

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 03-12189-RWZ

UNITED STATES OF AMERICA *ex rel.*  
MARK EUGENE DUXBURY and DEAN McCLELLAN

v.

ORTHO BIOTECH PRODUCTS, L.P.

MEMORANDUM OF DECISION AND ORDER

January 28, 2008

ZOBEL, D.J.

Relators Mark Duxbury (“Duxbury”) and Dean McClellan (“McClellan”) (collectively, “Relators”) have filed this action against defendant Ortho Biotech Products, L.P. (“OBP”) under the qui tam provisions of the False Claims Act (“FCA”), 31 U.S.C. § 3730, which permits a private person to file an action on behalf of the United States. The case is before me on defendant’s motion to dismiss. For the reasons discussed below, the motion is allowed.

**I. Procedural History**

Duxbury originally filed this action in November 2003. The FCA requires that the relator file his action under seal, during which time the United States may investigate and evaluate the allegations and determine whether to intervene in the action. 31 U.S.C. § 3730(b)(2). On July 12, 2005, the United States gave notice of its declination to intervene, and the court ordered Duxbury to serve defendant. After a succession of requests for extensions, defendant was served on October 12, 2006. Duxbury

subsequently moved to amend the complaint as of right and add McClellan as a co-relator pursuant to Federal Rule of Civil Procedure 15(a). This court allowed the motion over defendant's objection, noting that defendant had not yet filed a responsive pleading, and although the amended complaint increased in size, it was "less clear that the proposed amendment adds entirely new violations" of the FCA. (Docket # 50, 2.)

The amended complaint explicitly states:

Relator Duxbury is the original source of the claims and allegations contained in the original Complaint and the Amended Complaint. Through the course of his investigation Relator Duxbury developed Relator McClellan as an additional Relator. Relator McClellan is an additional relator who provides additional supporting facts and information. Relator McClellan does not bring any new legal claims against Defendant, but rather adds additional supporting facts to the legal claims previously made.

(First Amended Complaint ("Am. Compl.") (Docket # 51-3) ¶ 28.) Defendant has moved to dismiss the amended complaint, arguing, *inter alia*, that this court lacks jurisdiction over the suit and that Relators have not pled their claims with the requisite particularity.

## II. Factual Background

### A. The FCA

The FCA prohibits false or fraudulent claims for payment to the federal government and permits civil actions based on such claims to be brought by the Attorney General or by private individuals acting in the government's name. 31 U.S.C. § 3730(a)-(b). When the individual brings a suit in the government's name, the individual is known as the "relator," and his action is a "qui tam" suit.<sup>1</sup> The FCA does

---

<sup>1</sup> "Qui tam" is shorthand for "qui tam pro domino rege quam pro se ipso in hac parte sequitur," meaning "who pursues this action on our Lord the King's behalf as well as his own." Rockwell Int'l Corp. v. United States, --- U.S. ---, 127 S. Ct. 1397, 1403 n.2 (2007).

not create a cause of action against all fraudulent conduct affecting the government. Rather, FCA liability attaches to a “false or fraudulent claim for payment” or to a “false record or statement [made] to get a false or fraudulent claim paid” by the government. 31 U.S.C. § 3729(a)(1)-(2); United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 727 (1st Cir. 2007).

The statute further limits the actions that may be brought in several ways, two of which are relevant for present purposes. First, when a private individual brings an FCA action, “no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.” 31 U.S.C. § 3730(b)(5). This so-called “first-to-file” rule operates to prevent multiplication of FCA suits that could lead to duplicative awards covering the same behavior. United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 233-34 (3d Cir. 1998). Second, under the “public disclosure” bar, the court does not have jurisdiction over a private individual’s action if his claims are “based upon” the “public disclosure” of allegations or transactions, unless the individual bringing the suit is an “original source” of the information. 31 U.S.C. § 3730(e)(4).<sup>2</sup>

---

<sup>2</sup> The relevant provision states in total:

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

(B) For purposes of this paragraph, “original source” means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the

The FCA's jurisdictional scheme serves two competing purposes. On one hand, it seeks "to inspire whistleblowers to come forward promptly with information concerning fraud so that the government can stop it and recover ill-gotten gains." United States ex rel. Findley v. FPC-Boron Employees' Club, 105 F.3d 675, 685 (D.C. Cir. 1997). On the other hand, it attempts to discourage so-called "parasitic" suits, in which opportunistic plaintiffs sue based upon information already publicly disclosed or that they did not otherwise discover. United States ex rel. S. Praver and Co. v. Fleet Bank of Maine, 24 F.3d 320, 326 (1st Cir. 1994). The FCA's qui tam provisions must be analyzed in the context of these twin goals. Id.

#### **B. Relators and Their Claims<sup>3</sup>**

Relator Duxbury was employed by defendant from 1992 to 1998, beginning as a Product Specialist and eventually becoming a Regional Key Account Specialist for OBP's Western Division Oncology sales force. Relator McClellan was employed by defendant from 1992 to 2004, beginning as a Product Specialist and eventually becoming a Territory Manager for OBP's Western Division Oncology sales force. In their positions, Relators were "responsible for the promotion and sale of [OBP's drug Procrit®<sup>4</sup>] for Defendant in the Western United States." (Am. Compl. ¶ 17.)

---

Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4).

<sup>3</sup> This subsection is drawn from allegations contained in Relators' First Amended Complaint (Docket # 51-3).

