IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA *ex rel.* KATY KENNEDY and FRANK A. MATOS, THE STATE OF ILLINOIS *ex rel.* KATY KENNEDY and FRANK A. MATOS, and KATY KENNEDY, individually,	)	
Plaintiffs,	)	**Case No. 03 C 2750**
vs.	)	
AVENTIS PHARMACEUTICALS, INC., and PHARMANETICS, INC.,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge:

Relators Katy Kennedy and Frank Matos have brought *qui tam* claims[1] on behalf of the United States and the State of Illinois under the False Claims Act, 31 U.S.C. § 3730(b) (FCA), and the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175/4(b) (IWRPA), against Aventis Pharmaceuticals, Inc. Kennedy has also brought a claim on her own behalf against Aventis, claiming retaliation in violation of the Illinois Whistleblower Act, 740 ILCS 174/20 (IWA). Aventis has moved to dismiss the *qui tam* claims in relators' third amended complaint (Counts 1-6) pursuant to Federal Rules of

[1] *Qui tam* is short for *qui tam pro domino rege quam pro se ipso in hac parte sequitur* ("who brings the action for the King as well as for himself.") *United States* ex rel. *Eunice Matthews v. Bank of Farmington*, 166 F.3d 853, 857 (7th Cir. 1999).

Civil Procedure 9(b) and 12(b)(6). For the following reasons, the Court grants Aventis's motion.

Facts

When considering a motion to dismiss a complaint, the Court accepts all the facts stated in the complaint as true and draws all reasonable inferences in favor of the plaintiff. *Newell Operating Co. v. Int'l Union of United Auto., Aerospace, and Agr. Implement Workers of Am.*, 538 F.3d 583, 587 (7th Cir. 2008).

Relators are former Aventis sales representatives. While at Aventis, relators promoted the prescription drug Lovenox, an anticoagulant used almost exclusively for inpatient hospital care. The Food and Drug Administration (FDA) approved Lovenox for seven indications. *See United States* ex rel. *Kennedy v. Aventis Pharms., Inc.*, 512 F. Supp. 2d 1158, 1162 (N.D. Ill. 2007).

Relators allege that Aventis marketed Lovenox for off-label uses and thereby induced doctors and hospitals to submit fraudulent Medicare reimbursement claims to the government. Relators allege that this marketing strategy caused doctors to prescribe Lovenox for atrial fribillation, acute myocardial infarction, mechanical heart valve replacement, coronary artery bypass graft surgery, ST-elevation myocardial infarction, bariatric surgery, arthroscopic-assisted surgery, hemodialysis patients, hip fracture surgery, trauma, lower or upper extremity fractures, neurosurgery, spinal cord injuries, acute ischemic stroke, stroke, percutaneous coronary intervention, general surgery, heparin-induced thrombocytopenia, IV dosing, and cardiac catheterization. Lovenox is not approved by the FDA for any of these indications.

Relators allege that Aventis provided things of value to doctors and hospitals to induce them to prescribe Lovenox for off-label indications. Specifically, they allege Aventis paid $34,000 to Ben Muoghalu, a pharmacist, for several speaking engagements. Relators contend that Aventis hired Muoghalu to induce him to keep Lovenox on hospital formularies under his control. In addition, Aventis gave various organizations grants ranging from $5,000 to $30,000. Relators contend that Aventis made the grants intending to induce those organizations to use or promote Lovenox for off-label indications.

In August 2000, Aventis entered into an agreement with PharmaNetics (PharmaNetics was previously a defendant in this case but was dismissed by stipulation with relators). According to the agreement, PharmaNetics developed a test, called the ENOX test, to detect the anticoagulant effects of Lovenox on patients with unstable angina. Relators contend that the purpose of the test was to convince unwilling doctors to perform interventional procedures on patients with unstable angina who receive Lovenox. Because the FDA did not approve Lovenox for use in such invasive procedures, relators contend that the development of the test was part of a scheme to create a new marketing tool designed to market Lovenox for an unapproved use.

Relators allege that Aventis purposely ordered its personnel to mislead doctors regarding the approved and safe uses of Lovenox. As a result, prescriptions for Lovenox increased, including prescriptions reimbursed through government health programs.

Relators identify two specific instances in which a hospital prescribed Lovenox for allegedly off-label indications due to Aventis' marketing tactics and then billed the government for reimbursement. First, relators contend that Lutheran General Hospital made a false claim to the government when, on January 5, 2002, it submitted a claim for Lovenox as a covered expense for atrial fribillation, an off-label use. Second, relators contend that Alexian Brothers Hospital made a false claim to the government in 2002 when it submitted a claim for Lovenox as a covered expense for atrial fribillation. Relators also attached two charts to their third amended complaint detailing other allegedly off-label uses of Lovenox in connection with which hospitals submitted claims to the government for payment. Finally, relators allege that the hospitals used false records or statements to get false or fraudulent claims paid or approved by the government when they included Lovenox, as prescribed for the off-label uses, in "cost report[s] and/or Medicare Cost Reconciliation[s]." 3d Am. Comp. ¶¶ 56, 58.

