UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, *ex. rel.* CAMPIE *et al.*,

Plaintiffs,

v.

GILEAD SCIENCES, INC., *et al.*,

Defendants.
_____/

No. C-11-0941 EMC

ORDER GRANTING DEFENDANT'S MOTION TO DISMISS

(Docket No. 128)

Relators Jeff and Sherilyn Campie filed this lawsuit against Defendant Gilead Sciences, Inc., asserting, *inter alia*, that it violated federal and state law by submitting or causing to be submitted false claims for payment under government payment programs such as Medicare and Medicaid. In December 2014, the Court granted Gilead's motion to dismiss Relators' first amended complaint ("FAC"), largely because they had failed to plead an actionable misrepresentation as part of the government payment process, but gave Relators leave to amend. Relators then filed their second amended complaint ("SAC") which is now the subject of the pending motion to dismiss.

I. FACTUAL & PROCEDURAL BACKGROUND

A. Claims Asserted

In the SAC, Relators have asserted the following claims against Gilead:

(1) Count 1: Violation of the False Claims Act ("FCA"), which imposes liability on a person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A).

(2) Count 2: Violation of the FCA, which also imposes liability on a person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* § 3729(a)(1)(B).

(3) Counts 3-28: Violation of the law of twenty-six states or localities, which generally impose liability on false claims for payment.

(4) Count 29: Retaliation in violation of the FCA. *See id.* § 3730(h) (providing that "[a]ny employee . . . shall be entitled to all relief necessary to make that employee . . . whole, if that employee . . . . is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of his employment because of lawful acts done by the employee . . . in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter [31 U.S.C. § 3721 *et seq.*]").

(5) Count 30: Whistleblower retaliation in violation of California Labor Code § 1102.5.

(6) Count 31: Retaliation in violation of California Labor Code § 98.6.

(7) Count 32: Termination in violation of California public policy.

As indicated by the above, each count can, in essence, be categorized as either: (1) a false claim cause of action or (2) a retaliation cause of action.

B. Facts Related to False Claim Causes of Action

With respect to the false claim causes of action, Relators' main allegations in the SAC are as follows.

Gilead manufactures a number of drug products, including those for the treatment of HIV/AIDS. *See* SAC ¶¶ 18; *see also* SAC ¶ 18. "The [federal] Government and the States pay for the majority of Gilead's drug products sold within the United States through [their] Government Payment Programs." SAC ¶ 19.

Some government payment programs are "reimbursement" programs (*e.g.*, Medicare, Medicaid, the Department of Defense TRICARE program); others are "direct pay" programs (*e.g.*, the Department of Veterans Affairs and the Federal Bureau of Prisons). *See* SAC ¶¶ 2, 24. Under the government reimbursement programs, Gilead is paid when a claim is submitted by a third party

such as a plan participant or sponsor; under the government direct pay programs, Gilead is paid when it submits a claim to the government directly. *See* SAC ¶ 24.

Gilead's drug products, for which it has been paid by federal, state, and/or local governments, contain active pharmaceutical ingredients ("API"). The API at issue here is emtricitabine ("FTC"), which is used in several Gilead drug products such as Emtriva, Emtriva Oral Powder, Truvada, and Atripla. *See* SAC ¶ 144.

As explained in the SAC, "[g]overnment approval of a new drug product under the FDCA [Food, Drug, and Cosmetics Act] takes two forms: initial and supplemental." SAC ¶ 28. Initial approval [from the Food and Drug Administration ('FDA')] is obtained through a new drug application ("NDA"). *See* SAC ¶ 29. "After an NDA has been approved . . . , drug manufacturers . . . must furthermore obtain Government approval of a PAS [prior approval supplemental] in the event of a change in the manufacturing process that has a substantial potential adverse effect on the identity, strength, quality, purity or potency of the previously approved NDA drug." SAC ¶ 30.

As required by the FDCA, Gilead obtained approval from the FDA for the drug products containing the API. However, subsequently, there were major changes to the drug products that required Gilead to obtain supplemental approval from the FDA. Under the FDCA, this new approval was needed *before* Gilead could distribute the drug products that had been changed. *See generally* SAC ¶ 144.

For drug products containing FTC, the major change was Gilead's use of a new manufacturing source for the API – *i.e.*, Synthetics China, which was an unregistered, uninspected, and unapproved manufacturing source. According to Relators, Gilead began to use Synthetics China as early as 2006 but failed to get supplemental approval from the FDA with respect to this major change before it began to distribute its drugs products containing FTC manufactured by Synthetics China. *See* SAC ¶¶ 145-47, 171. In October 2008, Gilead eventually did seek supplemental approval through a PAS, but the PAS it submitted contained falsified information. For example, the PAS concealed that Synthetics China had produced contaminated batches of FTC. *See* SAC ¶¶ 4, 148, 163. Gilead amended its PAS in April 2009 in an attempt to correct this problem. *See* SAC ¶¶

163, 235. In mid-2009 or early 2010, the FDA gave its approval to the amended PAS. *See* SAC ¶¶ 168, 235.

