APPENDIX A

OPINION

(JULY 7, 2017)

FOR PUBLICATION
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA ex rel. JEFFREY CAMPIE and SHERILYN CAMPIE,

Plaintiffs-Appellants

v.

GILEAD SCIENCES, INC.,

Defendants-Appellee.

No. 15-16380

D.C. No. 3:11-cv-00941-EMC

Opinion

Appeal from the United States District Court
for the Northern District of California
Edward M. Chen, District Judge, Presiding

Argued and Submitted April 19, 2017

San Francisco, California

Filed July 7, 2017

Before: Stephen Reinhardt and A. Wallace Tashima, Circuit Judges and Donald W. Molloy,* District Judge.

Opinion by Judge Molloy

SUMMARY**

False Claims Act

The panel reversed the district court's Fed. R. Civ. P. 12(b)(6) dismissal of claims under the False Claims Act by relators Jeff and Sherilyn Campie alleging that their former employer, Gilead Sciences, Inc., made false statements about its compliance with Food and Drug Administration regulations regarding certain HIV drugs, resulting in the receipt of billions of dollars from the government; and alleging retaliation against relator Jeff Campie.

The panel held that the relators stated a plausible claim that Gilead's claims seeking payment for non-compliant drugs were a basis for liability under the

* The Honorable Donald W. Molloy, District Judge for the U.S. District Court for the District of Montana, sitting by designation.

** This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

False Claims Act. Considering the four elements of False Claims Act liability, first, the panel held that relators alleged a "false claim" under theories of factually false certification, implied false certification, and promissory fraud. Second, relators adequately pled "scienter." Third, the relators sufficiently pled "materiality" at this stage of the case where they alleged more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations. Fourth, the relators sufficiently alleged that Gilead submitted false claims in a number of ways.

The panel held that the relators adequately pled a claim for retaliation in violation of the False Claims Act. Specifically, the panel held that the second amended complaint sufficiently alleged facts showing that Jeff Campie had an objectively reasonable, good faith belief that Gilead was possibly committing fraud against the government; that Gilead knew Campie was engaged in protected activity: and that Gilead discriminated against Campie because he engaged in protected activity.

The panel declined to decide in the first instance the question of whether relators' claims pursuant to 31 U.S.C. § 3729(a)(1)(A), (B) met the heightened pleading standard under Fed. R. Civ. P. 9(b).

COUNSEL

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Ethan M. Posner (argued) and Joshua N. DeBold, Washington, D.C.; Gretchen Hoff Varner, Covington & Burlington LLP, San Francisco, California; for Defendant-Appellee.

Douglas N. Letter (argued), Benjamin Schultz, and Michael S. Raab, Attorneys, Appellate Staff; Brian Stretch, Acting United States Attorney; Benjamin Mizer, Principal Deputy Assistant Attorney General; Civil Division, United States Department of Justice, Washington, D.C.; for Amicus Curiae United States.

Charles S. Siegel, Waters & Kraus LLC, Dallas, Texas, for Amicus Curiae Professor Peter Linzer.

OPINION

MOLLOY, District Judge:

This case involves allegations under the False Claims Act, 31 U.S.C. §§ 3729–33, that Defendant-Appellee Gilead Sciences, Inc. (Gilead) made false statements about its compliance with Food and Drug

Administration (FDA) regulations regarding certain HIV drugs, resulting in the receipt of billions of dollars from the government. Relators Jeff and Sherilyn Campie (relators), two former Gilead employees, allege that these noncompliant drugs were not eligible to receive payment or reimbursement and, therefore, any claims presented to the government for payment were false under the False Claims Act. Relators further allege that Gilead violated the False Claims Act when it fired relator Jeff Campie, who discovered and ultimately reported the violations. *See* 31 U.S.C. § 3730(h). The district court dismissed relators' claims under Federal Rule of Civil Procedure 12(b)(6). It did so before the Supreme Court decided *Universal Health Servs., Inc. v. United States (Escobar)*, ___ U.S. ___, 136 S. Ct. 1989 (2016). We reverse.

I.

Gilead is a large drug producer, with a majority of its prescription drug product sales occurring in the United States. Relevant here, Gilead produces anti-HIV drug therapies, including the drugs Atripla, Truvada, and Emtriva. In 2008 and 2009 alone, the government spent over $5 billion on these anti-retrovirals. Relators claim that in its sale of these drugs to the government, Gilead concealed violations of FDA regulations and knowingly made false statements regarding its regulatory compliance. The facts recited in the relators' complaints, which are taken as true at this stage, *Escobar*, 136 S. Ct. at 1997, are as follows.

When a drug manufacturer wishes to get a drug approved for manufacture and sale in the United States, it must submit a "new drug application"

(NDA) to the FDA, in which it states the chemical composition of a drug and specifies the facilities where it will be manufactured, as well as methods and controls used in the manufacturing process. 21 U.S.C. § 355(a), (b)(1); 21 C.F.R. § 314.50(d)(1). Acceptable facilities must meet federal standards, known as "good manufacturing practices." *See* 21 C.F.R. Parts 210, 211. The FDA may refuse an application or withdraw a previously approved application if the methods or facilities "are inadequate to preserve [the drug's] identity, strength, quality, and purity." 21 U.S.C. § 355(d), (e). Once approved, the manufacturer must obtain FDA approval to make major changes to the manufacturing process "before the distribution of the drug" by submitting an application called a Prior Approval Supplement, or PAS. 21 U.S.C. § 356a(c)(2); 21 C.F.R. § 314.70(b)(3). Both an NDA and PAS require the applicant to certify that all statements in the application are true and agree to comply with all applicable laws and regulations. *See* Form 356h.

In the mid-2000s, Gilead submitted NDAs and received FDA approval for Emtriva, Truvada, and Atripla. These drugs contain the active ingredient[1] emtricitabine (commonly known as FTC).[2] In its NDA

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[1] The term "active ingredient" refers to the biologically active component of a drug, i.e., any "component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure of any function of the body." 21 C.F.R. § 210.3(b)(7).