Relators filed their first complaint, under seal pursuant to the FCA, on April 24, 2003. The government declined to intervene in December 2006. After the Court unsealed the complaint, relators served it on Aventis and PharmaNetics.

Aventis has twice moved the Court to dismiss relators' claims. First, in March 2007, Aventis moved the Court to dismiss relators' first amended complaint on multiple grounds. The Court granted Aventis's motion in part, dismissing Kennedy's whistleblower retaliation claims, but declining to dismiss relators' *qui tam* claims. *Aventis Pharms.*, 512 F. Supp. 2d at 1169. Kennedy amended her retaliation claims, and Aventis again moved to dismiss. On February 11, 2008, the Court granted

Aventis's motion as to Kennedy's FFA and IWPRA claims but declined to dismiss Kennedy's IWA claim. *United States* ex rel. *Kennedy v. Aventis Pharms. Inc.*, No. 03 C 2750, 2008 WL 4371323 (N.D. Ill. Feb. 11, 2008).

On November 13, 2007, the Court bifurcated discovery into two phases and set deadlines for the completion of each. The purpose of the first phase was to allow relators to attempt to identify specific allegedly false claims. The deadline for completing that phase was extended by approximately three months at relators' request. Following completion of the first phase, relators filed a third amended complaint.

Discussion

The FCA imposes civil liability on "[a]ny person" who "knowingly presents, or causes to be presented, to . . . the United States . . . a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1). In addition, a person violates the FCA if she "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved." *Id.* § 3729(a)(2). For liability to attach, the fraudulent claim, statement, record must be material to the government's decision to pay. *See United States* ex rel. *Gross v. AIDS Research Alliance-Chicago*, 415 F.3d 601, 604 (7th Cir. 2005); *Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 732-33 (7th Cir. 1999) ("plaintiff must show . . . that the omitted facts were material to the listener's decision").

A. Materiality of false claims

Relators allege that Aventis violated the FCA and parallel Illinois statutes by marketing off-label uses of Lovenox. They contend that Aventis's marketing scheme caused hospitals to submit false claims to the United States and the State of Illinois for reimbursement of off-label uses of Lovenox. Relators have identified several specific prescriptions for off-label uses of Lovenox at Lutheran General and Alexian Brothers as the subjects of false claims submitted to the government for payment.

Aventis contends that none of the charges for Lovenox prescriptions referenced in relators' complaint qualifies as a false claim because, it argues, individual prescriptions are immaterial to the amount paid by the government for the treatment of a given patient. Medicare and Illinois Medicaid both reimburse hospitals for inpatient services under a prospective payment system that provides fixed payments based on the diagnosis related group code ("DRG") assigned to each patient. 42 U.S.C. § 1395ww(d). A patient's DRG is based on her diagnosis and age, not on the particular care or services she receives. 42 C.F.R. § 412.60. The Centers for Medicare and Medicaid Services ("CMS"), the federal agency that administers Medicare and Medicaid, sets DRGs according to national averages for the costs of treating particular illnesses. 42 U.S.C. § 1395ww(d)(1)(D). In most cases, the DRG rate constitutes full payment for all items and services provided by the hospital, including prescription drugs. 42 C.F.R. § 412.60(c)(2). CMS and Illinois Medicaid reimburse outpatient services in a similar way; pharmaceuticals are included in a prospective payment rate

for the primary procedure. 42 C.F.R. § 419.2; Ill. Admin. Code tit. 89, §§ 148.140(a), (b).

Several other courts have recognized that individual charges on a patient bill are immaterial to the government's Medicare/Medicaid reimbursement decisions and, therefore, cannot serve as the basis of FCA liability. *United States* ex rel. *DiGiovanni v. St. Joseph's Candler Health System, Inc.*, No. CV404-190, 2008 WL 395012, *6 (S.D. Ala. Feb. 8, 2008); *United States* ex rel. *Magid v. Wilderman*, No. Civ. A. 96-CV-4346, 2004 WL 945153, *9 (E.D. Pa. April 29, 2004); *United States* ex rel. *Schell v. Battle Creek Health Systems*, No. 1:00-CV-143, 2004 WL 784978 *4 (W.D. Mich. Feb. 25, 2004), *rev'd on other grounds*, 419 F.3d 535 (6th Cir. 2005).[2] Although these case are not controlling, they are based on a materiality requirement similar to that articulated by the Seventh Circuit. *Gross*, 415 F.3d at 604.

