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.,	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge:

Relators Katy Kennedy and Frank Matos have filed this *qui tam* action against Aventis Pharmaceuticals, Inc. 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). Kennedy has also made a claim on her own behalf against Aventis, claiming retaliation in violation of the Illinois Whistleblower Act, 740 ILCS 174/20. Aventis asks the Court to dismiss the *qui tam* claims in relators' fourth amended complaint pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6) and to decline supplemental jurisdiction over Kennedy's state law claim.

On December 10, 2008, the Court granted Aventis's motion to dismiss the FCA claims in relators' third amended complaint for failure to state a claim. The Court stated

that it would convert the order into a final judgment unless relators filed a proposed fourth amended complaint that satisfied Rules 9(b) and 12(b)(6). Relators filed a fourth amended complaint on December 31, 2008. Aventis has again moved to dismiss. For the following reasons, the Court grants Aventis's motion in part and denies it in part.

Background

When considering a motion to dismiss for failure to state a claim, the Court accepts as true the facts alleged in the complaint 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 allege that Aventis aggressively marketed its prescription drug Lovenox to medical providers to induce them to prescribe it for "off-label" uses – in other words, uses for which it had not been approved by the Food and Drug Administration. Charges for off-label prescriptions, relators allege, are not properly reimbursable under the Medicare program. They allege that by promoting off-label use of Lovenox, Aventis knowingly caused hospitals to submit false claims for Medicare reimbursement. Relators also allege that Aventis made payments to hospitals and to Ben Muoghalu, a pharmacist at Provena St. Joseph Medical Center and a member of that hospital's pharmacy formulary committee, to encourage them to prescribe Lovenox. Relators characterize these payments as illegal kickbacks. The Court will discuss the pertinent details of relators' allegations in the body of this decision.

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). To establish a claim under this section, a relator must prove that there was a false or fraudulent claim; the defendant knew the claim was false; and the defendant presented the claim or caused it to be presented to the United States for payment or approval. *United States* ex rel. *Fowler v. Caremark Rx, LLC*, 496 F.3d 730, 740-41 (7th Cir. 2007).

A person also violates the FCA if he "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." 31 U.S.C. § 3729(a)(2). To establish a claim under this provision, a relator must prove that the defendant made, or caused someone to make, a statement to receive money from the government; the statement was false; and the defendant knew it was false. *See Fowler*, 496 F.3d at 741. If the claim under section 3729(a)(2) is premised upon a false certification of regulatory compliance, the relator must also prove that the certification was a condition of or prerequisite to payment by the government. *United States* ex rel. *Crews v. NHS Healthcare of Ill., Inc.*, 460 F.3d 853, 858 (7th Cir. 2006); *United States* ex rel. *Gross v. AIDS Research Alliance-Chicago*, 415 F.3d 601, 604 (7th Cir. 2005).

The FCA "is an anti-fraud statute and claims under it are subject to the heightened pleading requirements of Rule 9(b)." *Fowler*, 496 F.3d at 740. Rule 9(b) requires a party to "state with particularity the circumstances constituting fraud . . . ." Fed. R. Civ. P. 9(b). This means that the complaint must allege "the who, what, when, where and how" of the alleged fraud. *Gross*, 415 F.3d at 605 (quoting *United States* ex

rel. *Garst v. Lockheed-Martin Corp.*, 328 F.3d 374, 376 (7th Cir. 2003)).

A. Outlier payments

The Medicare claims process, at least as relators describe it in their fourth amended complaint, appears rather complicated. The Court will attempt to simplify things to the extent possible.

The process for submitting claims for Medicare patients, relators allege, is entirely electronic. 4th Am. Compl. ¶ 22. Hospitals submit claims data to a "fiscal intermediary" on an electronic document called a Universal Billing (UB) form. *Id.* ¶¶ 22, 24. The claims data, relators allege, includes all pharmaceutical products dispensed to the patient. *Id.* ¶ 24.

Relators allege that when a Medicare patient is discharged, "procedure codes" are assigned and entered on the UB form to reflect the patient's treatment. The patient is also assigned a "diagnosis related group" (DRG) code that corresponds to her diagnosis. The DRG code is likewise recorded on the UB form. *Id.* ¶ 25. When the fiscal intermediary receives the UB form from the hospital, it extracts the relevant data, processes it, and determines the amount to be paid to the hospital. *Id.* ¶¶ 22-23. The fiscal intermediary pays the hospital a fixed amount based on the patient's DRG code. *Id.* ¶¶ 22, 25, 32.