[2] In addition to using the term FTC, relators use the term "API" to refer to "active pharmaceutical products" throughout

applications, Gilead represented to the FDA that it would source the FTC from specific registered facilities in Canada, Germany, the United States, and South Korea. But, relators allege that as early as 2006, Gilead contracted with Synthetics China to manufacture unapproved FTC at unregistered facilities. For a period of sixteen months beginning in December 2007, Gilead brought illicit FTC from a Synthetics China facility into the United States to use in its commercial drugs, claiming that the FTC had come from its approved South Korean manufacturer. Gilead allegedly began using Synthetics China to save money and trigger price reduction clauses in contracts with other FTC suppliers.

Gilead ultimately sought approval from the FDA to use Synthetics China's FTC in October 2008, but according to relators, Gilead had been including products from Synthetics China in its finished drug products for at least two years before this approval was obtained in 2010. Relators also allege that Gilead falsified or concealed data in support of its application to get Synthetics China approved by the FDA. For example, Gilead claims in its application that it had received three full-commercial-scale batches of FTC from Synthetics China that passed testing and were consistent with or equivalent to FTC batches made from existing, approved manufacturers. Relators contend that this representation was false as two of three batches had failed internal testing. One of the batches

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their complaints. To avoid confusion, this opinion uses only the term FTC.

purportedly contained "residual solvent levels in excess of established limits" and other impurities. A second batch had "microbial contamination" and showed the presence of arsenic, chromium and nickel contaminants. Gilead did not report this to the FDA, but rather secured two new batches from the unapproved Chinese site and amended its PAS on April 24, 2009, to include the substitute data. The FDA approved the amended PAS in May 2009 and the Synthetics China facility was registered in 2010. Gilead also began using FTC from another, unapproved Synthetics China facility, but ultimately stopped using Synthetics China as a supplier in October 2011, following continued contamination issues. Two recalls of contaminated products occurred in 2014.

Gilead never acknowledged or notified the FDA about the bad test results or the contamination and adulteration problems. Despite being aware of manufacturing problems with Synthetics China, Gilead allegedly released 77 lots of FTC produced by Synthetics China to its contract manufacturers before the FDA approval of the Synthetics China facility. Relators allege that the drug products made with FTC affecting the quality and purity of the drug and produced at a different, uninspected manufacturing site are not FDA-approved. And, according to relators, had the FDA been aware of these issues, it would not have approved the use of the Synthetics China manufacturing facility. Relators make a similar argument for the use of unapproved sites in Alberta, Canada to produce ambrisentan, the active ingredient in Letairis, and contamination of tenofovir disoproxil fumarate (a.k.a. Viread), another active ingredient.

Relators insist that Gilead actively concealed it use of illicit FTC products by Synthetics China in a number of ways. First, Gilead imported the FTC through its Canadian facilities and used fraudulent labeling. Second, the labels and paperwork for the FTC were obscured or augmented to conceal where the FTC was actually produced. Third, Gilead credited its approved FTC manufacturers with the production of the Synthetics China FTC. Relators allege Gilead's false statements and fraudulent conduct resulted in government payments both directly, through programs such as the Department of Defense, Department of Veterans Affairs, Federal Bureau of Prisons, USAID, and the Public Health Service, and through reimbursement programs, such as Medicare, Medicaid, TRICARE, FEHBP, and the Ryan White Program. Payment for drugs under these programs is contingent upon FDA approval. *See, e.g.*, 48 C.F.R. § 46.408 (direct payment); 42 U.S.C. § 1396r-8(k)(2)(A)(i) (Medicaid); 42 U.S.C. § 1395w-102(e) (Medicare Part D). Relators allege that because the drugs paid for by the government contained FTC sourced at unregistered facilities, they were not FDA approved and therefore not eligible for payment under the government programs.

Relators further claim that these drugs were "adulterated" or "misbranded" in violation of the law. Congress expressly prohibits any person from introducing or receiving any "adulterated" or "misbranded" drugs in interstate commerce. 21 U.S.C. § 331(a), (c). A drug is "adulterated" if "the methods used in, or the

facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice," or if "any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor." 21 U.S.C. § 351(a)(2)(B), (d). A drug is "misbranded" if, *inter alia*, "it is an imitation of another drug," or "it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered" under the Food, Drug, and Cosmetic Act. 21 U.S.C. § 352(i)(2), (o). Violations of that restriction are crimes and adulterated or misbranded drugs can be seized. 21 U.S.C. §§ 333(a), 334.

Relators finally raise a retaliation claim regarding the termination of Relator Jeff Campie. *See* 31 U.S.C. § 3730(h). Mr. Campie worked at Gilead as its Senior Director of Global Quality Assurance from July 2006 to July 2009. His "regular job duties focused on commercial drug product quality assurance/control issues[, but] he was (based on job requirements) expected to review [active ingredient] submissions as well." While employed with Gilead, Campie had quality control oversight of (1) all commercially released drug products by Gilead; (2) Gilead's policies, practices, and good manufacturing practice compliance; and (3) the development of quality systems. It appears that Campie raised concerns about "the integrity of the data being generated to support the release of Gilead drugs" as early as July 2007. In 2008, Campie became worried about Gilead's use of FTC manufac-

tured by Synthetics China, and in January 2009, convened a meeting to caution Gilead management that FTC could not be shipped from an unapproved manufacturing site. Through the remainder of his employment, "Mr. Campie continued to voice strenuous objections to the false representations and omissions being made to the Government concerning the source and lack of purity of the [active ingredients] from Synthetics China and that [sic] lack of a truthful, valid and approved PAS." "Although Mr. Campie was supposed to be responsible for commercial quality input on regulatory filings implicating quality or supply issues, Gilead began to selectively circumvent Mr. Campie's review and effectively removed or excluded him from Gilead's regulatory review process." In a March 2009 meeting, "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." In April 2009, Campie initiated a quarantine to prevent non-approved Letairis from entering the supply chain. That quarantine was lifted and Campie was chastised by management. During this time, Campie continued to voice his concerns.

