PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 12-4050

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THOMAS FOGLIA,
In the Name of the United States Government pursuant to the False Claims Act, 31 U.S.C. Section 3730; the State of New Jersey False Claims Act, Title 2A of the New Jersey Statutes and Amending 3 P.L. 1968, C. 413; The State of Texas pursuant to TEX.HUM.RES.CODE Sect. 36.001-26.117 and individually pursuant to the New Jersey Conscientious Employee Protection Act, N.J.S.A. 34:19-1 et Seq.,
Appellant

v.

RENAL VENTURES MANAGEMENT, LLC

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On Appeal from the United States District Court
for the District of New Jersey
(D.C. No. 1-09-cv-01552
District Judge: Honorable Noel L. Hillman

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Argued: September 11, 2013

Before: MCKEE, *CHIEF JUDGE*, SMITH, and SLOVITER, *Circuit Judges*

(Opinion Filed: June 6, 2014)

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O P I N I O N

SLOVITER, *Circuit Judge*.

Thomas Foglia appeals the District Court's order dismissing his *qui tam* claim brought under the False Claims Act, 31 U.S.C. § 3729 et. seq. Foglia's complaint arises out of claims submitted or presented to Medicare by Defendant Renal Ventures ("Renal") that Foglia alleges are fraudulent. The District Court dismissed on the ground that the complaint failed to state a claim.[1]

I.

[1] The District Court had jurisdiction over Relator Foglia's federal claims pursuant to 28 U.S.C. § 1331, and over Relator's related state law claim under 28 U.S.C. § 1367. We have jurisdiction pursuant to 28 U.S.C. § 1291. We review *de novo* a district court's grant of a motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). *See Jordan v. Fox, Rothschild, O'Brien & Frankel*, 20 F.3d 1250, 1261 (3d Cir. 1994). We "are required to accept as true all allegations in the complaint and all reasonable inferences that can be drawn from them after construing them in the light most favorable to the non-movant." *Id.* (citations omitted).

Foglia is a registered nurse who was employed with Renal starting on March 13, 2007, and was terminated around November 7, 2008. (App. 34) Renal is a dialysis care services company. (App. 34) Foglia filed a *qui tam* complaint against Renal on behalf of himself as a relator and on behalf of the United States under the False Claims Act ("FCA") in April 2009. (App. 25) The United States chose not to intervene. (App. 25) Foglia filed an amended complaint, and the District Court granted Renal's motion for judgment on the pleadings and gave Foglia twenty days to file a second amended complaint. (App. 67, 29) It was Foglia's second amended complaint ("SAC") that was before the District Court in the proceeding below. (App. 33)

In the argument before us, counsel for Foglia described his claim as in two parts; one was certification and the other was retaliation.[2] He claimed that Renal violated the FCA by falsely certifying that it was in compliance with state regulations regarding quality of care, by falsely submitting claims for reimbursement for the drug Zemplar, and by reusing single-use Zemplar vials. (App. 50-56) The District Court granted Renal's Motion to Dismiss the FCA complaint under Federal Rule of Civil Procedure 12(b)(6) because it

[2] The retaliation claim was not considered by the District Court and is not relevant to this appeal. Foglia also sued under the New Jersey False Claims Act for the same violations and brought suit under the New Jersey Conscientious Employee Protection Act. (App. 56-58) Because Renal had not moved to dismiss Foglia's state law claims, the District Court chose not to exercise supplemental jurisdiction over these claims and dismissed them without prejudice. We therefore need not consider them here.

determined that Foglia had failed to state his claim with the heightened level of particularity required by Federal Rule of Civil Procedure 9(b) for fraud claims. (App. 12-13) In particular, the District Court focused on Foglia's failure to provide a "representative sample" (App. 12) or to "identify representative examples of specific false claims made to the Government." (App. 16) The District Court also determined that even if Foglia's claim had met the requirement of Rule 9(b), Foglia "provided no authority under an express or implied false certification theory that the claims submitted by defendant violated a rule or statute establishing compliance as a condition of payment." (App. 16) The District Court dismissed the SAC with prejudice, stating that it did so in light of the fact that Foglia had twice amended his complaint and had engaged in initial discovery. (App. 22) Foglia here appeals the dismissal of his claim in relation to over-billing on Zemplar.

II.

Before we are able to decide whether Foglia has met the higher pleading requirements set by Federal Rule of Civil Procedure 9(b), and so whether he has stated a claim under Federal Rule of Civil Procedure 12(b)(6), we must first determine what Rule 9(b) requires of an FCA claimant, an issue this court has not had occasion to rule on specifically. Rule 9(b) states, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). However, the various Circuits disagree as to what a plaintiff, such as Foglia, must show at the pleading stage to

satisfy the "particularity" requirement of Rule 9(b) in the context of a claim under the FCA.

