UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA *et al. ex rel.* TIMOTHY LEYSOCK,	)	
Plaintiffs,	)	**Civil No. 12-11354-FDS**
v.	)	
FOREST LABORATORIES, INC., and FOREST PHARMACEUTICALS, INC.,	)	
Defendant.	)	

MEMORANDUM AND ORDER ON MOTION TO DISMISS THE SECOND AMENDED COMPLAINT

SAYLOR, J.

This is a *qui tam* action alleging the submission of claims to Medicare for the off-label use of pharmaceuticals. Relator Timothy Leysock has brought suit against defendants Forest Laboratories, Inc., and Forest Pharmaceuticals, Inc., which market and sell the drug Namenda.

Relator filed a second amended complaint on April 30, 2014. The second amended complaint alleges that defendants caused the submission of false claims for payment to Medicare by unlawfully marketing Namenda for the off-label use of treating mild Alzheimer's disease. It alleges three violations of the False Claims Act, 31 U.S.C. § 3729 *et seq.*

Defendants have moved to dismiss the second amended complaint. For the following reasons, the motion will be granted in part and denied in part.

I. Background

A. Factual Background

The facts summarized below are set forth in the second amended complaint unless otherwise noted.

1. The Parties

Forest Laboratories, Inc., is a Delaware corporation with a principal place of business in New York, New York. Forest Pharmaceuticals, Inc., which is a wholly owned and controlled subsidiary of Forest Laboratories, is a Delaware corporation with a principal place of business in St. Louis, Missouri.[1] Forest sells a drug called Namenda (also known as memantine or Namenda-XR).

Timothy Leysock is a resident of Florida. From August 1996 until May 2012, he was employed by Forest as a sales representative. His sales territory covered the counties of Palm Beach, Indian River, Martin, St. Lucie, and Okeechobee in Florida.

2. Regulatory Framework

Under the Food and Drug Cosmetic Act, 21 U.S.C. § 301 *et seq.*, pharmaceutical manufacturers may not market or promote a drug for a use that the Food and Drug Administration has not approved. 21 U.S.C. §§ 331(a), (d). When a drug is used for a treatment not approved by the FDA, the use is called "off-label."

Medicare is a government healthcare program. Medicare Part D covers reimbursement for the use of prescription drugs. A patient can only be reimbursed by Medicare under Part D if the drug is being used in an FDA-approved manner. *See* 42 U.S.C. §§ 1396b(i)(10), 1396r-8(k).

[1] The two companies will be referred to as a single entity for the sake of convenience.

In other words, Medicare does not reimburse a patient for the off-label use of a prescription drug.

2. Alleged Fraudulent Scheme

Alzheimer's disease is an irreversible progression of dementia. Physicians commonly use a test called the mini-mental state examination to determine the severity of a patient's Alzheimer's disease, which can be classified as mild, moderate, or severe.

In 2003, Namenda was approved by the FDA for the use of treating moderate or severe Alzheimer's disease. In July 2005, the FDA declined to approve the drug for the use of treating mild Alzheimer's because research indicated that it was not effective for that use. In 2006, the FDA approved the use of a drug named Aricept, manufactured by a competitor, for treatment of all stages of Alzheimer's disease, including mild Alzheimer's.

The second amended complaint alleges that Forest believed that Aricept would hurt its sales of Namenda. It believed that physicians would initially prescribe Aricept to mild Alzheimer's patients, and that it would be difficult to convince physicians to change drugs or prescribe two drugs to treat the same disease in the same patient. It therefore believed that physicians would start Alzheimer's patients with Aricept when their symptoms first started and would never prescribe Namenda.

According to the second amended complaint, Forest then began a nationwide scheme to promote the off-label use of Namenda for mild Alzheimer's. It alleges that Forest's managers instructed the company's sales representatives to tell physicians falsely that Namenda was effective for all stages of Alzheimer's, that Namenda had fewer harsh side-effects than Aricept, and that Namenda protected the gastrointestinal tract. Sales representatives were also instructed to tell physicians that they should start treating Alzheimer's with Namenda and add Aricept later.

The second amended complaint alleges that Forest's managers were careful not to discuss the off-label marketing program by text or e-mail. It also alleges that the company's sales representatives received off-label training in break-out sessions instead of all at once. It alleges that this was done so that Forest could falsely claim that any off-label marketing was done by rogue sales representatives.