On June 20, 2009, Campie was informed he would be terminated effective July 2009. He was told that his "heart wasn't in the job anymore." Campie maintains, however, that he was terminated because he "discovered, investigated, and raised concerns over Gilead's release and distribution … of tons of contaminated and adulterated [active ingredients] that had been manufactured at unregistered and uninspected" facilities and thus "were not eligible for payment under the Government Payment Programs, causing the

submission of false claims paid by the [federal] Government and the States." Upon termination, Campie was asked to sign a severance agreement agreeing not to initiate any claims under the False Claims Act. He refused.

The district court dismissed relators' first amended complaint on January 7, 2015, under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim, but gave relators an opportunity to amend. On June 12, 2015, the district court dismissed relators' second amended complaint with prejudice, holding that it also failed to state a claim under the False Claim Act.[3] Relators timely appealed. Although it declined to intervene in the case below, the United States Department of Justice submitted a brief as amicus curiae supporting reversal of the district court.

II.

We have jurisdiction pursuant to 28 U.S.C. § 1291. We review the dismissal of claims under the False Claims Act de novo. *United States ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1170 (9th Cir. 2006). We assume the facts as alleged are true and examine only whether relators' allegations support a cause of action under the False Claims Act under the theories presented. *Id*. A Rule 12(b)(6) dismissal "can be based on a lack of a cognizable legal theory

[3] The parallel state claims were dismissed without prejudice.

or the absence of sufficient facts alleged under a cognizable legal theory." *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990). A complaint must plead "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim under the False Claims Act must not only be plausible, Fed. R. Civ. P. 8(a), but pled with particularity under Rule 9(b), *Cafassao ex rel. United States v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1054–55 (9th Cir. 2011). The district court based its dismissal on Rule 12(b)(6) and did not address whether the relators' complaints met Rule 9(b)'s heightened pleading standard.

III.

The False Claims Act makes liable anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A), (B). A "claim" includes direct requests for government payment as well as reimbursement requests made to the recipients of federal funds under a federal benefits program. 31 U.S.C. § 3729(b)(2)(A); *Escobar*, 136 S. Ct. at 1996. A claim under the False Claims Act requires a showing of "(1) a false statement or fraudulent course of conduct, (2) made with the scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *Hendow*, 461 F.3d

at 1174. It is not enough to allege regulatory violations, *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996); rather, the false claim or statement must be the "*sine qua non* of receipt of state funding," *Ebied ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010). We construe the Act broadly, as it is "intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." *Hendow*, 461 F.3d at 1170 (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)).[4] Such broad construction has thus given rise to a number of doctrines "that attach potential False Claims Act liability to claims for payment that are not explicitly and/or independently false." *Hendow*, 461 F.3d at 1171.

Relators insist that Gilead's claims seeking payment for noncompliant drugs are a basis for liability under the False Claims Act for three reasons. First, Gilead charged the government for approved drugs, knowing that it had delivered unapproved "knock-offs" (factually false certification). Second, by selling its drugs to the government and causing others to

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[4] Although the Supreme Court admonished in *Escobar* that "[t]he False Claims Act is not 'an all-purpose antifraud statute,' or a vehicle for punishing garden variety breaches of contract or regulatory violations," 136 S. Ct. at 2003 (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 555 U.S. 662, 672 (2008) (citation omitted)), this instruction related only to the "demanding" materiality requirement of a False Claims Act claim, *see id.*, and therefore did not displace this court's obligation to construe broadly any theory of liability in which materiality can be proven.

seek reimbursement for them, Gilead implicitly certified that the drugs were approved for distribution when it knew otherwise (implied false certification). Third, Gilead lied to the FDA to secure approval of Chinese facilities, making them eligible for government payments (promissory fraud). The district court below rejected all three of relators' theories for recovery under the False Claims Act. First, the district court rejected relators' formulation of a factually false theory based on the provision of nonconforming goods. As to relators' second and third arguments, the district court recognized claims brought under either an implied false certification or promissory fraud theory could be viable, but concluded that relators failed to state a claim under either one because they failed to allege Gilead made a false statement related to a material precondition for payment. The United States, while not taking a position on the merits of relators' claims, identifies in its amicus briefing two rulings by the district court as particularly significant to the government. First, it argues that the district court's dismissal of relators' nonconforming goods theory improperly limits liability under the False Claims Act. Second, it argues that the district court improperly rejected a promissory fraud theory where the fraud was initially directed at a non-payor agency. We address each of the relevant theories for recovery under the False Claims Act and conclude that relators state a plausible claim.

A. Factually False Certification

Relators insist that Gilead's HIV drugs were not manufactured at an approved facility and thus were

not approved by the FDA, and therefore Gilead's sale of those medicines, and attendant receipt of government payments, constituted a material false statement. Although the district court analyzed this claim in part as a failed claim for worthless services, *United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1053 (9th Cir. 2001), the claim is one of nonconforming goods, *United States v. Nat'l Wholesalers*, 236 F.2d 944, 950 (9th 1956); *see United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 305 (3d Cir. 2011) ("A claim is factually false when the claimant misrepresents what goods or services that it provided to the Government ...."). The value of the goods at issue is dispositive under the first characterization, *Lee*, 245 F.3d at 1053–54, and immaterial to the latter, *Nat'l Wholesalers*, 236 F.2d at 949–51 (finding a violation of the False Claims Act despite substitute goods of "equal" performance); *United States v. Aerodex, Inc.*, 469 F.2d 1003, 1007–08 (5th Cir. 1972) ("The mere fact that the item supplied under contract is as good as the one contracted for does not relieve defendants of liability if it can be shown that they attempted to deceive the government agency."). Although relators failed to allege that the drugs paid for by the government were "worthless," that failure does not affect relators' claim for nonconforming goods.

