NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, et al., ex rel. GERASIMOS PETRATOS,	**Civ. Action No. 11-3691**
Plaintiffs,	
v.	**OPINION**
GENENTECH, INC., et al.,	
Defendants.	**December 18, 2014**

WIGENTON, UNITED STATES DISTRICT JUDGE.

I. INTRODUCTION

Before this Court is Relator Gerasimos Petratos's ("Relator") motion to amend. Defendant Genentech, Inc. ("Genentech") opposes the motion.

This Court has jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1331, and 28 U.S.C. § 1345. Venue is proper under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391.

This motion was decided without oral argument pursuant to Federal Rule of Civil Procedure 78 and Local Civil Rule 78.1. For the reasons set forth below, Relator's motion to amend is **GRANTED.**

II. BACKGROUND

On June 6, 2011, Relator initiated this *qui tam* suit against Genentech and the Roche Group (collectively, "Defendants"), alleging violations of the False Claims Act ("FCA") and related state analogues. Relator, a former Genentech employee, claimed Defendants and their employees

engaged in a conspiracy to mislead regulators and the medical community as to the appropriateness of their Avastin[1] product for treating certain at-risk patient groups. In his initial Complaint, Relator alleged, *inter alia*, Defendants: (1) underreported the prevalence and severity of Avastin's adverse effects; (2) made their disclosures to regulators and the medical community using databases that they knew lacked the requisite information to identify at-risk subgroups even though Defendants could have used more robust databases; and (3) did not adequately examine and report dose-related effects.

Relator claimed these actions resulted in doctors prescribing Avastin when it was medically unreasonable or unnecessary, thereby causing the submission of false claims to government health care systems, including Medicare, Medicaid, the Federal Employees Health Benefits Program ("FEHBP"), the Department of Defense's TRICARE program, and the Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA").

On July 18, 2013, Genentech moved to dismiss Relator's Complaint. On January 30, 2014, the Hon. Dennis M. Cavanaugh, U.S.D.J. (now retired), granted Genentech's motion as to Relator's claims under two provisions of the FCA: (1) Count One – knowingly presenting or causing to be presented a false claim under 35 U.S.C. § 3729(a)(1)(A) and (2) Count Two – knowingly making, using, or causing to be used a false record or statement material to a false or fraudulent claim under 35 U.S.C. § 3729(a)(1)(B).

Genentech then moved for a judgment on the pleadings as to Relator's remaining causes of action. In response, Relator filed the instant motion to amend his Complaint. Relator argues that his proposed amendments would cure both the pleading deficiencies that formed the basis for

[1] Avastin is used in the treatment of cancer. (Compl. ¶ 5.)

Judge Cavanaugh's dismissal opinion and Genentech's arguments in support of a judgment on the pleadings.

Genentech opposes the motion.[2] First, Genentech contends Judge Cavanaugh dismissed Count One and Count Two with prejudice. Alternatively, Genentech argues that Relator's amendment is futile as Relator's proposed amended complaint ("Amended Complaint") does not state a cause of action under 31 U.S.C. § 3729(a)(1)(A) or 31 U.S.C. § 3729(a)(1)(B).

The parties have agreed that Genentech will withdraw its motion for judgment on the pleadings if the instant motion to amend is granted. See Stipulation, Dkt. No. 51.

III. ANALYSIS

a. Court's Opinion and Order dated January 30, 2014

Genentech argues Relator's motion must be denied because Judge Cavanaugh's dismissal was with prejudice. Judge Cavanaugh's January 30, 2014 Order simply states that "Defendant's Motion to Dismiss is **granted in part and denied in part.**" Order, Dkt. No. 44 (emphasis in original). Further, the Order does not state whether Counts One and Two were dismissed with prejudice.

Genentech asserts that granting the instant motion to amend would "overturn" Judge Cavanaugh's decision or contradict his reasoning. When granting a motion to dismiss, the decision of whether to permit a subsequent amendment rests within the sound discretion of the trial court. See Fed. R. Civ. P. 15(a)(2); cf. Reed Elsevier, Inc. v. Inherent.com, Inc., No. 05-4048, 2006 WL 3827414, at *9 (D.N.J. Dec. 27, 2006). Additionally, within the Third Circuit, even when a

[2] While Relator initiated suit against both Genentech and the Roche Group, Genentech's counsel has stated that the Roche Group is not a legal entity and, in any event, has not been served with the Complaint. As part of his motion, Relator seeks to amend his complaint to add F. Hoffman La Roche, Ltd., Hoffman-La Roche Inc., and Roche Holding Ltd. as defendants.