According to Relators, because of Gilead's failure to get supplemental approval from the FDA for the major changes to the drug products, the drug products were not approved drugs under the FDCA, and therefore the drug products were not eligible for payment under the government payment programs. *See* SAC ¶ 152.

C. Facts Related to Retaliation Causes of Action

Mr. Campie worked at Gilead from about July 2006 to July 2009. *See* SAC ¶¶ 13, 206, 238. During this entire period, Mr. Campie was employed as Gilead's Senior Director of Global Quality Assurance ("QA"). *See* SAC ¶ 13. "Mr. Campie's regular job duties focused on commercial drug product quality assurance/control issues[,] [but] he was (based on job requirements) expected to review API submissions as well." SAC ¶ 155.

At the time Gilead terminated his employment, Mr. Campie was told that "'heart wasn't in the job anymore.'" SAC ¶ 238. Mr. Campie maintains that he was actually terminated because

> he discovered, investigated, and raised concerns over Gilead's release and distribution (much of it for commercial sale in the United States and paid for by the Government and the States under the Government Payment Programs) of tons of contaminated and adulterated API that had been manufactured at an unregistered and uninspected CMO [contract manufacturing organization]; that had not properly been demonstrated to be (and in fact was not) equivalent to FDA-approved API; that was of substandard strength, quality, purity, potency, safety and/or efficaciousness; that had been used to submit falsified testing, data, and statements to the FDA; and that had been used to manufacture the Affected Drug Products which were not approved under the FDCA and thus were not eligible for payment under the Government Payment Programs, causing the submission of false claims paid by the Government and the States.

SAC ¶ 417. According to Mr. Campie, while his termination was the ultimate retaliation, he was also retaliated against in other ways prior to his termination – *e.g.*, by being harassed, by being demoted, by being stripped of job duties, by being ostracized from the regulatory submission review process, and by being removed from his position on Gilead's Quality Council. *See* SAC ¶ 417.

It appears that Mr. Campie raised concerns about "the integrity of the data being generated to support the release of Gilead drugs" as early as July 2007. SAC ¶ 220. For example, on multiple

occasions, including at senior staff meetings (the date of which is not clear from the pleading), "Mr. Campie discussed the contamination and adulteration problems with the API being used by Gilead and, more particularly, with Gilead's knowing use of falsified data and test results for the express purpose of introducing non-approved and contaminated drugs into commerce." SAC ¶ 221. In response, "Mr. Campie was told that it was 'none of his concern.'" SAC ¶ 221. In mid-2008, Mr. Campie was removed as head of the internal Quality Control council that he had been chairing since the time he was hired by Gilead. *See* SAC ¶ 209.

In late 2008 (which would appear to be around the time that Gilead submitted its Synthetics China PAS to the FDA), "Mr. Campie was presented with a document . . . authorizing the use of API manufactured by Synthetics China." SAC ¶ 222. Because he was concerned, Mr. Campie "held multiple meetings with both the commercial operations group and the API procurement personnel in an effort to remind and warn the company that drugs containing API sourced from the unregistered, unlicensed and non-approved Synthetics China plant could not be shipped or otherwise distributed into commerce without violating the applicable laws." SAC ¶ 222. In January 2009, Mr. Campie held a meeting with Gilead management to discuss the same. *See* SAC ¶ 223.

In February 2009, "Mr. Campie participated in the review and approval of a Health Canada submission associated with the use of Synthetics China API." SAC ¶ 225. According to Mr. Campie, "[d]uring his review, [he] identified failing and inconsistent data which he brought to the attention of Tyler Rodgers (Regulatory Affairs/Canada)." SAC ¶ 225. Subsequently, "Mr. Campie continued to voice strenuous objections" regarding Synthetics China – directing his objections to, among others, his manager. SAC ¶ 226.

Thereafter, "Gilead began to selectively circumvent Mr. Campie's review and effectively removed and excluded him from Gilead's regulatory review process," even though he "was supposed to be responsible for commercial quality input on regulatory filings implicating quality or supply issues." SAC ¶ 227. For example, "Gilead management bypassed Mr. Campie completely on the review of the Synthetics China PAS submissions." SAC ¶ 227. Furthermore, in February 2009, Mr. Campie was told during his annual performance review that "he was 'not effective in influencing peers' and should therefore start looking for employment elsewhere." SAC ¶ 229.

In March 2009, Mr. Campie met with Gilead's Chief Compliance Officer "to discuss the falsified data and test results in the Synthetics China PAS." SAC ¶ 230. Mr. Campie "threatened to inform the FDA if Gilead continued its fraudulent conduct." SAC ¶ 230. Subsequently, in April 2009, Mr. Campie received an e-mail from the GM of the Gilead San Dimas facility that stated: "'Well, at least I won't have to put up with you much longer.'" SAC ¶ 231.

In April 2009, Mr. Campie learned that Gilead was preparing to release and distribute a drug containing another API (ambrisentan) that had been manufactured at an unregistered and unapproved facility. *See* SAC ¶ 232. Mr. Campie instructed that "the batches be removed from the company's supply chain and placed into quarantine until Gilead received Government approval to place them into the stream of commerce." SAC ¶ 233. Mr. Campie's manager "told Mr. Campie that initiating quarantine was not in his job description and stated in no uncertain terms that Mr. Campie had no authority to order one. He then continued to state: 'If you guys can't protect product supply, you are of very little use to me.'" SAC ¶ 234. The product was ultimately released back into Gilead's supply chain. *See* SAC ¶ 234. Shortly thereafter, Gilead decided to amend the Synthetics China PAS that it had submitted to the FDA. *See* SAC ¶ 235.

