IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA ex rel. YOASH GOHIL,	:	
Plaintiff,	:	
	:	**CIVIL ACTION**
v.	:	
	:	**02-2964**
SANOFI-AVENTIS U.S. INC., et. al.	:	
Defendant.	:	

MEMORANDUM

Stengel, J. **March 30, 2015**

Yoash Gohil, relator, brings this False Claims Act lawsuit on behalf of the United States against his former employer Sanofi-Aventis U.S., Inc. [Aventis] and its subsidiaries. Mr. Gohil alleges that Aventis engaged in a fraudulent marketing scheme which caused numerous healthcare providers to submit false claims to federally funded health insurance programs. Aventis has moved to dismiss the Second Amended Complaint. I will grant the motion in part.

I. Background

Mr. Gohil was employed by Aventis and its predecessor companies from February 1982 until his resignation in June 2002. Second amended complaint (SAC) ¶ 1. At all relevant times, Mr. Gohil was a Senior Oncology Sales Specialist whose duties included the marketing, promotion and sale of pharmaceuticals manufactured by Aventis. Id. ¶ 2. This case concerns the marketing of Taxotere, a chemotherapy agent manufactured by

Aventis which Mr. Gohil was assigned to promote and sell in the Philadelphia region. Id. ¶ 20.

Originally, the Food and Drug Administration (FDA) approved Taxotere for the treatment of patients with Non-Small Cell Lung Cancer (NSCLC) and Breast cancer, but only after the failure of prior platinum based chemotherapy. Id. This is also known as second line treatment. In November 2002, the FDA approved Taxotere for first line treatment of NSCLC. Id. ¶ 22. There were no other approved medical indications. Id. Between 1996 and 2004, Taxotere was the most expensive taxane on the market. Id. ¶ 25. A substantial portion of individuals who are treated with Taxotere are participants in a federal insurance program including Medicare, Medicaid, CHAMPUS/Tricare,[1] and the Federal Employee Health Benefit Plan (FEHBP).

From 1996 until 2004, Aventis engaged in a marketing plan which promoted Taxotere for off-label uses. Id. ¶ 15. An off-label use is a use which is not approved by the FDA. This scheme took two forms. First, Aventis trained and directed its employees, such as Mr. Gohil, to misrepresent the safety and effectiveness of the off-label use of Taxotere to expand the market for Taxotere into unapproved settings. Id. ¶ 16, 60. Second, Aventis paid healthcare providers illegal kickbacks in the form of sham unrestricted grants, speaking fees, travel, entertainment, sports and concert tickets, preceptorship fees,[2] free samples an free reimbursement assistance[3] to encentivize

[1] CHAMPUS/Tricare provides medical care for members of the Uniformed Services. 10 U.S.C.A. § 1071 (West 2015). CHAMPUS is an acronym for Civilian Health and Medical Program of the Uniformed Services.

[2] Through a preceptorship an Aventis sales representative would pay a physician $500 - $1000 to observe the physician during the day with patients. SAC ¶¶ 148, 151. “In reality and practice, the preceptorship program was a

providers to prescribe Taxotere for off-label uses. Id. ¶ 17. By the means of this fraudulent marketing scheme, Aventis dramatically increased revenue on sales of Taxotere from $424 million in 2000 to $1.4 billion in 2004. Id. ¶ 182.

Federal Insurance Programs will pay for an off label use of a prescription drug if the drug is used for a medically accepted indication or the drug is medically necessary. Id. ¶¶ 44-48. Aventis marketed Taxotere for off-label use in the first line treatment of Breast Cancer and NSCLC, second line treatment of Ovarian Cancer and for the treatment of other unspecified medical indications. Id. ¶ 58-63, 98, 100, 101, 105. According to Mr. Gohil, the prescription of Taxotere in these settings would not be eligible for reimbursement. Id. ¶ 50. Additionally, prescriptions of Taxotere which were "produced through the payment directly or indirectly of a kickback" were ineligible for reimbursement. Id. ¶ 112-113. "Consequently, Defendant Aventis' fraudulent marketing scheme caused a substantial number of healthcare providers to submit claims for reimbursement to Governmental medical reimbursement systems for the use of Taxotere, which would not have otherwise been paid had the Government reimbursement programs known of Aventis' fraudulent marketing scheme." Id. ¶ 186.

Mr. Gohil filed his original *qui tam* complaint on May 17, 2002 and the case was assigned to Chief Judge Tucker. He filed an amended complaint on July 19, 2002. In June

---

sham designed to disguise payments of money to gain access to physicians to promote, and influence them to prescribe, off-label uses of Taxotere, thereby increasing Taxotere sales. Id. ¶ 150.

[3] "Under [free reimbursement assistance], Defendant Aventis knew and knows that the physicians who are prescribing Taxotere in unapproved settings that are not listed on the drug reporting compendia or approved by the fiscal intermediary would encounter difficulty in receiving reimbursement from the Government for the cost of the drug. Thus Defendant Aventis implemented a plan to provide free assistance to physicians and healthcare providers to obtain reimbursement from Medicare, Medicaid, and other federal reimbursement programs." Id. ¶ 171.

2002, Mr. Gohil resigned from Aventis, and he initiated a wrongful termination action against Aventis in New Jersey Superior Court pursuant to New Jersey's Conscientious Employee Protection Act and New Jersey's Law Against Discrimination (the CEPA action). In the state court lawsuit, Mr. Gohil alleged that Aventis retaliated against him because he objected to sales activities which violated federal and state laws, including FDA regulations.

While the Government was deciding whether to intervene in this action, the parties engaged in discovery in the CEPA action. Aventis produced tens of thousands of pages of training materials, manuals, and journal abstracts about Taxotere. Mr. Gohil took depositions of several current and former Aventis employees. At the close of discovery, Aventis moved for summary judgment. On October 31, 2005, before any decision was rendered on that motion, the parties settled the CEPA action, and the case was dismissed. The settlement agreement included a broad a release of liability in favor of Aventis.

On August 15, 2006, the Government elected to decline intervention in this *qui tam* case. The case was unsealed and a summons issued as to Aventis on September 11, 2006. With leave of court, Mr. Gohil filed the SAC under seal on February 9, 2007 giving the Government another opportunity to intervene which it declined. On February 29, 2008, Chief Judge Tucker unsealed the SAC and ordered jurisdictional discovery. Discovery was contentious, and Mr. Gohil took an unsuccessful appeal from one of Chief Judge Tucker's rulings. Discovery finally concluded on October 5, 2010, and the pending motion to dismiss followed on December 15, 2010. The action was reassigned to my

docket on November 27, 2013, and I heard oral arguments on the motion to dismiss on February 19, 2014.

