



violations with particularity as required by Federal Rule of Civil Procedure 9(b). For the reasons that follow, Zimmer's motion to dismiss will be granted and the complaint will be dismissed with leave to amend.<sup>1</sup>

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<sup>1</sup> The Third Circuit considered Schmidt's First Amended Complaint and assumed without deciding that it failed Rule 9(b)'s particularity requirement:

[W]e have held that FCA claims must be pleaded with particularity in accordance with Fed. R. Civ. P. 9(b). See United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 234 (3d Cir. 1998). Here, the District Court held that Schmidt's first amended complaint did not satisfy Rule 9(b) with respect to the FCA claim against Mercy, but nonetheless expressed its belief that the defects as to particularity could be cured easily by amending the complaint to specify the precise Form HCFA-2552 cost reports that were alleged to be false. The District Court subsequently held that Schmidt's second amended complaint against Mercy was sufficient under Rule 9(b). We will therefore assume that Schmidt's first amended complaint with respect to Zimmer was similarly deficient under Rule 9(b), but that such deficiency may be cured in the same manner as was the second amended complaint. See Fed. R. Civ. P. 15(a) (stating that leave to amend "shall be freely given when justice so requires").

Schmidt, 386 F.3d at 242 n.9.

Additionally, the Third Circuit specifically reserved for this Court the question whether Schmidt may proceed against Zimmer with respect to unnamed hospitals that Schmidt alleges filed false claims with Medicare:

Although raised by the parties, the District Court did not reach the issues of whether Schmidt may proceed against Zimmer with respect to unnamed Premier Participants that were also alleged to have filed false certifications of compliance with applicable law. It is more appropriate, we believe, to reserve this issue for the District Court's consideration on remand.

## II. DISCUSSION

Rule 9(b) provides that "in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind of a person may be averred generally." Fed. R. Civ. P. 9(b). This heightened pleading standard requires "plaintiffs to plead with particularity the 'circumstances' of the alleged fraud in order to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior." Seville Indus. Machinery Corp. v. Southmost Machinery Corp., 742 F.2d 786, 791 (3d Cir. 1984). Stated differently, "Rule 9(b) requires, at a minimum, that plaintiffs support their allegations of . . . fraud with all of the essential factual background that would accompany the first paragraph of any newspaper story--that is, the 'who, what, when, where and how' of the events at issue." In re Rockefeller Ctr. Props. Secs. Litig., 311 F.3d 198, 217 (3d Cir. 2002) (citation and internal quotations omitted). FCA claims must be plead with particularity in accordance with Rule 9(b). See United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 234 (3d Cir. 1998).

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Id. at 245 n.13.

A relator may establish a prima facie claim under 31 U.S.C. § 3729(a)(1)--known as the false claims prong of the FCA-- by showing that: "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." Schmidt, 386 F.3d at 242 (citations omitted). In order to establish a prima facie claim under § 3729(a)(2)--known as the false statements prong of the FCA--"a plaintiff must also show that the defendant made or used (or caused someone else to make or use) a false record in order to cause the false claim to be actually paid or approved." Id.

The central question under either of the above two subsections of the FCA is whether a "false or fraudulent" claim, in fact, was submitted to the government. See United States ex rel. Quinn v. Omnicare, Inc., 382 F.3d 432, 434, 439-40 (3d Cir. 2004) (concluding that plaintiff's "failure to present evidence of the actual submission of a single false claim to Medicaid is fatal to [the] qui tam action"); United States ex rel. Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301, 1311 (11th Cir. 2002) (explaining that the sine qua non of an FCA violation is the submission of a false claim). Accordingly, under Rule 9(b), relators must identify with particularity the precise claims submitted to the government that are alleged to be false or

fraudulent.<sup>2</sup> Clausen, 290 F.3d at 1311 (affirming dismissal of complaint for failure to comply with Rule 9(b) where relator failed to identify any specific claims that were submitted to the government); United States ex rel. King v. Alcon Labs., Inc., No.Civ.A.4:01-469-Y, 2005 WL 20372, at \* 3 (N.D. Tex. Jan. 4, 2005) (same); United States ex rel. Waris v. Staff Builders, Inc., Civ.A.No. 96-1969, 1999 U.S. Dist. Lexis, at \*21 (E.D. Pa. Mar. 5, 1999) (same).

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<sup>2</sup> The Court agrees with the First Circuit's articulation of the particularity requirement, as applied in the FCA context:

In a case [alleging FCA violations], details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a relator to state his or her claims with particularity. These details do not constitute a checklist of mandatory requirements that must be satisfied by each allegation included in a complaint. However, like the Eleventh Circuit, we believe that "some of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b)."

United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 233 (1st Cir. 2004) (quoting Clausen, 290 F.3d at 1312 n.21).

