FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES, et al. ex rel. GERASIMOS PETRATOS ***Plaintiff,*** **v.** **GENENTECH, INC., et al.** ***Defendants.***	**Civil Action No. 11-3691** **OPINION**

ARLEO, UNITED STATES DISTRICT JUDGE

Before the Court are Defendant Genentech, Inc.'s and Defendant Hoffman La-Roche Inc.'s motions to dismiss Plaintiff Gerasimos Petratos' Amended Complaint. Dkt. Nos. 68, 70. On September 3, 2015, the Court heard oral argument. This case concerns whether the False Claims Act can be extended to cover wrongful behavior that does not lead to a false claim. It cannot, so Plaintiff's Amended Complaint must be dismissed.

I. FACTS

This is a *qui tam* action brought by relator Gerasimos Petratos ("Plaintiff") on behalf of the United States government and various state governments. Plaintiff was previously Global Head of Healthcare Data Analytics for Defendants, which include Genentech, Inc., F. Hoffman La Roche Ltd., Hoffman-La Roche Inc., and Roche Holding Ltd. Dkt. No. 77, Am. Compl. (Corrected) ¶ 24.[1]

[1] Two of these defendants, F. Hoffman-La Roche Ltd. and Roche Holding Ltd. ("Foreign Defendants") filed a motion challenging personal jurisdiction. See Dkt. No. 85. Because the Court finds no claim has been stated as Defendants Genentech, Inc. and Defendant Hoffman La-Roche

Defendants own Avastin, one of the world's highest-grossing cancer drugs with 2010 revenues estimated at $6.5 billion. Am. Compl. ¶ 5. Avastin is a monoclonal antibody cancer drug that limits the growth of tumors by preventing the growth of blood vessels that feed tumors. Id. ¶ 89. In February 2004, Avastin received approval from the Food and Drug Administration ("FDA") as a treatment in combination with chemotherapy for patients with metastatic colorectal cancer. Id. ¶ 90. In December 2007, the Oncologic Drugs Advisory Committee ("ODAC") of the FDA recommended denial of Avastin for metastatic breast cancer, highlighting a number of concerns with the clinical trial data provided by Defendants. In December 2007, however, the FDA approved Avastin for treatment for patients with metastatic breast cancer. Id. ¶¶ 91-95. This approval was conditioned on completion of adequate studies showing the drug's clinical benefit. Id. ¶ 97. By December 2010, subsequent clinical studies showed no extension of lifespan and serious side effects to Avastin, so the FDA removed breast cancer as an approved use. Id. ¶ 99. Defendants appealed that decision, but the FDA removed the metastatic breast cancer indication from Avastin's label in 2011. Id. ¶¶ 99-100, 229.

Avastin remains FDA-approved for treatment of metastatic colorectal cancer, non-squamous non-small cell lung cancer, glioblastoma, and metastatic renal cell carcinoma. Id. ¶ 101. Avastin is also used for a variety of uses not approved by the FDA, known as "off-label uses." Id. ¶ 102. These treatments include renal (kidney) cancer, ovarian cancer, pancreatic cancer, and various eye diseases such as macular degeneration. Id. Side-effects from Avastin can be serious, stemming from hypertension to kidney failure. Id. ¶ 103.

Inc. ("U.S. Defendants") and because the allegations against the Foreign Defendants are identical to those against the U.S. Defendants, the claims against the Foreign Defendants are dismissed as well without the Court reaching the issue of personal jurisdiction.

Plaintiff alleges that Defendants knowingly based regulatory submissions on patient databases that contained inadequate information about Avastin's real-world risks and did not use electronic medical records which would have better answered questions about Avastin safety. Id. ¶ 125. In February 2010, Plaintiff recommended use of a different database to Defendants, but no action was taken. Id. ¶¶ 134-39. The different database, Plaintiff alleges, better integrated both inpatient and outpatient data, and so more accurately reflected actual Avastin side effects. Id. ¶ 141-42. Certain of Defendants' employees recognized that the database proposed by Plaintiff was more relevant than those used by Defendants, but declined to examine it because there was too much "business risk." Id. ¶ 146. In April 2010, Plaintiff met with higher level executives for Defendants, including the head of product development and the head of regulatory affairs, requesting use of a different database to study Avastin side effects. Id. ¶ 150. The executives declined to act and Plaintiff subsequently received a scathing email from his supervisor. Id. ¶ 152. At this point, no health authority had questioned the company's data sources. Id. ¶¶ 139, 147.