II. Discussion

a. The False Claims Act

Under the False Claims Act (FCA), persons who submit fraudulent applications for payment to the United States are liable to the Government in a civil action for civil penalties and treble damages. 31 U.S.C.A. § 3729(a)(1) (West 2015). In addition to the Attorney General, the q*ui tam*[4] provisions of the act empower private individuals, like Mr. Gohil, to file lawsuits on behalf of the United States seeking damages sustained by the Government for the payment of false claims. § 3730(b). Relators, the citizen plaintiff in FCA parlance, must file their complaints under seal and serve the Government with a copy of the complaint and disclosure of all material evidence. § 3730(b)(2). The court cannot lift the seal until the Government investigates the claims and either decides to take over the action or notifies the court that it declines to intervene in the case. §3730 (b)(4). If the Government declines to intervene, it retains the right to veto any settlement negotiated by the relator, and it may move to intervene at a later date upon a showing of good cause. §3730(b)(1);(b)(3)

Congress enacted the *Qui tam* provisions to employ citizens in the quest to recover money depleted from the national treasury as a result of fraud against the Government. U.S. ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 650 (D.C. Cir. 1994)

[4] "*Qui tam* is short for '*qui tam pro domino rege quam pro se ipso in hac parte sequitur,*' which means 'who pursues this action on our Lord the King's behalf as well as his own.'" Rockwell Int'l Corp. v. United States, 549 U.S. 457, 463 (2007).

(discussing legislative history). "On the downside, overly generous qui tam provisions present the danger of parasitic exploitation of the public coffers…." Id. at 649 (citing United States ex rel. Marcus v. Hess, 317 U.S. 537 (1943)). In an effort to strike a balance between private enforcement and avoiding opportunistic lawsuits, the FCA contains a specific jurisdictional provision which I will address first.

b. Aventis's 12(b)(1) Motion

1. Standard of Review

Aventis moves to dismiss this case pursuant to Rule 12(b)(1) for lack of subject matter jurisdiction. To select the correct standard of review, I first note that Aventis's motion is a factual attack on jurisdiction. Unlike a facial challenge which concerns a pleading deficiency, Aventis maintains that Mr. Gohil has not complied with the jurisdictional prerequisites contained in the False Claims Act. United States ex rel. Atkinson v. Pa. Shipbuilding, 473 F.3d 506, 512 (3d Cir. 2007). Accordingly, "[I] may consider and weigh evidence outside the pleadings to determine if [the court] has jurisdiction." Gould Electronics Inc. v. United States, 220 F.3d 169, 178 (3d Cir. 2000) (citing Mortensen v. First Fed. Sav. & Loan Ass'n, 549 F.2d 884, 891 (3d Cir. 1977)). "[N]o presumptive truthfulness attaches to plaintiff's allegations." Mortensen v. First Fed. Sav. & Loan Ass'n, 549 F.2d 884, 891 (3d Cir. 1977). A *qui tam* relator must establish by a preponderance of the evidence that the court has jurisdiction. *See* Gould, 220 F.3d at 178 (citing Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir.1991)); United States ex rel. Biddle v. Bd. of Trustees of the Leland Stanford Jr. University, 161 F.3d 533, 540 (9th Cir.1998).

2. The False Claims Act Public Disclosure Bar

Following the Supreme Court's decision in Marcus v. Hess, Congress revised the FCA to prohibit *qui tam* actions which are based of publicly available information. Springfield Terminal, 14 F.3d at 649. In Marcus, the relator "copied the information on which his *qui tam* suit was based from the Government's own criminal indictment." Id. (citing Marcus, 317 U.S. at 537). Obviously, such parasitic lawsuits do not aid the Government's efforts to recover fraudulently paid funds. Rather, such lawsuits are an additional drain on the public fisc. Thus, the statute seeks to reserve *qui tam* actions for those relators with independent knowledge of the fraud as follows:

> No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C.A. § 3730(e)(4)(A) (West 2009), amended by Pub. L. No. 111-148, Title X, § 10104(j)(2), 124 Stat 119.[5] In turn, an original source is:

---

[5] The Patient Protection and Affordable Care Act amended the jurisdictional bar to read:

> (4)(A)The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed--
>
> (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
>
> (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
>
> (iii) from the news media,
>
> unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, 'original source' means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the *902 Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge

> an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

§ 3730(e)(4)(B) (West 2009), amended by Pub. L. No. 111-148, Title X, § 10104(j)(2), 124 Stat 119.

The Court of Appeals has identified the following five elements of the public disclosure bar, and I will analyze Mr. Gohil's claims accordingly:

> (1) there was a "public disclosure";
> (2) "in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government [General] Accounting Office report, hearing, audit, or investigation, or from the news media";
> (3) of "allegations or transactions" of the fraud;
> (4) that the relator's action was "based upon"; and
> (5) the relator was not an "original source" of the information.

U.S. ex rel. Paranich v. Sorgnard, 396 F.3d 326, 332 (3d Cir. 2005). If I find there was no public disclosure, I need not consider Mr. Gohil's original source status.[6] U.S. ex rel Dunleavy v. Count of Delaware, 123 F.3d 734, 740 (3d Cir. 1997).

I start with the first two elements. *See* Atkinson, 473 F.3d at 519. Aventis has submitted two documents which it contends block Mr. Gohil's suit.[7] The first document

---

> that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

31 U.S.C.A. § 3730(e)(4)(A) (West 2015). The ACA amendments were not made retroactively applicable; therefore, I will apply the Pre-ACA public disclosure bar and relevant precedent. U.S. ex rel. Zizic v. Q2Administrators, LLC, 728 F.3d 228, 232 n.3 (3d Cir. 2013).

[6] This includes Aventis's new argument that Mr. Gohil failed to voluntary disclose the information supporting his claim to the Government prior to filing this *qui tam* action. *See* doc. no. 109. The pre-filing disclosure provided for by 31 U.S.C.A. § 3730(e)(4)(B) (West 2009) goes to a *qui tam* relator's original source status and is not implicated if there is no public disclosure.