<sup>4</sup> Procrit® ("Procrit") is the brand name for epoetin alfa, a drug which is marketed by OBP and used to treat anemia caused by chemotherapy, chronic kidney disease,

The amended complaint alleges three separate violations of the FCA. First, Relators allege that beginning in 1992, OBP undertook a scheme to give kickbacks to providers and hospitals to induce them to prescribe Procrit. The kickbacks allegedly included free samples, off-invoice discounts, rebates, consulting fees, educational grants, payments to participate in studies or trials and advisory board honoraria. (Am. Compl. ¶¶ 228.) Relators allege that the kickbacks caused providers and hospitals to submit false claims for payment to Medicare. They claim that the time period of the false claims is from “December 1992 to the present.” (Id. ¶¶ 232.)

Second, Relators allege that defendant engaged in a scheme to publish inflated “Average Wholesale Prices” for Procrit that did not represent a real average of the wholesale prices for the drug. The parties have jointly stipulated to the dismissal of this claim (see Docket # 79), and the court will not consider it further.

Third, Relators allege that defendant promoted off-label dosing of Procrit in violation of the Food, Drug and Cosmetic Act and used “sham drug trials” to falsify eligibility for Medicare reimbursement for off-label uses of the drug. (Am. Compl. ¶¶ 271.) Relators claim that the time period for this claim is from January 1998 to the present. (Id. ¶¶ 273.)

Defendants move to dismiss the First Amended Complaint in its entirety on the grounds that the court lacks jurisdiction under the FCA’s public disclosure bar, that certain claims are barred by the “first-to-file” rule, and that plaintiffs have not pled fraud with the requisite particularity. Additionally, defendants assert that the “off-label” claims

---

HIV infection, and blood loss from certain types of surgery.

fail to state violations of the FCA.

### III. Subject Matter Jurisdiction

A qui tam relator's qualification to bring a suit is an issue of subject matter jurisdiction. Rockwell Int'l Corp. v. United States, --- U.S. ---, 127 S. Ct. 1397, 1405-06 (2007). Jurisdiction is based upon Relators' amended complaint. Id. at 1409. Plaintiffs bear the burden of establishing that the court has jurisdiction to hear their claims. Murphy v. United States, 45 F.3d 520, 522 (1st Cir. 1995). The court treats all well-pleaded facts as true and indulges all reasonable inferences in favor of the plaintiff. Aversa v. United States, 99 F.3d 1200, 1210 (1st Cir. 1996). "In addition, the court may consider whatever evidence has been submitted, such as depositions and exhibits . . . ." Id. Statutes such as the FCA which confer jurisdiction on federal courts "are to be strictly construed, and doubts resolved against federal jurisdiction." United States ex rel. Precision Co. v. Koch Indus., Inc., 971 F.2d 548, 552 (10th Cir. 1992).

The FCA does not permit "jurisdiction in gross." Rockwell, 127 S. Ct. at 1410. Instead, the court must examine Relators' ability to assert each claim. Id. ("The plaintiff's decision to join all of his or her claims in a single lawsuit should not rescue claims that would have been doomed by section (e)(4) if they had been asserted in a separate action. And likewise, this joinder should not result in the dismissal of claims that would have otherwise survived." (quoting United States ex rel. Merena v. SmithKline Beecham Corp., 205 F.3d 97, 102 (3d Cir. 2000) (Alito, J.))). Accordingly, I will analyze the two remaining claims individually.

## **A. Count I: Kickbacks**

Count I alleges a scheme to give kickbacks in the form of free samples, off-invoice discounts, rebates, consulting fees, educational grants, payments to participate in studies or trials and advisory board honoraria to providers and hospitals to induce them to prescribe Procrit. The parties disagree regarding whether the public disclosure bar prohibits this claim.

The FCA prohibits qui tam actions when the relator's allegations are "based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media . . . ." 31 U.S.C.

§ 3730(e)(4)(A). The jurisdictional inquiry under Section 3730(e)(4) proceeds in three steps. The court must determine: (1) whether the allegations or transactions have been publicly disclosed in a manner provided by the statute; (2) if so, whether the relator's suit is "based upon" those allegations or transactions; and (3) if the answer to both questions is yes, whether the relator falls within the "original source" exception to the jurisdictional bar. United States ex rel. O'Keefe v. Sverdup Corp., 131 F. Supp. 2d 87, 91 (D. Mass. 2001).

### **1. Public Disclosure**

The widely accepted framework for determining whether a public disclosure of the qui tam complaint's allegations or transactions has occurred is set forth in United States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 654-55 (D.C. Cir. 1994). As the court in Quinn explained, "if  $X + Y = Z$ , Z represents the allegation of

fraud and X and Y represent its essential elements.” Id. at 654. A public disclosure has occurred when either: (1) an allegation of fraud has been made (Z); or (2) both of the “essential elements” of the fraud – “a misrepresented state of facts and a true state of facts” (X and Y) – are in the public domain. Id. at 655.

OBP asserts that the essential elements supporting Count I were publicly disclosed in prior civil litigation and various government and media reports prior to Duxbury filing his initial complaint in November 2003.<sup>5</sup> Although the First Circuit has not addressed the issue, “every court of appeal to have addressed the question has held that any information disclosed through civil litigation and on file with the clerk’s office should be considered a public disclosure . . . for purposes of section 3730(e)(4)(A).” United States v. Northrop Corp., 59 F.3d 953, 966 (9th Cir. 1995) (quoting United States ex rel. Siller v. Becton Dickinson & Co., 21 F.3d 1339, 1350 (4th Cir. 1994) (collecting cases)); see also Walburn v. Lockheed Martin Corp., 431 F.3d 966, 974 (6th Cir. 2005); Quinn, 14 F.3d at 652.