"[O]n June 30, 2009, Mr. Campie was called into a meeting and told he would be terminated, effective July of 2009." SAC ¶ 238. During this meeting, when Mr. Campie "raise[d] the topic of Gilead's noncompliant practices, including the problems at Synthetics China," he was asked: "'Who are you working for – the company or the FDA?'" SAC ¶ 238.

In July 2009, Mr. Campie met with Gilead's Legal Department, at which time he was asked to sign a severance agreement containing a provision stating that he would not initiate a FCA claim against Gilead. *See* SAC ¶ 240. "Mr. Campie refused." SAC ¶ 240.

II. DISCUSSION

A. Legal Standard

Under Federal Rule of Civil Procedure 12(b)(6), a defendant may move to dismiss for failure to state a claim for relief.

> "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" A claim is facially plausible "when the plaintiff

> pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." The plausibility standard requires more than the sheer possibility or conceivability that a defendant has acted unlawfully. "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." Dismissal under Rule 12(b)(6) is proper only when the complaint either (1) lacks a cognizable legal theory or (2) fails to allege sufficient facts to support a cognizable legal theory.

Li v. Kerry, 710 F.3d 995, 999 (9th Cir. 2013) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007).

B. False Claim Causes of Action – Federal

Although Relators' SAC refers to various theories underlying their FCA causes of action, their opposition brief makes clear that there are really only two theories at issue: (1) an implied false certification and (2) a factually false certification. The Court addresses each of these theories in turn.

1. Implied False Certification

False claims – or false certifications – to the government can be either legal or factual in nature. There is a legally false certification when the claimant falsely certifies that it has complied with a statute or regulation, and that compliance is a condition to government payment (*e.g.*, as reflected in a statute, rule, regulation, or contract). *See United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1171 (9th Cir. 2006); *United States ex rel. Ebeid v. Lungwitz*, 616 F.3d 993, 1000 (9th Cir. 2010); *see also Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 786 (4th Cir. 1999) (stating that "[a] number of courts in a variety of contexts have found violations of the False Claims Act when a government contract or program required compliance with certain conditions as a prerequisite to a government benefit, payment, or program; the defendant failed to comply with those conditions; and the defendant falsely certified that it had complied with the conditions in order to induce the government benefit").

Legally false certifications can be either express or implied. There is an express false certification when there is an actual certification of compliance made by the claimant "as part of the process through which the claim for payment is submitted." *Ebeid*, 616 F.3d at 998. There is an implied false certification when the claimant "seeks and makes a claim for payment from the

Government without disclosing that it violated regulations that affected its eligibility for payment." *United States ex rel. Wilkins*, 659 F.3d 295, 305 (3d Cir. 2011) (emphasis added); *United States ex rel. Klein v. Empire Educ. Corp.*, 959 F. Supp. 2d 248, 255 (N.D.N.Y. 2013) (noting that there is "an implied false legal certification theory, where, although the claim for payment does not certify compliance with a statute or regulation on its face, compliance is a prerequisite to payment under the express statutory or regulatory terms").

In its prior decision dismissing Relators' FAC, the Court acknowledged that Relators had presented an implied false certification theory but found it problematic on various grounds. Notably, the Court indicated that, although reimbursement under, *e.g.*, Medicare and Medicaid was conditioned on the drugs being approved by the FDA, "[h]ere, Gilead had obtained FDA approval of all the drugs in question." *United States ex rel. Campie*, No. C-11-0941 EMC, 2015 U.S. Dist. LEXIS 1635, at *34 (N.D. Cal. Jan. 7, 2015); *see also id.* at *40-41 (stating that "there is no dispute that the affected drugs at issue in this case were, in fact, 'approved' by the FDA"). The fact that Gilead had allegedly engaged in fraud before the FDA in obtaining the FDA's approval did not negate the fact that the condition for payment – approval by the FDA – had in fact been obtained.

In their current papers, Relators now argue that they have made allegations in the SAC which make clear the necessary FDA approval was in fact lacking in the instant case. More specifically, Relators argue that, even though Gilead got approval through the NDA process for the drugs in question, there was, subsequently, a major change to the drug products which, under the FDCA, required Gilead to submit a PAS to the FDA and obtain *new approval* for those changes. As noted above, the major change that Relators point to concerned Gilead's use of an unapproved manufacturing source: Synthetics China.

Although Relators have put at issue in their case various government payment programs (both reimbursement and direct pay), the Court shall focus on Medicare/Medicaid as a representative program, particularly as that is consistent with Relators' approach in their papers. *See, e.g.*, Opp'n at 5.