[7] A third set of document are letters between the FDA's Division of Drug Marketing, Advertising, and Communication and Aventis. A fourth document is brochure Mr. Gohil saw in a doctor's office. Neither party has

is Mr. Gohil's Statement of Facts (SoF) filed in opposition to Aventis' Motion for Summary Judgment in the CEPA action. As a filing in a civil hearing, the SoF is a source listed in § 3730(e)(4)(A). U.S. ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. The Prudential Insurance Company, 944 F.2d 1149, 1155 - 56 (3d Cir. 1991) (expansively construing the term "civil hearing"). The second document is a September 15, 1997 article in the *Wall Street Journal* titled "Off the Label: Staffers of Drug Maker Say it Pushed Product for Unapproved Uses." Mot. to Dismiss Ex. 12. The article was published in the "news media" making the article a source listed in §3730(e)(4)(A).

Next, I determine whether the SoF or the article disclosed allegations or transactions of fraud. The Court of Appeals has adopted an algebraic formula to represent when information in a public disclosure qualifies as an allegation or transaction of fraud:

> [I]f X + Y = Z, Z represents the allegation of fraud and X and Y represent its essential elements. In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed.

Dunleavy, 123 F.3d at 741 (citing U.S. ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 654 (D.C.Cir.1994)). For the purpose of this test, the essential elements of a fraud are, "a misrepresented state of facts and a true state of facts." Id. "Injected into the above formula the variables take on the following labels: 'X (misrepresented state of facts) + Y (true state of facts) = Z (fraud).'" Id. (citing U.S. ex rel. Findley v. FPC-Boron Employees' Club, 105 F.3d 675, 686 (D.C. Cir. 1997)). "Thus, the public disclosure bar applies if either Z (fraud) or both X (misrepresented facts) and Y (true facts) are

---

submitted the letters or brochure as exhibits for this motion. Therefore, I am unable to evaluate whether the letters publicly disclosed the allegations of fraud or the fraudulent transactions.

[publicly] disclosed by way of a listed source." U.S. ex rel. Zizic v. Q2Administrators, LLC, 728 F.3d 228, 236 (3d Cir. 2013) (citing Atkinson, 473 F.3d at 519).

I will consider the Dunleavy analysis in conjunction with whether Mr. Gohil's claims are "based on" the publicly disclosed allegations and transactions of fraud. A *qui tam* complaint is based on a public disclosure when the claims in the complaint are "supported by" or "substantially similar" to the public disclosures. Zizic, 728 F.3d at 237 citing U.S. ex rel Mistick PBT v. Hous. Auth. of City of Pittsburgh, 186 F.3d 376, 385-88 (3d Cir. 1999). In other words, "a qui tam action is 'based upon' a qualifying disclosure if the disclosure sets out either the allegations advanced in the qui tam action or all of the essential elements of the qui tam action's claims." Mistick PBT, 186 F.3d at 388. In order to determine if Mr. Gohil's claims are based on the public disclosures, I will first parse out the essential elements of each claims. *See* Atkinson, 473 F.3d at 513 (approving of the district court's claim by claim Dunleavy analysis).

Count I asserts a conspiracy to submit false claims in violation to § 3729(a)(3).[8] Pursuant to Dunleavy, [9] the true state of facts (Y) are: 1.) an agreement between Aventis and healthcare providers; 2.) to submit claims for payment to federal insurers for an non-reimbursable use of Taxotere; and 3.) to submit claims to federal insurers which were

[8] As I discuss in greater detail at section II d 2, I will refer to the statute by its pre-FERA numbering.

[9] The Dunleavy Court dissected the relator's claims this way:

> "We view the fraudulent scheme pled in Dunleavy's Second Amended Complaint as having four essential elements for purposes of our jurisdictional inquiry under the FCA's public disclosure bar: (1) the County was the recipient of funds belonging to the federal government; (2) the County had an obligation to repay those funds to the federal government; (3) the County failed to repay those funds to the federal government after the obligation became owing; and (4) the County failed to disclose to the federal government that funds belonging to it were in the County's possession. Elements one through three account for the 'actual state of facts,' while the fourth element corresponds to the 'misrepresented state of facts.'"

Dunleavy, 123 F.3d at 741

tainted by illegal kickbacks. The false state of fact (X) is that the providers submitted claims to federal insurers for the non-reimbursable use of Taxotere or which failed to disclose the existence of an illegal kickback.[10]

Count II alleges violations of the Anti-Kickback Act in contravention of § 3729(a)(2). The true state of facts are: 1.) the payment of an illegal kickback by Aventis to a healthcare provider; and 2.) the kickback influenced the providers to prescribe Taxotere to patients who were insured by federal program. The false state of fact is that the physician submits claims to a federal insurer without disclosing the receipt of an illegal kickback.

Counts III and IV state a cause of action pursuant to subsections (a)(1) and (a)(2) of § 3729. Both counts are premised on the same true state of facts which are: 1.) Aventis marketed Taxotere for non-reimbursable uses; and 2.) Aventis' marketing scheme influenced doctors to prescribe Taxotere for non-reimbursable uses to federally insured patients. The common false state of fact is that physicians submitted claims to a federal progam without disclosing the non-reimbursable use of Taxotere.

While the true state of facts varies, each count in the complaint depends on the same false state of facts. In each instance, Mr. Gohil contends that physicians submitted claims to the federal government which did not disclose the existence of an illegal kickback or concealed Taxotere's non-reimbursable use. This similarity is significant

[10] Mr. Gohil posits that the Government's payment of the Medicare and Medicaid claims is an essential element of each count. I disagree. The relator need only prove that the Government honored false claims to recover damages above the civil penalties. *See* U.S. ex rel. Grubbs b. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009).

because neither the article nor the SoF disclose the submission of claims to a federal insurer.

The Wall Street Journal article discusses a wrongful termination and RICO lawsuit filed against Rhone-Polenc Rorer (RPR) by four of its former employees. Def. Mot. to Dismiss, doc. no. 91, ex. 12. RPR was a drug manufacturer which merged with Hoescht in 1998 to form Avenits. SAC ¶ 5. According to the article, RPR marketed its drug Lovenox for off-label uses. The former employees allege "they were coerced to expand off-label promotion and destroy evidence of it." Id. at 2. The article makes passing reference to Taxotere allowing a reader to conclude that RPR also marketed Taxotere for off-label uses. Id. at 3. The article discusses how the off-label promotion may run afoul of FDA regulations, but it contains no mention of a claim submitted to a federal insurer.