More than 95 percent of Alzheimer's patients are over 65 years old and on Medicare. According to the second amended complaint, many of those patients were prescribed Namenda for mild Alzheimer's by physicians who were misled by fraudulent statements made by Forest's sales representatives. Reimbursement claims were presented on behalf of those patients to Medicare.

Leysock alleges that he observed Forest's fraudulent scheme while working for the company as a sales representative from 2006 until 2012.

3. Forest's Previous Settlement Agreement

In September 2010, Forest entered into a settlement with the United States Department of Justice addressing violations of the FCA. The FCA claims alleged that Forest violated the statute by promoting the off-label use of a drug called Celexa. As a result of the settlement, Forest signed a corporate integrity agreement with the government. The agreement requires Forest to ensure that its policies and procedures address appropriate ways to promote its products in a way that is compliant with all applicable federal healthcare-program requirements. It also obligates Forest to submit an annual report to the government certifying that it is in compliance with those requirements.

The second amended complaint alleges that after entering into the settlement agreement,

Forest made reports to the government falsely certifying that it was complying with federal healthcare-program requirements. It alleges those reports were false because of the company's promotion of Namenda for the off-label use of treating mild Alzheimer's disease.

5. Specific Instances of False Claims

The second amended complaint alleges eight specific instances where a false claim was submitted to Medicare for the off-label use of Namenda to treat mild Alzheimer's. It also includes a chart of 28 physicians who allegedly prescribed Namenda for off-label uses to Medicare beneficiaries.

a. Dr. Frank Attenello

Dr. Frank Attenello practices family and internal medicine in Long Beach, California. The Forest sales representative assigned to Attenello was Keith Atardo.

The second amended complaint alleges that Atardo falsely told Dr. Attenello that Namenda was effective in treating mild Alzheimer's, did not have harsh gastrointestinal side effects, and protected the gastrointestinal tract. It alleges that more than 52 percent of Dr. Attenello's Namenda prescriptions were written for Medicare beneficiaries for off-label uses.

For example, on June 21, 2013, Dr. Attenello, relying on Forest's off-label promotional marketing, prescribed Namenda-XR to treat a 71-year-old female patient with mild Alzheimer's. On February 4, 2014, the prescription was filled. The prescription was then presented to the Medicare program for payment.

b. Dr. Meria Aulds

Dr. Meria Aulds practices internal medicine in Decatur, Texas. The second amended complaint alleges that Forest sales representatives falsely told Dr. Aulds that Namenda was

effective in treating mild Alzheimer's, did not have harsh gastrointestinal side effects, and protected the gastrointestinal tract. It alleges that more than 50 percent of Dr. Aulds's Namenda prescriptions were written for Medicare beneficiaries for off-label uses.

For example, on September 13, 2013, Dr. Aulds, relying on Forest's off-label promotional marketing, prescribed Namenda to treat a male patient with mild Alzheimer's. Dr. Aulds provided him with a single sample packet of Namenda. On November 21, 2013, the prescription was filled. The prescription was presented to the Medicare program for payment.

c. Dr. David Austin

Dr. David Austin practices family medicine in Manhattan Beach, California. The second amended complaint alleges that Forest sales representatives falsely told Dr. Austin that Namenda was effective in treating mild Alzheimer's, did not have harsh gastrointestinal side effects, and protected the gastrointestinal tract. It alleges that it was Dr. Austin's regular practice to write off-label Namenda prescriptions for Medicare beneficiaries with mild Alzheimer's.

For example, on January 29, 2014, Dr. Austin, relying on Forest's off-label promotional marketing, prescribed Namenda to treat a 79-year-old female patient with mild Alzheimer's. In March 2014, the prescription was filled. The prescription was presented to the Medicare program for payment.

d. Dr. Mouhannad Azzouz

Dr. Mouhannad Azzouz practices neurology in Fairmont, West Virginia. The second amended complaint alleges that Forest sales representatives falsely told Dr. Azzouz that Namenda was effective in treating mild Alzheimer's, did not have harsh gastrointestinal side effects, and protected the gastrointestinal tract. It alleges that it was Dr. Azzouz's regular

practice to write off-label Namenda prescriptions for Medicare beneficiaries with mild Alzheimer's, and that approximately 50 percent of his Namenda prescriptions were written for off-label uses to Medicare beneficiaries.