The prior litigation in this instance is a multi-district litigation termed In re Pharmaceutical Industry Average Wholesale Price Litigation, MDL No. 1456, Civ. No. 01-12257-PBS (“AWP MDL”), currently pending in this District. The AWP MDL includes both private class action suits and suits on behalf of various States and other Medicare

---

<sup>5</sup> OBP does not suggest that the court consider public disclosures made during the period between the initial and amended complaints. See United States ex rel. Montgomery v. St. Edward Mercy Med. Ctr., No. 4:05-CV-00899, 2007 WL 2904111, at \*8 (E.D. Ark. Sept. 28, 2007). However, because the public disclosures made prior to the filing of Duxbury’s initial complaint are sufficient it is not necessary to consider subsequent disclosures.

and Medicaid payors against a large number of pharmaceutical manufacturers. Plaintiffs in the AWP MDL filed a Master Consolidated Class Action Complaint (“MCC”) in September 2002, more than a year before Duxbury filed his qui tam complaint in November 2003. (MCC (AWP MDL Docket # 148), Sept. 6, 2002.) The MCC alleged that OBP and its co-defendants engaged in widespread fraudulent conduct, including kickbacks, improper use of free samples, discounts, rebates and “other hidden and improper inducements and price reductions.” (See MCC ¶¶ 108-09, 131, 153, 162-172, 294-98.)

Relators argue that the MCC did not publicly disclose OBP’s alleged fraud because (1) “it only revealed the component of Ortho’s scheme that involved consumers, insurers and third party payers but not the manipulation of the Medicare reimbursement system,” and (2) “it did not contain elements of the scheme of having Ortho’s sales force intentionally cause the submission of false claims to the Government.” (Relators’ Mem. in Opp. to Def.’s Mot. to Dismiss (Docket # 65), 20.) These arguments are strained, to say the least. Allegations regarding reimbursement by Medicare Part B based upon published Average Wholesale Prices (“AWPs”) are a central component of the MCC, to the point that the MCC expends numerous paragraphs describing the Medicare insurance and reimbursement system and the impact of allegedly inflated AWPs on this system. (See, e.g., MCC ¶¶ 3-4, 133, 140-165.) Moreover, the “AWP Scheme” alleged in the MCC, in which pharmaceutical companies “marketed the spread” to providers to induce them to prescribe drugs based upon the “profit” generated by receiving reimbursements from Medicare which were

higher than their actual costs,<sup>6</sup> has at its very root the submission of false claims to the government. (See *id.* ¶¶ 139, 157-165; see also *id.* ¶ 171 (“Defendant Drug Manufacturers incentivize [*sic*] providers under Medicare Part B to use (and submit reimbursement claims for) the drugs with the highest-inflated AWP. . . .”). The MCC’s allegations of kickbacks and other fraudulent inducements made by OBP and its co-defendants to providers more than adequately “set government investigators on the trail of fraud.” *Quinn*, 14 F.3d at 655.<sup>7</sup>

---

<sup>6</sup> The AWP MDL court summarized the plaintiff’s allegations:

The pharmaceutical companies vastly overstate the AWP’s of many drugs . . . .

This overstatement in the reporting creates a “spread” . . . between the actual cost of a drug to a health care provider, and the reimbursement paid to the provider by the federal government. . . . Defendants actively market this “spread” to providers, who are encouraged to buy drugs from defendants at the highly “discounted” actual prices, and are urged to keep the reimbursement and co-payment spreads for themselves. . . .

For some defendants, the AWP scheme is not the only mechanism used to create the artificial “spreads.” Another method involves the provision of “free samples” to health providers who are sometimes encouraged to bill their customers for the samples as they would any other drug. This “free sample” scheme lowers the providers’ overall costs while not reducing the amount they receive in reimbursements from the federal government, or co-payments from consumers, which remain tied to the reported AWP’s. Other fraudulent pricing practices include off-invoice pricing, phony consulting fees, as well as debt forgiveness, rebates, and grants. All of these incentives were designed to lower the providers’ net cost of purchasing the drugs.

*In re Pharm. Indus. Avg. Wholesale Price Litig.*, 263 F. Supp. 2d 172, 178-79 (D. Mass. 2003). The court issued this opinion in May 2003, nearly six months prior to Duxbury’s initial complaint.

<sup>7</sup> The government argues that its prior reports do not constitute public disclosures because they did not contain either the allegation of fraud or both of the essential elements of fraud. (See United States’ Statement of Interest in Resp. to

## 2. Based Upon

Courts do not uniformly agree about the standard for judging whether an action is “based upon” a public disclosure, and the First Circuit has not yet spoken on the issue. Within the District of Massachusetts, four judges have considered the issue. Three have adopted the “minority rule,” which says that an action is “based upon” a public disclosure “only when the allegations supporting the action are ‘derived from’ the public disclosure.” E.g., United States ex rel. Rost v. Pfizer, Inc., 446 F.Supp.2d 6, 19 (D. Mass. 2006) (discussing cases and adopting minority view), vacated on other grounds, Rost, 507 F.3d at 734. One judge has adopted the “majority rule,” which states that an action is “based upon” a public disclosure “when the supporting allegations are similar to or the same as those that have been publicly disclosed . . . regardless of where the relator obtained his information.” O’Keeffe, 131 F. Supp. 2d at 92 (internal quotation marks, citation and emphasis omitted) (adopting majority view).

I adopt the majority view, which I believe better comports with both the policies underlying the provision and the Supreme Court’s recent Rockwell decision. In Rockwell the Court held that the “information” in §§ 3730(e)(4)(A) and (B) is the information underlying the allegations in the relator’s action, not the information underlying the publicly disclosed allegations.<sup>8</sup> 127 S. Ct. at 1407-08. The Court

---

Def.’s Mot. to Dismiss Compl. (Docket # 63), 4-6.) Because the MCC constitutes sufficient public disclosure of the alleged fraud, I do not consider whether the government reports also qualify.