The Fourth, Sixth, Eighth, and Eleventh Circuits have held that a plaintiff must show "representative samples" of the alleged fraudulent conduct, specifying the time, place, and content of the acts and the identity of the actors. *See United States ex rel. Noah Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 455-56 (4th Cir. 2013), *cert. denied*, 2014 WL 1271321 (U.S. Mar. 31, 2014) (No. 12-1349); *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 510 (6th Cir. 2007); *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 557 (8th Cir. 2006); *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1308, 1312 (11th Cir. 2002). The First,[3] Fifth, and Ninth Circuits, however, have taken a more nuanced reading of the heightened pleading requirements of Rule 9(b), holding that it is sufficient for a plaintiff 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." *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009); *see also Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998-99 (9th Cir. 2010).

In *United States ex Rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 308 (3d Cir. 2011), we noted that

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[3] The First Circuit previously held the more restrictive view. *See United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 226* (1st Cir. 2004*)*, but has recently moved to a more relaxed approach much closer to that followed by the Fifth Circuit. *See United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29 (1st Cir. 2009).

we had never "held that a plaintiff must identify a specific claim for payment *at the pleading stage* of the case to state a claim for relief." (Emphasis in the original, citation omitted). While that conclusion does not itself commit us to the more nuanced standards favored by the First, Fifth, and Ninth Circuits, it is hard to reconcile the text of the FCA, which does not require that the exact content of the false claims in question be shown, with the "representative samples" standard favored by the Fourth, Sixth, Eighth, and Eleventh Circuits. As the Fifth Circuit has stated, requiring this sort of detail at the pleading stage would be "one small step shy of requiring production of actual documentation with the complaint, a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates." *Grubb*, 565 F.3d at 190 (citations and footnote omitted).

Furthermore, in a recent brief for the United States as *amicus curiae*, filed in relation to the petition for a writ of certiorari in *United States ex rel. Noah Nathan*, 707 F.3d 451, a case presenting a factual situation similar to that presented here, the Solicitor General indicated that the United States also believes that the heightened or "rigid" pleading standard required by the Fourth, Sixth, Eighth, and Eleventh Circuits is "unsupported by Rule 9(b) and undermines the FCA's effectiveness as a tool to combat fraud against the United States." The Solicitor General's brief further states that "pleading the details of a specific false claim presented to the government is not an indispensable requirement of a viable FCA complaint." Brief for the United States as Amicus Curiae at 10-11, *United States ex rel Noah Nathan v. Takeda Pharm. N. Am., Inc.*, 2014 WL 1271321 (U.S. Mar. 31, 2014) (No. 12-1249), denying cert. to 707 F.3d 451. The Solicitor

General also noted that even the Circuits which purport to follow the "rigid understanding of Rule 9(b)" have "not consistently adhered" to it, *id*. at 13, providing a further ground for doubting whether the "rigid" understanding of Rule 9(b) could be the correct one.[4] Insofar as the purpose of Rule 9(b) is to "provide[] defendants with fair notice of the plaintiffs' claims," *id*., the more "nuanced"[5] approach followed by the First, Fifth, and Eleventh Circuits will suffice. That standard is also compatible with our earlier ruling in *Wilkins*, and we will use that standard in this case.

III.

We thus turn to the question of whether Foglia has met the requirements of Rule 9(b) as set out above. Although not presented as clearly as it might be, Foglia's "overfill" claim is best understood as a "factually false" claim. "A claim is factually false when the claimant misrepresents what goods or services that it provided to the Government." *Wilkins*, 659 F.3d at 305. Foglia contends that Renal over-charged the government for Zemplar, a prescription drug used for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease. Zemplar comes in vials of three sizes, but Renal only uses 5 microgram ("mcg")

[4] For reasons unrelated to the proper pleading standard required by Rule 9(b) in a FCA case, the Solicitor General did not recommend granting certiorari in *United States ex rel. Noah Nathan*, even though the Solicitor General argued that the incorrect standard had been applied by the Fourth Circuit. *Id*.