For example, on February 18, 2010, Dr. Azzouz, relying on Forest's off-label promotional marketing, prescribed Namenda to treat an 80-year-old female patient with mild Alzheimer's. On March 27, 2012, the prescription was filled. The prescription was presented to the Medicare program for payment.

e. Dr. Richard Bendinger

Dr. Richard Bendinger practices family medicine in Abbeville, Alabama. The second amended complaint alleges that Forest sales representatives falsely told Dr. Bendinger that Namenda was effective in treating mild Alzheimer's, did not have harsh gastrointestinal side effects, and protected the gastrointestinal tract. It alleges that more than ten percent of Bendinger's Namenda prescriptions were written for off-label uses to Medicare beneficiaries.

For example, on January 13, 2014, Dr. Bendinger, relying on Forest's off-label promotional marketing, prescribed Namenda to treat a 76-year-old female patient with mild Alzheimer's. On February 13, 2014, the prescription was filled. The prescription was presented to the Medicare program for payment.

f. Dr. Amit Bhalodia

Dr. Amit Bhalodia practices family medicine in Camden, New Jersey. The second amended complaint alleges that Forest sales representatives falsely told Dr. Bhalodia that Namenda was effective in treating mild Alzheimer's, did not have harsh gastrointestinal side effects, and protected the gastrointestinal tract. It alleges that it was Dr. Bhalodia's regular

practice to write off-label Namenda prescriptions for Medicare beneficiaries with mild Alzheimer's.

For example, on October 20, 2009, Dr. Bhalodia, relying on Forest's off-label promotional marketing, prescribed Namenda to treat a 76-year-old female patient with mild Alzheimer's. On February 4, 2011, and June 3, 2011, the prescription was filled. The prescription was presented to the Medicare program for payment.

g. Dr. William Bell

Dr. William Bell practices family medicine in Robbins, North Carolina. The second amended complaint alleges that it was Dr. Bell's regular practice to write off-label Namenda prescriptions for Medicare beneficiaries with mild Alzheimer's, and that more than 20 percent of his Namenda prescriptions were written for off-label uses to Medicare beneficiaries.

For example, on February 17, 2010, Dr. Bell, relying on Forest's off-label promotional marketing, prescribed Namenda to treat an 86-year-old patient with mild Alzheimer's. On February 24, 2011, the prescription was filled. The prescription was presented to the Medicare program for payment. That same day, Dr. Bell also prescribed the patient Aricept.

h. Dr. Yim Chan

Dr. Yim Chan practices psychiatry in San Francisco, California. The second amended complaint alleges that Forest sales representatives falsely told Dr. Chan that Namenda was effective in treating mild Alzheimer's, did not have harsh gastrointestinal side effects, and protected the gastrointestinal tract. It alleges that it was Dr. Chan's regular practice to write off-label Namenda prescriptions for Medicare beneficiaries with mild Alzheimer's, and that 30 percent of his Namenda prescriptions were written for off-label uses to Medicare beneficiaries.

For example, on December 3, 2007, Dr. Chan, relying on Forest's off-label promotional marketing, prescribed Namenda to treat a 66-year-old female patient with mild Alzheimer's. On January 21, 2008, the prescription was filled. The prescription was presented to the Medicare program for payment.

B. Procedural Background

On July 24, 2012, relator filed the complaint in this case. The complaint was amended twice, on October 2, 2012, and again on April 30, 2014. The second amended complaint alleges claims of (1) causing false or fraudulent claims for payment to be presented to the United States in violation of 31 U.S.C. § 3729(a)(1)(A); (2) knowingly making, using, or causing to be made or used false records or statements material to a false of fraudulent claim paid by the United States in violation of 31 U.S.C. § 3729(a)(1)(B); and (3) conspiracy to violate the FCA in violation of 31 U.S.C. § 3729(a)(1)(C). On April 16, 2014, the government declined to intervene in the case. On April 30, the complaint was unsealed.

On June 30, 2014, defendants filed a motion to dismiss. They contend (1) that the substantive FCA claims fail to satisfy the pleading requirements of Fed. R. Civ. P. 9(b); (2) that the alleged non-compliance with the settlement agreement should be struck from the complaint because it is not actionable; and (3) that the conspiracy claim fails to satisfy the requirements of Rule 9(b).