In *National Wholesalers*, a wholesaler contracted with the United States to furnish proprietary engine regulators but instead delivered regulators manufactured by the wholesaler bearing spurious proprietary labels. 236 F.2d at 945–47. Even though the substitute regulators functioned equally to those contracted for,

we found liability under the False Claims Act because the wholesaler "misbrand[ed]" the substitutes to make them appear to be the genuine article. *Id.* at 950. The Fifth Circuit reached a similar conclusion in *Aerodex*, where the defendants sold the United States Navy engine bearings different from the ones contracted for, admitting that they both reworked and renumbered the bearings to appear compliant with their contract. 469 F.2d at 1007. Despite the fact that the bearings provided were also approved for use in the engines at issue, the Fifth Circuit found liability under the False Claims Act due to the defendant's deliberate mislabeling. *Id.* at 1007–08.

Contrary to the position taken by Gilead, a claim for nonconforming goods is not limited to situations where there is an express specification in a payment contract between a supplier and the government regarding the disputed aspect of the product to be supplied. Such a circumscribed view of False Claims Act liability was expressly rejected by the Supreme Court in *Escobar*, 136 S. Ct. at 2001, a case decided after the district court had ruled in this case. Additionally, as we have previously explained, the False Claims Act "was enacted during the Civil War with the purpose of forfending widespread fraud by government contractors who were submitting inflated invoices and shipping faulty goods to the government." *Hopper*, 91 F.3d at 1265–66. That core purpose would not be served if a defendant could escape liability for delivering nonconforming goods merely because the goods retained some value or in the absence of a bilateral contract. It is fraudulent conduct that gives rise to li-

ability, regardless of whether the underlying relationship is based in contract, regulation, or statute. *Nat'l Wholesalers*, 236 F.2d at 950.

As we have previously held, the provision of nonconforming goods can be a basis of liability under the False Claims Act. *See Hopper*, 91 F.3d at 1266 (citing *Aerodex* for proposition that "[False Claims Act] actions have also been sustained under theories of supplying substandard products or services"). But, unlike the situation in *Lee*, where a claim for medically "worthless" drugs does not require a showing of "false certification," 245 F.3d at 1053, a claim for nonconforming goods must include an intentionally false statement or fraudulent course of conduct that was material to the government's decision to pay, *Nat'l Wholesalers*, 236 F.2d at 950.

B. Implied False Certification

Claims under an implied false certification theory can also be viable under the False Claims Act. *Escobar*, 136 S. Ct. at 1999. Under such a theory, "when a defendant submits a claim, it impliedly certifies compliance with all conditions of payment. But if the claim fails to disclose the defendant's violation of a material statutory, regulatory, or contractual requirement . . . the defendant has made a misrepresentation that renders the claim 'false or fraudulent' under § 3729(a)(1)(A)." *Id.* at 1995. In *Escobar*, the Supreme Court recently "clarif[ied] some of the circumstances in which the False Claims Act imposes liability" under this theory. *Id.* As pointed out above, the district court

did not have the benefit of *Escobar* in making its decision.

In *Escobar*, parents brought suit following the death of their daughter after she was treated at a mental health clinic by various unlicensed and unsupervised staff in violation of state Medicaid regulations. *Id.* at 1997. The operative complaint asserted that the healthcare provider "submitted reimbursement claims that made representations about the specific services provided by specific types of professionals, but that failed to disclose serious violations of regulations pertaining to staff qualifications and licensing requirements for those services." *Id.* at 1997–98 (footnote omitted). The state Medicaid program, "unaware of these deficiencies, paid the claims." *Id.* at 1998. The Court concluded that "by submitting claims for payment using payment codes that corresponded to specific counseling services, [the healthcare provider] represented that it had provided individual therapy, family therapy, preventive medication counseling, and other types of treatment." *Id.* at 2000. Moreover, staff members "submitt[ed] Medicaid reimbursement claims by using National Provider Identification numbers corresponding to specific job titles. And these representations were clearly misleading in context." *Id.*

The Supreme Court held that although the implied certification theory can be a basis for liability, two conditions must be satisfied. *Id.* at 2000. First, the claim must not merely request payment, but also make specific representations about the goods or services provided. *Id.* Second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or

contractual requirements must "make[] those representations misleading half-truths." *Id.* at 2001 (footnote omitted). The violation need not be of a contractual, statutory, or regulatory provision that the Government expressly designated as a condition of payment. *Id.* However, the misrepresentation must be "material to the Government's payment decision." *Id.* at 2002. Although *Escobar* clarifies the conditions upon which an implied false certification claim can be made, the four essential elements identified above remain the same. *See Hendow*, 461 F.3d at 1174; *see also United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 332–33 (9th Cir. 2017) (applying Escobar to former employee of a defense contractor alleging that his employer's submission of vouchers constituted a false certification of work performed under a contract).

C. Promissory Fraud

Another approach to finding liability under the False Claims Act in the absence of an explicitly false claim is the "promissory fraud" or "fraud-in-the-inducement" theory. *Hendow*, 461 F.3d at 1173. Under this theory, "liability will attach to each claim submitted to the government under a contract, when the contract or extension of the government benefit was originally obtained through false statements or fraudulent conduct." *Id.* "In other words, subsequent claims are false because of an *original fraud* (whether a certification or otherwise)." *Id.* The elements of a claim for promissory fraud are very similar to those necessary for an implied false certification claim, requiring a false claim wherein the falsity is knowingly perpetrated and the underlying

fraud is material to the government's decision to pay. *Id.* at 1174.

D. Elements

Under all three theories the essential elements of False Claims Act liability are: (1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due. *Escobar*, 136 S. Ct. at 2000-02, *Nat'l Wholesalers*, 236 F.2d at 950; *Hendow*, 461 F.3d at 1174. Here, the dispute focuses primarily on the first and third elements, falsity and materiality. The district court rejected relators' claims for a number of reasons, including that the fraud was directed at the FDA, not the payor agency; payment was not conditioned on compliance with FDA regulations, but merely FDA approval; and the False Claims Act was not meant to intrude on the FDA's complex regulatory regime.

