a strong inference that actual false claims were submitted to the government. *See, e.g.*, *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1326 (11th Cir. 2009) (rejecting relators' statistical inferences and rejecting relators' claims under Rule 9(b) because "the Complaint does not allege the existence of a single actual false claim") (citing *U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311-12 (11th Cir. 2002)); *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 308 (3d Cir. 2011) ("[T]he question of whether a plaintiff, at the pleading stage, must identify representative examples of specific false claims that a defendant made to the Government in order to plead an FCA claim properly, is a requirement under the more particular pleading standards of Rule 9(b)."); *Ebeid ex rel. US v. Lungwitz*, 616 F.3d 993, 998-99 (9th Cir. 2010) ("[I]t is sufficient to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.") (quotation omitted). The Fourth Circuit's decision in *Nathan* adds weight to the stricter end of the spectrum by rejecting the more "relaxed" pleading standards in some other circuits and by rejecting relator's attempt to rely on statistics instead of actual false claims.

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