III. Analysis

Under the FCA, it is unlawful for a person or entity to (1) knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval to the United States, (2) knowingly make, use, or cause to be made or used, a false record or statement material to a false

or fraudulent claim; or (3) conspire to commit a violation of the statute. 31 U.S.C. §§ 3729(a)(1)(A)-(C). Private persons, known as relators, can file civil *qui tam* actions on behalf of the United States against persons or entities who violate the act. *Id.* § 3730(b). The government can intervene in a *qui tam* action and assume primary responsibility over it. *Id.* § 3730(b)(2), (b)(4), (c)(1). The relator is eligible to collect a portion of any damages awarded in a *qui tam* action, regardless of whether or not the government intervenes. *Id.* § 3730(d).

A. Rule 9(b)

Defendants first contend that the FCA claims should be dismissed because the complaint does not satisfy the pleading requirements of Rule 9(b). That rule requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Those heightened pleading requirements apply to claims brought under the FCA. *United States ex rel. Ge v. Takeda Pharm. Co. Ltd.*, 737 F.3d 116, 123-24 (1st Cir. 2013). Thus, "[r]elators are required to set forth with particularity the 'who, what, when, where, and how' of the alleged fraud." *Id.* at 123 (quoting *United States ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 147 (D. Mass. 2000)).

As the First Circuit explained in *Ge*:

> A relator must provide details that identify particular false claims for payment that were submitted to the government. In a case such as this, 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, we believe that some of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b).

Id. (quoting *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232-33 (1st Cir. 2004) (alterations omitted) (internal quotation marks omitted)).

"Because FCA liability attaches only to false *claims*, merely alleging facts related to a defendant's alleged *misconduct* is not enough. Rather, a complaint based on § 3729(a)(1)(A) must 'sufficiently establish that false claims were submitted for government payment' as a result of the defendant's alleged misconduct." *Id.* at 124 (citations omitted) (emphasis in original) (quoting *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007)). However, "[i]n a qui tam action in which the defendant is alleged to have induced third parties to file false claims with the government, a relator can satisfy this requirement by 'providing factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim.'" *Id.* at 123-24 (quoting *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29 (1st Cir. 2009)).[2]

Thus, a *qui tam* complaint alleging that a defendant induced a third party to submit false claims to the government for reimbursement must allege two things: (1) particular details of a scheme to cause the submission of false claims to the government and (2) factual or statistical evidence that strengthens the inference of fraud on the government beyond a mere possibility. *Duxbury*, 579 F.3d at 29. While conclusory allegations are insufficient, Rule 9(b) may be satisfied "when some questions remain unanswered, provided the complaint as a whole is sufficiently particular to pass muster." *United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009).

Defendants contend that the amended complaint does not state sufficient factual or

[2] This standard also applies to FCA claims under 31 U.S.C. § 3729(a)(1)(B). *Ge*, 737 F.3d at 125 n.5.

statistical evidence showing that defendant caused the submission of a false claim to the government. An FCA relator can satisfy that requirement without necessarily providing details as to each false claim. *Ge*, 737 F.3d at 123-24. The two most recent First Circuit cases on the issue, *Ge* and *Duxbury*, offer some guidance on when factual evidence is sufficient to satisfy the requirements of Rule 9(b).

In *Ge*, the relator's FCA claim was dismissed because she "made no attempt in her complaints to allege facts that would show that some *subset* of claims for government payment for the four subject drugs was rendered false as a result of [defendant's] alleged misconduct." *Id.* at 124 (emphasis in original). The court found that the relator had alleged no factual or statistical evidence to strengthen the inference of fraud beyond a mere possibility. *Id.*

In contrast, the *Duxbury* court found that the relator sufficiently alleged factual evidence to strengthen the inference of fraud beyond a mere possibility. 579 F.3d at 30. In that case, the relator set forth allegations of kickbacks provided by the defendant that resulted in the submission of false claims by eight healthcare providers in the state of Washington. *Id.* The court found that those eight specific allegations were sufficient factual support to satisfy the requirements of Rule 9(b), but described the matter as "a close call." *Id.*

The First Circuit in *Duxbury* quoted one of the specific allegations the plaintiff made in that case:

> In 1997–98 Western Washington Treatment Center in Olympia, Washington, received more than $5,000 of free commercially packaged ProCrit from [defendant] under the direction of Robert Ashe so that Western Washington could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product. [Defendant] intended the free commercially packaged ProCrit to be a "cash equivalent" "kickback" to Western Washington in order to induce the provider to purchase ProCrit and to administer ProCrit at the "off-label" once a week dosing regiment. Western Washington was

> reimbursed by Medicare for the free commercially packaged ProCrit. As a result, [defendant] knowingly caused the presentation by Western Washington of these false claims to the United States Government.