In the present case, the Third Amended Complaint alleges that:

[S]ince at least February 1, 1999, Zimmer has knowingly and willfully induced and knowingly and willfully continued to induce the order and/or purchase of Zimmer orthopaedic hardware implants by Premier members/participants situated throughout the United States by paying such healthcare providers unlawful remunerations disguised as incentives and/or bonuses in violation of § 1320a-7b(b)(2).

. . . .

The cost reports on the Form HCFA-2552 certifications filed by each of the Premier members/participants who purchased orthopaedic equipment pursuant to the Zimmer contract (certifying that each cost report is not infected by a kickback or other unlawful activity) include costs and expenses for orthopaedic hardware implants sold by Zimmer to Premier members/participants for which they received unlawful remunerations disguised as incentives and/or bonuses in violation of § 1320a-7b(b)(2), thus causing the certification on [these] Form HCFA-2552 reports to be "false records or statements."

. . . .

The cost reports on the Form HCFA-2552 certifications filed by each of the Premier members/participants who purchased orthopaedic equipment pursuant to the Zimmer contract (certifying that each cost report is not infected by a kickback or other unlawful activity) include claims for orthopaedic implant-related care and treatment involving Zimmer's orthopaedic implant hardware furnished pursuant to a referral prohibited under 42 U.S.C. § 1395nn(a), thus causing the certification on these Form HCFA-2552 reports to be "false records or statements."

Third Am. Compl. ¶¶ 40, 43, 47.<sup>3</sup>

Schmidt's theory of Zimmer's FCA liability is syllogistic: Zimmer contracts via a purchasing cooperative (Premier Purchasing Partners, L.P.) with approximately 1600 unidentified hospitals (the Premier Participants). Under Zimmer's separate contracts with each of the 1600 hospitals, Zimmer provides certain remunerations to each hospital. These remunerations are part of a marketing scheme on the part of Zimmer that violates the Anti-Kickback and Stark laws.

In turn, each participating hospital submits Form HCFA-2552 cost reports to Medicare. Each participating hospital certifies in the cost reports that the services identified in its cost reports were provided in compliance with the laws and regulations regarding the provision of health care services (including the Anti-Kickback and Stark laws). Because Zimmer's marketing scheme violates the Anti-Kickback and Stark laws, the cost reports that a participating hospital submits to Medicare must be false or fraudulent claims for payment.

Based on these premises, Schmidt contends (tracking the elements of fraud under the FCA) that Zimmer violated the FCA by

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<sup>3</sup> In a related claim, Schmidt also contends that the "false certifications which Zimmer caused to have been made concealed the obligation to . . . the Federal Government in violation of 31 U.S.C. § 3729(a)(7) of the Act." Third Am. Compl. ¶ 50. The discussion of Schmidt's claims under § 3729(a)(1),(2) applies to this claim as well.

knowingly<sup>4</sup> causing a false or fraudulent claim for payment to be presented to the United States, in violation of 31 U.S.C. § 3729(a)(1), or by knowingly causing each participating hospital to make or use a false record in order to cause the false claim to be actually paid or approved, in violation of § 3729(a)(2).<sup>5</sup>

Notably absent from the Third Amended Complaint are the circumstances surrounding the allegedly false claims for payment submitted by any of the participating hospitals to the government. Schmidt fails to identify which, out of approximately 1600 hospitals, submitted false claims to Medicare. Indeed, Schmidt has not identified even one allegedly false claim that was submitted to Medicare.

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<sup>4</sup> Schmidt alleges that "Zimmer knew that the Premier members/participants could not receive the remunerations provided by the subject contract unless these Premier members/participants falsely certified in the annual cost reports their compliance with federal laws." Third Am. Comp. ¶ 44.

<sup>5</sup> In addition to alleging FCA violations by Zimmer, Schmidt alleges that Zimmer improperly failed to disclose to the federal government certain illegal remunerations paid to Premier Participants, in violation of the Anti-Kickback Act, § 42 U.S.C. § 1320a-7b(a)(1) and (a)(3). However, the Anti-Kickback Act is a criminal statute for which no private right of action exists. See West Allis Memorial Hosp., Inc. v. Bowen, 852 F.2d 251, 255 (7th Cir. 1988) (holding that "neither the structure of § 1395nn [now § 1320a-7b] nor its legislative history suggests that Congress intended to provide a private remedy"). Therefore, Schmidt may not pursue this theory of liability.

As the Eleventh Circuit held under similar circumstances:

Rule 9(b)'s directive that "the circumstances constituting fraud or mistake shall be stated with particularity" does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government.