1. Falsity

The first requirement of a False Claims Act claim is a false claim. *Hendow*, 461 F.3d at 1171; *Hopper*, 91 F.3d at 1266 ("Violations of laws, rules, or regulations alone do not create a cause of action. It is the false *certification* of compliance which creates liability when certification is a prerequisite to obtaining a government benefit."). Relators allege a false claim here.

a. Factually false certification

Relators have adequately satisfied the falsity requirement under a theory of factually false certification. As in *National Wholesalers*, Gilead committed factually false certification by supplying "misbrand[ed]" goods. 236 F.2d at 950. Specifically, Gilead represented to the FDA that its active ingredients had been manufactured in approved facilities that had been registered therewith.

b. Implied false certification

Relators have also adequately satisfied the falsity requirement under a theory of implied false certification. To succeed on such a claim, pursuant to *National Wholesalers* and *Escobar*, Gilead must not merely request payment, but also make specific representations about the goods or services provided. *Escobar*, 136 S. Ct. at 2000; *Nat'l Wholesalers*, 236 F.2d at 950. Here, relators allege that by submitting claims for payment or reimbursement for Truvada, Emtriva, and Atripla, Gilead represented that it provided medications approved by the FDA that were manufactured at approved facilities and were not adulterated or misbranded. Just as payment codes correspond to specific health services, *Escobar*, 136 S. Ct. at 2000, and proprietary labels indicate that engine regulators are a proprietary design, *Nat'l Wholesalers*, 236 F.2d at 950, these drug names necessarily refer to specific drugs under the FDA's regulatory regime. *Escobar* further requires that Gilead's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements must "make[] those representations misleading half-truths." 136 S. Ct. at 2000 (footnote omitted). Setting aside the question of materiality, relators

allege Gilead's representations were misleading in this context because Gilead acquired unapproved FTC from a Chinese supplier, re-labeled it to conceal its true nature, falsified test results that showed it was contaminated, and then used that unapproved and contaminated FTC in drugs for which payment was requested and received. Although the drugs at issue were at all times ostensibly "FDA approved," relators allege Gilead requested payment for drugs that fell outside of that approval and omitted critical information regarding compliance with FDA standards.

The district court rejected relators' claims in part because the alleged fraud was directed at the FDA, not the payor agency. That concern is factually assuaged to some degree for the purposes of this case in that both the FDA and the Center for Medicare & Medicaid Services (CMS) (the primary payor agency for reimbursement claims) are overseen by the Secretary of Health and Human Services. Therefore, the fraud was, at all times, committed against the Department of Health and Human Services. But more importantly, the False Claims Act imposes no such limitation. *See* 31 U.S.C. § 3729(a)(1)(B) (extending liability to those who cause false statements to be used). It is not the distinction between the agencies that matters, but rather the connection between the regulatory omissions and the claim for payment. *See United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 492 (3d Cir. 2017) ("[O]ur focus here should not be whether the alleged fraud deceived the prescribing physicians, but rather whether it affected CMS's payment decision."). As we stated in *Hendow*,

"if a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork." 461 F.3d at 1174. *Hendow* itself involved false statements submitted to the Department of Education where claims were submitted to private lenders. *Id.* at 1169–80; *see also, e.g.*, *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 12, 29–30 (1st Cir. 2009) (alleging defendant's fraud caused medical providers to submit false claims); *Hutchenson*, 647 F.3d at 378 (similar). Moreover, relators allege that in addition to making a number of false and fraudulent statements to the FDA, Gilead's submission of alleged unapproved and noncompliant drugs to the payor agencies was itself an alleged false certification. *Escobar*, 136 S. Ct. at 2000.

The district court also rejected relators' claims because payment was not "conditioned on the falsity." As made clear in Escobar, "'[I]nstead of adopting a circumscribed view of what it means for a claim to be false or fraudulent,' concerns about fair notice and open-ended liability 'can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements.'" 136 S. Ct. at 2002 (quoting *United States v. Science Applications Int'l Corp.*, 626 F.3d 1257, 1270 (D.C. Cir. 2010)). We therefore address the district court's concern in the context of materiality.

Gilead insists its certification was not "false" pursuant to *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 701–02 (4th Cir. 2014). In *Omnicare*, the Fourth Circuit concluded that

> once a new drug has been approved by the FDA and thus qualifies for reimbursement under the Medicare and Medicaid statutes, the submission of a reimbursement request for that drug cannot constitute a "false" claim under the [False Claims Act] on the sole basis that the drug has been adulterated as a result of having been processed in violation of FDA safety regulations.

745 F.3d at 701–02. In *Omnicare*, the relator alleged only regulatory violations, not a false claim. *Id*. Although we rejected a regulatory violation claim in *Hopper*, 91 F.3d at 1265–67, we have since clarified that the "fatal defect" in that case "was not that the claimed infraction was a regulatory violation, but that there was a 'lack of a false claim,'" *Hendow*, 461 F.3d at 1171; *see also Kelly*, 846 F.3d at 333 (finding no evidence of a "false claim" where dispute was over *format* of cost reports). Here, relators allege false statements permeating the regulatory process. They allege Gilead mislabeled and misbranded nonconforming drugs and misrepresented its compliance with FDA regulations by omitting critical information. They allege that Gilead established policies and practices to violate the FDA's regulatory requirements and allege specific instances of such violations, such as altering inventory codes, and mislabeling or altering shipping and tracking information. All the while, Gilead was submitting claims for payment for "FDA approved" drugs. Moreover, they allege that Gilead made false statements regarding test results in order to get FDA approval and thus become eligible for government funds. As was the

case in *Escobar*, "[t]he claims in this case do more than merely demand payment. They fall squarely within the rule that half-truths—representations that state the truth only so far as it goes, while omitting critical qualifying information—can be actionable misrepresentations." 136 S. Ct. at 2000 (footnote omitted). Relators adequately plead falsity under the False Claims Act. To hold otherwise would reduce FDA regulations akin to approval of the curate's egg.

c. Promissory fraud

Finally, relators have adequately satisfied the falsity requirement under a theory of promissory fraud. Because Gilead committed either factually false or impliedly false certification through its representations to the FDA and labeling of its products, *see supra*, each claim was fraudulent even if false representations were not made therein. *See Hendow*, 461 F.3d at 1173.