[5] The Solicitor General's brief uses this construction, and we find it appropriate.

vials. The vials were originally designed to be single-use only, with any unused medicine (characterized, somewhat misleadingly, as "overfill" by Foglia[6]) discarded. When Zemplar vials are used in this single-use fashion, Medicare is charged for the full content of the vial, no matter how much of the content is actually used. Foglia contends that Renal charged Medicare as if Renal were using the 5 mcg vials in the recommended "single use" fashion, when in fact it harvested unused portions from vials and used this harvested amount on other patients. (App. 47-48)

Originally, the Department of Health and Human Services ("HSS") required that Zemplar always be used in a single use fashion. However, in September of 2002 (several years before the alleged false claim in this case), HSS issued a memorandum allowing for the multiple use of individual Zemplar vials and other injectable medicines if six conditions were followed, so as to ensure the safe use of the medicine. (App. 60)[7] Foglia contends that Renal "continued multiple

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[6] Put most accurately, "overfill" is the "extra" amount of a medicine in a vial which is always included so as to ensure that a full dose of the labeled amount for the vial is possible, despite any incidental waste. For example, when, only 2 mcgs of a 5 mcg vial are used, the remaining 3 mcgs are not strictly "overfill." The name used here is not important, however. What matters is the claim that Renal was harvesting "extra" Zemplar from already-used vials to administer to patients.

[7] Foglia, in his brief and in his SAC, styles these conditions as "express 'conditions for receiving payment'." (App. 46) Though we have not directly ruled on the issue, it is highly doubtful these conditions for safe use are properly

use of single use vials of injectable medications such as Zemplar consistently without regard to complying with the conditions set forth by HHS." (App. 47) Because we are at the complaint stage in the proceedings we must accept as true all allegations in the complaint, and therefore must accept the allegation that Renal did not, in fact, comply with the required recommendations by HHS for the safe re-use of Zemplar vials.

In order for Foglia to satisfy the standards of Rule 9(b), as we have adopted them here, he must provide "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *See Grubbs*, 565 F.3d at 190. Describing a mere opportunity for fraud will not suffice. Sufficient facts to establish "a plausible ground for relief" must be alleged. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009) (internal citation omitted). While not presented as clearly as it might be, the essentials of Foglia's factually false claim argument seem to be as follows. Inventory logs maintained by Renal show that, during the month of October 2008, Renal used from 29 to 35 vials of Zemplar per day. (App. 75-6) Because Renal orders Zemplar

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"conditions for receiving payment." *Cf. Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001) ("the False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations—but rather only those regulations that are a precondition of payment.") However, while this would be relevant for a "legally false" claim argument, Foglia seems to have abandoned this argument, and the "conditions for receiving payment" aspect is not directly relevant for a "factually false" claim argument.

in only 5 mcg vials (App. 48), it would have needed 50 vials of Zemplar each of the days in question for the number of patients actually seen each day, if the 5 mcg vials were used in the single use fashion. (App. 76) Foglia contends that because renal was using only 29-35 vials of Zemplar per day, it must have been harvesting unused Zemplar from previously used vials. However, these allegations are not enough to establish a "strong inference" that false claims were submitted, as the use of harvested "extra" Zemplar is permitted if the HHS recommendations noted above are followed, and it is therefore possible that Renal was not over-charging.

We are therefore faced with two possible scenarios. Either, as Foglia alleges, Renal was charging the government as if it were using vials of Zemplar in the single use fashion while actually harvesting and using "extra" Zemplar from the vials, or Renal was using the "extra" Zemplar from bottles and only charging the government for the actual volume of Zemplar used, despite not being in compliance with the regulations for using Zemplar in this fashion. While both scenarios are possible, it is unclear what would motivate the second, as it would expose Renal to possible sanctions for failure to comply with required procedures, and would not provide any financial incentive.

This is a close case as to meeting the requirements of Rule 9(b). Accepting the factual assertions made by Foglia as true, we have patient logs that show that less Zemplar was used than would be required if it were used in the single use fashion. We know that Medicare will reimburse for the full vial of Zemplar, regardless of whether all of the Zemplar is used, and that this provides an opportunity for the sort of

fraud alleged by Foglia. At this point we must assume that Foglia is correct in alleging that Renal did not follow the procedures that it should have followed if it was to harvest the "extra" Zemplar from the used vials. Although we recognize that this hypothesis could be challenged, it certainly suffices to give Renal notice of the charges against it, as is required by Rule 9(b). This conclusion is further supported by the fact that Renal, and only Renal, has access to the documents that could easily prove the claim one way or another—the full billing records from the time under consideration. Under these circumstances, Foglia has provided sufficient facts to meet the requirements under Rule 9(b), and has therefore also met the requirements to state a claim under 12(b)(6).

IV.

For the foregoing reasons, we will reverse the dismissal of the factually false claim portion of Foglia's SAC and remand to the District Court for further appropriate proceedings in accordance with this opinion.