The SoF is a closer question. The document exhaustively details Aventis' off-label promotion of Taxotere. Mot. to Dismiss, doc. no. 91, Ex. 8, pp 23-71. It describes Aventis' use of illegal kickbacks to influence doctors to prescribe Taxotere. Id. at pp 73-75. The SoF also discloses that the majority of Taxotere prescriptions were for off-label uses. Id. at 17. Additionally, the SoF mentions that Aventis' would reduce the bulk rate at which physicians could purchase Aventis pharmaceuticals, "including Azemet." As a result, the physicians acquisition cost would be lower than the Government reimbursement rates, and the resulting "spread" would be profit to the doctor. Id.

I am not persuaded that the false state of facts in the SAC is based on the disclosure of Aventis' price manipulation. First of all, in addition to the fraudulent marketing scheme, Mr. Gohil's first amended complaint (FAC) included allegations

related to Aventis' manipulation of the cost of Anzemet. Mr. Gohil removed the counts related to Anzemet from the SAC, and Mr. Gohil has disavowed any recovery under this theory. *See* Defs.' Mot. to Dismiss, Ex. 6; Pl.'s Brief in Opposition at 12. Second, the SoF does not state that any doctor ever submitted a claim to a federal insurer, false or otherwise. On these facts, it would be a fair inference that doctors submitted reimbursement claims to the Government tainted by price manipulation, but I am unaware of any precedent which would allow me to infer the disclosure of a fraudulent transaction that is not specifically "set out" in the qualifying document.

The statute does not "specify the degree to which the 'action' must be 'based upon' the public disclosure in order to fall within the jurisdictional bar." Mistick PBT, 186 F.3d at 388. The Third Circuit has extensively considered this ambiguity and has settled on the "substantially similar" standard. Zizic, 728 F.3d at 237. It seems that "substantially similar" requires more than an inference. Indeed, the only time an inference is acceptable is when both the true state of facts and the false state of facts (i.e. the fraudulent transactions) are disclosed. Dunleavy, 123 F.3d at 741 (citing Springfield Terminal Ry. Co., 14 F.3d at 654). At that point, it is fair to infer the allegation of fraud. Id.; *see also* Springfield Terminal Ry. Co., 14 F.3d at 655 ("Fraud requires recognition of two elements: a misrepresented state of facts and a true state of facts. The presence of one or the other in the public domain, but not both, cannot be expected to set Government investigators on the trail of fraud."). To add another layer of inference to reach the allegation of fraud would impermissibly broaden the scope of the public disclosure bar and restrict private enforcement of the FCA hindering the remedial purpose of the statute.

Finally, I note that Aventis has not attempted to identify how the article and SoF disclosed the false state of facts. Eschewing the Dunleavy analysis, Aventis argues "[t]he better test, however, is to rely on the words of Gohil's counsel prior to the filing of the SAC…." While Mr. Gohil has the burden to establish jurisdiction, Aventis' total failure to link the SAC to a disclosed set of misrepresented facts does not help its cause. *See* U.S. ex rel. Johnson v. Shell Oil Co., 26 F. Supp. 2d 923, 928 (E.D. Tex. 1998) ("It is the burden of the movant …, to show that the allegations or transactions which form the basis of the False Claims Act suit are the same as those which are [publicly disclosed]."). Furthermore, Aventis insistence that the SAC is based on a new theory and is different from the FAC is inaccurate. The only real difference between the two complaints is that the Anzemet allegations in the FAC are not included in the SAC. Otherwise, the Taxotere allegations are present in both versions. While this argument pertains more to the original source analysis, which I do not reach, the fallacy of Aventis' assertion suggests that its jurisdictional argument is a red herring.

Accordingly, I find that the claims in the SAC have not been publicly disclosed, and I have jurisdiction over this *qui tam* action. I will now proceed to review the merits of the case. Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991) (citing Bell v. Hood, 327 U.S. 678, 682 (1946)) ("Ordinarily, a court must assume jurisdiction over a case before deciding legal issues on the merits.").

c. CEPA Settlement

Next, Aventis contends that Mr. Gohil relinquished his rights to prosecute this *qui tam* action when he executed the settlement agreement in the CEPA action. The agreement states in relevant part:

> In consideration of the foregoing payment, Gohil does hereby forever release and discharge Aventis … of any and all claims, charges, causes of action, or liability of any nature whatsoever, which he has or may have against [Aventis] as of the date of this agreement, whether known or unknown….

Confidential Settlement Agreement and Release, Defs.' Mot. to Dismiss, doc. no. 91 ex. 3, ¶ 2. According to Aventis, the release of liability is broad in scope and includes this *qui tam* action. However, the timing of the release prohibits its enforcement.

A *qui tam* relator may only dismiss an FCA action "if the court and the Attorney General give written consent to the dismissal and their reasons for consenting." 31 U.S.C.A. § 3730(b)(1) (West 2015). The cases to consider this provision typically deal with a fact pattern similar to this case. Relator discovers fraud while working for the prospective defendant. Relator then notifies his employer of the potential fraud, and in response, relator is terminated. Relator then sues for wrongful termination and then files a separate *qui tam* action. Inevitably, defendant settles the wrongful termination case and relator executes an expansive release of liability. The critical issue becomes: when did relator sign the release – before or after filing the *qui tam* action?