Relators allege that the Medicare statute and regulations provide that an additional payment, called an outlier payment, is made to the hospital when "charges, adjusted to cost" exceed a threshold. *Id.* ¶¶ 25, 32. According to relators, the charges used to calculate outlier payments are all the charges reported on the UB form for the

particular patient; the hospital does not submit a separate outlier claim. *Id.* ¶¶ 25, 32. Relators allege that the requisite adjustment of the charges to the hospital's costs is based on a total of the hospital's costs for the prior year. *Id.* ¶ 33. Those costs are found on a "cost report" that the hospital is required to submit to the fiscal intermediary each year, showing the costs it incurred during the year and the proportion of those costs attributable to Medicare. *Id.* ¶¶ 39, 45. Relators allege that the higher the hospital's costs, the higher its "charges, adjusted to cost" will be – as best as the Court can tell, because a smaller "adjust[ment]" is required. *See id.* ¶¶ 33-34.

Relators allege that once the hospital's charges for a patient are adjusted to cost, the adjusted figure is compared to a cutoff point designed to eliminate from eligibility for outlier payments hospital stays that are not unusually costly. *Id.* ¶ 35. The cutoff point, according to relators, is the sum of the basic DRG payment, certain other standard Medicare reimbursements, and a fixed dollar amount that the government sets called the "outlier threshold." *Id.* ¶ 36. If the hospital's adjusted charges for a particular patient exceed the cutoff point, it receives an outlier payment consisting of eighty percent of the excess. *Id.* ¶¶ 36-37.

Relators allege that Aventis deliberately marketed Lovenox for off-label uses, *see id.* ¶¶ 112-13, for the purpose of obtaining government payment for such uses. *Id.* ¶ 114. Relators allege that charges for off-label Lovenox are not properly reimburseable under the Medicare program. *Id.* ¶¶ 5 & 38.

Relators do not contend – nor could they, from what the Court can determine – that use of Lovenox off-label for a Medicare patient affects the DRG payment for that

patient. That payment, as the Court has indicated, is a fixed amount that does not depend on the actual charges for the patient.

Rather, relators contend that the use of Lovenox off-label for a Medicare patient affects outlier payments to the hospital, both for that particular patient and for all other Medicare patients. First, relators allege that the inclusion of a charge for off-label Lovenox on a UB form increases the hospital's costs and thus results in a smaller adjustment of charges to costs in calculating outlier payments generally (not just for the particular patient that was prescribed the drug). *Id.* ¶¶ 23, 33, 34 & 43. Relators specifically allege that off-label Lovenox use was, in fact, included as a covered charge in hospitals' cost reports. *Id*. ¶ 45. Second, relators appear to allege that the inclusion of a charge for off-label Lovenox on a patient's UB form will result in an outlier payment for that particular patient if the total charges for the payment, adjusted to cost, exceed the cutoff point. *See id.* ¶¶ 23, 42, 44 & 114.

In their fourth amended complaint, relators identify a number of specific UB forms submitted by Alexian Brothers Hospital and Lutheran General Hospital that, relators say, included line item charges for off-label Lovenox prescribed to the particular patient.[1] *Id.* ¶¶ 115-63 & Ex. O. Relators do not appear to allege that the treatment of any of these patients triggered an outlier payment for that particular patient. *See id.* Rather, relators allege that these non-reimburseable charges were among those aggregated on the hospitals' cost reports for the relevant years. *Id.* Relators do not attempt to quantify the non-reimburseable charges for off-label Lovenox, but they allege

[1] Relators do not allege that Alexian Brothers Hospital or Lutheran General Hospital received kickbacks from Aventis.

those charges were included in a line item on the hospitals' cost reports for "Total Program inpatient costs." *See id.* & Exs. B1-B7, line 49. [2]

Relators allege that the inclusion of charges the off-label Lovenox on the hospitals' cost reports inflated all of those hospitals' outlier payments once the formula described earlier was applied. *Id.* ¶¶ 115-63. They allege that the inclusion of these non-reimbursable charges in the cost reports was false and material to the government's decision in determining the hospitals' outlier payments. *Id.* Relators have not attempted to quantify the amount by which the hospitals' outlier payments allegedly was affected.

In short, relators have largely focused their claims concerning outlier payments on the inclusion of charges for off-label Lovenox on the hospital's cost report and the allegedly consequent inflation of subsequent outlier payments generally.