<sup>8</sup> As discussed more fully infra, if a qui tam suit is based upon public disclosure, the court lacks jurisdiction unless the relator is an “original source of the information.” To be an “original source” the relator must, inter alia, have “direct and independent

reasoned:

It is difficult to understand why Congress would care whether a relator knows about the information underlying a publicly disclosed allegation (e.g., what a confidential source told a newspaper reporter about insolid pondcrete) when the relator has direct and independent knowledge of different information supporting the same allegation (e.g., that a defective process would inevitably lead to insolid pondcrete). Not only would that make little sense, it would raise nettlesome procedural problems, placing courts in the position of comparing the relator's information with the often unknowable information on which the public disclosure was based. Where that latter information has not been disclosed (by reason, for example, of a reporter's desire to protect his source), the relator would presumably be out of court. To bar a relator with direct and independent knowledge of information underlying his allegations just because no one can know what information underlies the similar allegations of some other person simply makes no sense.

Id. Under the minority view, the Court's exemplar relator – one with “direct and independent knowledge of different information supporting the same allegation” – would not fall into the public disclosure bar at all because his allegations would not be “derived from” the public disclosure. However, the Court's discussion presupposes that a relator's allegation which is similar to or the same as the publicly disclosed allegation is subject to the public disclosure bar and must show that he has direct and independent knowledge of the information underlying his allegations.

In the same vein, other courts have noted that the minority view's narrow reading of “based upon” renders the original source exception superfluous. The minority view, which would not find a qui tam action “based upon” the public disclosure so long as the relator possesses independent knowledge of the allegations, “swallows the original

---

knowledge of the information on which the allegations are based.” 31 U.S.C. §§ 3730(e)(4)(A), (B).

source exception whole.” Findley, 105 F.3d at 684; accord United States ex rel. Biddle v. Bd. of Trs. of Leland Stanford, Jr. Univ., 161 F.3d 533, 538 (9th Cir. 1998); United States ex rel. Mistick PBT v. Housing Auth. of the City of Pittsburgh, 186 F.3d at 386-87 (3d Cir. 1999).

Additionally, a broader interpretation of “based upon” is more consistent with the policies underlying the public disclosure bar. O’Keefe, 131 F. Supp. 2d at 93 (minority view “would contravene the congressional policy of prohibiting qui tam actions where the government has sufficient information to pursue the false claim itself” (citing Findley, 105 F.3d at 685)).

As the kickback allegations in the Amended Complaint are the same as those alleged in the MCC, the conclusion is inescapable that Relators’ claims are based upon the public disclosures.

### **3. Original Source Exception**

Given the public disclosures, Relators may only maintain this action if they qualify as “original sources” for the kickback allegations. 31 U.S.C. § 3730(e)(4)(A). An “original source” is defined as “an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.” Id. § 3730(e)(4)(B).

On this issue, too, the Supreme Court recently provided guidance in Rockwell. The Court first emphasized that the “original source” inquiry is an issue of subject matter jurisdiction. 127 S. Ct. at 1406. It then determined that “the ‘information’ to

which subparagraph [3730(e)(4)](B) speaks is the information upon which the relators' allegations are based," meaning that the inquiry should not focus on whether the relator was the source of the public disclosure, but rather whether he is an original source of the information underlying his own suit. Id. at 1407-08. Finally, the Court held that the term "allegations" in the phrase "information on which the allegations are based" is not limited to the allegations of the original complaint, but "includes (at a minimum) the allegations in the original complaint as amended." Id. at 1408 (emphasis in original).

#### **a. Duxbury**

OBP asserts that Duxbury cannot qualify as an original source because he did not provide the government with his information prior to the public disclosure. Duxbury denies that this is a requirement under the statute. Courts have split on this issue.<sup>9</sup> See Rost, 446 F. Supp. 2d at 22-23 (discussing cases). The plain language of the FCA only requires the relator to provide his information to the government prior to filing his action. See § 3730(e)(4)(B). This unambiguous statutory language must guide the court's interpretation. Lamie v. United States, 540 U.S. 526, 534 (2004); cf. Rost, 507 F.3d at 730 (rejecting an interpretation of the FCA that would "create a new exclusion not articulated in the text"). Accordingly, to be an original source, a relator must: "(1) have independent knowledge of the fraud alleged in his complaint; (2) have direct knowledge of that fraud; and (3) have disclosed this information to the government before filing suit," Rost, 446 F. Supp. 2d at 24, but need not have disclosed the

---

<sup>9</sup> The Supreme Court did not grapple with this issue in Rockwell, as the relator in that case provided the information to the government prior to the public disclosure. See Rockwell, 127 S. Ct. at 1402.

information to the government prior to the public disclosure.

“A relator’s knowledge is ‘direct’ if she acquired it through her own efforts without an intervening agency, and it is ‘independent’ if her knowledge is not dependent on the public disclosure.” O’Keefe, 131 F. Supp. 2d at 93 (citing Quinn, 14 F.3d at 656). In his position as a Product Specialist and later Regional Key Account Specialist for OBP’s Western Division Oncology sales force, Duxbury was responsible for the promotion and sale of Procrit in the western United States. The complaint alleges that, at defendant’s direction, he gave providers free samples of Procrit and instructed the providers to submit Medicare claims for the samples, see, e.g., Am. Compl. ¶¶ 91-93, 99-100, and directly provided discounts, rebates, educational grants, and other “off-invoice” discounts to providers to lower the actual acquisition cost of Procrit, see id. ¶¶ 106-109. His knowledge of the alleged fraud is both independent and direct. Duxbury also alleged in his initial complaint instigating the action that he had provided the information to the government prior to filing the suit. (See Compl. ¶ 9.)