The Courts of Appeals have uniformly determined that § 3130(b)(1) prohibits a relator from unilaterally settling an FCA case **after** a *qui tam* lawsuit has been filed. U.S.

ex rel. Radcliffe v. Purdue Pharma L.P., 600 F.3d 319, 328 (4th Cir. 2010) (citing U.S. ex rel. Ritchie v. Lockheed Martin Corp., 558 F.3d 1161, 1168 (10th Cir. 2009)) ("[T]he statute only governs the enforceability of settlement agreements made after the filing of a qui tam claim."); U.S. ex rel. Longhi v. United States, 575 F.3d 458, 474 (5th Cir. 2009) ("The district court correctly found that Longhi signed the release eleven days after he filed the *qui tam* complaint and was therefore unable to personally dismiss the case."); s*ee also* Hoyte v. Am. Nat. Red Cross, 518 F.3d 61, 64 n.2 (D.C. Cir. 2008) ("Thus, a motion to dismiss by the relator requires the consent of both the Government and the court '[e]ven where the Government has declined to intervene.'"); United States v. Health Possibilities, P.S.C., 207 F.3d 335, 339 (6th Cir. 2000) ("[A] relator may not seek voluntary dismissal of any *qui tam* action without the Attorney General's consent."); U.S. ex rel. Killingsworth v. Northrop Corp., 25 F.3d 715, 722 (9th Cir. 1994) ("[T]he consent provision contained in § 3730(b)(1) applies only during the initial sixty-day (or extended) period.").[11] While the Third Circuit has not reached the issue, it has recognized that ample authority supports voiding an after filed release. *See* Rodriguez v. Our Lady of Lourdes Med. Ctr., 552 F.3d 297, 301 (3d Cir. 2008) ("most courts have held that the

[11] The Ninth Circuit stands alone in finding that the Government's power to veto a settlement applies only during the period the complaint remains under seal for the Government's investigation. The Fifth and Sixth Circuits have specifically rejected that interpretation. Health Possibilities, P.S.C., 207 F.3d at 339; Searcy v. Philips Electronics N. Am. Corp., 117 F.3d 154, 159 (5th Cir. 1997). Even if the Ninth Circuit rule applied, Mr. Gohil signed the release before the seal was lifted. *See* doc. nos. 5, 7, 8, 12, 14, 17, 21 and 23 (extending seal until August 18, 2006).

Government retains the right to veto any settlement agreement reached by a private False Claims Act plaintiff.").[12]

When the relator releases the defendant from liability **before** he files a *qui* tam lawsuit, the Fourth and Tenth Circuits have determined that the *qui tam* action is barred. Radcliffe, 600 F.3d at 328 ("[T]he consent of the Government is not a necessary condition precedent to enforcement of an otherwise valid release where such a release is executed prior to filing a *qui tam* action"); Ritchie, 558 F.3d at 1168 ("When there is a release preceding the filing of the qui tam action, as in this case, no action has been filed, so there is neither an action to dismiss nor a judge to consent to the agreement."). A more nuanced rule in the Ninth Circuit holds that a pre-filing release will only preclude a *qui tam* action if the Government has prior knowledge of the underlying fraud. U.S. ex rel. Hall v. Teledyne Wah Chang Albany,104 F.3d 230 (9th Cir. 1997); U.S. ex rel. Green v. Northrop Corp., 59 F.3d 953, 963 (9th Cir. 1995).

Aventis relies on Hall arguing that the Government had prior knowledge of Gohil's claims and the release should be enforced. Aventis's faith in Hall is misplaced because, unlike Hall, Mr. Gohil signed the release after filing the *qui tam* action.[13] Mr. Gohil initiated the *Qui Tam* lawsuit on May 17, 2002. Three months later, he filed the CEPA action in New Jersey Superior Court. In October 2005, Mr. Gohil and Aventis

[12] In the alternative, Aventis urges that the Government released any claim related to the marketing of Anzemet. Aventis has withdrawn this argument relying on Mr. Gohil representation that he is not seeking damages for reimbursements pertaining to Anzemet prescriptions.

[13] According to Aventis, the release is binding because it was executed before Mr. Gohil filed the second amended complaint. The second amended complaint is not "essentially a new *qui tam* action." Rather, it relates back to the original complaint.

entered into an agreement settling the CEPA litigation. Thus, Mr. Gohil's *qui tam* action pre-dates the CEPA settlement agreement. Neither the attorney general nor I gave our written consent to the settlement in writing; therefore, the release is of no effect in this litigation.

Notwithstanding Aventis' arguments, the Supreme Court's decision in Town of Newton v. Rumery supports invalidating the CEPA release. 480 U.S. 386 (1987). "The relevant principle is well established: a promise is unenforceable if the interest in its enforcement is outweighed in the circumstances by a public policy harmed by enforcement of the agreement." Id. at 392. Here, the Government's interest in rooting out fraud outweighs the interest in enforcing the release. Longhi, 575 F.3d at 474 (citing Rumery, 480 U.S. at 392) ("To enforce the release and indemnification clauses contained in the stock sale agreement against Longhi would ignore the public policy objectives expressly spelled out by Congress in the FCA and would provide disincentives to future relators."). In the alternative, Aventis suggests that the release is only effective as to Mr. Gohil, and it would not object to dismissal without prejudice to allow the Government to take over the case. However, this recommendation ignores the clear congressional intent of encouraging private enforcement of the FCA. Accordingly, I will not enforce the CEPA settlement agreement.

d. Aventis's Rule 12(b)(6) Motion

1. Standard of Review

Typically, a complaint must set forth "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). However, a *qui tam* complaint is governed by the heightened pleading standards of Rule 9(b). U.S. ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 234 (3d Cir. 1998). The relator must plead the circumstances constituting fraud with particularity. Fed. R. Civ. P. 9(b). As Rule 9(b) is supplemental to Rule 8(a), the Third Circuit has adopted a liberal construction of Rule 9(b). Instead of "focusing exclusively on the particularity language," a district court must keep in mind "the general simplicity and flexibility contemplated by the rules." Christidis v. First Pennsylvania Mortgage Trust, 717 F.2d 96, 100 (3d Cir. 1983). The purpose of Rule 9(b) is "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. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 791 (3d Cir. 1984).

In keeping with this jurisprudence, the Third Circuit recently clarified the application of Rule 9(b) to *qui tam* actions. A relator is not required to plead the details of particular false claims which were submitted to the Government for payment.[14] Rather, "it is sufficient for a plaintiff to allege 'particular details of a scheme to submit false

[14] In doing so, the Court of Appeals rejected the approach adopted by the Fourth, Sixth, Eighth and Eleventh Circuits. *See* U.S. ex rel. Noah Nathan v. Takeda Pharm. N. Am., Inc., 707 F.3d 451, 455–56 (4th Cir.2013), U.S. ex rel. Bledsoe v. Cmty. Health Sys., Inc., 501 F.3d 493, 510 (6th Cir.2007); U.S. ex rel. Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 557 (8th Cir.2006); U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301, 1308, 1312 (11th Cir.2002).

claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.'" U.S. ex rel. Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153, 155 (3d Cir. 2014) (citing U.S. ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009)). The allegations must suggest more than a "mere opportunity for fraud." Id. at 157. The complaint must contain "[s]ufficient facts to establish 'a plausible ground for relief'…" Id. (citing Fowler v. UPMC Shadyside, 578 F.3d 203, 211 (3d Cir.2009)).