Given the effect of the system of DRG-based payments, as noted earlier, it would not appear that the UB form itself could be considered a false claim submitted for payment – at least not with regard to inflated outlier payments. A hospital's cost report, however, may be considered to be a claim submitted to receive payment. *See United States v. Bourseau*, 531 F.3d 1159, 1164 n.1 (9th Cir. 20008). Alternatively, the UB forms that list charges for off-label Lovenox and the cost reports on which that information is aggregated may be considered to contain false information that the government uses, via the formula referenced earlier, to calculate subsequent outlier payments to the hospital. Accordingly, the Court will assess relators' claim regarding

[2] This line item is a sum of several other figures on the cost reports. Relators do not say what particular line item contained the alleged charges for off-label Lovenox.

outlier payments under both section 3729(a)(1) and section 3729(a)(2).

As the Court previously discussed, to state a claim under section 3729(a)(1), relators must allege that Aventis caused a hospital to make a false claim to the government, knowing the claim to be false. To state a claim under section 3729(a)(2), relators must allege that Aventis caused a hospital to make a false statement to the government in order to get a claim paid, knowing the statement to be false, and the statement was a condition of payment.

Relators have adequately alleged the making of false claims and false statements to get claims paid. Again, the alleged false claims / statements involve the inclusion of off-label Lovenox, a non-reimburseable expense, as part of "Total Program inpatient costs" on the hospitals' cost report. Aventis contends that relators are speculating that any particular cost report includes charges for off-label Lovenox. But relators allege exactly that. 4th Am. Compl. ¶¶ 115-63. They do not have to prove their case in the complaint.

Similarly, relators have alleged that Aventis knew the hospitals' statements were false. *Id.* ¶¶ 179, 182. Federal Rule of Civil Procedure 9 allows a plaintiff to allege a defendant's state of mind generally; particularized pleading is not required. Fed. R. Civ. P. 9(b).

Relators likewise have adequately alleged that Aventis caused the hospitals to make false statements on their cost reports. Defendants argue that relators offer no link between anything they allege Aventis did and the inclusion of off-label Lovenox on cost reports and that relators allege only that Aventis tried to increase sales for off-label

uses. Under the FCA, a defendant is answerable for "the natural, ordinary and reasonable consequences of his conduct," though not for anything beyond that. *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123, 2130 (2008) (internal quotation marks and citation omitted). It is certainly true that someone other than Aventis – specifically the hospitals – had to take its own action to include non-reimburseable charges for off-label Lovenox on its UB forms and on its cost reports. But at least for purposes of a motion to dismiss, these later intervening factors do not break the chain of causation as a matter of law. As one court stated in dealing with a similar point, "such an intervening force only breaks the causal connection when it is unforeseeable. In this case, when all reasonable inferences are drawn in favor of the Relator, the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud." *United States* ex rel. *Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, 147 F. Supp. 2d 39, 52-53 (D. Mass. 2001).

Finally, relators have sufficiently alleged that a hospital's statements on its cost report are a condition of its receipt of, and the amount of, outlier payments. *See* 4th Am. Compl. ¶¶ 115-63. Relators have sufficiently alleged that a hospital's statement of expenses in its cost report is a condition of payment vis-à-vis outlier payments. Specifically, their description of the role of the cost report in obtaining outlier payments is adequate to constitute an allegation that the total of expenses that a hospital lists on the report plays an essential role in determination of the amount of the hospital's outlier payments.

The Court's decision concerning relators' third amended complaint may be read as suggesting there is a separate "materiality" requirement for claims under the FCA. *See United States* ex rel. *Kennedy v. Aventis Pharms., Inc.*, No. 03 C 2750, 2008 WL 5211021, at *2-*3 (N.D. Ill. Dec. 10, 2008). It is not clear that a materiality requirement, as such, exists for all types of FCA claims. Neither of the two cases the Court cited for that proposition so held. *Luckey v. Baxter Healthcare Corp.,* 183 F.3d 730, 732-33 (7th Cir. 1999), required materiality, but it did so in the context of a claim alleged to be false due to omissions, not misrepresentations. (*United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008), which likewise requires materiality, similarly concerned omissions, not false statements.) And *Gross*, the other case the Court cited, did not impose a materiality requirement in so many words but rather imposed a "condition of payment" requirement. This serves the same function in a section 3729(a)(2) claim as requiring materiality – making sure the false statement is significant and not tangential – but the terminology is different.[3] *Gross* specifically states that there are four requirements for a claim under section 3729(a)(2), and "materiality," as such, is not one of them. *Gross*, 415 F.3d at 604.