Duxbury therefore qualifies as an original source. However, his direct knowledge of OBP’s activities only extends to the time he was employed by the company. He has no direct knowledge of OBP activities occurring after he was terminated in 1998. Therefore, he qualifies as an original source only with regard to allegations concerning the 1992-1998 time period. See Rockwell, 127 S. Ct. at 1409-10.

#### **b. McClellan**

McClellan does not qualify as an original source. By the express terms of the statute, he would only qualify if he “voluntarily provided the information to the

Government before filing an action” based on the information. § 3730(e)(4)(B). Here, McClellan does not assert any new claims of his own, but only “adds additional supporting facts to the legal claims previously made.” (Am. Compl. ¶ 28.) He therefore must show that he provided the information to the government prior to the claims being made, *i.e.*, prior to Duxbury filing suit in November 2003. Although McClellan claims to have “provided such information to the United States before filing suit,” Am. Compl. ¶ 16, Relators have proffered no support for this conclusory assertion, and given that Duxbury did not move to add McClellan as a relator until October 2006, the court cannot reasonably infer it. Murphy, 45 F.3d at 522 (party invoking jurisdiction “carries the burden of proving its existence” and “may not rest merely on unsupported conclusions”) (internal quotation marks and citations omitted).<sup>10</sup> See also United States ex rel. McBride v. Halliburton Co., Civ. A. No. 05-00828, 2007 WL 1954441, at \*3-\*4 (D. D.C. July 5, 2007); United States ex rel. Hockett v. Columbia/HCA Healthcare Corp., 498 F. Supp. 2d 25, 51 n.14 (D. D.C. 2007) (“Rockwell . . . strongly indicate[s] that each party who wishes to bring a qui tam suit must be able to invoke the court’s jurisdiction. To do otherwise would permit the kind of ‘claim smuggling’ – or in this case, party smuggling – that Rockwell forbids.”).<sup>11</sup>

Even if he qualified as an original source, McClellan would be barred by the

---

<sup>10</sup> As discussed *supra*, the conclusory assertion suffices for Duxbury because it was made in his initial complaint instigating the action. However, there is no indication that McClellan gave his information to the government prior to Duxbury filing suit.

<sup>11</sup> Relators filed an “Offer of Proof” with regard to providing information to the government relating to their third claim for “off-label” marketing. (Docket # 78.) As the Offer consists of a June 2004 letter to the government, it does not support the assertion that McClellan provided the government with the information prior to November 2003.

“first-to-file” bar. As discussed more fully infra, the first-to-file bar in § 3730(b)(5) prevents private plaintiffs “from bringing related actions based on the same underlying facts.” United States ex rel. Lujan v. Hughes Aircraft Co., 243 F.3d 1181, 1187 (9th Cir. 2001). The first-to-file bar is “exception-free,” id., and cannot be circumvented simply by amending the complaint to add McClellan as a relator when his claims would have been barred had they been brought on their own. United States ex rel. Fry v. Guidant Corp., Civ. A. No. 3:03-0842, 2006 WL 1102397, \*6 (M.D. Tenn. Apr. 25, 2006); see also Fed. Recovery Servs., Inc. v. United States, 72 F.3d 447, 453 (5th Cir. 1995); LaCorte, 185 F.3d at 191.

**B. Count III: Off-Label Marketing<sup>12</sup>**

OBP argues that both the first-to-file bar and the public disclosure bar preclude this court from exercising jurisdiction over Relators’ off-label marketing claim. Because the former does bar the claim, I do not consider the latter.

Section 3730(b)(5)’s “first-to-file” rule provides: “When a person brings an [FCA qui tam] action . . . no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.” 31 U.S.C. § 3730(b)(5). The first-to-file bar furthers the policy of the FCA in that “[t]he first-filed claim provides the government notice of their essential facts of an alleged fraud, while the first-to-file bar stops repetitive claims.” Lujan, 243 F.3d at 1187 (citing LaCorte, 149 F.3d at 232).

---

<sup>12</sup> “Off-label marking” refers to the promotion of a product for a use not approved by the Food and Drug Administration (“FDA”).

Duxbury filed his original complaint in November 2003 (“Duxbury Complaint”) (Docket # 1). In December 2003, a separate relator, Kurt Blair (“Blair”) filed a qui tam complaint in the District of Colorado which alleged a scheme by OBP to market off-label uses of Procrit. See United States ex rel. Blair v. Ortho Biotech, Inc., Civ. No. 03-02585 (D. Colo. Dec. 22, 2003) (“Blair Complaint”) (Docket # 59). The Blair Complaint was unsealed in November 2005, nearly a year before the First Amended Complaint was filed in this action in October 2006. OBP asserts that the Duxbury Complaint did not include the amended complaint’s allegations regarding off-label marketing, and those allegations are therefore barred under the first-to-file rule because of the Blair Complaint. Plaintiffs counter that the Duxbury Complaint contained sufficient allegations of off-label marketing by OBP, such that the Blair Complaint was not filed “first” and does not act as a bar to the claim.

### **1. Legal Standard**

Although the First Circuit has not yet spoken to this issue, the majority of courts interpret § 3730(b)(5) to bar a later allegation which “states all the essential facts of a previously-filed claim,” even if the later claim “incorporates somewhat different details.” LaCorte, 149 F.3d at 232; see also Lujan, 243 F.3d at 1189; Walburn, 431 F.3d at 971; United States ex rel. Hampton v. Columbia/HCA Healthcare Corp., 318 F.3d 214, 217-18 (D.C. Cir. 2003). The “common principle is that section 3730(b)(5) precludes a subsequent relator’s claim that alleges the defendant engaged in the same type of wrongdoing as that claimed in a prior action even if the allegations cover a different time period or location within a company.” Lujan, 243 F.3d at 1188 (internal quotation marks

and citation omitted); see also LaCorte, 149 F.3d at 232.

