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CLIENT ALERT

Supreme Court Declines to Opine on Circuit Split Over Rule 9(b) Pleading Requirements for FCA Claims

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On March 31, 2014, in *U.S. ex rel. Nathan v. Takeda Pharmaceuticals North America*, the Supreme Court of the United States declined to review a decision by the U.S. Court of Appeals for the Fourth Circuit upholding a district court's dismissal of False Claims Act ("FCA") allegations for failure to plead fraud claims with the level of particularity required by Federal Rule of Civil Procedure 9(b).[1] The Supreme Court's inaction leaves intact the circuit split on applying Rule 9(b) to FCA claims, as well as the attendant uncertainty among health care providers, life science companies, and any others litigating FCA actions. Because circuit courts of appeal embrace different standards for applying Rule 9(b), it is critical that litigants pursuing or defending FCA actions remain mindful of the applicable jurisdiction's approach—as circuit choice may have a dispositive difference at the motion-to-dismiss stage. Moreover, because the Fourth Circuit's *Nathan* decision deepens the circuit split on applying Rule 9(b) to FCA claims, litigants may find it easier to establish grounds for interlocutory appeal under 28 U.S.C. § 1292(b).

Mechanics of Rule 9(b)

Rule 9(b) provides that "[i]n alleging fraud," a "party must state with particularity the circumstances constituting fraud." Although courts generally agree on Rule 9(b)'s theoretical implications—namely, that the plaintiff must marshal facts sufficient to show the "who, what, when, where, and how" of the alleged fraud—courts remain divided on how to apply this heightened pleading standard.[2] Rule 9(b) not only challenges a plaintiff to present particularized evidence that fraud was occurring, but also places concomitant pressure on the remaining components of the plaintiff's prima facie FCA

[1] U.S. *ex rel.* Nathan v. Takeda Pharms. et al., 707 F.3d 451 (4th Cir. 2013), *cert. denied*, 81 U.S.L.W. 3650 (U.S. Mar. 31, 2014) (No. 12-1349).
[2] *See* U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 903 (5th Cir. 1997).

claim—such as whether there was a direct nexus between the alleged misconduct and the resulting claim submitted for federal health care program payment.

The Circuit Split on Applying Rule 9(b)

While all circuits require *qui tam* complaints to allege fraud "with particularity" consistent with Rule 9(b), circuits are split on the issue of whether "particularity" requires the plaintiff to identify specific false claims that were submitted for payment by a federal health care program.

Reasoning that an actual false claim is "the *sine qua non* of a False Claims Act violation," the Fourth, Sixth, Eighth, and Eleventh Circuits have held that Rule 9(b) requires dismissal of an FCA complaint unless it identifies at the pleading stage at least one claim for payment that, if submitted to the government, is necessarily false.[3] Accordingly, the court in *Nathan* dismissed the complaint under Rule 9(b) because the relator failed to "allege with particularity that specific false claims actually were presented to the government for payment."[4]

The First, Fifth, Seventh, and Ninth Circuits follow a more flexible standard, holding that Rule 9(b) requires an FCA complaint 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."[5] Under this approach, it is not "essential for a relator to produce" in the complaint the "specific request for payment."[6]

Case Background

On May 18, 2011, a relator/sales manager, Noah Nathan, filed a third amended *qui tam* complaint in the U.S. District Court for the Eastern District of Virginia under the False

[3] U.S. *ex rel.* Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301, 1311–12 (11th Cir. 2002), *cert. denied*, 537 U.S. 1105 (2003); *see also* U.S. *ex rel.* Bledsoe v. Cmty. Health Sys., Inc., 501 F.3d 493, 504 (6th Cir. 2007); U.S. *ex rel*. Joshi v. St. Luke's Hospital, Inc., 441 F.3d 552, 560 (8th Cir.), *cert. denied*, 549 U.S. 881 (2006).

[4] 707 F.3d at 457.

[5] U.S. *ex rel.* Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009); *see also* U.S. *ex rel.* Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 29 (1st Cir. 2009), *cert. denied*, 130 S. Ct. 3454 (2010); U.S. *ex rel.* Lusby v. Rolls-Royce Corp., 570 F.3d 849, 854–55 (7th Cir. 2009); Ebeid *ex rel.* U.S. v. Lungwitz, 616 F.3d 993, 998–99 (9th Cir.), *cert. denied*, 131 S. Ct. 801 (2010). Interestingly, though the First Circuit has traditionally been identified as applying the more flexible standard, that trend may be shifting. On December 6, 2013, in U.S. *ex rel.* Ge v. Takeda Pharmaceutical Co., the First Circuit affirmed the district court's dismissal of the relator's complaint, finding that the relator had alleged, "at most, aggregate expenditure data for one of the four subject drugs, with no effort to identify specific entities who submitted claims or government program payers, much less times, amounts, and circumstances." *See* 737 F.3d 116, 124 (1st Cir. 2013). The First Circuit in *Ge* cited with approval the Fourth and Eleventh Circuits—circuits known for applying the more stringent Rule 9(b) interpretation. *See id.* at 125 (citing United States *ex rel.* Nathan v. Takeda Pharms. et al., 707 F.3d 451, 457 (4th Cir. 2013) and United States *ex rel.* Atkins v. McInteer, 470 F.3d 1350, 1359 (11th Cir. 2006)).

[6] *Lusby*, 570 F.3d at 854.