- With respect to Medicaid, 42 U.S.C. § 1396r-8 provides that, "[i]n order for payment to be available under section 1903(a) [42 U.S.C. § 1396b(a)] or under part B of title XVIII [42

U.S.C. § 1395j *et seq.*] *for covered outpatient drugs* of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States . . . , and must meet the requirements of paragraph (5) . . . ." *Id.* § 1396r-8(a)(1) (emphasis added). Thus, under Medicaid, there is payment only where there is a "covered outpatient drug." "Covered outpatient drug" is defined in § 1396r-8 as a drug "approved for safety and effectiveness as a prescription drug under section 505 or 507 of the [FDCA, 21 U.S.C. § 355 or former 357] or which is approved under section 505(j) of such Act [21 U.S.C. § 355(j)]." *Id.* § 1396r-8(k)(2)(A)(i).

- Medicare appears to be consistent with Medicaid. For example, under Medicare, a covered part D drug means, *e.g.*, "[a] drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1927(k)(2) [42 U.S.C. § 1396r-8(k)(2)]." *Id.* § 1395w-102(e).

Therefore, as Relators contend, under Medicare/Medicaid, it appears that a condition of payment is FDA approval.

That being said, Relators gloss over *what kind* of FDA approval is required. Section 1396r-8(k)(2)(A)(i) does not refer to any kind of FDA approval but rather "approv[al] for safety and effectiveness as a prescription drug *under section 505 or 507 of the [FDCA, 21 U.S.C. § 355 or former 357] or which is approved under section 505(j) of such Act [21 U.S.C. § 355(j)]*." *Id.* § 1396r-8(k)(2)(A)(i) (emphasis added). Because § 507 is now repealed, the critical FDA approval is approval under § 505. But § 505 (21 U.S.C. § 355) concerns only approval for a *NDA*, and not supplemental approval of a *PAS*. Supplemental approval is covered by a completely different statute – *i.e.*, § 506a. *See* 21 U.S.C. § 356a(c) (providing that "a drug made with a major manufacturing change may be distributed only if, before the distribution of the drug as so made, the holder involved submits to the Secretary a supplemental application for such change and the Secretary approves the application"). Thus, contrary to what Relators suggest, payment under Medicare/Medicaid is conditioned only on *NDA* approval, and *not supplemental* approval. Because the only condition for payment is NDA approval, then the alleged failure of Gilead to obtain the necessary supplemental approval does not preclude eligibility for federal payment. Gilead's failure to get the needed

supplemental approval may lead to other consequences for Gilead; however, it cannot be the basis for a false claim cause of action.

The Court also notes that, from a policy perspective, it makes sense that a false claim cause of action cannot be based on a company's failure to get a supplemental approval. In the Court's prior order, it emphasized that it found Relators' earlier position based on fraud before the FDA problematic because,

> [w]ere the FCA [False Claims Act] construed to allow an FCA claim to be based on misrepresentation and omissions made to the FDA during the FDA approval process, the Court sitting on an FCA case would have to delve deeply into the complexities, subtleties and variabilities of the FDA approval process. Ultimately, to determine materiality under the FCA and the "but-for cause in the chain of causation" analysis advocated by Plaintiff, the Court would have to determine whether the FDA would have in fact approved each drug in question. Given the wide range of administrative responses and action that could have been taken by the FDA (*e.g.*, corrective notices, warnings, plan of remediation, requirement of monitoring), the Court would be tasked not only with determining whether a falsity was presented to the FDA, but also predicting the institutional response of the FDA and the ultimate outcome of a specialized and complex administrative proceeding. Given the range of actions available to the FDA, this would be a daunting task. The Court is ill-equipped to make that kind of prediction. Such an inquiry stands in contrast to the inquiry in a more typical FCA case – determining whether a particular statement or certification made to the payor agency is in fact false and material to the decision to pay. Absent a clear directive from Congress, the Court is unwilling to read into the FCA such an expansive sweep.

Campie, 2015 U.S. Dist. LEXIS 1635, at *38-39. A similar policy concern is at work here even with Relators' new position as articulated in its current papers.

Payment conditioned on NDA approval is an easy determination that does not require the Court to delve into the complexities of the FDCA regulatory process. NDA approval is required whenever there is a new drug that a company seeks to market and distribute, and either there is NDA approval or there is not. However, supplemental approval is required only where there is a major "manufacturing change" to an already approved drug. *See* 21 U.S.C. § 356a(c) (providing that "a drug made with a major manufacturing change may be distributed only if, before the distribution of the drug as so made, the holder involved submits to the Secretary a supplemental application for such change and the Secretary approves the application"). Thus, if a FCA claimant is arguing – as

Relators do here – that supplemental approval was needed but not obtained, the court would be forced into an evaluation of the FDCA regulatory scheme and into making determinations likely dependent upon the expertise of the FDA in the first instance – *i.e.*, is the manufacturing change at issue "major" or not? Indeed, a major manufacturing change could include many areas beyond the manufacturing facility itself – *e.g.*, the composition of the drug, the processing of the drug, the packing of the drug, the labeling of the drug, and so forth. *See generally* 21 U.S.C. § 355(b)(1).