In June 2010, an independent study found a dose-dependent relationship for proteinuria occurrence in Avastin patients. Id. ¶ 175. Dr. Richard Lafayette, a doctor who has significant influence in prescription practices, also known as a "Key Opinion Leader," subsequently requested information from Defendants concerning the incidence of proteinuria in Avastin patients. Id. ¶ 176. Defendants did not provide that data to Dr. Lafayette, claiming it was not available. Id. ¶ 178. Plaintiff claims that Dr. Lafayette would likely have changed his opinion on the risk-benefit profile for Avastin if he was given more complete information, which would have had an impact on prescribing habits of oncologists. Id. ¶ 221.

In January 2011, the Center for Medicare and Medicare Services ("CMS"), the agency responsible for reimbursement decision for Medicare, asked Defendants to provide it with

information to determine appropriate reimbursement from the federal government. Id. ¶ 21. Defendants allegedly supplied data which projected significantly reduced annual costs associated with the drug's side effects across the patient population. Id.

Plaintiff alleges that Defendants' data deficiencies were the result of an intentional campaign to maximize profits by suppressing clinical and epidemiological information. Id. ¶¶ 12, 182-88. Data deficiencies allegedly led to underreporting of side effects facing at-risk patients, including higher rates of various adverse events: cardiac arrhythmia, renal failure, pulmonary and cranial hemorrhages, and microangiopathic haemolytic anaemia. Id. ¶ 16.

Plaintiff challenges a variety of components of the FDA-approved label for Avastin, including dose dependency, id. ¶ 180, and proteinuria, id. ¶¶ 216-17. Plaintiff further claims that a variety of statements made to the FDA were misleading. Id. ¶¶ 213-25. Defendants also allegedly failed to report adverse events promptly during clinical trials. Id. ¶¶ 167-70.

Plaintiff also alleges generally that if Defendants revealed complete information about Avastin, many doctors would have more carefully evaluated their patients to determine if Avastin use was appropriate. Id. ¶ 19. One physician, Dr. Mark Levin, confirmed that had he known of the risks of Avastin, he would not have prescribed it for some of his patients. Id. ¶ 240-42. Plaintiff also argues that federal and state governments would have reimbursed for fewer Avastin indications, for lower dosages, or not at all. Id. ¶ 19. Plaintiff claims hundreds of millions of dollars in damages. Id. ¶ 20.

Plaintiff's initial complaint was filed on June 27, 2011. Dkt. No. 1. Following a motion to dismiss, the complaint was dismissed in part on January 29, 2014, by the Hon. Dennis M. Cavanaugh, U.S.D.J. Dkt. No. 43. The Court subsequently granted Plaintiff's motion to amend

its complaint, Dkt. No. 56, and the Amended Complaint was filed on December 22, 2014. Dkt. No. 58. [2] The motions to dismiss followed.

Plaintiff's Amended Complaint includes four federal causes of action: (1) presentation of false claims in violation of 31 U.S.C. § 3729(a)(1)(A); (2) knowingly making a false statement material to a false claim in violation of 31 U.S.C. § 3729(a)(1)(B); (3) making or using a false statement to avoid an obligation to refund in violation of 31 U.S.C. § 3729(a)(1)(G); and (4) conspiracy in violation of 31 U.S.C. § 3729(a)(1)(C). Plaintiff also includes separate claims under state law analogues in California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin, and Washington, D.C.