A defendant may challenge the sufficiency of a complaint under Rules 8(a) or 9(b) through a motion to dismiss pursuant to Rule 12(b)(6). In deciding a motion to dismiss, I may consider "the allegations contained in the complaint, exhibits attached to the complaint and matters of public record." Pension Ben. Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993). I am required to accept as true all of the factual allegations in the complaint, Erickson v. Pardus, 551 U.S. 89 (2007), and all reasonable inferences permitted by the factual allegations, Watson v. Abington Twp., 478 F.3d 144, 150 (3d Cir. 2007), viewing them in the light most favorable to the plaintiff. Kanter v. Barella, 489 F.3d 170, 177 (3d Cir. 2007). I am not, however, "compelled to accept unsupported conclusions and unwarranted inferences or a legal conclusion couched as a factual allegation." Baraka v. McGreevey, 481 F.3d 187, 195 (3d Cir. 2007) (quotations and citations omitted). If the facts alleged are sufficient to "raise a right to relief above the speculative level" such that the plaintiff's claim is "plausible on its face," a complaint will survive a motion to dismiss. Bell Atlantic Corp. v. Twombly, 127 S.Ct. 1955, 1965, 1974 (2007); Victaulic Co. v. Tieman, 499 F.3d 227, 234-35 (3d Cir. 2007).

2. Count III and Count IV – Submission of a False Claim in Violation of § 3729(a)(1) and § 3729(a)(2)

Mr. Gohil pleads a violation of § 3729(a)(1) in Count III and a violation of § 3729(a)(2) in Count IV. In 2009, Congress enacted the Fraud Enforcement and Recovery Act [FERA] which amended and renumbered § 3729 of the False Claims act. Pub. L. No. 111–21, 123 Stat. 1617 (2009). The pre-FERA FCA imposed liability on any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> (2) 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 by the Government.

31 U.S.C.A. § 3729(a) (West 2008). The version of the FCA in force today imposes liability on any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval [to the Government];
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

§ 3729(a)(1) (West 2015). The amendment to § 3729(a)(2) was made retroactively applicable to all claims pending on or after June 7, 2008.[15] FERA, PL 111-21, §4(f)(1), 123 Stat 1617; U.S. ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 303 (3d

[15] "The primary difference between the former and amended versions of the provision is the replacement of the phrase 'to get' with the word 'material.' ... [T]he FERA amendments to the FCA were responding, in part, to the Supreme Court's suggestion in Allison Engine Co., Inc. v. U.S. ex rel. Sanders, 553 U.S. 662, (2008), that section 3729(a)(2) contained an intent requirement, and by striking the words 'to get,' Congress intended to eliminate that requirement." U.S. ex rel. Loughren v. Unum Group, 613 F.3d 300, 307 n. 7 (1st Cir.2010).

Cir. 2011). Therefore, the FERA amendment to § 3729(a)(2) applies to this case. For ease of reference, I will cite to the sections according to their pre-FERA numbering.

The submission of a false claim is a necessary element to state a cause of action under § 3729(a)(1) and § 3729(a)(2). U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1217 (10th Cir. 2008). According to Mr. Gohil and the Government, "a claim is 'false' if, among other things, it seeks payment for treatment that is not statutorily eligible for reimbursement." United States Statement of Interest, doc. no. 93, 6. Mr. Gohil pleads that Aventis engaged in a fraudulent marketing scheme to cause doctors to submit claims to the federal insurers which were not eligible for reimbursement. Each insurance program employs different standards for payment, and I will address the different standards separately. However, under each standard, Mr. Gohil has not pleaded his allegations with sufficient specificity to satisfy Rule 9(b).

i. Medicare and Medicaid

"Although prescriptions for unapproved uses are not prohibited by the [Food, Drug and Cosmetic Act], they may be ineligible for reimbursement under the federal Medicare and Medicaid programs." Amicus Brief of the United States, U.S. v. Takeda Pharmaceuticals North America, Inc., 134 S.Ct. 1759 (2014) (No. 12-1349), 2014 WL 709660 at 4. Under either the Medicare or Medicaid program, the Government will only pay a claim when the drug is used for a medically accepted indication. 42 U.S.C.A. § 1395w-102(e)(1) (West 2015) (Medicare); § 1396r-8(a)(1) (West 2015)[16] (Medicaid).

[16] § 1396r-8(a)(1) provides payment for covered outpatient drugs. Covered outpatient drugs exclude "a drug used for a medical indication which is not a medically accepted indication." § 1396r-8(k)(3).

A medically accepted indication is a use which is approved by the FDA or a use which "is supported by one or more citations included or approved for inclusion in any of the [statutory] compendia." § 1395x(t)(2)(B) (Medicare);[17] § 1396r-8(k)(6) (Medicaid). The United States Pharmacopeia-Drug Information (USP-DI) is a statutory compendia. § 1395x(t)(2)(B) (Medicare); § 1396r-8(g)(1)(B)(i) (Medicaid). Accordingly, Aventis is liable if it fraudulently marketed Taxotere to treat medical indications which were neither approved by the FDA nor listed in a statutory compendia.

While Mr. Gohil is not required to plead the details of any false claim submitted for payment, he is required to plead "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." Foglia, 754 F.3d at 155. 113 paragraphs of SAC paint a broad picture of Aventis' aggressive marketing plan for Taxotere. The SAC provides specific details of who executed the plan, the duration of the plan, and where and how the sales pitches were made. The SAC also explains what made the plan allegedly fraudulent. In 2002, the FDA had approved Taxotere for the second line treatment of Breast Cancer and NSCLC. SAC ¶ 22. Yet as early as 2001, Aventis marketed the off label use of Taxotere for first line treatment of Breast Cancer and NSCLC and second line treatment of Ovarian Cancer. SAC ¶ 58-63, 98, 100, 101, 105.

[17] For most drugs, the Medicare statute defines medically accepted indication with reference to the Medicaid statute. § 1395w-102(e)(4)(A). However, Medicare covers chemotherapy drugs, such as Taxotere, pursuant to §1395x(t)(2)(B). For the purpose of this motion, there is no real difference between the definitions of a medically accepted indication between the two statutes.