Here, the court must determine which of the complaints – the Duxbury Complaint or the Blair Complaint – was the “first” to assert claims for off-label marketing of Procrit. Stated differently, the court must determine whether the Duxbury Complaint sufficiently alleged an off-label marketing scheme such that the Blair Complaint would be barred by the first-to-file rule. Resolution of this issue requires the court to compare the allegations in the Duxbury and Blair Complaints. See LaCorte, 149 F.3d at 234 n.6 (determining whether later complaint alleges the “same material elements” as claims in the earlier complaint requires “simply [] comparing the original and later complaints”); Merena, 205 F.3d at 102 (same).<sup>13</sup>

## 2. Duxbury Complaint

Relators assert that three paragraphs in the Duxbury Complaint sufficiently alleged an off-label marketing scheme:<sup>14</sup>

40. Another method of inflating reimbursement for use of Procrit was through Phase IV Clinical Trials. Phase IV Trials are defined by the FDA as a method of evaluating a drug in a “real world” clinical setting. Ortho Biotech extensively used Phase IV Marketing Trials as a way to accomplish a number of marketing goals:
  - a) To provide cash payments to a physician, clinic or hospital which lowers the effective net acquisition cost of the drug. This allows the manufacturer to provide a lower “best price” to

---

<sup>13</sup> Because neither party raised the issue, I do not address whether the status of the Blair action – i.e., whether the action was “pending” at the time Relators filed their amended complaint – is material to the first-to-file bar in this instance.

<sup>14</sup> These allegations are found under subsection IV.A, “Ortho Commits AWP Fraud to Increase Market Share For Drugs Covered by Medicare Part B,” specifically in subsection IV.A.2.d(2), “Phony Drug Studies.” (Duxbury Compl. ¶¶ 40-42.)

physicians than what it reports to the Federal Government, resulting in inflated Medicaid payments for the drug.

- b) To provide cash payments to a physician, clinic or hospital to influence the physician to use more of the drug in practice.
- c) To provide cash payments in order to encourage the physician, clinic or hospital to use the drug in a way which is inconsistent with its FDA approved indications and administration methods. In 1997, Ortho Biotech launched a massive Phase IV Marketing Trial which paid physicians to dose Procrit at 40,000iu in a once per week dose instead of the FDA approved dosage of 10,000iu three times per week dosage in cancer-chemotherapy patients. The trial was very successful and the once per week dosage is now universally accepted among oncologists. The trial's success also resulted in Medicare Part B paying for 40,000iu/week of Procrit in cancer chemotherapy patients instead of 30,000iu/week - an increase of 33% in payments for each Medicare Beneficiary receiving Procrit for treatment of their chemotherapy related anemia.

41. The approved dosage by the FDA is 10,000iu three times a week. By dosing at 40,000 units once a week, Ortho increases the provider's take, but in doing so, intentionally has established a practice whereby Medicare pays more than the approved FDA dosage. The 40,000iu dosage scheme was successful for Ortho and doctors, but Ortho has not received FDA approval for such dosage. Thousands of patients have been treated with this dosage. In 1997, Medicare was spending close to \$1 billion for EPO.

42. Ortho Biotech's Phase IV Trials also provided thousands of dollars worth of free commercially packaged Procrit to the participating physicians, clinics or hospitals which were billed to Medicare. Again, a simple audit of the account's purchases of Procrit around the time of the trial period and comparison to the amount of Procrit billed to Medicare will identify fraudulent billing practices.

(Duxbury Compl. ¶¶ 40-42) (emphases omitted).

### **3. The Blair Complaint**

The Blair Complaint alleged that OBP:

engaged in a widespread scheme to market and promote to physicians and pharmacists the use of Procrit at dosing levels exceeding what is approved

by the FDA. Relator alleges that the activities of Ortho Biotech in marketing Procrit for these non-approved uses were intended to, and did in fact, cause the submission of hundreds of thousands of false claims for reimbursement to the Medicare and Medicaid programs. . . .

(Blair Compl. ¶ 8.) The complaint states that the predominant dosing regimen for Procrit was initially 10,000 units administered three times weekly, for a total of 30,000 units per week. OBP received approval to manufacture a 40,000 unit vial in 1998 or 1999 in order to accommodate an FDA-approved dosing regimen for an elective surgery indication. The 40,000 unit vials are dosed once per week. In 2000, OBP unsuccessfully sought FDA approval for a 40,000 unit once per week dosing regimen for the drug's oncology indication. (Id. ¶¶ 18-20.) According to Blair, OBP nonetheless embarked on a scheme to market the 40,000 unit vial to physicians for use with oncology patients, because it desired (1) to increase the revenue stream that would result from selling an extra 10,000 units per week; (2) to increase the use of the drug by physicians due to its convenient once per week, instead of thrice per week, dosage; and (3) to compete with another drug expected to obtain FDA approval in the near future which would only require once per week dosage. (Id. ¶¶ 22-26.)

Blair alleged that OBP carried out its scheme through a variety of marketing and incentive programs, including: (1) direct off-label marketing to medical professionals; (2) influencing the results of purportedly independent clinical studies; (3) illegal payments to medical professionals in the form of "educational grants" and "clerkships;" (4) payments to medical professionals for giving presentations on increased dosage of Procrit; or (5) attending consulting conferences sponsored by OBP which pushed

increased dosage of Procrit; and (6) rebate programs offered to induce increased prescriptions of Procrit. (Id. ¶ 27.) The complaint describes each of these alleged methods in further detail in over fifty paragraphs. (See id. ¶¶ 28-79.) Blair alleges that the scheme began in 1998. (Id. ¶ 90.)