As a final point, the Court notes that, at the hearing, Relators changed their argument because of the Court's analysis above. They contended that, even if *supplemental* approval was not a condition of payment, *NDA* approval in effect was rendered void once Gilead decided to change its manufacturing facility to Synthetics China because NDA approval was conditioned on the use of the manufacturing facility identified in the NDA. Relators correctly note that, in the NDA, a company must provide, among other things, information about the manufacturing facility to be used:

> (b) Filing application; contents.
>
> (1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, *and the facilities and controls used for, the manufacture, processing, and packing of such drug*; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required under section 505B [21 U.S.C. § 355c].

21 U.S.C. § 355 (emphasis added).

But nothing in the NDA statute, § 355, provides that NDA approval is rendered void if a manufacturing facility changes from that listed in the NDA. Indeed, Relators have effectively conceded that a minor change from the NDA approval does not render that approval void *ab initio*. Furthermore, as Gilead points out, the fact that § 355(e) addresses withdrawal of approval makes Relators' contention of void *ab initio* problematic. *See id.* § 355(e) (providing that "[t]he Secretary

shall . . . withdrawal approval of an application with respect to any drug under this section if the Secretary" makes certain findings – *e.g.*, if he or she finds "that the application contains any untrue statement of material fact"). That is, given that the legislature specifically provided for *withdrawal* of approval, affirmative steps must be taken to void approval.

Accordingly, the Court concludes that, as a matter of law, Relators have again failed to plead a claim for violation of the FCA, at least based on an implied false certification theory. Relators have failed to cite to, *e.g.*, a statute, rule, or regulation that makes payment conditioned on *supplemental* approval by the FDA (as opposed to NDA approval). Indeed, the statute makes clear that such payment is conditioned on NDA approval, not PAS approval. Because the Court previously gave Relators an opportunity to amend on the FCA claim but Relators have failed to correct the same deficiency, the Court dismisses the implied false certification claim with prejudice.

2. Factually False Certification

As noted above, Relators have asserted not only a legally false certification theory but also a factually false one. "A claim is factually false when the claimant misrepresents what goods or services that it provided to the government." *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 305 (3d Cir. 2011). For example, a certification that a company makes to the government is factually false if it incorrectly describes the goods or services provided or requests reimbursement for goods or services never provided. *See United States ex. rel. Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001).

Here, Relators' claim of factually false certification is based on two different subtheories: (1) that the drugs at issue were nonconforming, *see id.*, because they "were not in fact 'approved' by the FDA for distribution in interstate commerce," and (2) that "a drug product not approved for marketing by the FDA is . . . 'effectively' and 'for all practical purposes' worthless" because it "cannot be introduced into interstate commerce" and is "subject to seizure by the government." Opp'n at 14.

Relators' first subtheory is duplicative of its implied false certification claim. The entire thrust of the implied false certification claim is that Gilead implied that it had obtained FDA

approval for its drugs (*i.e.*, were conforming) when it sought payment for the drugs. For the reasons stated above, that claim is legally without merit.

The second subtheory is problematic as well. To have a factually false certification claim based on worthless services, the services must be *medically* worthless. *See, e.g.*, *United States ex rel. Lee v. Smithkline Beecham Clinical Labs.*, 245 F.3d 1048, 1053 (9th Cir. 2001) ("The district court . . . over-looked the allegations . . . that supported a different theory – that SmithKline violated the FCA by seeking and receiving payment for *medically* worthless tests.") (emphasis added); *see also Mikes*, 274 F.3d at 702 ("An allegation that defendants violated the Act by submitting claims for worthless services is not predicated upon the false certification theory. Instead, a worthless services claim asserts that the knowing request of federal reimbursement for a procedure with no *medical* value violates the Act irrespective of any certification.") (emphasis added); *Chesbrough v. VPA P.C.*, 655 F.3d 461, 468 (6th Cir. 2011) ("If VPA sought reimbursement for services that it knew were not just of poor quality but had *no* medical value, then it would have effectively submtited claims for services that were not actually provided.") (emphasis in original). In *Mikes*, the Second Circuit emphasized that a worthless services claim is independent of any false certification claim. *See Mikes*, 274 F.3d at 703 ("We agree that a worthless services claim is a distinct claim under the [FCA]. It is effectively derivative of an allegation that a claim is factually false because it seeks reimbursement for a service not provided.").

In the instant case, Relators have made allegations that suggest *reduced* medical value, but have failed to adequately plead *no* medical value at all. In its prior order dismissing the FAC, the Court concluded that there were insufficient allegations of no medical value, *see Campie*, 2015 U.S. Dist. LEXIS 1635, at *48-49 (noting that some of the allegations "touch on the resulting quality of the drug" but these allegations, "while troubling, do not establish that the affected lots or products were not only 'worth less' or defective, but truly 'worthless' for the purposes for which the drugs were designed"), and, in their papers, Relators have not really pointed to any additional facts that should dictate a different result. The case that Relators cite in their brief, *United States v. Marcus*, 82 F.3d 606, 610 (4th Cir. 1996), is not completely on point as, there, the Fourth Circuit focused on the economic value of the drug specifically, and not its medical value, and for purposes of

sentencing a defendant in a criminal proceeding. That is an entirely different inquiry from the issue now before the Court.

The Court thus dismisses Relators' FCA claim to the extent it is based on a factually false certification theory. As above, the dismissal is with prejudice in light of Relators' prior opportunity to amend but the still-remaining deficiency with the claim.