579 F.3d at 30. The court concluded that the complaint's collection of eight specific examples of similar specificity, along with allegations of the defendant's fraudulent scheme, were enough to satisfy the requirements of Rule 9(b). *Id.* As the court noted, the plaintiff "identified, as to each of the eight medical providers (the who), the illegal kickbacks (the what), the rough time periods and locations (the where and when), and the filing of the false claims themselves." *Id.*

Here, the specific examples in the second amended complaint allege information in a format almost identical to the information alleged in *Duxbury*. For example, it alleges:

> 89. For example, Dr. Frank Attenello practices family and internal medicine at 1201 East Bixby Road in Long Beach, California. One of the Forest sales reps assigned to Dr. Attenello is Keith Atardo. ("Atardo")
>
> 90. For years, Forest sales reps, including Mr. Atardo, regularly promoted off-label uses of Namenda to Dr. Attenello in his office, including promoting the use of Namenda (particularly Namenda-XR) to treat mild AD, at least as recently as late January or early February, 2014. In reliance of those off-label messages, it is and has been Dr. Attenello's regular practice to write off-label Nemanda prescriptions for mild AD to Medicare beneficiaries, which he did at least as recently as late January, 2014.
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> 91. Among the off-label messages Dr. Attenello received from Forest, and relied on in writing off-label prescriptions of Namenda to Medicare beneficiaries, were that Namenda is effective for all stages of AD (mild, moderate and severe), that Namenda does not have the harsh GI side-effects of ACHEI's (e.g. Aricept), and that Namenda is GI-protective, so he should start treating AD with Namenda and then add an ACHEI (e.g. Aricept) later. Dr. Attenello received these messages from sales rep Atardo and via Forest-sponsored physician speakers, including Continuing Medical Education ("CME") events.
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> . . .
>
> 93. As a result of Forest's off-label promotion, over 52% of Dr. Attenello's Namenda prescriptions are written for Medicare beneficiaries for off-label

> uses, and thus constitute false claims under the FCA, all of which false claims were caused by Defendants.
>
> 94. Dr. Attenello provided the example of a 4' 11", 166 lb. 71 year old female Medicare beneficiary ("Patient A"), with mild AD, documented in part by a MMSE score of 19 out of 30 on June 21, 2013. On . . . June 21, 2013, relying on Forest's off-label promotional messages, Dr. Attenello prescribed Namenda-XR (28 mg once per day) to treat Patient A's mild AD, a use that Dr. Attenello knew was off-label. . . .
>
> 95. When Patient A returned to Dr. Attenello's office in Long Beach on February 4, 2014, she had had her Namenda-XR prescription filled and was continuing to take Namenda-CR. She had had her prescription filled at the CVS at 311 West Pacific Coast Highway in Wilmington, CA.
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> . . .
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> 97. Patient A is a Medicare beneficiary who was prescribed Namenda for an "off-label" use (i.e., a use that was neither approved by the FDA nor supported in an authorized compendium) as a direct and foreseeable result of Forest's promotion of that use. Patient A's off-label Namenda prescription was filled and presented to the Medicare program for payment.

(Second Am. Compl. ¶¶ 89-97). The seven other specific examples are similar to the one involving Attenello.

Those quoted paragraphs of the second amended complaint identify one of defendants' sales representatives, the doctor, and the patient (the who), the specific misrepresentations made by defendants (the what), time periods and locations (the where and when), and the filing of the false claims themselves. That is exactly what the specific examples in *Duxbury* identified. Although there are no specific details regarding the claim for payment, such detail is not necessary under the precedent in this circuit. *See Ge*, 737 F.3d at 124 (explaining that relator can satisfy Rule 9(b) "without necessarily providing details as to each false claim"); *Duxbury*, 579 F.3d at 29 (the same); *Rost*, 507 F.3d at 733 (the same). And in *Duxbury*, the most specific information about the false filing itself was that "Western Washington was reimbursed by

Medicare for the free commercially packaged ProCrit." 579 F.3d at 30. That satisfied the requirements of Rule 9(b) even though the dollar amount or the date of claim was not alleged.

