

United States Court of Appeals For the First Circuit

No. 08-1409

UNITED STATES, ex rel. Mark Eugene Duxbury and Dean McClellan,

Plaintiffs,

MARK EUGENE DUXBURY; DEAN MCCLELLAN,

Plaintiffs, Appellants,

v.

ORTHO BIOTECH PRODUCTS, L.P.,

Defendant, Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Rya W. Zobel, U.S. District Judge]

Before

Torruella, Circuit Judge,
Siler,* Senior Circuit Judge,
and Howard, Circuit Judge.

Jan R. Schlichtmann, with whom Paul Simmerly, Heman Recor Araki Kaufman Simmerly & Jackson, PLLC, Robert Foote, Mark Bulgarelli, Foote Meyers Mielke & Flowers, LLC, Kathleen Chavez, and Chavez Law Firm, PC, was on brief for appellants.

Ethan M. Posner, with whom Patrick S. Davies, Jennifer L. Saulino, Andrew W. Lamb, Covington & Burling LLP, Susan L. Burke, and Burke O'Neil LLC, was on brief for appellee.

Jamie Ann Yavelberg, with whom Charles W. Scarborough, Douglas N. Letter, Attorneys, Appellate Staff, Civil Division, Gregory G.

* Of the Sixth Circuit, sitting by designation.

Katsas, Assistant Attorney General, and Michael J. Sullivan, United States Attorney, was on brief as amicus curiae for the United States.

Cleveland Lawrence III, on brief as amicus curiae of Taxpayers Against Fraud Education Fund in support of appellants.

August 12, 2009

TORRUELLA, Circuit Judge. This appeal concerns the qui tam provisions of the False Claims Act (the "FCA"), 31 U.S.C. § 3730, which allow whistleblowers (called "relators") to bring certain fraud claims on behalf of the United States.¹ The relators in this case, the plaintiffs-appellants Mark Duxbury and Dean McClellan (together, the "Relators"), alleged that defendant-appellee Ortho Biotech Products, L.P. ("OBP") violated the FCA in unlawfully promoting the sale of its drug Procrit. The district court dismissed all of the Relators' claims, and this appeal followed. After careful consideration, we affirm in part and reverse in part.

I. Background

A. The FCA

To provide context, we start with the statutory scheme. The FCA contains qui tam provisions that "supplement federal law enforcement resources by encouraging private citizens to uncover fraud on the government." Rost, 507 F.3d at 727. The qui tam

¹ As we have previously noted:

"Qui tam" comes from the phrase "qui tam pro domino rege quam pro se ipso in hac parte sequitur," which translates as "who pursues this action on our Lord the King's behalf as well as his own."

United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 727 n.4 (1st Cir. 2007) (quoting Rockwell Int'l Corp. v. United States, 549 U.S. 457, 463 n.2 (2007)), overruled on other grounds by Allison Engine v. United States ex rel. Sanders, 128 S. Ct. 2123 (2008).

provisions permit whistleblowers (known as relators) to bring certain fraud claims on behalf of the United States; in return, "[a] private relator is entitled to a portion of any proceeds from the suit, whether the United States intervenes as an active participant in the action or not." Id. at 727.

"The qui tam mechanism has historically been susceptible to abuse, however, by 'parasitic' relators who bring FCA damages claims based on information within the public domain or that the relator did not otherwise uncover." Id. Accordingly, Congress has amended the FCA several times "to walk a fine line between encouraging whistle-blowing and discouraging opportunistic behavior." See United States ex rel. S. Praver v. Fleet Bank of Me., 24 F.3d 320, 324-26 (1st Cir. 1994) (quoting United States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 651 (D.C. Cir. 1994) (detailing the history of such amendments to the FCA's qui tam provisions)).

As a result of these amendments, the FCA includes jurisdictional bars that limit a district court's subject matter jurisdiction over qui tam actions. Two of these bars are relevant to this action. The first, known as the "public disclosure" bar, provides that a court does not have subject matter jurisdiction over any qui tam action that is "based upon the public disclosure of allegations or transactions" concerning the alleged fraud, unless, among other things, "the person bringing the action is an

original source of the information." 31 U.S.C. § 3730(e)(4)(A). A relator qualifies as an "original source" if (1) she has "direct and independent knowledge" of the information supporting her claims and (2) she "provided the information to the Government before filing an action." Id. § 3730(e)(4)(B). The second, known as the "first-to-file" bar, provides that when a potential relator 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." Id. § 3730(b)(5).

B. The Complaints

OBP distributes and promotes Procrit -- the brand name for epoetin alfa -- a drug approved by the FDA for use to treat anemia resulting from chemotherapy, chronic kidney disease, HIV infection, and blood loss from certain types of surgery. Both Relators were sales representatives for OBP who were responsible for the promotion and sale of Procrit in the Western United States. From 1992 to 1998, OBP employed Relator Duxbury, first as a Product Specialist and later as a Regional Key Account Specialist for OBP's Western Division Oncology sales force. From 1992 to 2004, OBP employed Relator McClellan, also first as a Product Specialist but later as a Territory Manager for OBP's Western Division Oncology sales force.

This appeal turns on a number of complaints filed by the Relators and other parties, which we discuss in some detail below.