Even if materiality is separately required for a claim under the FCA, relators have made the necessary allegations. A statement is material if it has a natural tendency to

[3] This is not meant to suggest that the Court's decision regarding the third amended complaint reached an incorrect result. The thrust of the Court's determination was that because of the DRG payment system, prescription of off-label Lovenox does not affect the basic amount paid for the treatment of the particular patient. That, of course, does not eliminate the possibility of an outlier payment, but relators identified no outlier payments in their third amended complaint. Thus the Court would have reached the same conclusion regarding that version of the complaint irrespective of whether there is a separate materiality requirement.

influence, or is capable of influencing, the decision of the body to which it was addressed. *See, e.g., Rogan*, 517 F.3d at 452. Aventis contends that relators' contention that inclusion of charges for off-label Lovenox in cost reports would increase the hospital's outlier payments is speculative. But relators do not have to prove this in their complaint, and in any event, on a motion to dismiss, a plaintiff is entitled to reasonable inferences from her allegations. *See, e.g., Estate of Sims* ex rel. *Sims v. County of Bureau*, 506 F.3d 509, 512 (7th Cir. 2007). Based on relators' description of how outlier payments are calculated, a reasonable inference may be drawn that the inclusion of non-reimbursable charges in a cost report does, in fact, increase outlier payments to the hospital. This, combined with relators' allegations that the hospitals in question actually received significant outlier payments for the relevant time periods, is sufficient to satisfy any separate materiality requirement that may exist.

For these reasons, the Court concludes that relators have stated a claim with regard to their allegations concerning the inclusion of charges for off-label Lovenox in hospital cost reports.

B. Kickback allegations

As noted earlier, relators allege that Aventis made payments to hospitals and others to encourage their use and promotion of Lovenox for unapproved indications. 4th Am. Compl. ¶ 82. They identify a number of hospitals to which Aventis allegedly gave "kickbacks disguised as unrestricted grants . . . to induce their continued use and/or promotion of Lovenox for unapproved indications." *Id.* ¶¶ 84-85; *see also id.* ¶¶ 102-03. Relators also allege that Aventis made significant payments to Muoghalu "to

give ten sham one hour talks," "in order to induce him to keep Lovenox on hospital formularies that [were] under his control." *Id.* ¶ 83; *see also id.* ¶¶ 89-100.

According to relators, each of the payments to the hospitals and Muoghalu was a kickback. *See, e.g., id.* ¶¶ 101-04. Specifically, relators allege that the payments violated the federal anti-kickback statute. The anti-kickback statute makes it a crime to (among other things) knowingly and willfully solicit, receive, offer, or pay remuneration in return for purchasing or ordering any item or service for which payment may be made under a federal health care program, including Medicare. 42 U.S.C. § 1320a-7b(b). Relators allege that Aventis violated this statute in connection with its payments to the hospitals and Muoghalu. 4th Am. Compl. ¶ 81.

Relators allege that entities that violate the anti-kickback statute are rendered ineligible to participate in the Medicare program and forfeit their ability to bill Medicare. *Id.* ¶¶ 65, 68. They also allege that to participate in the Medicare program, a hospital is required to enter into an agreement with the government in which it certifies that it will comply with laws and regulations concerning Medicare providers, including the anti-kickback statute, and that compliance with the provider agreement is a condition for payment under the Medicare program. *Id.* ¶ 68.

In addition, relators allege that hospitals that receive Medicare reimbursement submit annual cost reports that include a certification that the hospital's chief administrator or her designee must sign. The certification, relators say, includes a notice that misrepresentation or falsification of information is punishable by law, and that "if services identified in this report were provided or procured through the payment

directly or indirectly of a kickback . . ., fines and/or imprisonment may result." *Id.* ¶ 76.

Relators also allege that a hospital that makes Medicare claims is required to submit a certification that it will abide by applicable laws and regulations and that it understands that "payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare." *Id.* ¶ 77. Relators further allege that a provider is required to disclose errors and omissions in its claims and cost reports. *Id.* ¶ 78.

Relators have not identified any particular Medicare claim for an individual patient that involved goods or services allegedly obtained via payment of a kickback. Rather, they allege that three particular hospitals – Provena St. Joseph (where Muoghalu worked), Rockford Memorial Hospital, and Christ Medical Center – were rendered ineligible for Medicare reimbursement for the year 2002 due to their receipt of the alleged kickbacks from Aventis. According to relators, each of these entities received tens of millions of dollars in Medicare reimbursement for that year despite its alleged ineligibility. *Id.* ¶¶ 101-03.