The second amended complaint in this case therefore alleges fraud with particularity found adequate in *Duxbury* to satisfy the requirements of Rule 9(b). Accordingly, defendants' motion to dismiss on Rule 9(b) grounds will be denied.[3]

B. Alleged Non-Compliance with Settlement Agreement

Defendants next contend that their alleged non-compliance with the settlement agreement should be struck because such non-compliance is not actionable under the FCA. Under 31 U.S.C. § 3729(a)(1)(B), if a false statement "is not made with the purpose of inducing payment of a false claim . . . the direct link between the false statement and the Government's decision to pay or approve a false claim is too attenuated to establish liability." *Allison Engine Co., Inc. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008). Thus, the "question here is whether [the] claims . . . misrepresented compliance with a material precondition of payment recognized by [Medicare]." *New York v. Amgen Inc.*, 652 F.3d 103, 110-11 (1st Cir. 2011).

Plaintiff contends that defendants could have been excluded from government healthcare programs if they did not certify, pursuant to the settlement agreement, that they were complying with federal healthcare regulations. He contends that defendants' certifications were therefore a

[3] Defendants also contend that the second amended complaint does not allege with particularity that they knowingly caused the submission of any false claim. However, "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). The allegations that (1) defendants vigorously promoted the off-label use of Namenda even though the medical literature showed it was not effective in treating mild Alzheimer's and (2) that physicians only prescribed Namenda for that off-label use because of defendants' false statements are enough to state a claim under the FCA.

Finally, defendants contend that the statistical evidence in the second amended complaint is not enough to make the FCA claims plausible. Because the factual allegations without statistical evidence are sufficient, it is not necessary to decide that issue.

precondition of reimbursement for its products by Medicare.

While failing to comply with the settlement agreement may have excluded defendants from participating in government healthcare programs, courts have differentiated those requirements from preconditions that are a prerequisite to a particular payment. *See United States ex rel. Landers v. Baptist Mem'l Health Care Corp.*, 525 F. Supp. 2d 972, 978 (W.D. Tenn. 2007) (explaining that conditions of participation in Medicare and Medicaid "are quality of care standards directed towards an entity's continued ability to participate in the Medicare program rather than a prerequisite to a particular payment"). Thus, a claim for payment "is not 'false' within the meaning of the FCA if the [person] is not required to certify compliance in order to receive payment. . . . [A] false certification of compliance, without more, does not give rise to a false claim for payment unless payment is conditioned on compliance." *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 269 (5th Cir. 2010).

Although the settlement agreement permits the government to exclude defendants from government healthcare programs wholesale, it does not require that sanction. Nowhere in the agreement is the payment of any specific claim for reimbursement from Medicare conditioned on defendants' compliance with the agreement. An FCA claim cannot be based on the allegations that defendant violated the settlement agreement alone.

However, the settlement agreement could be relevant to defendants' knowledge of the FCA and its relation to the off-label promotion of Namenda. Under Rule 12(f), a court may strike from a pleading "any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). Because the allegations involving defendants' breach of the settlement agreement

appear to be relevant to defendants' knowledge, those allegations will not be struck.[4]

C. FCA Conspiracy Claim

Finally, defendant contends that the second amended complaint does not allege conspiracy with particularity as required by Rule 9(b). FCA conspiracy claims are subject to the requirements of Rule 9(b). *Gagne*, 565 F.3d at 45. The rule, however, only requires that a complaint allege "fraud or mistake" with particularity. As described above, the second amended complaint satisfies that requirement.

The second amended complaint alleges that defendants "combined, conspired, and agreed together with physicians and others to defraud the United States." (Second Am. Compl. ¶ 218). However, it does not allege any facts as to (1) who the co-conspirators are, (2) when or where they entered into an agreement, or (3) what overt acts they took in furtherance of the conspiracy. Absent such allegations, a conspiracy claim under the FCA cannot survive a motion to dismiss. *See United States ex rel. Estate of Cunningham v. Millennium Labs. of Cal.*, 2014 WL 309374, at *1-2 (D. Mass. Jan. 27, 2014) (holding that relator did not plead facts sufficient to show a conspiracy).

In addition, plaintiff did not offer any opposition to dismissal of the conspiracy claim in his memorandum. If there is a reason to deny the motion to dismiss the conspiracy claim, plaintiff has not supplied it.

Accordingly, the motion to dismiss will be granted as to the FCA conspiracy claim.

V. Conclusion

For the foregoing reasons, defendant's motion to dismiss is GRANTED as to the FCA

[4] The Court makes no ruling at this stage whether the settlement agreement would be admissible at any trial of this action.

conspiracy claim (Count 3) and otherwise DENIED.

So Ordered.

/s/ F. Dennis Saylor
F. Dennis Saylor IV
United States District Judge

Dated: October 27, 2014