The off-label uses of Lovenox charged on a patient's bill did not cause the government to pay any more money than it would have paid had the charges not been included in the bill. Under the applicable law and regulations, the government paid the hospitals according to the previously determined PRG rate, which has nothing to do with the particular drugs prescribed or used in the patient's treatment. Under the circumstances, the allegedly false claims do not meet of the Seventh Circuit's

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[2] Aventis contends that the district court's decision in *Schell* was reversed by the Sixth Circuit on grounds not related to the materiality of individual charges to the amount actually paid by the government for inpatient care. Relators contest that characterization of the case. A careful reading uncovers that the Sixth Circuit left intact the lower court's determination of the inpatient issue because that ruling was not appealed. *Schell*, 419 F.3d at 537 n.1.

materiality requirement, because there is no causal relationship between the alleged falsehood and amount the government paid. *See id.* (claim must be "knowingly and falsely made in order to deceive the government"); *Luckey*, 183 F.3d at 732-33 (false statement must be material to government's decision to pay the claim). Because relators cannot show that individual patient bills were material to the government's decision to pay, they cannot prove an essential element of their claim.

B. Outlier claims

In their response to Aventis's motion, relators propose an alternate theory of liability under the FCA.[3] They contend that hospitals can claim compensation from the government for inpatient care above the DRG rate for a particular patients whose conditions are "extraordinarily costly to treat." Relators' Resp. at 9. Relators contend that because Lovenox prevents clotting, patients on Lovenox who undergo invasive procedures are more likely to require additional treatment due to complications like excessive bleeding. Relators contend that such complications likely lead to claims for additional payment above and beyond the DRG rate, also known as outlier claims.

A hospital may submit outlier claims to receive additional payments from Medicare for inpatient hospital services when its operating and capital costs exceed the DRG payment by a specified amount. 42 C.F.R. §§ 412.80(a)(1)(ii) & 412.84(a). In such cases, a hospital must specifically request the additional payment and submit

[3] Relators also contend that Medicare adjusts compensation by factoring a hospital-specific rate into the reimbursement calculus. The regulations cited by relators, however, refer to adjustments for capital costs. 42 C.F.R. § 412.328. Expenditures for pharmaceuticals are operating costs, not capital costs. *See id.* § 412.2(c).

itemized charges to verify the necessity and appropriateness of the course of treatment. *Id.* § 412.84(f).

Though an outlier claim based on off-label use of Lovenox could constitute an actionable false claim, relators have failed to allege this with the particularity needed to satisfy Federal Rule of Civil Procedure 9(b). In their third amended complaint, relators included several instances of alleged off-label uses of Lovenox that were submitted in claims to the government. Relators have, however, failed to identify any particular instance of an outlier claim that included a Lovenox prescription, much less an off-label use of Lovenox.

Although the Court relaxed the particularity requirement of Rule 9(b) in considering Aventis's first motion to dismiss, the reasoning behind that decision no longer applies. In its September 13, 2007 ruling, the Court noted that "the requirements of Rule 9(b) are relaxed when the plaintiff lacks access to all facts necessary to detail his claim." *Aventis*, 512 F. Supp. 2d at 1167. Because the facts regarding particular claims were under the control of third parties, the Court allowed relators' complaint to stand because their allegations, though not identifying any particular claim, gave rise to a reasonable inference that false claims had been made. *Id.*

This is no longer the case. After nine months of discovery, relators have had ample opportunity to discover and present to the Court outlier claims that list Lovenox as itemized charges. They have not done so. Instead, relators are asking the Court to infer that hospitals must have submitted such outlier claims due to the nature to the drug. They have offered, however, no basis for such an inference on the present

record. After months of discovery, this fails to meet the particularity requirements of Rule 9(b).

C. Cost reports as false statements in support of a claim

Relators allege that Aventis induced hospitals to submit cost reports, as required by Medicare, itemizing off-label uses of Lovenox in support of claims for Medicare reimbursement. Relators contend that the cost reports amount to records or statements used to get a false claim paid in violation of the FCA. *See* 31 U.S.C. § 3729(a)(2).

CMS requires hospitals to submit annual cost reports. 42 C.F.R. § 413.20(b). The cost report data is part of the overall Medicare reimbursement calculus, but the parties dispute the way in which it is used. Relators contend that CMS uses the cost reports to determine DRG rates. Aventis contends that the cost reports are used only to compute cost-to-charge ratios for use in outlier claim calculations. The dispute centers around 42 C.F.R. § 413.64(a). Aventis argues that relators misread section 412.64(a) to state that DRGs are based on hospital operating costs. Instead, the regulation states that DRGs are set "*for* inpatient operating costs." *Id.* § 413.64(a) (emphasis added).