II. LEGAL STANDARD

In order to state a claim for violation of the False Claims Act, 31 U.S.C. 3729(a)(1) ("FCA"), a plaintiff must provide facts sufficient to plausibly show that "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 242 (3d Cir. 2004). "A private individual, otherwise known as a relator, may bring a civil action in the name of the United States to enforce this provision of the FCA and may share a percentage of any recovery resulting from

[2] Permitting an amendment over a futility objection does not categorically preclude consideration of a motion to dismiss. See, e.g., Bussicolo v. Babcock Power, Inc., No. 13-07192, 2014 WL 6908771, at *2-3 (D.N.J. Dec. 8, 2014) (addressing defendant's motion to dismiss amended complaint after defendant previously argued futility); Ashcroft v. Dep't of Corrections, No. 05-488, 2007 WL 1989265, at *6-7 (W.D.N.Y July 6, 2007) (same).

the suit." Wilkins v. United Healthcare Group, Inc., 659 F.3d 295, 305 (3d Cir. 2011); 31 U.S.C. § 3730(b), (d).

An FCA claim must satisfy the pleading requirements of Federal Rule of Civil Procedure 9(b). See Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153, 157 (3d Cir. 2014). The allegations of fraud "must provide particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." Id. at 156-57. "Describing a mere opportunity for fraud will not suffice." Id. at 159.

Claims under the FCA may be factually or legally false. Id. "A claim is factually false where a claimant misrepresents what goods or services it provided to the Government and a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." Id.

Legally false claims are based on a false certification theory of liability. See Rodriquez v. Our Lady of Lourdes Med. Ctr., 552 F.3d 297, 303 (3d Cir. 2008), overruled in part on other grounds by United States ex rel. Eisenstein v. City of New York, 556 U.S. 928 (2009). They may be based on express or implied certifications. See Wilkens, 659 F.3d at 305. Express certifications are those actually stated. Id. Implied certifications occur where "a claimant seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment." Id. The underlying basis for implied certification liability under the FCA is "the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment." Mikes v. Straus, 274 F.3d 687, 699 (2d Cir. 2001); see also United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1266 (D.C. Cir. 2010) ("Courts infer implied certifications from silence where certification was a prerequisite to the government action sought.") (internal quotation marks and citation omitted).

Under the implied certification theory, "a plaintiff must show that if the Government had been aware of the defendant's violations of the Medicare laws and regulations that are the basis of a plaintiff's FCA claims, it would not have paid the defendant's claims." Wilkins, 659 F.3d at 307; see also United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1219-20 (10th Cir. 2008). "Absent this requirement, the FCA could turn into a blunt instrument to enforce compliance with all regulations rather than only those regulations that are a precondition to payment." Wilkins, 659 F.3d at 307 (quotation marks and ellipses omitted).

III. ANALYSIS

Plaintiff relies on three federal statutory hooks for FCA liability.[3] 31 U.S.C. § 3729(a)(1)(A)-(B), (G). Sections (A) and (B) each require a false claim. See United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 242 (3d Cir. 2004).

A. False Claims Under § 3729(a)(1)(A)-(B).

"Claim" is defined within the statute as:

> any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—
> (i) is presented to an officer, employee, or agent of the United States; or
> (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—
>
> (I) provides or has provided any portion of the money or property requested or demanded; or
> (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded

[3] Plaintiff alleges a violation of § 3729(a)(1)(C) as well, but that section imposes liability for any person who "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)." Without an underlying violation, there can be no liability for conspiracy under the FCA. Thus, this count rises or falls with the others.

31 U.S.C. § 3729(b)(2)(A).

Defendants' submissions to the FDA to get Avastin approved are not claims for payment. Nor are their submissions to third-party compendia authors or "Key Opinion Leaders." The only conceivable claims discussed in the Amended Complaint are the submissions doctors make for Medicare and Medicaid reimbursements. Therefore, in order to state a claim, Plaintiff must allege that the claims made by doctors for Medicare and Medicaid reimbursements are false.[4]

1. "Medically Reasonable and Necessary"

Plaintiff argues that doctors' claims were false because certain procedures were not "medically reasonable and necessary" as required by statute and regulations. Defendants reply that doctors do not make this determination, CMS does, and there are no allegations that CMS would make a different decision as to whether Avastin is medically reasonable and necessary for any particular use. Defendants prevail here.