C. Cause of Action for Retaliation – Federal

The Court now turns to Mr. Campie's federal retaliation claim, which is also based on the FCA. The FCA provides in relevant part that

> [a]ny employee . . . shall be entitled to all relief necessary to make that employee . . . whole, if that employee . . . . is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of his employment because of lawful acts done by the employee . . . in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter [31 U.S.C. § 3721 *et seq.*].

31 U.S.C. § 3730(h). Under Ninth Circuit law,

> [a] plaintiff alleging a FCA retaliation claim must show three elements: (1) that he or she engaged in activity protected under the statute; (2) that the employer knew the plaintiff engaged in protected activity; and (3) that the employer discriminated against the plaintiff because he or she engaged in protected activity.

Mendiondo v. Centinela Hosp. Med. Ctr., 521 F.3d 1097, 1103 (9th Cir. 2008).

In its motion to dismiss, Gilead contends that Mr. Campie has failed to adequately allege a FCA retaliation claim because the allegations in the SAC do not show that (1) Mr. Campie "was investigating actual false claims for payment," as opposed to "mere regulatory violations," and that (2) "Gilead had notice of any such protected activity prior to any alleged adverse employment action." Mot. at 19.

1. Investigation of Fraud on the Government

As noted above, Gilead argues first that, "[t]o be covered by the False Claims Act, [a] plaintiff's investigation must concern 'false or fraudulent' claims." *United States ex rel. Yesudian*, 153 F.3d 731, 740 (D.C. Cir. 1998); *see also Eberhardt v. Integrated Design & Constr., Inc.*, 167 F.3d 861, 868 (4th Cir. 1999) (noting the same); *Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1051 (N.D. Ill. 1998) (noting that "[m]any courts have interpreted the 'in furtherance of'

language by emphasizing that the employee's activity must be fueled by, or at least somewhat connected to, her employer's fraudulent activity in submitting false claims for payment to the government"). Here, Gilead contends, Mr. Campie was not investigating false claims but rather only violations of the FDCA, *i.e.*, regulatory violations. *See United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, No. 01-10583-DPW, 2003 U.S. Dist. LEXIS 8846, at *32-33 (D. Mass. May 21, 2003) (stating that "[p]rotected activity includes 'investigating fraud' with a goal of 'trying to recover money for the government,' not simply correcting 'regulatory problems'").

Gilead's position is meritorious. In *United States ex rel. Hopper v. Anton*, 91 F.3d 1261 (9th Cir. 1996), the Ninth Circuit considered whether the plaintiff failed to show she was engaged in "furtherance of an action" under the FCA. 31 U.S.C. § 3730(h). The plaintiff was a special education teacher who worked for a school district. She had complained to her superiors that the school district "was failing to comply with federal and state laws regarding the handling of special education children. Specifically, she alleged that the School District conducted Individualized Education Program ('IEP') evaluations of potential special education students with special education teachers rather than with the students' classroom teachers." *Hopper*, 91 F.3d at 1263. The Ninth Circuit held that the plaintiff had failed to establish she

> was engaged in "furtherance of an action" under the FCA [because] the record quite clearly shows Hopper was merely attempting to get the School District to comply with Federal and State regulations. Her numerous written complaints, seventy letters and over fifty telephone calls were all directed toward this end. *She was not trying to recover money for the government; she was attempting to get classroom teachers into IEP evaluation sessions. She was not investigating fraud.* She was not whistleblowing as envisioned in the paradigm *qui tam* FCA action. Quite plainly, the thrust of her complaints was that the School District was failing to meet its IDEA obligations to its students. Correcting regulatory problems may be a laudable goal, but one not actionable under the FCA in the absence of actual fraudulent conduct.

Id. at 1269 (emphasis added).

The analysis in *Hopper* is on point. While, arguably, Mr. Campie was unlike the plaintiff in *Hopper* because he was in fact investigating fraud, the bottom line is that the fraud with which he was concerned was fraud on the FDA, an agency tasked with ensuring the safety and effectiveness

of drugs. Nothing in the SAC indicates that Mr. Campie was concerned about fraud on the government as it relates to money being improperly paid to Gilead by the government.

In his opposition, Mr. Campie argues that *Hopper* actually weighs in his favor because, in the case, the Ninth Circuit also stated that "the plaintiff must be investigating matters which are calculated, *or reasonably could lead*, to a viable FCA action." *Id.* (emphasis added). Presumably, Mr. Campie's argument is that his investigation of the FDA problems would reasonably lead to a viable FCA action because, without FDA approval, Gilead could not sell its drugs and Gilead's major customers in the United States are the federal and state/local governments. *See, e.g.*, SAC ¶ 19 (alleging that "[t]he Government and the States pay for the majority of Gilead's drug products sold within the United States through the Government Payment Programs").