complaint is vulnerable to Rule 12(b)(6) dismissal, the district court should allow the party a curative amendment, unless the amendment would be futile or inequitable. See Hughes v. New Jersey, No. 11-1442, 2013 WL 1847030, at *7 (D.N.J. Apr. 30, 2013). This Court concludes that the January 30, 2014 Order granting Genentech's motion to dismiss was without prejudice.

b. Proposed Amendments

i. Standard of Review

Under Rule 15(a)(2), a plaintiff may amend his complaint "when justice so requires." The Third Circuit has repeatedly directed that "motions to amend pleadings [under Rule 15(a)] should be liberally granted." Long v. Wilson, 393 F.3d 390, 400 (3d Cir. 2004). The court may deny a motion to amend only where there is: (1) undue delay, (2) bad faith or dilatory motive, (3) undue prejudice, (4) repeated failures to cure deficiencies, or (5) futility of amendment. Foman v. Davis, 371 U.S. 178, 182 (1962). Here, Genentech argues only that the proposed amendment is futile.

A court will consider an amendment futile if it "is frivolous or advances a claim or defense that is legally insufficient on its face." Harrison Beverage Co. v. Dribeck Imps., Inc., 133 F.R.D. 463, 468 (D.N.J. 1990) (internal citations and quotations omitted). To determine whether an amendment is insufficient on its face, courts employ the standard applied to a motion to dismiss, which is typically governed by Rule 12(b)(6). In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1434 (3d Cir. 1997). Under this standard, the question before the court is not whether the movant will ultimately prevail, but whether the complaint sets forth "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007).

As a *qui tam* case involves allegations of fraudulent conduct, Rule 9(b) also applies. See United States ex rel. Wilkins v. United Health Grp., 659 F.3d 295, 301 n.9 (3d Cir. 2011). Rule 9(b) states, "In alleging fraud or mistake, a party must state with particularity the circumstances

constituting fraud or mistake." "This heightened pleading standard is intended 'to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior.'" United States ex rel. Underwood v. Genentech, Inc., 720 F. Supp. 2d 671, 676 (E.D. Pa. 2010) (quoting Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 791 (3d Cir. 1984)).

ii. The False Claims Act

Relator seeks to bring claims under 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(1)(B).

"Establishing a prima facie claim under § 3729(a)(1)(A) requires showing 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. Portilla v. Riverview Post Acute Care Ctr., No. 12-1842, 2014 WL 1293882, at *8 (D.N.J. Mar. 31, 2014) (quoting United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 242 (3d Cir. 2004) and recognizing that Schmidt remains good law following the 2009 amendments to the statute). "The elements of a § 3729(a)(1)(B) claim are that 1) the defendant made, or caused someone else to make, a false or fraudulent record or statement; 2) the defendant knew the statement to be false or fraudulent; and 3) the statement was material to a claim." Id.

In the Amended Complaint, Relator alleges a number of legally false claims. "[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." Wilkins, 659 F.3d at 305. Id. (internal quotations and citations omitted). There are two theories of false certification that give rise to liability:

> Under the "express false certification" theory, an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds. There is a more expansive version of the express false certification theory called "implied false certification" liability which attaches when a claimant seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment. Thus, an implied false certification theory of liability is premised on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment.

Id. (internal quotations and citations omitted). Not every failure to comply with a statute or regulation gives rise to a false certification claim. Instead, the relator "must show that compliance with the regulation which the Defendant allegedly violated was a condition of payment from the Government." Id. at 309. In other words, the plaintiff must prove that "if the Government had been aware of the defendant's violations of the [] law and regulations that are the basis of the plaintiff's FCA claims, it would not have paid the defendant's claims." Id. at 307; see also Portilla, 2014 WL 1293882, at *14 (applying this framework to post-FERA FCA claims).

iii. Application

Relator further alleges multiple express false certification and implied false certification theories. It must therefore be determined whether any of these theories support a 35 U.S.C. § 3729(a)(1)(A) or 35 U.S.C. § 3729(a)(1)(B) claim.

A claim submitted to Medicare may only be reimbursed if the medical treatment was "reasonable and necessary." See 42 U.S.C. § 1395y. "Because the statute permits reimbursement only for 'reasonable and necessary' treatments . . . a prescription [] in a context where it is not 'reasonable' or 'necessary' would be statutorily ineligible for reimbursement. This satisfies the FCA's requirement of a 'false' statement." United States ex rel. Strom v. Scios, Inc., 676 F. Supp. 2d 884, 891 (N.D. Cal. 2009); see also United States ex rel. Colquitt v. Abbott Labs., 864 F. Supp.