Even if, as relators assert, the cost reports directly affect the DRG rates, the connection between the allegedly false items in a particular cost report and the government's decision to pay is too attenuated to sustain a claim of materiality. As an initial matter, a DRG is, by definition, a prospective rate. That is, the DRG rate is an estimate of the average cost of treating the illness during the following year. Thus, a

cost report may only affect future DRGs. Second, a single hospital's cost report, or even several hospitals' reports, amount to a small portion of the data that inform the decision to increase or decrease DRGs. The FCA imposes liability only when a false statement or record is used "to get a false or fraudulent claim paid by the Government." 31 U.S.C. § 3729(a)(2). In a false statement or record case, "liability is imposed based on the use of a false statement in relation to the fraudulent claim, rather than simply because a false statement was made." *United States* ex rel. *A+ Homecare, Inc. v. Medshares Mgmt. Co.*, 400 F.3d 428, 443-44 (6th Cir. 2005).[4] Thus, the mere existence of a false statement is insufficient. Instead, the false statement or record must be used to support a particular claim. Because relators have not tied the cost reports to particular claims, they have failed to allege that an individual hospital's cost reports are material to the payment of any given claim.

In any event, relators have failed to identify any particular cost report submitted to CMS that contains a claim for an off-label use of Lovenox as a covered expense. At this stage, given relators' ample opportunity to take claims-related discovery, this is simply insufficient to meet the requirements of Rule 9(b).

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[4] In *A+ Homecare*, the court found that a false statement on a cost report submitted by a home health agency to a Medicare intermediary was material to the government's decision to pay. *A+ Homecare*, 400 F.3d at 447. The regulations governing Medicare reimbursement for home health care provide that home health agencies are reimbursed according to "costs actually incurred" by the agency. 42 U.S.C. § 1395x(v)(1)(A); 42 C.F.R. § 413.9(c)(3). This is, of course, quite different from the regulations at issue in this case, which provide for reimbursement on the basis of the PRG rate.

D. Anti-kickback statute

Relators' failure to produce a single false claim similarly dooms their claims premised on violations of the anti-kickback statute, 42 U.S.C. § 1320a-7b(b). An allegedly false certification of compliance with statutory or regulatory requirements can serve as the basis for a claim under the FCA so long as "the certification of compliance [with the statute or regulation is] a condition or prerequisite to government payment."[5] *Gross*, 415 F.3d at 604. The particularity requirements of Rule 9(b) apply to FCA claims based on an allegedly false certification of compliance. *Id.* Thus, under Rule 9(b), relators must allege a link between the government's decision to pay and an allegedly false certification. *See id.* (noting that Rule 9(b) applies to FCA claims, including the requirement that the certification of compliance be a prerequisite to payment).

Relators have not alleged any link between payments or grants made by Aventis and an actual claim submitted by a hospital. They allege that Aventis's payments and grants caused hospitals to falsely certify compliance with the anti-kickback statute. Just as relators have failed to identify a material false claim, however, they have failed to identify any particular allegedly false certification of compliance. Although relators list several organizations to which Aventis allegedly gave "unrestricted grants," Alexian Brothers and Lutheran General do not appear on the list. Relators also allege that Aventis paid Ben Muoghalu, a pharmacist, for several speaking engagements to induce

[5] Relators do not specifically allege that a certification of compliance with the Anti-Kickback Statute is a prerequisite for payment. Avetnis, however, does not contest this point.

him to keep Lovenox on hospital formularies under his control. Relators, however, fail to allege that Muoghalu was in any way connected with either Alexian Brothers or Lutheran General. Because those are the only two hospitals that relators have specifically identified as having made false claims, relators have failed to allege with particularity that Aventis "cause[d] [a false claim] to be presented" or "cause[d] [a false record or statement] to be made." 31 U.S.C. § 3729(a)(1), (2). As a result, their anti-kickback statute claims fail to meet the particularity standard of Rule 9(b).

Conclusion

For the foregoing reasons, the Court grants Aventis's motion to dismiss [# 156]. Counts 1 through 6 of relators' third amended complaint are dismissed pursuant to Rule 9(b) and 12(b)(6). The dismissal will be converted to a dismissal with prejudice unless relators file, within twenty-one days of this decision, a proposed fourth amended complaint that satisfies Rules 9(b) and 12(b)(6). Aventis's request that the Court take judicial notice of certain facts is denied as moot, and its motion for excess pages is terminated [# 155]. The case is set for a status hearing on January 8, 2009 at 9:30 a.m. Counsel should be prepared to discuss resetting the deadlines for the remainder of the discovery schedule.

MATTHEW F. KENNELLY
United States District Judge

Date: December 10, 2008