Clausen, 290 F.3d at 1311; Quinn, 382 F.3d at 440 (citing Clausen for the above-quoted proposition). Consistent with Clausen, Schmidt may not simply hypothesize<sup>6</sup> that, based on Zimmer's

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<sup>6</sup> As the Eleventh Circuit stated in Clausen, "neither the Federal Rules nor the [FCA] offer[s] any special leniency [to corporate outsiders] to justify [their] failing to allege with the required specificity the circumstances of the fraudulent conduct he asserts in his action." Clausen, 290 F.3d at 1314. Even if, under the circumstances of this case, the pleading standard could be "relaxed," Schmidt has offered only conclusory statements to the effect that the facts relating to the alleged fraud is peculiarly within Zimmer's knowledge or control. These statements do not suffice to justify a more lenient pleading standard. At a minimum, Schmidt must "delineate at least the nature and scope of [his] effort to obtain, before filing the complaint, the information needed to plead with particularity" and demonstrate that he has "thoroughly investigated all possible sources of information, including but not limited to all publicly available relevant information, before filing a complaint." Shapiro v. UJB Financial Corp., 964 F.2d 272, 285 (3d Cir. 1992); Clausen, 290 F.3d at 1314 n.25. Even then, assuming Schmidt were permitted to plead on information and belief, "such 'information and belief' allegations remain subject to the particularity requirements of Rule 9(b)," and Schmidt must set forth the facts on which his belief is founded. Karvelas, 360 F.3d 231 (holding that "a qui tam relator may not present general allegations in lieu of the details of actual false claims in the hope that such details will emerge through subsequent discovery") (emphasis

allegedly illegal marketing scheme, false claims must have been submitted. Instead, Schmidt "must come to court with [at least one] 'claim in hand.'" Quinn, 382 F.3d at 440 (citing United States ex rel. Alfatooni v. Kitsap Physicians Serv., 314 F.3d 994, 1002-03 (9th Cir. 2002)).

Because Schmidt has failed to identify with particularity a specific false claim, there is no nexus between the allegedly illegal marketing scheme and the FCA. See Harrison v. Westinghouse Savanna River Co., 176 F.3d 776, 785 (4th Cir. 1999) ("The [FCA] attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment.'"); Quinn, 382 F.3d at 438 (quoting Harrison for the proposition that "[t]he FCA reaches 'all fraudulent attempts to cause the Government to pay out sums of money'"); Karvelas, 360 F.3d at 232 ("Underlying schemes and other wrongful activities that result in the submission of fraudulent claims are included in the 'circumstances constituting fraud or mistake' that must be pled with particularity pursuant to Rule 9(b). However, such pleadings invariably are inadequate unless they are linked to allegations, stated with particularity, of the actual false claims submitted to the government that constitute the essential element of an FCA qui tam action.").

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added).

Because the Third Amended Complaint lacks the requisite nexus, it does not pass muster under Rule 9(b).<sup>7</sup>

### III. CONCLUSION

In view of the foregoing discussion, Schmidt's Third Amended Complaint does not satisfy Rule 9(b)'s requirement that the circumstances of the alleged fraudulent conduct be pleaded with particularity. Accordingly, the Third Amended Complaint will be dismissed with leave to replead. An appropriate order follows.

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<sup>7</sup> The result achieved here is consistent with the Third Circuit's resolution of the issue previously addressed on appeal. The Third Circuit reversed the District Court's decision to dismiss for failure to state a claim Schmidt's claim against Zimmer. Schmidt, 386 F.3d at 245. Assuming Schmidt could comply with Rule 9(b), the Third Circuit concluded Schmidt could state a valid FCA claim against Zimmer under Rule 12(b)(6). Nonetheless, the question whether Schmidt can state an FCA claim against Zimmer under Rule 12(b)(6) is independent of the question whether Schmidt has satisfied Rule 9(b). In re Rockefeller Ctr. Props. Secs. Litig., 311 F.3d at 216 ("Independent of the standard applicable to Rule 12(b)(6) motions, Rule 9(b) imposes a heightened pleading requirement of factual particularity with respect to allegations of fraud."). Therefore, the Third Circuit's ruling did not relieve Schmidt of the obligation to plead his FCA claim with particularity in accordance with Rule 9(b).

UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, : CIVIL ACTION  
EX REL. RICHARD G. SCHMIDT, : NO. 00-1044  
M.D., :  
Plaintiff, :  
v. :  
ZIMMER, INC. et al., :  
Defendants. :

ORDER

**AND NOW** this **29th** day of **July, 2005**, upon consideration of the Motion to Dismiss the Third Amended Complaint filed by Zimmer, Inc. (doc. no. 94), it is hereby **ORDERED** that the Motion is **GRANTED**, plaintiff having failed to comply with Federal Rule of Civil Procedure 9(b).

**IT IS FURTHER ORDERED** that plaintiff has leave to file an amended complaint not later than **August 10, 2005**.

**AND IT IS FURTHER ORDERED** as follows:

1. The Motion for Leave to File a Reply to Plaintiff's Opposition to Defendant's Motion to Dismiss the Third Amended Complaint filed by Zimmer, Inc. (doc. no. 97) is **GRANTED**.
2. The Motion for Leave to File a Supplemental Memorandum in Support of its Motion to Dismiss Realtor's Third

Amended Complaint filed by Zimmer, Inc. (doc. no. 99)  
is **GRANTED**.

**AND IT IS SO ORDERED.**

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**EDUARDO C. ROBRENO, J.**