The complaint refers to a Phase IV trial known as the “Gabrilove study.” (Id. ¶¶ 38-43.) It is unclear whether this is the same Phase IV trial referenced in the Duxbury Complaint. The Gabrilove study concluded that, for the oncology indication, once weekly dosing at 40,000 units was as effective as three times weekly dosing at 10,000 units per dose. Blair alleged that the study was improperly influenced by OBP’s selection of participating physicians and patients. Blair further alleged that OBP used the study to financially reward physicians for proscribing Procrit at higher doses.

Blair’s FCA claim was based upon health providers’ improper claims for Medicare and Medicaid reimbursement of the 40,000 unit prescription, which was not eligible for reimbursement. “But for Ortho’s promotion of off-label uses, most of the ineligible claims for payment of Procrit prescriptions would never have been filed. Every off-label Procrit prescription caused by Ortho Biotech’s off-label promotion of Procrit is a false claim caused by Ortho Biotech for the purposes of the [FCA].” (Blair Complaint ¶ 83; see also id. ¶ 88.)

#### **4. Discussion**

A superficial comparison of the allegations in the two complaints suggests they are similar. Both allege that oncology providers are improperly dosing Procrit at 40,000iu once per week instead of the FDA-approved dosage of 10,000iu three times a

week, resulting in higher reimbursement payments by Medicare and Medicaid.

However, similar allegations about the behavior of providers are unimportant; it is OBP's behavior which is relevant in this instance. Providers may lawfully prescribe a drug for an off-label use; the sine qua non of manufacturer liability is the promotion of the unapproved use.<sup>15</sup> Viewed through this lens, the differences between the Duxbury and Blair Complaints become apparent.

Although the Duxbury Complaint alleged that OBP paid physicians to participate in clinical trials and used Phase IV trials “[t]o provide cash payments in order to encourage the physician, clinic or hospital to use the drug in a way which is inconsistent with its FDA approved indications and administration methods,” (Duxbury Compl. ¶ 40(c)), this allegation does not provide the essential facts regarding a widespread scheme to promote off-label uses of Procrit. To the contrary, the complaint alleges that one trial in 1997, and not any other OBP activities or initiatives, led physicians to switch to the higher dosage of Procrit. This bare bones allegation cannot act as a placeholder for the widespread off-label marketing scheme that Relators now wish to allege.<sup>16</sup> See

---

<sup>15</sup> See Allegations of Waste, Fraud and Abuse in Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and the Federal Taxpayer: Hearing Before the House Oversight and Government Reform Committee, 110th Cong. 6-7 (Feb. 9, 2007) (statement of Lewis Morris, Chief Counsel, Office of Inspector General, Department of Health and Human Services) (“While physicians may lawfully prescribe a drug for an off-label use, manufacturers are prohibited from promoting a drug for uses other than FDA-approved uses.”).

<sup>16</sup> The Amended Complaint alleges an “inflated dosing scheme” which consisted of (1) promoting off-label dosing of Procrit; (2) promoting the higher-dose of Procrit for an oncology indication even though it was only approved for a surgery indication; (3) paying kickbacks to induce use of Procrit; (4) using “sham drug trials” to falsify eligibility for Medicare reimbursement of a higher dose of Procrit; and (5) changing the vial size in which free Procrit was distributed. (Am. Compl. ¶ 132.)

Lujan, 243 F.3d at 1187.<sup>17</sup> The first-to-file rule accordingly would not operate to bar the Blair Complaint's allegations of an off-label marketing scheme. However, as the "first" complaint to allege claims based upon OBP's alleged off-label marketing of Procrit, the Blair Complaint bars Relators' off-label marketing claims. See Grynberg v. Kock Gateway Pipeline Co., 390 F.3d 1276, 1279 (10th Cir. 2004). Count III is therefore dismissed.

#### **IV. Rule 9(b)**

Defendant next challenges Relators' claims as deficient under Rule 9(b), which requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). Rule 9(b) applies to FCA claims and "requires relators to 'provide details that identify particular false claims for payment that were submitted to the government.'" Rost, 507 F.3d at 731 (quoting United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 232 (1st Cir. 2004)). Because the court only has jurisdiction over Duxbury's allegations of kickbacks occurring from 1992 to 1998 (see supra Section III.A.3.a), I will only evaluate those claims for sufficiency under Rule 9(b).

FCA liability attaches only to false claims, not to any underlying fraudulent activity or to the government's wrongful payment. "Evidence of an actual false claim is

---

<sup>17</sup> Indeed, correspondence between the plaintiff and the government suggests that the Duxbury Complaint failed to put the government on notice of OBP's alleged off-label marketing scheme. (See June 18, 2004 Letter (Docket # 78), 6 ("We believe the following paragraph describes a more important and damaging fraud identified in Mr. Duxbury's complaint, which we described (see Complaint ¶¶ 40-42) but are not sure you have grasped based on your letter and the interview of Mr. Duxbury."))

the sine qua non of a False Claims Act violation.” Karvelas, 360 F.3d at 225 (internal quotation marks and citation omitted). The Amended Complaint alleges particularized details about OBP’s underlying scheme to induce doctors to prescribe Procrit by granting them a variety of kickbacks, including rebates and other off-invoice discounts, educational grants, and the like. (See, e.g., Am. Compl. ¶ 211 (identifying particular amounts of money or percentages of discounts given to particular providers).) However, it is not enough to allege details of the scheme if there are not also particularized allegations regarding the false claims that were actually submitted to the federal government. As the First Circuit stated in Karvelas, a case in which a relator alleged that a health care provider submitted false Medicare and Medicaid claims to the federal government,

Underlying schemes and other wrongful activities that result in the submission of fraudulent claims are included in the ‘circumstances constituting fraud or mistake’ that must be pled with particularity pursuant to Rule 9(b). However, such pleadings invariably are inadequate unless they are linked to allegations, stated with particularity, of the actual false claims submitted to the government that constitute the essential element of an FCA qui tam action. As applied to the FCA, Rule 9(b)’s requirement that averments of fraud be stated with particularity . . . means that a relator must provide details that identify particular false claims for payment that were submitted to the government. In a case such as this, details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a relator to state his or her claims with particularity. These details do not constitute a checklist of mandatory requirements that must be satisfied by each allegation included in the complaint. However, . . . we believe that some of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b).