2. Scienter

Had Gilead accidentally produced adulterated pills and unwittingly shipped them and requested payment from the government, the intent requirement under the False Claims Act would not be met. That is not the case. Relators allege a false statement or course of conduct made knowingly and intentionally. *See* 31 U.S.C. § 3729(b)(1). They allege Gilead took internal actions perpetuating its fraud: altering test results, batch numbers, and Inventory Control Numbers, and representing that nonapproved FTC came from approved facilities. They also allege Gilead established practices to deceive the government, and

repeatedly took actions to hide its fraud. In other words, relators allege Gilead provided statements to the government that were "intentional, palpable lie[s]," made with "knowledge of the falsity and with intent to deceive." *Hopper*, 91 F.3d at 1265, 1267. The scienter element is adequately pled.

3. Materiality

Under the False Claims Act, a falsehood is material if it has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). In *Escobar*, the Supreme Court clarified that "[t]he materiality standard is demanding." 136 S. Ct. at 2003. "A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance." *Id.* Materiality also "cannot be found where noncompliance is minor or insubstantial." *Id.* Proof of materiality can include whether "the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated." *Id*.

FDA approval is the "the *sine qua non*" of federal funding here. *Hendow*, 461 F.3d at 1176. Eligibility for federal funding and reimbursement is conditioned on FDA approval under Medicaid, 42 U.S.C. § 1396r-8 (limited to "covered outpatient drug," which is defined

as "approved for safety and effectiveness as a prescription drug" by the FDA), Medicare, 42 U.S.C. § 1395w-102e (similar), and the direct payment programs identified by relators, 48 C.F.R. § 46.408 (assigning FDA responsibility for ensuring quality of drugs purchased by agencies). All of these payment programs look to FDA-approval as a determination of the "safety and effectiveness" of the drugs at issue.[5] It is undisputed that at all times relevant, the drugs at issue were FDA-approved,[6] and that the government continues to make direct payments and provide reimbursements for the sale of the three drugs. Relators thus face an uphill battle in alleging materiality sufficient to maintain their claims.

We note that other courts have cautioned against allowing claims under the False Claims Act to wade into the FDA's regulatory regime. *See Omnicare,* 745 F.3d at 702–03; *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 9 (1st Cir. 2016); [7] *Petratos*, 855 F.3d at 490. However,

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[5] Payment can also be conditioned on other aspects of the drug not regulated by the FDA, such as whether the product is "reasonable and necessary" under Medicare. *See* 42 U.S.C. § 1395y(a)(1)(A).

[6] The district court focused extensively on the difference between NDA-approval and PAS-approval, ultimately concluding NDA-approval was the sole condition of payment. That distinction is not persuasive post-*Escobar*. *See* 136 S. Ct. at 1999.

[7] In *D'Agostino*, the First Circuit went as far as to conclude that "[t]he FDA's failure actually to withdraw its approval of [a medical device] … precludes [the relator] from resting his claims on a contention that the FDA's approval was fraudulently ob-

just as it is not the purpose of the False Claims Act to ensure regulatory compliance, it is not the FDA's purpose to prevent fraud on the government's fisc. Mere FDA approval cannot preclude False Claims Act liability, especially where, as here, the alleged false claims procured certain approvals in the first instance.[8] A conclusion to the contrary would not be consistent with *Escobar*:

> By punishing defendants who submit "false or fraudulent claims," the False Claims Act encompasses claims that make fraudulent misrepresentations, which include certain misleading omissions. When, as here, a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided.

136 S. Ct. at 1999. The dispositive question is rather one of materiality, which turns on a number of factors:

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tained" and that "the absence of some official agency action confirming its position and judgment in accordance with the law renders [a relator]'s fraud-on-the-FDA theory futile." 845 F.3d at 9.

[8] Take the hypothetical posed by relators: if a reimbursement request was submitted for 10 pills of Atripla, but Gilead actually provided 10 pills of Tylenol, that request for payment would be undeniably false. Even though Tylenol is FDA approved, it is not what the government paid for.

> when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Id. at 2003–04.

Here, Gilead insists that because the government continued to pay for the medications after it knew of the FDA violations, those violations were not material to its payment decision. Relators outline a variety of facts that speak to the government's knowledge, such as a September 2010 warning letter regarding impurities in the form of black specks and spots a June/July 2012

inspection and noncompliance letter regarding product from Synthetics China, December 2012 and July 2013 inspections of a specific facility, and two recalls that took place in 2014. Gilead's argument is premised on the continued FDA approval of the drugs even after the agency became aware of certain noncompliance.

Relators and the United States persuasively argue, however, that to read too much into the FDA's continued approval—and its effect on the government's payment decision—would be a mistake. First, to do so would allow Gilead to use the allegedly fraudulently-obtained FDA approval as a shield against liability for fraud. Second, as argued by Gilead itself, there are many reasons the FDA may choose not to withdraw a drug approval, unrelated to the concern that the government paid out billions of dollars for nonconforming and adulterated drugs. Third, unlike *Kelly*, where the government continued to accept noncompliant vouchers, 846 F.3d at 334, Gilead ultimately stopped using FTC from Synthetics China. Once the unapproved and contaminated drugs were no longer being used, the government's decision to keep paying for compliant drugs does not have the same significance as if the government continued to pay despite continued noncompliance. In making its argument, Gilead specifically cites to *Petratos*, where the Third Circuit concluded the materiality standard was not met where the relator did "not dispute that CMS would reimburse these claims even with full knowledge of the alleged reporting deficiencies." 855 F.3d at 490. Beside the fact that the relator in *Petratos* did not allege regulatory or statutory violations, *id.* ("Petratos does not claim that [the defendant]'s safety-related reporting violated any statute or

regulation."), no such concession is made here. Rather, the parties dispute exactly what the government knew and when, calling into question its "actual knowledge." Although it may be that the government regularly pays this particular type of claim in full despite actual knowledge that certain requirements were violated, such evidence is not before us.