These allegations only specify off-label uses which were medically accepted indications. According to the 2001 USP-DI, medically accepted indications for Taxotere included first line treatment of Breast Cancer and NSCLC as well as second line treatment of Ovarian Cancer. Mot. to Dismiss Ex. 15. Thus, a Taxotere prescription for any of the indications specifically alleged in the SAC would have been eligible for reimbursement from both the Medicare and Medicaid programs. Since the claims would have been eligible for reimbursement, it is simply implausible that the marketing scheme could have caused the submission of false or fraudulent claims.

Rather than dispute the authority of the USP-DI or the authenticity of the exhibit, Mr. Gohil counters that his allegations are sufficient to survive this motion to dismiss. For example, the SAC alleges "Defendant Aventis promoted certain off-label indications and dosages of Taxotere, knowing they were not eligible for reimbursement because the indication or dosage was [not] listed on the drug reporting compendia …." SAC ¶ 50. This is a conclusory statement which would barely meet the plausibility standard of Rule 8(a), and it utterly fails to comport with the heightened pleading requirements of Rule 9(b). Rule 9(b) demands to know specifically why the prescriptions would not be eligible for reimbursement. To satisfy this standard, Mr. Gohil must plead for what unaccepted medical indications Aventis promoted Taxotere.[18]

[18] Mr. Gohil also pleads, *ad nauseum*, the various FDA regulation which govern the branding and marketing of prescription drugs. I fail to see the relevance of these allegations as they do not plausibly support a theory that Aventis promoted Taxotere for unaccepted medical indications. Furthermore, the FDA labeling regulations cannot support a false certification theory because compliance with the regulations is not a precondition to payment under the federal insurance programs. U.S. ex rel. Simpson v. Bayer Corp., 05-CV-3895, 2014 WL 1418293, at *7 (D.N.J. Apr. 11, 2014); *see also* U.S. ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 309 (3d Cir. 2011) (discussing preconditions to payment generally).

Mr. Gohil's allegations provide far less detail than the relator in Foglia. Foglia concerned the multiple uses of single use vials containing the medication Zemplar. As a condition of receiving payment from Medicare and Medicaid for the multiple uses of Zemplar, the relator alleged that the defendant was required to follow a detailed and very specific directive from the Department of Health and Human Services.[19] By asserting that the defendant failed to comply with the directive, the Court of Appeals found that the relator provided enough detail to "give defendant notice of the charges against it." Foglia, 754 F.3d at 158. [20] On the other hand, the Medicaid and Medicare statutes do not provide the same level of detail. Taxotere is only accepted for a limited number of indications. There are any number of ways in which Aventis could have marketed Taxotere which could have disqualified the drug for reimbursement. Thus, to properly limit the scope of

[19] The Department required physicians to follow the following CDC recommendations:

1. All doses must be drawn up by a licensed professional whose scope of practice includes administration of parenteral medications and knowledge of aseptic technique.
2. All doses from a given vial should be drawn-up and administered within a 4-hour period.
3. Only one vial of a given concentration of the medication should be opened and used by the administering professional at any given time. A second vial of the same medication must not be opened until the previous vial is discarded.
4. Any opened vials or filled syringes (with epoetin alpha, iron or vitamin D) must be discarded if not used within 4 hours of the first puncture of the vial. Vials must be labeled to document the time of first entry and maintained at a temperature of 2-8 degrees Celsius (or 36.046 degrees Fahrenheit) during non-use.
5. Residual amounts of these medications (either in the vial or syringes) must never be pooled with medication from another vial or syringe. If a patient requires more medication than is in a single, drawn syringe, then medication from a separate vial should be drawn into a separate syringe for administration.
6. Each facility must have in place a process monitoring (quality assurance) program which ensures compliance with these policies and procedures. These policies must include: a) recording data on infections in treated dialysis patients; and b) unannounced practice audits involving quality assurance staff observing performance of re-use techniques.

Second amended complaint at ¶ 34, U.S. ex rel Foglia v. Renal Ventures Management, LLC, 830 F.Supp.2d 8 (D.N.J. 2011) (No. 09-cv-1552)

[20] The Court of Appeals noted that its "conclusion is further supported by the fact that [defendant], and only [defendant], has access to the documents that could easily prove the claim on way or another – the full billing records from the time under consideration." Foglia, 754 F.3d at 158. Here, Aventis is not in possession of any billing records. These records will have to be subpoenaed from the prescribing physicians.

this complaint and provide Aventis sufficient notice of the claim, Mr. Gohil must alleged unaccepted medical indications.[21]

Furthermore, requiring Mr. Gohil to plead the unaccepted medical indications "comports with Rule 9(b)'s objective[] of … prevent[ing] plaintiffs from filing baseless claims then attempting to discover unknown wrongs." Grubbs, 565 F.3d at 190. By pleading a "scheme" to promote Taxotere for medically accepted indications, the Counts III and IV appear baseless. Rule 9(b) does not allow a relator to proceed on a fishing expedition on the basis of such weak allegations. Id. at 191. However, this is a defect which Mr. Gohil can easily cure. Mr. Gohil was allegedly trained in the fraudulent marketing scheme. He should have no trouble pleading the specific medical indications which made the scheme fraudulent. Therefore, I will dismiss the SAC without prejudice. Mr. Gohil will have leave to file a third amended complaint in which he must plead the exact medical indications for which Taxotere was marketed. If Aventis was marketing Taxotere for non-reimbursable uses, recalling these details should not be an onerous task.

ii. Tricare and the Federal Employee Health Benefit Program

The different standard for reimbursement under CHAMPUS/Tricare does not alter my conclusion. CHAMPUS will reimburse the prescription of off-label drugs when the prescription is medically necessary. 32 C.F.R. § 199.4(g)(15)(i)(A). When reviewing an

[21] I note that the relator in Foglia did not plead exactly how defendants failed to comply with the regulation, yet I am requiring Mr. Gohil to aver precise medical indications. As the Grubbs Court recognized, "[Rule 9(b)] is context specific and flexible …." 565 F.3d at 190. In Foglia, the HHS directive was so exacting that very little detail was required to plead a violation and give defendant sufficient notice of the claim. Here, the converse is true. The Medicare and Medicaid statutes are drafted broadly. Thus, the flexibility of Rule 9b requires Mr. Gohil to plead more facts in order to put Aventis on notice of the claim.

off-label prescription, CHAMPUS will take into consideration nationally accepted standards of practice in the medical community. Id. A prescription is medically necessary when it is "generally accepted by qualified professionals to be reasonable and adequate for the diagnosis and treatment of illness…." 32 C.F.R. § 199.2. This represents a much more flexible standard than the rigid citations required for reimbursement under the Medicare and Medicaid programs. Certainly, publication in the nationally recognized USP-DI represents general acceptance. Thus, I fail to see how promoting Taxotere for a medically accepted indication could plausibly lead to the submission of false claims to CHAMPUS/Tricare.