Claims Act, 31 U.S.C. § 3729.[7] Nathan alleged that his employer, Takeda Pharmaceuticals, violated the FCA by knowingly causing prescriptions of Kapidex (now known as Dexilant), a drug which suppresses production of stomach acid, to be written for off-label uses and presented to Medicare and Medicaid for reimbursement.[8] Nathan alleged that Takeda was urging doctors to prescribe 60-milligram doses of Kapidex to gastroesophageal reflux disease ("GERD") patients because it believed that a 60-milligram dose was more effective in treating GERD than the 30-milligram dose specified in the U.S. Food and Drug Administration-approved labeling.[9] Because Takeda's actions had caused doctors to write prescriptions for unapproved uses, and because some of those prescriptions had likely gone to patients covered by Medicare and Medicaid, Nathan alleged that false claims resulted when those patients or their health care providers sought reimbursement from federal health care programs.[10]

Nathan's argument failed under Rule 9(b) because it relied on statistical inference instead of identifying specific false claims submitted for payment. For example, Nathan alleged that, out of a sample of 98 prescriptions written by 16 primary care physicians, it was reasonable to infer that more than 90 percent of the 98 prescriptions were for the off-label 60-milligram doses because the 16 physicians identified had received only 60-milligram samples of Kapidex and because 90 percent of all Kapidex sales are of 60-milligram doses.[11] The complaint failed under Rule 9(b) because, *inter alia*, Nathan failed to produce any prescriptions or submissions to the government for payment, and he failed to plausibly allege that the prescriptions were written based on anything other than the physicians' independent judgment (i.e., that Takeda's alleged off-label promotion of the drug induced physicians to write the prescriptions).

In affirming the district court and declining to adopt a more flexible pleading standard, the Fourth Circuit articulated the following standard for plaintiffs pleading FCA claims under Rule 9(b):

> [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.[12]

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[7] Third Amended *Qui Tam* Complaint at 8, U.S. *ex rel.* Nathan v. Takeda Pharms. et al., No. 1:09-cv-01086-AJT-JFA (E.D. Va. May 18, 2011), ECF No. 73.
[8] *Id.* at 11.
[9] *Id.* at 10–11.
[10] *Id.* at 11–12.
[11] *See* Brief for United States as Amicus Curiae at 6–7, U.S. *ex rel.* Nathan v. Takeda Pharms. et al., No. 12-1349 (2014).
[12] 707 F.3d at 457–58.

Accordingly, the Fourth Circuit dismissed the complaint because the "[r]elator essentially has alleged that some claims must have been presented to the government for payment" because they "frequently and routinely" are.[13]

Following the Fourth Circuit's unanimous opinion, and while Nathan's petition for certiorari was pending, the Supreme Court on October 7, 2013 (for the second time in three years), invited the Solicitor General to express the government's views on the Rule 9(b) particularity issue.[14] Requesting that the Supreme Court deny Nathan's petition, Solicitor General Verrilli observed that the case was "not a suitable vehicle" for resolving the particularity question because the relator's complaint failed to satisfy even the more lenient Rule 8 "plausibility" standard that applies to federal civil complaints generally.[15]

Key Takeaways—Familiarity with Circuit-Specific Rule 9(b) Pleading Standards

Litigants pursuing or defending *qui tam* actions must remain attuned to the significant differences in pleading requirements among circuits relative to the Rule 9(b) "particularity" requirement. *Nathan* clarifies the Fourth Circuit's position as aligned with the other circuits requiring FCA relators, as part of Rule 9(b), to meet a more stringent pleading standard and identify a specific false claim that was submitted for payment to a federal health care program (the Sixth, Eighth, and Eleventh Circuit approach). When litigating in circuits applying the more stringent Rule 9(b) standard, defendants should carefully consider moving to dismiss a *qui tam* complaint that fails to identify at least one specific false claim being submitted for federal health care program payment.[16]

Conclusion

Nathan expands the circuit split in applying Rule 9(b) to FCA complaints. Relators alleging FCA violations in the Fourth, Sixth, Eighth, and Eleventh Circuits generally have to clear a more difficult evidentiary hurdle at the pleading stage than relators in the First, Fifth, Seventh, and Ninth Circuits. Relators in the former category may have more difficulty surviving a motion to dismiss, as they are generally required to identify a specific false claim that was submitted for federal health care program payment—a demanding standard when a whistleblower notices fraud but lacks access to submitted claims. And relators in the latter category need not produce a specific request for payment but can generally survive a motion to dismiss by alleging the details of the

[13] *Id.* at 461.
[14] *See* Brief for United States as Amicus Curiae, Ortho Biotech Prods., L.P. v. U.S. *ex rel.* Duxbury, No. 09-654 (2010).
[15] Brief for United States as Amicus Curiae at 11, U.S. *ex rel.* Nathan v. Takeda Pharms. et al., No. 12-1349 (2014).
[16] Another key, though less often employed, takeaway is the possibility of interlocutory appeal. Although denial of a motion to dismiss on Rule 9(b) grounds is normally not immediately appealable, defendants in certain circumstances may move the district court pursuant to 28 U.S.C. § 1292(b) to certify an issue for interlocutory appeal. However, litigants should not presume the right to an interlocutory appeal—they are granted "sparingly and only in exceptional cases" and the court of appeals retains complete discretion to grant or deny permission to appeal. *See In re* City of Memphis, 293 F.3d 345, 350 (6th Cir. 2002).

fraudulent scheme, bolstered by facts leading to a "strong inference" that false claims were submitted.

Because the Supreme Court denied Nathan's petition for certiorari, this split will remain in place until further Congressional or judicial action. In the interim, precedent from the Fourth Circuit, and from other circuits applying the more stringent pleading standard, continues to support the use of Rule 9(b) as a powerful gatekeeping tool.

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