Medicare provides for payment for "a drug or biological." 42 U.S.C. § 1395u(o)(1). The term "drugs" is defined to include any drugs used in an anticancer chemotherapeutic regimen for a "medically accepted indication." 42 U.S.C. § 1395x(t)(2)(A). "Medically accepted indication" is defined to include any use of a drug or biologic that has been approved by the FDA and other uses of a drug or biologic (i.e., off-label uses), so long as the drug or biologic is (1) FDA approved, and (2) "such use is supported by one or more citations which are included . . . in one or more" specified compendia, "unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia." See 42 U.S.C. § 1395x(t)(2)(B). Medicaid similarly reimburses drugs used for "medically accepted indications,"

[4] Plaintiff's allegations that doctors would have prescribed less Avastin do not make the Avastin prescriptions "false claims," i.e. claims that would not be reimbursed by CMS.

which include indications approved by the FDA and uses "supported by one or more citations included or approved for inclusion in any of the compendia." 42 U.S.C. § 1396r-8(d)(1)(B); 42 U.S.C. § 1396r-8(k)(6).

CMS regulations prohibit compensation for "items and services . . . that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C.A. § 1395y(a)(1)(A). The central question is therefore whether the "reasonable and necessary" limitation found in 42 U.S.C. § 1395y(a)(1)(A)[5] is a determination made by the relevant administrative agencies or individual doctors. The substantial majority of courts that address this question find that the relevant administrative agency determines what is medically reasonable and necessary under the regulations.

Language from the Supreme Court indicates that the decision is controlled by the agency, not individual doctors: "The [HHS] Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision . . . are clearly discretionary decisions." Heckler v. Ringer, 466 U.S. 602, 617 (1984). Other courts frequently recite that the agency makes the "reasonable and necessary" determination. See, e.g., Hays v. Leavitt, 583 F. Supp. 2d 62, 65 (D.D.C. 2008) aff'd sub nom. Hays v. Sebelius, 589 F.3d 1279 (D.C. Cir. 2009) (stating that the "reasonable and necessary" determination of section 1395y(a) is made by the Secretary of HHS, though it may be outsourced to specific contractors); Willowood of Great Barrington, Inc. v. Sebelius, 638 F. Supp. 2d 98, 105 (D. Mass. 2009) (detailing different mechanisms by which the Secretary may decide what is "reasonable and necessary").

[5] Though the parties claim a variety of statutory sections provide a "reasonable and necessary" requirement, the clearest language for such a requirement is found in 42 U.S.C. § 1395y(a)(1)(A).

Addressing the more particular context of this case, Judge Linares held that an indication approved by the FDA or supported by a compendia is "medically accepted" and therefore "reasonable and necessary." United States ex rel. Simpson v. Bayer Corp., No. 05-3895, 2013 WL 4710587 (D.N.J. Aug. 30, 2013). Simpson, therefore, directly rejected the theory that doctors make some individualized assessment or certification that a particular procedure or drug is "reasonable and necessary." Simpson also clearly identified the "reasonable and necessary" standard as coterminous with the "medically accepted" requirement. Earlier in the instant case, this Court followed Simpson, holding that "Avastin is approved by the FDA and supported by compendia listings . . . . Relator cannot make this concession and still argue that prescriptions [for] Avastin were not 'reasonable and necessary.'" United States ex rel. Petratos v. Genentech, Inc., No. 11-3691, 2014 WL 345332, at *3 (D.N.J. Jan. 30, 2014). This Court does not see a compelling reason to depart from that ruling here.

Another recent opinion in this district supports this outcome. Judge Wolfson recently held that where the FDA has approved a drug for a particular use, that use is "reasonable and necessary," no matter what an individual doctor thinks. In re Plavix Mktg., Sales Practices & Products Liab. Litig., No. 13-1039, 2015 WL 4997077, at *15 (D.N.J. Aug. 20, 2015) ("[A] drug prescribed for its on-label use—by definition—means that the prescription is medically reasonable for its intended purpose by virtue of the FDA approval process."). That a doctor cannot override the FDA is implicit in this holding. Though not squarely before her, Judge Wolfson did note that many cases agreed that "if the particular use of the drug is supported by a listing in a major drug compendium—even if the use is for an off-label purpose—that drug may fall within the 'reasonable and necessary' standard of Medicare." Id. at *16.