The Federal Employee Health Benefit Plan is more complicated. The FEHB is administered by private health insurers.[22] *See* 5 U.S.C. § 8902; 5 CFR § 890.201. There is no law or regulation mandating when a prescription drug is insurable and reimbursable. Rather, reimbursement is governed by the various plan documents. *See* 5 CFR § 890.105. Mr. Gohil asserts that a medically necessary standard governs all the plan documents. SAC ¶¶ 44 and 45. Thus for the same reasons outlined in my discussion of CHAMPUS/Tricare, Mr. Gohil has not plausibly pleaded the submission of false claims to an FEHB plan.

[22] While claims are not submitted directly to the Government, fraud committed against and FEHBP plan is actionable under the FCA. U.S. ex. rel. Piacentile v. Merck-Medco Managed Care, L.L.C., 336 F. Supp. 2d 430, 442 (E.D. Pa. 2004).

3. Count II – Anti-Kickback Act and False Certification in Violation of § 3729(a)(2)

According to the SAC, Aventis paid several healthcare providers illegal kickbacks. Consequently, these providers falsely certified compliance with the Anti-Kickback act[23] when they submitted claims to federal insurers for reimbursement. Aventis moves to dismiss Count II on three grounds. First, the Third Circuit has not adopted an express or implied false certification theory. Second, Mr. Gohil has not identified a single false certification that was submitted to the Government. Third, compliance with the Anti-Kickback statute is not a condition of payment under the federal reimbursement programs. Aventis' arguments have been debunked by U.S. ex rel. Wilkins v. United Health Group, Inc. which the Third Circuit decided after this motion was fully briefed. 659 F.3d 295 (3d Cir. 2011).[24] Thus, my discussion of Count II will be short.

[23] The AKS, in relevant part, provides that

> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any time or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C.A. § 1320a–7b(b)(2) (West 2015).

[24] In making its arguments, Aventis primarily relied on the district court's opinion in Wilkins. The Court of Appeals directly rejected the district court's holdings which are critical to Aventis' argument.

The Wilkins Court adopted both the express and implied false certification theories.[25] Id. at 305 (citing Rodriguez v. Our Lady of Lourdes Med. Ctr., 552 F.3d 297, 303 (3d Cir.2008)). While Wilkins suggested that a relator need not plead the submission of a false claim, Id. at 308("[W]e never have held that a plaintiff must identify a specific claim for payment at the pleading stage of the case to state a claim for relief."), Foglia resolved any doubts in Mr. Gohil's favor. 754 F.3d at 155. Finally, Wilkins clearly established that certifying compliance with the Anit-Kickback Act is a pre-condition to payment for both Medicaid and Medicare, and such false certification is actionable under the FCA. Wilkins, 659 F.3d at 312 (citing Kosenske, 554 F.3d at 94).

Thus, "[t]o plead a claim for relief under an implied certification theory, [relator] [is] required to allege … that [defendants] submitted claims for payment to the Government at a time that they knowingly violated [the Anti-Kickback Statute]." Id. at 313. Mr. Gohil alleges Aventis provided numerous illegal kickbacks to healthcare providers throughout the Philadelphia area. SAC ¶¶ 123 – 176. Aventis and the healthcare providers were aware that compliance with the Anti-Kickback Act was a condition precedent to payment from the federal reimbursement programs. SAC ¶¶ 119 – 122. Nonetheless, the healthcare providers, with the assistance of Aventis, submitted claims to the federal insurers. Id. These allegations plausibly plead a violation of the Anti-Kickback Act and the FCA. I will deny the motion to dismiss Count II.

[25] "Under the 'express false certification' theory, an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds." Wilkins, 659 F.3d. at 305 (citing Rodriguez v. Our Lady of Lourdes Med. Ctr., 552 F.3d 297, 303 (3d Cir.2008)). "'[I]mplied false certification' liability [] attaches when a claimant seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment." Id.

4. Count I – Conspiracy in Violation of § 3729(a)(3)

To plead a violation of § 3729(a)(3), "a relator must show '(1) the existence of an unlawful agreement between defendants to get a false or fraudulent claim allowed or paid by [the Government] and (2) at least one act performed in furtherance of that agreement.'" Grubbs, 565 F.3d at 193; *see also* Atkinson, 473 F.3d at 517. According to the SAC, "Aventis, various healthcare providers, Aventis' outside consultants and members of Aventis' sales force, knowingly combined and conspired with each other to violate the False Claims Act." The claims were false because they were tainted by illegal kickbacks.

Aventis denies that Mr. Gohil has adequately pleaded the existence of an agreement between Aventis and the healthcare providers.[26] Viewing the pleadings in the light most favorable to Mr. Gohil, as I must, I can easily infer the existence of an agreement. Twombly, 550 U.S. at 556. The SAC avers several specific incidents where Aventis paid some form of an illegal kickback to a physician followed by the physician's increased use of Taxotere. The SAC also details how Aventis assisted physicians in submitting insurance claims to a federal reimbursement program. This is sufficient circumstantial evidence that the doctors agreed with Aventis to increase their usage of Taxotere and to submit false certifications that the claims were not tainted by an illegal kickback. I will deny the motion to dismiss Count I.[27]

[26] There appears to be no real dispute that Aventis could not conspire with its consultants and sales force.

[27] The conspiracy claim only survives as to a claim that Aventis conspired with healthcare providers to falsely certify compliance with the Anti-Kickback Act.

III. Conclusion

For the foregoing reasons, I will dismiss Counts III and IV without prejudice. Aventis' motion to dismiss is otherwise denied.

An appropriate order follows.