2d 499, 530 (N.D. Tex. 2012); United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 51-53 (D. Mass. 2001).

Moreover, even though the "reasonable and necessary" certifications at issue were made by physicians, and not Defendants, Defendants may still be held liable under the FCA if Defendants caused these physicians to make claims that were not "reasonable and necessary." Strom, 676 F. Supp. 2d at 891 n.2; United States ex rel. Bergman v. Abbott Labs., 995 F. Supp. 2d 357, 367-70 (E.D. Pa. 2014); United States ex rel. Brown v. Celgene Corp., No. 10-3165, 2014 WL 3605896, at *3 (C.D. Cal. July 10, 2014).

Here, the Amended Complaint addresses the deficiencies articulated in the Court's January 30, 2014 Opinion and Order dismissing Relator's initial 35 U.S.C. § 3729(a)(1)(A) and 35 U.S.C. § 3729(a)(1)(B) claims.

First, Relator alleges that Defendant's actions have compromised the reliability of the various drug compendia entries that list the medically acceptable (and therefore reasonable and necessary) off-label uses of Avastin. See, e.g., Am. Compl. ¶¶ 16, 19, 125, 138, 176-181, 197-251. For example, Relator alleges that Defendants misled the key opinion leaders whose reviews of Avastin impacted what off-label uses would be listed in the compendia. See, e.g., Am. Compl. ¶ 248. These allegations distinguish this case from United States ex rel. Simpson v. Bayer Corp., in which the relator did not challenge the drug compendia's reliability. See No. 05-3895, 2014 WL 1418293, at *9-10 (D.N.J. Apr. 11, 2014); see also Brown, 2014 WL 3605896, at *6 (distinguishing Simpson and denying motion to dismiss when relator alleged that the drug manufacturer attempted to improperly influence the compendia); Bergman, 995 F. Supp. 2d at 369-70 (same); cf. United States ex rel. Galmines v. Novartis Pharma. Corp., No. 06-3213, 2013 WL 2649704, at *11 (E.D. Pa. June 13, 2013)

Second, Relator's Amended Complaint does not merely provide a general and conclusory challenge to all Avastin prescriptions as not "reasonable and necessary." See Simpson, 2013 WL 4710587, at *9; see also No. 05-3895, Dkt. No. 102 ¶ 332. Instead, Relator asserts that had Defendants not engaged in the alleged fraud, physicians, when treating certain at-risk patient groups, would not have determined that Avastin (or the particular dosage of Avastin) was "reasonable and necessary."[3] See, e.g., Am. Compl. ¶¶ 126-27. In fact, Relator identifies one particular oncologist who "stated that, had he known of the safety and adverse event risks that were suppressed by Defendants, he would not have certified Avastin as medically necessary and/or reasonable and necessary for some of his patients." Id. at ¶ 240.

Based upon the foregoing, this Court concludes that Relator has sufficiently alleged causes of action under 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(1)(B). See Strom, 676 F. Supp. 2d. at 891-92; Brown, 2014 WL 3605896, at *6; Galmines, 2013 WL 2649704, at *11; see also Bergman, 995 F. Supp. 2d at 369-70 (noting that TRICARE and FEHBP programs contain more stringent reimbursement restriction than those of Medicare and Medicaid).

[3] These allegations also distinguish the instant case from United States ex rel. Ge v. Takeda Pharma. Co. Ltd., Nos. 10-11043, 110343, 2012 WL 5398564, at *1 (D. Mass. Nov. 1, 2012), in which the trial court granted a motion to dismiss when the relator failed to provide any details of allegedly false claims but instead merely suggested that all of the claims were rendered false by the drug company's failure to properly report adverse effects. See United States ex rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13 (1st Cir. 2009) (reversing district court's dismissal of FCA claim when the relator had identified eight specific healthcare providers that submitting false claims as a result of the drug company's actions). The Court notes that Ge is further distinguishable in that many of the false certification theories advanced in this case were not raised by Ge in her complaint. See United States ex rel. Ge v. Takeda Pharma Co., 737 F.3d 116, 126 (1st Cir. 2013) (refusing to consider Ge's "reasonable and necessary" arguments because they were not presented to the trial court prior to dismissal).

IV. CONCLUSION

For the reasons set forth above, Relator's motion to amend [Dkt. No. 52] is **GRANTED.** Because Genentech has stipulated that it would withdraw its motion for a judgment on the pleadings if Relator's motion to amend was granted, Genentech's motion is **DENIED AS MOOT.** An appropriate Order accompanies this Opinion.

/s/ Susan D. Wigenton
United States District Judge

Orig: Clerk
cc: Parties
Judge Mannion