Id. at 232-33 (footnotes and internal quotation marks and citation omitted).

Karvelas suggests that Rule 9(b) may be satisfied if the complaint as a whole is sufficiently particular to pass muster under the FCA, although some questions remain unanswered. Karvelas, 360 F.3d at 233 n.17. Nonetheless, even giving Duxbury the “benefit of such flexibility,” Rost, 507 F.3d at 732, the allegations are inadequate because they are indistinguishable from those found insufficient in Karvelas. In Karvelas, the relator, a former employee of the defendant health care provider, filed a 93-page complaint which alleged sixteen complex schemes of fraud “at considerable length.” Karvelas, 360 F.3d at 232-33. However, the complaint “never specific[ed] the dates or content of any particular false or fraudulent claim allegedly submitted for reimbursement by Medicare or Medicaid,” and “did not set forth the specifics . . . of any one single cost report, or bill, or piece of paper that was sent to the Government to obtain funding.” Id. at 233. Although the relator alleged serious violations of federal regulations, his allegations were insufficient to support a claim under the FCA because he “fail[ed] to identify with particularity any actual false claims that the defendants submitted to the government.” Id. at 235.

The same is true here. Although Duxbury identifies providers and approximate amounts of free samples, discounts, “off-invoice” rebates, or educational grants, he fails to identify a single false claim consequently filed by these providers. (See, e.g., Am. Compl. ¶ 211.) In the closest case, Duxbury alleges that St. Joseph’s Hospital in Tacoma, Washington, was given “off-invoice” rebates of 14% for the purchase of Procrit, and submitted “approximately 4,800 claims a month for Medicare reimbursement.” (Id. ¶ 211(a).) However, this allegation fails to provide even one

(much less “some”) of the specifics required by Karvelas for “at least some of the claims,” viz., the “dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices . . . .” 360 F.3d at 232-33.

Duxbury argues that he cannot identify all the false claims submitted to the government because the claims “were submitted by Providers with most of whom Relator has had no dealings, and the records of the false claims are not within Relator’s control.” (Am. Compl. ¶ 232.) Yet, this is precisely the point of requiring relators to identify particular claims, for under Karvelas and Rost the court is not permitted to surmise that false claims “must have” occurred as a result of defendant’s conduct. “No matter how likely the existence of false claims, this court cannot speculate that such claims inevitably flowed from Defendants’ activities.” Rost, 446 F. Supp. 2d at 28 (citing Karvelas, 360 F.3d at 235).

Similarly, although Duxbury alleges that providers submitted HCFA Forms 1500 and 2552 and other certifications of compliance with the anti-kickback statute in order to get false claims paid (see Am. Compl. ¶¶ 230, 234-37), the mere identification of the template forms which providers used to submit reimbursement in the abstract is insufficient when not tied to a particular claim filed by a particular provider. Karvelas, 360 F.3d at 231 n.13 (Rule 9(b) standard applies to documents that are “regularly-filed,” i.e., relator is not absolved of the requirement to plead particulars simply because the

document is one routinely filed with the government).<sup>18</sup>

## V. Conclusion

Although the court has subject matter jurisdiction to hear Duxbury's claims of alleged kickbacks which occurred during his employment at OBP, his allegations lack the particularity required under Rule 9(b) and this Circuit's precedent. This complaint was initially filed in 2003 and unsealed in 2005, and it is now 2008. Relators have already amended their complaint once as of right, and the court is not inclined to allow further amendments. Accordingly, defendant's motion to dismiss the amended complaint with prejudice (Docket # 56) is ALLOWED.<sup>19</sup>

---

<sup>18</sup> Duxbury alleges that the kickbacks violated 31 U.S.C. §§ 3729(a)(1) and (2). Section 3729(a)(1) imposes liability upon a person who "knowingly presents, or causes to be presented . . . a false or fraudulent claim for payment or approval" to the United States Government. Section 3729(a)(2) imposes liability upon a person who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." Neither party suggests that the particularity requirements should be analyzed separately for the two subsections, and the court does not deem it necessary, as its analysis applies equally to both subsections. See Rost, 507 F.3d at 733 (rejecting assertion that subsections must be analyzed separately). Duxbury also includes a puzzling reference to stating a claim under § 3732(b), which provides federal court jurisdiction for state law claims based upon FCA violations. (See Am. Compl. Count I, at 58.) As the complaint does not allege violations of any specific state law (in Duxbury's sales region in the western United States or otherwise), § 3732(b) is inapplicable.

<sup>19</sup> As the government has not intervened, the court does not dismiss this action with prejudice as to the United States. See United States ex rel. Williams v. Bell Helicopter Textron Inc., 417 F.3d 450, 455 (5th Cir. 2005) (improper to dismiss FCA claims with prejudice as to United States when government did not intervene in qui tam action which was deficient under Rule 9(b)).

Judgment may be entered for defendant.

January 28, 2008

DATE

/s/Rya W. Zobel

RYA W. ZOBEL

UNITED STATES DISTRICT JUDGE