Had relators alleged that one or more of the hospitals falsely certified, in connection with a Medicare claim, that it had complied with the anti-kickback statute, that might be sufficient to state a claim under section 3729(a)(2). *See, e.g., United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 94 (3d Cir. 2009) ("Falsely certifying compliance with the . . . Anti-Kickback Act[ ] in connection with a claim

submitted to a federally funded insurance program is actionable under the FCA."). But relators have identified no express false certification of compliance with the anti-kickback statute. Rather, they allege only that the hospitals promised they would comply with the statute and affirmed their understanding that if they did not do so, they would be ineligible for Medicare participation. This is a forward-looking statement – a promise or undertaking – not a false representation. Relators have not alleged, let alone identified, any certification by a hospital, in connection with a Medicare claim, that it had acted in compliance with the anti-kickback statute.

Some courts (though, as best as this Court can determine, not the Seventh Circuit), have concluded that a relators can make out a claim under section 3729(a)(2) on what is referred to as a theory of *implied* false certification. As the Second Circuit described it in *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2000), "[a]n implied false certification claim is based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment." *Id.* at 699. The Court agrees with the Second Circuit, however, that this theory is viable in the Medicare context only when the underlying statute upon which the FCA relator relies *expressly* states that the provider must comply in order to be paid. *Id*. at 700. That is not true of the anti-kickback statute.

A conviction for violating the anti-kickback statute renders a person or entity ineligible to participate in federal health care programs. *See* 42 U.S.C. § 1320a7b(b)(1). None of the hospitals in question, however, has been convicted of violating the statute. Relators appear to allege that simple receipt of a kickback renders a hospital ineligible

to participate in Medicare. *See* 4th Am. Compl. ¶ 104. This, however, is an allegation regarding a proposition of law, not an allegation regarding a fact, and thus the Court is not required to accept it in deciding a motion to dismiss. *See, e.g., County of McHenry v. Ins. Co. of the West*, 438 F.3d 813, 818 (7th Cir. 2006). In their response to the motion to dismiss, relators cite only two district court decisions to support their contention that simple receipt of a kickback renders a hospital ineligible. One of those cases, *United States* ex rel. *Bidani v. Lewis*, 264 F. Supp. 2d 612 (N.D. Ill. 2003), is quite clearly a case about false certifications. The other, *United States v. Rogan*, 459 F. Supp. 2d 692 (N.D. Ill. 2006), contains a sentence to the effect that compliance with the anti-kickback statute is a condition of Medicare payment, but it does so in the context of a citation to the prohibition that applies upon a conviction for violating the statute. *Id.* at 714. The Court cannot rule out the possibility that some other statute or regulation renders a hospital ineligible due to simple receipt of a kickback – i.e., without a false statement or certification – but relators have cited none, and the Court is not required to hunt on its own.

The Court also notes that the Seventh Circuit stated in *Gross* that to make out a false certification claim, the certification must be a condition of payment of a claim. *Gross*, 415 F.3d at 604. This suggests that making a false certification involving a matter that is a condition of program eligibility, not a condition of payment of a claim, does not give rise to FCA liability. *See generally United States* ex rel. *Conner v. Salinas Regional Health Center, Inc.*, 543 F.3d 1211, 1218 (10th Cir. 2008). But because relators have not identified any express false certification, the Court need not

decide this point definitively.

For these reasons, the Court concludes that relators have failed to state a claim under the FCA in connection with their kickback allegations. The Court thus need not address Aventis's other arguments in support of dismissal of relators' kickback-related claims in this regard.[4]

Conclusion

For the foregoing reasons, the Court grants Aventis's motion to dismiss [docket no. 171] in part and denies it in part. Counts 2, 3, 5, and 6 of the fourth amended complaint are dismissed to the extent they are premised upon a false certification theory arising from relators' kickback allegations. Aventis's motion is otherwise denied. The Court directs Aventis to answer the fourth amended complaint by May 11, 2009. The parties are directed to file a joint status report by May 18, 2009, with an agreed-upon or separate proposals for a discovery and pretrial schedule. The case is set for a status hearing on May 20, 2009 at 9:30 a.m.

MATTHEW F. KENNELLY
United States District Judge

Date: April 20, 2009

[4] This does not mean that relators' kickback allegations are no longer part of the case. Those allegations also form a significant part of their claim that Aventis caused hospitals to make false cost reports that included charges for off-label Lovenox.