The problem for Mr. Campie is that he has misconstrued the Ninth Circuit's use of the language "reasonably could lead." "Reasonably could lead," as that term was used in *Hopper*, refers to the fact that a FCA retaliation claim may be viable *even if a FCA action is not actually filed*. This was made clear by the Ninth Circuit's citation to *Neal v. Honeywell Inc.*, 33 F.3d 860 (7th Cir. 1994), and *Robertson v. Bell Helicopter Textron*, 32 F.3d 948 (5th Cir. 1994). As the Fifth Circuit stated in *Robertson*, "in *Neal*, the [Seventh Circuit] explained that the *actual filing* of a qui tam suit should not be a prerequisite to protection under § 3730(h)." *Id.* at 951 (emphasis added).

Moreover, even if the "reasonably could lead" language could be read along the lines suggested by Mr. Campie, he still would not prevail. That the FDA problems could lead or even would likely lead to a FCA suit does not mean that Mr. Campie's concern in investigating was false claims; rather, his concern about fraud on the FDA could well have been related to, *e.g.*, public safety issues rather than payment issues. *Cf. Boyd v. Accuray, Inc.*, 873 F. Supp. 2d 1156, 1164 (N.D. Cal. 2012) (Koh, J.) (noting that "the record quite clearly shows that Plaintiff was merely attempting to get Accuray to comply with FDA's 'traceability' regulatory requirement and was concerned about patient safety, not fraud against the U.S. government"); *see also United States ex rel. Kennedy v. Aventis Pharm., Inc.*, No. 03 C 2750, 2008 U.S. Dist. LEXIS 11904, at *7 (N.D. Ill. Feb. 11, 2008) (rejecting plaintiff's FCA retaliation claim even though she had alleged her employer had improperly promoted a product for a use other than its FDA-approved use because "[t]he

Seventh Circuit has made it clear that an employee's complaints about internal improprieties or violation of federal regulations do not amount to FCA-protected activity"). In this regard, *Iqbal* is instructive – *i.e.*, here, Mr. Campie has simply made allegations that are "'merely consistent with'" an investigation into false claims, but consistency is not enough to get into the realm of plausibility, *i.e.*, that his motive related to an FCA violation, rather than a general public safety concern vis-a-vis the FDA. *Iqbal*, 556 U.S. at 678.

2. Notice

For the reasons stated above, dismissal of the FCA retaliation claim is appropriate. The Court, however, also concludes that there is an independent reason to dismiss the retaliation cause of action. More specifically, as Gilead argues, the FCA retaliation claim is problematic because there are insufficient allegations that Gilead knew Mr. Campie was engaging in any activity protected by the FCA. *See Hopper*, 91 F.3d at 1269 (stating that, "unless the employer is aware that the employee is investigating fraud, the employer could not possess the retaliatory intent necessary to establish a violation of § 3730(h)"). As noted by the D.C. Circuit, "the kind of knowledge the defendant must have *mirrors the kind of activity in which the plaintiff must be engaged*." *Yesudian*, 153 F.3d at 742 (emphasis added). If Mr. Campie only notified Gilead about FDA violations, then Gilead would not thereby know that false claims to the government were also an issue. The Court acknowledges Mr. Campie's allegation that, post-termination, Gilead asked him to sign a severance agreement which included a provision stating that he would not bring a FCA claim. *See* SAC ¶ 240 ("Gilead . . . asked Mr. Campie to sign a severance agreement in which he would agree not to initiate a FCA claim[] against Gilead, [thus] confirming Gilead's awareness that Mr. Campie reasonably believed – and had communicated to Gilead his belief – that Gilead was committing a fraud against the Government."). But this allegation, by itself, is not sufficient to give rise to a plausible inference of knowledge on the part of Gilead of an impending FCA claim. Mr. Campie did not allege that his severance agreement was unique in including a waiver of any FCA claim. *See* Mot. at 21 (arguing that "generalized or boilerplate releases encompassing a litany of claims against a former employer are utterly inadequate to show notice of false claims activity"). Mr. Campie's

reliance on *Mendiondo* is unavailing as, there, the plaintiff specifically alleged that she complained to her employer about "false billing and reimbursement practices. *Mendiondo*, 521 F.3d at 1100.

Furthermore, there is, as Gilead asserts, another basis for concluding that there are insufficient allegations of knowledge – more specifically, because it was part of Mr. Campie's "job to investigate and internally report on the alleged FDA regulatory matters at issue." Mot. at 20-21. Gilead cites in support of this argument *United States ex rel. Ramseyer v. Century Healthcare Corp.*, 90 F.3d 1514 (10th Cir. 1996). There, the complaint simply alleged that

> plaintiff advised her superiors that defendants were not complying with the minimum program requirements of Medicaid. Yet plaintiff never suggested to defendants that she intended to utilize such noncompliance in furtherance of an FCA action. Plaintiff gave no suggestion that she was going to report such noncompliance to government officials, *cf. Clemes*, 843 F. Supp. at 596; *Neal*, 33 F.3d at 861, nor did she provide any indication that she was contemplating her own qui tam action. Rather, the monitoring and reporting activities described in plaintiff's complaint were exactly those activities plaintiff was required to undertake in fulfillment of her job duties, and plaintiff took no steps to put defendants on notice that she was acting "in furtherance of" an FCA action – e.g., that she was furthering or intending to further an FCA action rather than merely warning the defendants of the consequences of their conduct. *See Robertson*, 32 F.3d at 951-52 (contract administrator's investigation into overcharging was part of employee's job and could not have put employer on notice); *X Corp. v. Doe*, 816 F. Supp. 1086, 1095-96 (E.D. Va. 1993) (lawyer's discussion of employer's potential qui tam liability was part of his job and, because lawyer did not indicate that he might bring such an action, employer was not on notice).