Dealing with a somewhat different issue, one district court noted that "[w]hether prescribing a drug for a particular condition is reasonable and necessary is typically determined by considering whether the drug is prescribed for a 'medically accepted indication' that is reimbursable under Medicare and Medicaid." U.S. ex rel. Cestra v. Cephalon, Inc., No. 14-1842, 2015 WL 3498761, at *8 (E.D. Pa. June 3, 2015).

Several cases that deny motions to dismiss FCA claims are consistent with this holding. In Strom ex rel. U.S. v. Scios, Inc., a district court denied a motion to dismiss an FCA claim. 676 F. Supp. 2d 884 (N.D. Cal. 2009). The claim there was premised on an alleged scheme to promote certain off-label uses. CMS found those off-label uses were not covered and a relator action followed. Id. at 889. Strom does not contradict this Court's holding. There was no indication that the alleged false claims in Strom were actually covered by the Medicare or Medicaid "medically accepted" standard. There was only one mention of drug compendia within the opinion, and that mention actually directly supports this Court's holding—indicating that "medically accepted" clarified "reasonable and necessary." Id. at 886 ("[T]his 'medically accepted' terminology clarifies the applicable statutory language, which provides coverage for uses that are 'reasonable and necessary.'").

In United States ex rel. Brown v. Celgene Corp., another district court permitted a claim to survive a motion to dismiss. No. 10-3165, 2014 WL 3605896 (C.D. Cal. July 10, 2014). The relator in that case alleged that false claims were submitted for off-label uses that were not "medically accepted," as defined in the statute. Id. at * 5. Though the parties disputed whether certain claims were medically accepted—i.e. supported by specified compendia and not precluded by any compendia—the court there found this dispute was a "complex, case-by-case inquiry not susceptible to resolution on a motion to dismiss." Id. Here, by contrast, Plaintiff does not allege

that any claim was submitted that was not "medically accepted" (or would not be medically accepted but-for the alleged misconduct). Brown v. Celgene, therefore, has little application here.

Two district courts denied motions to dismiss FCA claims based on similar arguments as those made by Defendants here. The Court is not persuaded by these decisions. In United States ex rel. Galmines v. Novartis Pharm. Corp., the court addressed a voluminous motion to dismiss FCA claims concerning off-label promotion of a drug. No. 06-3213, 2013 WL 2649704, at *2 (E.D. Pa. June 13, 2013). The Galmines court rejected the argument that defendant's off-label marketing did not affect government payment decisions, juxtaposing "risky" procedures with "necessary" ones. Id. at *12. Because this opinion did not discuss who makes the determination of whether a procedure is medically reasonable and necessary, it is not persuasive here. United States ex rel. Bergman v. Abbot Laboratories also denied a motion to dismiss an FCA claim based on off-label marketing. 995 F. Supp. 2d 357, 370 (E.D. Pa. 2014). Defendant Abbot Laboratories argued a listed compendia supported "use of fenofibrates such as TriCor" for the disputed indications. The Bergman court rejected that argument, assuming without discussion that at least some off-label uses in that case were not covered. Id. at 369. Because the Bergman court did not discuss whether the "reasonable and necessary" determination (1) is made by a doctor or the relevant agency or (2) is coterminous with the "medically-accepted" definition, this Court is unpersuaded by Bergman's assumption that some claims would not be covered.

Put simply, this dispute comes down to whether medically "reasonable and necessary" is assessed by doctors individually or is defined by the regulatory scheme. Here that scheme requires approval by the FDA for a particular use or approval in a specified compendia without rejection by any specified compendia for that use. Reasoning from the Supreme Court and the majority of

courts that have directly discussed this issue make clear that medically "reasonable and necessary" is a determination made by the relevant agency, not individual doctors.[6]

Given that, the Amended Complaint is clearly deficient. It does not allege any facts to show that CMS would find Avastin not to be medically reasonable and necessary for any particular use in the but-for world. This is fatal to Plaintiff's claim that some doctors would not have prescribed Avastin had they been given more information about its risks. Plaintiff does not allege that CMS would have changed its reimbursement schedule or that any compendia would have changed its indication from supporting to non-supporting or to opposing use for any given indication. Thus, Avastin would have legally still been reasonable and necessary for the uses at issue. Plaintiff has not alleged any false claim based on the "reasonable and necessary" requirement.