The issues raised by the parties here are matters of proof, not legal grounds to dismiss relators' complaint.[9] *See Kelly*, 846 F.3d at 334 (concluding relator "failed to establish a genuine issue of material fact regarding [] materiality"). And, other statutes regulating "adulterated" and "misbranded" drugs reinforce the idea that violations of the FDA regulatory regime have ramifications beyond FDA enforcement actions. *See* 21 U.S.C. § 331; *see, e.g., United States v. Marcus*, 82 F.3d 606, 610 (4th Cir. 1996) (upholding criminal liability for manufacturer's undisclosed addition of two inactive pharmaceutical ingredients not included in FDA-approved NDA given their unknown effect on safety and efficacy of the drug product).

In sum, relators allege more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations, *Kelly*, 846 F.3d at 334, sufficiently pleading materiality at this stage of the case.

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[9] In *D'Agostino*, the First Circuit highlighted the "[p]ractical problems of proof" in how a relator would show that the FDA would not have granted approval but for the fraudulent representations. 845 F.3d at 9. That concern is exactly that: a problem of proof. At the pleading stage we assume the facts alleged by the relators to be true. *Hendow*, 461 F.3d at 1170.

4. Claim

Relators allege Gilead submitted false claims in a number of ways, including submitting direct requests for payment from government agencies, as well as submitting requests for reimbursement. Those allegations are sufficient under the False Claims Act. *Hendow*, 461 F.3d at 1177.

Ultimately, relators have alleged sufficient facts under the False Claims Act to state a claim for relief that is plausible on its face. Fed. R. Civ. P. 8(a); *Ashcroft*, 556 U.S. at 678. We do not reach whether that claim is alleged with sufficient particularity to meet the requirements of Rule 9(b), as that question was not addressed by the district court.

IV.

Relator Jeff Campie also alleges Gilead retaliated against him in violation of the False Claims Act. 31 U.S.C. § 3730(h). To state a claim for retaliation, a plaintiff must demonstrate that: (1) he "engaged in activity protected under the statute"; (2) the employer knew the plaintiff engaged in a protected activity; and (3) the employer discriminated against the plaintiff "because he … engaged in protected activity." *Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1103 (9th Cir. 2008) (holding that the heightened pleading requirements of Rule 9(b) do not apply). The district court dismissed Campie's retaliation claim, holding that he failed to show either that he was engaged in a protected

activity or that Gilead had notice of such activities. We reverse.

A. Protected Activity

An employee engages in a protected activity by "'investigating matters which are calculated or reasonably could lead to a viable [False Claims Act] action.'" *Moore v. Cal. Inst. of Tech. Jet Propulsion Lab.*, 275 F.3d 838, 845 (9th Cir. 2002) (quoting *Hopper*, 91 F.3d at 1269). The district court relied extensively on *Hopper* to conclude that because Campie's allegations are consistent with an investigation into regulatory noncompliance—as opposed to an effort to uncover fraud against the government—he failed to show he engaged in a protected activity. *See* 91 F.3d at 1263–65. However, in *Moore* we subsequently clarified "that an employee engages in protected activity where (1) the employee in good faith believes, and (2) a reasonable employee in the same or similar circumstances might believe, that the employer is possibly committing fraud against the government." 275 F.3d at 845–46 (footnote omitted). The Second Amended Complaint sufficiently alleges facts showing that Campie had an objectively reasonable, good faith belief that Gilead was possibly committing fraud against the government.

B. Notice

It is not enough for relators to allege that Jeff Campie was engaged in a protected activity; they must also show that Gilead knew Campie was engaged in such activity. *Mendiondo*, 521 F.3d at 1103; *Hopper*, 91 F.3d at

1269. As made clear in *Mendiondo*, an allegation of knowledge is not a high bar:

> For the second element of her … retaliation claims, Mendiondo alleges she complained to [the defendant]'s … about possible "civil and criminal violations." Although vague, the reference to "civil violations" can be construed to include the suspected Medicare fraud described above. Because Mendiondo complained to [the CEO] about the suspected civil violations, [the defendant] was informed of Mendiondo's protected activity.

521 F.3d at 1104. Here, the Second Amended Complaint alleges Campie was told it was "none of his concern" when he discussed contamination and adulteration problems on multiple occasions, and he was asked to sign a severance agreement stating he would not bring a False Claims Act claim. Further, "Mr. Campie explicitly complained that Gilead was violating FDA regulations in order to sell its drugs to the Government and States notwithstanding their lack of compliance with [regulatory requirements] …." These allegations are sufficient under *Mendiondo*.

That said, as noted by the district court, the monitoring and reporting activities outlined by relators are by-and-large the types of activities Campie was required to undertake as part of his job. Courts have held that when an employee is tasked with such investigations, it takes more than an employer's knowledge of that activity to show that an employer was on notice of

a potential *qui tam* suit. *See United States ex rel. Ramseyer v. Century Healthcare Corp.*, 90 F.3d 1514, 1523 (10th Cir. 1996) (holding retaliation allegation insufficient where plaintiff's job duties entailed the monitoring and reporting activities at issue); *see also Robertson v. Bell Helicopter Textron, Inc.*, 32 F.3d 948, 952 (5th Cir. 1994) (concluding that relator failed to rebut defendant's *trial testimony* regarding lack of knowledge).

Although *Ramseyer* is instructive, it is distinct from this case. First, the plaintiff in *Ramseyer* "gave no suggestion that she was going to report [the] noncompliance to government officials." 90 F.3d at 1523. Here, the Second Amended Complaint alleges that "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." Second, Campie alleges he was "selectively circumvent[ed]" and "exclud[ed]" from the regulatory review process in which he was meant to take part, was told certain regulatory compliance actions, such as issuing a quarantine, were "not in his job description," and had conversations outside of his chain of command regarding his concerns. The Second Amended Complaint alleges sufficient facts to show Gilead knew of Campie's protected activity.