Id. at 1523; *see also Eberhardt*, 167 F.3d at 868 ("hold[ing] that an employee tasked with the internal investigation of fraud against the government cannot bring a [FCA] action for retaliation unless the employee puts the employer on notice that a *qui tam* suit under section 3730 is a reasonable possibility"); *Robertson*, 32 F.3d at 952 (stating that "the record contains no evidence that Robertson expressed any concerns to his superiors other than those typically raised as part of a contract administrator's job").

In his opposition, Mr. Campie does not really challenge the general legal principles articulated in *Ramseyer*. Instead, he argues that, as alleged in the SAC, the investigative activity in which he engaged went well beyond his job duties or description, and therefore Gilead had notice.

The problem for Mr. Campie is that the SAC contains conflicting allegations about his duties as a QA director. For example, in the SAC, Mr. Campie does allege: "Mr. Campie's investigation [of Gilead's use of Synthetics China as a source of FTC] was not within the typical scope of his normal job duties because, as alleged above, Mr. Campie's job function concerned commercial quality assurance (the quality of finished job product) as opposed to the ongoing quality of API or other drug ingredients." SAC ¶ 157. But just two paragraphs before that, Mr. Campie alleges: "[W]hile Mr. Campie's regular job duties focused on commercial drug quality assurance/control issues[,] *he was (based on job requirements) expected to review API submissions as well*." SAC ¶ 155 (emphasis added); *see also* SAC ¶ 225 (alleging that "Mr. Campie participated in the review and approval of a Health Canada submission associated with the use of Synthetics China API").

Furthermore, contrary to what Mr. Campie argues, ¶ 234 of the SAC is not particularly helpful to his position. There, Mr. Campie alleges his manager told him "initiating quarantine was not in his job description" and that he "had no authority to order one." SAC ¶ 234. But even if Mr. Campie had no specific authority to order a quarantine, that does not detract from the allegation in ¶ 155 (see above) that part of his job duties was to review API submissions.

Moreover, to the extent Mr. Campie argues that Gilead was on notice of his engagement in protected activity because he reported "outside the chain-of-command and beyond Gilead's corporate complaint resolution process," Opp'n at 26, nothing in the SAC adequately establishes such. That Mr. Campie talked to people other than his direct manager and people in other groups within Gilead is not enough to lead to a reasonable inference that he was thereby intending to go outside the chain of command, particularly when there are no allegations about what exactly the chain of command was.

Finally, to the extent Mr. Campie argues that, at the very least, he was clearly acting outside of his job duties when he threatened to report Gilead's actions to the federal government, the SAC indicates that he threatened to report to the FDA specifically, and not, *e.g.*, CMS (the payor agency for Medicare and Medicaid). *See* SAC ¶ 230 ("Mr. Campie made clear that he expected Gilead to stop its deceptive practices and threatened to inform the FDA if Gilead continued its fraudulent conduct."). Thus, this gets Mr. Campie back to the issue of whether giving Gilead notice of a FDA

problem would necessarily have alerted Gilead to a FCA problem. *Cf. Eberhardt*, 167 F.3d at 868 ("hold[ing] that an employee tasked with the internal investigation of fraud against the government cannot bring a [FCA] action for retaliation unless the employee puts the employer on notice that a *qui tam* suit under section 3730 is a reasonable possibility"). As alleged, it did not.

Accordingly, the Court dismisses the FCA retaliation claim. As above, the dismissal is with prejudice in light of the fact that the Court previously gave Mr. Campie leave to amend and the claim as now pled is still deficient.

D. State Claims

Because the Court is dismissing the federal causes of action described above, the only claims remaining are all based on state law (either false claims or retaliation). The Court declines to exercise supplemental jurisdiction over the state law claims, especially as this case has not advanced beyond the pleadings. *See* 28 U.S.C. § 1367(c)(3) (providing that a district court "may decline to exercise supplemental jurisdiction over a claim . . . if . . . the district court has dismissed all claims over which it has original jurisdiction"); *see also Sanford v. MemberWorks, Inc.*, 625 F.3d 550, 561 (9th Cir. 2010) (stating that, "'[i]n the usual case in which all federal-law claims are eliminated before trial, the balance of factors to be considered under the pendent jurisdiction doctrine – judicial economy, convenience, fairness, and comity – will point toward declining to exercise jurisdiction over the remaining state-law claims'").

III. CONCLUSION

For the foregoing reasons, the Court grants Gilead's motion to dismiss. The federal claims are dismissed with prejudice. The Court declines to exercise supplemental jurisdiction over the state claims and therefore those claims are dismissed without prejudice.

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The Clerk of the Court is instructed to enter judgment in accordance with this opinion and close the file in this case.

This order disposes of Docket No. 128.

IT IS SO ORDERED.

Dated: June 12, 2015

EDWARD M. CHEN
United States District Judge