2. Regulatory Violations

Plaintiff also argues that the claims were false based on an implied certification that Defendants complied with certain regulations. Plaintiff alleges three violations of an implied certification: (1) reliance on self-serving data sources; (2) inadequate examination or reporting of dose-related effects of Avastin; and (3) delay in reporting adverse events.[7]

[6] Local medical contractors approved by CMS may also make decisions concerning what is "reasonable and necessary" for their area of coverage, but such coverage decisions may not conflict with a national coverage decision, if one is active. See, e.g., Medicare Program; Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services, 66 FR 58788-01 (Nov. 23, 2001) (detailing that CMS and contractors may make coverage decisions concerning what is "reasonable and necessary").

[7] Plaintiff also argues in a footnote that some claims for Avastin were a "worthless service," thus implicating the FCA. The Amended Complaint is plainly inadequate to state a claim for a worthless service FCA violation; it never alleges that Avastin had no medical use for certain indications. Plaintiff cites nothing to the contrary in the Amended Complaint.

Violations of regulations only give rise to FCA liability if such regulations are preconditions of payment. The fact that a company "may have knowingly violated these statutes and regulations, without more, does not suffice to state a FCA claim." United States ex rel. Campie v. Gilead Sci., Inc., 2015 WL 106255, at *8 (N.D. Cal. 2015); see also United States ex rel. Hopper v. Anton, 91 F.3d 1261, 1266 (9th Cir. 1996) ("Violation of laws, rules, or regulations alone do not create a cause of action under the FCA."); Wilkins, 659 F.3d at 307 ("[T]he implied certification theory of liability should not be applied expansively, particularly when advanced on the basis of FCA allegations arising from the Government's payment of claims under federally funded health care programs."); Mikes v. Straus, 274 F.3d 687, 696 (2d Cir. 2001) ("The language of [the FCA] plainly links [a defendant's] wrongful activity to the government's decision to pay."). "There must be a direct and immediate link between a false statement or fraudulent conduct and the resulting request for payment; payment must be conditioned on the falsity." Campie, 2015 WL 106255, at *9; accord Foglia v. Renal Ventures Mgmt., LLC, 830 F. Supp. 2d 8, 19 (D.N.J. 2011).

Plaintiff cites nothing to show that the databases used violated any regulation at all, much less one which was a precondition of payment. Nor does Plaintiff cite anything showing that the alleged inadequacy in examining and reporting adverse effects violated any regulation. And this Court has already held that compliance with adverse-event reporting requirements is not a material precondition to payment here. Dkt. No. 43, at 6 (citing United States ex rel. Ge v. Takeda Pharmaceuticals Co., No. 10-11043, 2012 WL 5398564 (D. Mass. Nov. 1, 2012), aff'd, 737 F.3d 116 (1st Cir. 2013)).

Therefore, Plaintiff alleges no facts showing that a precondition of payment has been violated. There are no factual allegations showing that CMS would not have reimbursed these claims had these deficiencies been cured. There are no allegations that the FDA would not have

approved Avastin for particular indications. There are no allegations dealing with preconditions of payment at all. This absence is fatal. As in Wilkins, the Amended Complaint "does not cite to any regulation demonstrating that a participant's compliance with [the disputed regulation] is a condition for its receipt of payment from the Government." Id. at 309-10.

This limitation is critical. Otherwise, the FCA could be used as a relator-driven enforcement mechanism for all healthcare regulations. That is not the purpose of the FCA. See Wilkins, 659 F.3d at 307; Mikes, 274 F.3d at 699 ("[T]he False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations—but rather only those regulations that are a precondition to payment"). Merely alleging a false statement is not enough to state a claim for violation of the FCA.