C. Causation

Finally, relators' pleading must show that Gilead discriminated against Mr. Campie "because he [] engaged in protected activity." *Mendiondo*, 521 F.3d at

1104. It is sufficient at the pleading stage for the plaintiff "to simply give notice that []he believes [the defendant] terminated h[im] because of h[is] investigation into the practices [] specified in the complaint." *Id.* Although the district court did not address this requirement because it found the operative complaint insufficient under the first two requirements, such a showing has been made here.

Based on the forgoing, the retaliation claim included in the Second Amended Complaint contains sufficient facts to survive dismissal under Rule 12(b)(6).

V.

Relators plead sufficient factual allegations to state a claim under the False Claims Act. Because the district court did not address whether relators' claims pursuant to 31 U.S.C. § 3729(a)(1)(A), (B) meet the heightened pleadings standard under Rule 9(b), we decline to decide that question in the first instance.

REVERSED AND REMANDED.

APPENDIX B

ORDER

(JUNE 12, 2015)

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 … overlooked 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 Ed-

ucation 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.

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

/s/ Edward M. Chen
EDWARD M. CHEN
United States District Judge

APPENDIX C

ORDER

(SEPTEMBER 27, 2017)

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA ex rel. JEFFREY CAMPIE and SHERILYN CAMPIE,

Plaintiffs-Appellants

v.

GILEAD SCIENCES, INC.,

Defendants-Appellee.

No. 15-16380

D.C. No. 3:11-cv-00941-EMC Northern District of California, San Francisco

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Before: REINHARDT and TASHIMA, Circuit Judges, and MOLLOY,* District Judge.

The panel has voted unanimously to deny the petition for rehearing. Judge Reinhardt voted to deny the petition for rehearing en banc, and Judge Tashima and Judge Molloy so recommended.

The full court was advised of the suggestion for rehearing en banc and no judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

The petition for rehearing and the suggestion for rehearing en banc are **DENIED**. No further petitions for panel or en banc rehearing will be entertained.

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* The Honorable Donald W. Molloy, United States District Judge for the District of Montana, sitting by designation.

APPENDIX D

RELEVANT STATUTORY AND REGULATORY PROVISIONS

21 U.S.C. § 331

§ 331. Prohibited Acts

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

***

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

***

21 U.S.C. § 355

§ 355. New Drugs

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless

an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

(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) of this section. 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;

***

(d) Grounds for refusing application; approval of application; "substantial evidence" defined

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that … (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity … he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that

clauses (1) through (6) do not apply, he shall issue an order approving the application. … The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs. Nothing in the preceding sentence shall alter the criteria for evaluating an application for marketing approval of a drug.

(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to public health

The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds … (5) that the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or (j) of this section with respect to any drug under this section if the Secretary finds … (2) that on the basis of

new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

***

21 U.S.C. § 356a

§ 356a. Manufacturing changes

(a) In general

With respect to a drug for which there is in effect an approved application under section 355 or 360b of this title or a license under section 262 of Title 42, a change from the manufacturing process approved pursuant to such application or license may be made, and the drug as made with the change may be distributed, if--

(1) the holder of the approved application or license (referred to in this section as a "holder") has validated the effects of the change in accordance with subsection (b) of this section; and

(2)(A) in the case of a major manufacturing change, the holder has complied with the requirements of subsection (c) of this section; or

(B) in the case of a change that is not a major manufacturing change, the holder complies with the applicable requirements of subsection (d) of this section.

***

(c) Major manufacturing changes

(1) Requirement of supplemental application

For purposes of subsection (a)(2)(A) of this section, 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. The application shall contain such information as the Secretary determines to be appropriate, and shall include the information developed under subsection (b) of this section by the holder in validating the effects of the change.

(2) Changes qualifying as major changes

For purposes of subsection (a)(2)(A) of this section, a major manufacturing change is a manufacturing change that is determined by the Secretary to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug. Such a change includes a change that--

(A) is made in the qualitative or quantitative formulation of the drug involved or in the specifications in the approved application or license referred to in subsection (a) of this section for the drug (unless exempted by the Secretary by regulation or guidance from the requirements of this subsection);

(B) is determined by the Secretary by regulation or guidance to require completion of an appropriate clinical study demonstrating equivalence of the drug to the drug as manufactured without the change; or

(C) is another type of change determined by the Secretary by regulation or guidance to have a substantial potential to adversely affect the safety or effectiveness of the drug.

31 U.S.C. § 3729

§ 3729. False claims

(a) Liability for certain acts.--

(1) In general.--Subject to paragraph (2), any person who--

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

***

is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410[1]), plus 3 times the amount of damages which the Government sustains because of the act of that person.

***

(2)(b) Definitions.--For purposes of this section—

***

(4) the term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

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[1] So in original. Probably should read "Public Law 101-410".

31 U.S.C. § 3730

§ 3730. Civil actions for false claims

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(b) Actions by private persons.–(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure.[1] The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

(3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint

[1] *See*, now, Rule 4(i) of the Federal Rules of Civil Procedure.

filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall--

(A) proceed with the action, in which case the action shall be conducted by the Government; or

(B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

***

(5)(c) Rights of the parties to qui tam actions….

***

(3) If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. …

***

(d) Award to qui tam plaintiff.—**(1)** If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action. … Any such

person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(2) If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

***

21 C.F.R. § 211.1

§ 211.1 Scope.

(a) The regulations in this part contain the minimum current good manufacturing practice for preparation of drug products … for administration to humans or animals.

***

48 C.F.R. § 46.408

46.408 Single-agency assignments of Government contract quality assurance.

(a) Government-wide responsibility for quality assurance support for acquisitions of certain commodities is assigned as follows:

(1) For drugs, biologics, and other medical supplies—the Food and Drug Administration ….

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