3. Fraud on the Compendia

Finally, Plaintiff claims to assert a fraud on the compendia theory. Only a single paragraph in the Amended Complaint provides any support for this theory, and it is plainly insufficient:

> As described previously, Roche/Genentech intentionally withheld such information from Dr. Lafayette, the Stanford expert in kidney function, after he had specifically asked for it. Had Relator's proteinuria-risk analysis been disclosed to Dr. Lafayette, it is likely that his opinion on the risk-benefit profile for Avastin would have changed. Given Dr. Lafayette's status as a Key Opinion Leader in the field, his opinion would certainly have a significant impact on prescribing habits of oncologists.

Am. Compl. ¶ 221. Conspicuously absent is any allegation that the compendia would have changed, either by making a particular indication non-approved or by including additional warnings. Even if there were more warnings, based on the Amended Complaint, the drug would be supported by specified compendia for the relevant indications and not excluded in any specified compendia. Thus, Plaintiff has not alleged any claims submitted for indications which would not be "medically accepted" under the regulations but-for the alleged misconduct. No alleged facts

show that any disclosure would cause CMS to refuse payment for any claim. As such, Plaintiff has failed to adequately plead a fraud on the compendia theory.

A false statement is not the same as a false claim for payment. Congress used particular words, and this statutory scheme is not a broad-based consumer protection statute designed to punish generalized wrongdoing. The allegations in this Complaint do not include any allegations showing any false claim for payment was ever made. Therefore, these claims are dismissed.

B. Reverse False Claims under Section 3729(a)(1)(G)

Plaintiff also seeks to allege a reverse false claim. In essence, a reverse false claim requires the failure to pay money owed to the government. The controlling statute, 31 U.S.C. § 3729(a)(1)(G), creates liability for two categories: one who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government" or one who "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." Both of these prongs only apply where there is an obligation to pay the Government. An "obligation" is defined as an "established duty." 31 U.S.C. § 3729(b)(3). There must be "a 'clear' obligation or liability to the [G]overnment." United States ex rel. Thomas v. Siemens, 708 F. Supp. 2d 505, 514 (E.D. Pa. 2010) (citing United States ex rel. Quinn v. Omnicare Inc., 382 F.3d 432, 444 (3d Cir. 2004)).

Claims raised under the FCA's reverse false claims provision "may not be redundant of FCA claims asserted under other provisions of [the FCA]." Sobek, 2013 WL 2404082, at *29; see also Siemens, 708 F. Supp. 2d at 514-15 (same). Siemens is almost identical to this case, in that the plaintiff was "essentially alleging that [the defendant] failed to refund the false claims that the government paid. He is merely recasting his false statement claim under § 3729(a)(2)." 708 F.

Supp. 2d at 514. The Court dismissed that claim. Here too, the allegations do not plausibly show that Defendants were obligated to pay funds to the Government. The allegedly false claims of the doctors have already been dismissed for not being false. Plaintiff provides no other basis for reverse false claims liability.

C. State Law Claims

Defendants argue that state law claims must be dismissed here for the same reasons as the federal claims. Plaintiff's only rebuttal is that the federal claims should not be dismissed, so the state claims should not either.

The Court has dismissed all federal claims. Because Plaintiff does not provide any allegations or analysis differentiating the state claims from the FCA claims, they are dismissed as well. See United States ex rel. Judd v. Quest Diagnostics Inc., No. 10-4914, 2014 WL 2435659, at *17 (D.N.J. May 30, 2014) (dismissing both FCA and state claims with prejudice concurrently); United States ex rel. Ge v. Takeda Pharm. Co., No. 10-11043, 2012 WL 5398564, at *6 (D. Mass. Nov. 1, 2012) (dismissing state law claims where complaint did not differentiate the state claims from the dismissed FCA claims).

IV. CONCLUSION

For the reasons stated above, Defendant Genentech, Inc.'s and Defendant Hoffman La-Roche Inc.'s motions to dismiss are **GRANTED**. An appropriate order follows.

Date: October 29, 2015

/s Madeline Cox Arleo
MADELINE COX ARLEO
UNITED STATES DISTRICT JUDGE