On November 6, 2003, Duxbury, but not McClellan, filed a complaint (the "Original Complaint") in the District Court for the District of Massachusetts. The Original Complaint contained allegations concerning OBP's fraudulent reporting of the Average Wholesale Price ("AWP") of Procrit, a benchmark used by the Medicare program for reimbursement purposes. It was filed hot on the heels of a master consolidated complaint (the "MCC") filed in September 2002 in a multi-district litigation concerning the fraudulent reporting of AWP. See generally In re Pharm. Indus. Average Wholesale Price Litig., MDL No. 1456, No. 01-12257-PBS (the "AWP MDL").²

The Original Complaint contained two counts, one alleging "substantive violations" of the FCA and the other a conspiracy count. (Compl. ¶¶ 47-55 (Count I); id. ¶¶ 56-60 (Count II)). In support of the counts, the Original Complaint alleged that OBP published a fraudulently inflated AWP for Procrit, which resulted in the filing of false claims for reimbursement with the Medicare program. (Id. ¶¶ 1, 29). The Original Complaint further alleged that OBP marketed the "spread" -- the difference between the higher, fraudulent AWP and the lower, actual cost of Procrit -- to induce medical providers to purchase Procrit. (Id. ¶¶ 23, 29).

² For background concerning the AWP MDL, which is quite complex, see In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. 61 (D. Mass. 2005); In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20 (D. Mass. 2007).

Thus, according to the Original Complaint, the "spread" not only caused the filing of false claims, but constituted an "illegal kickback" to health care providers. (Id. ¶¶ 23, 30).

The Original Complaint also alleged that OBP provided "free samples" of Procrit as well as "non-public financial inducements," such as rebates, discounts, "unrestricted education grants," and "phony drug studies." (Id. ¶¶ 31, 34, 38, 40, 43). OBP allegedly used these inducements "to lower the providers' net cost of purchasing Procrit," and further "inflate[] the AWP," as "the value of these services was kept off the book, so as not [to] be reflected in the AWP." (Id. ¶ 34; see also id. ¶¶ 32-33). The Original Complaint alleged that these inducements also constituted illegal kickbacks. (See id. ¶¶ 3, 45).

With respect to the "phony drug studies," the Original Complaint alleged at Paragraphs 40 through 42 that OBP utilized "Phase IV Marketing Trials" to, among other things, "encourage the physician, clinic, or hospital to use the drug in a way which [wa]s inconsistent with its FDA approved indications and administration methods." (Id. ¶ 40(c)). The Original Complaint referred specifically to a 1997 trial in which OBP allegedly

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 in 33% in payments for each Medicare Beneficiary receiving Procrit for treatment of their chemotherapy related anemia.

(Id.) (emphasis in original). The Original Complaint further alleged that "[t]he 40,000iu dosage scheme was successful for Ortho and doctors, but Ortho ha[d] not received FDA approval for such dosage." (Id. ¶ 41) (emphasis in original).

On December 19, 2003, about one month after the filing of the Original Complaint, Kurt Blair, also a former OBP sales representative, filed a qui tam complaint (the "Blair Complaint") against OBP in the District Court for the District of Colorado. The Blair Complaint contained two counts. Count I alleged that, beginning in 1998, OBP promoted "a dosing regimen of 40,000 units once per week" even though it had not received approval from the FDA for such a high dosage. (Blair Compl. ¶¶ 22-27). Blair claimed that OBP promoted this unapproved, "off-label" dosage through a variety of means, such as direct off-label marketing to medical professionals; influencing the results of purportedly independent clinical studies; and rebate programs offered to induce increased prescriptions of Procrit, among other things. (Id. ¶¶ 27, 28-79). Blair alleged that OBP's promotion of this off-label use caused the filing of "false" claims for reimbursement with Medicare and Medicaid, insofar as the providers sought reimbursement for "nonreimbursable" uses. (Id. ¶¶ 88-91). Count

II alleged that OBP caused the submission of false claims by, among other things, "paying thousands of kickbacks to Medicaid and Medicare providers, causing the providers to write tens of thousands of prescriptions for Procrit that would otherwise not have been written." (Id. ¶ 93).

As required under the FCA, both the Original Complaint and the Blair Complaint were filed under seal to allow the United States time to review both complaints and decide whether to intervene. 31 U.S.C. § 3730(b)(2).³ On March 23, 2004, the Blair district court allowed the government's motion to partially lift the seal on the Blair Complaint in order to disclose it to Duxbury.

On July 18, 2004, Duxbury, through his counsel, provided a written disclosure of information (the "Information") to the Department of Justice (the "DOJ"). The Information was sent in response to a April 6, 2004 letter by the DOJ summarizing the

³ 31 U.S.C. § 3730(b)(2) provides in full:

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

(footnote omitted).

allegations in the Original Complaint and requesting further information. The Information stated that "[w]e 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 "following paragraph" stated in part:

In 1997, [OBP] initiated an intentional scheme to promote an illegal, off-label dosage of Procrit for cancer patients that would increase sales and federal reimbursements by approximately a third. [OBP]'s scheme worked, and starting in around 1999 Medicare began reimbursing for Procrit at a one-third higher dosage than it had previously, without FDA approval for this dosage and contrary to the Medicare Act's rules for reimbursement of cancer drugs. The injury to the Medicare program alone is in the hundreds of millions.

The Information then went on to discuss this "scheme" in more detail.⁴

On July 12, 2005, after an investigation, the DOJ declined to intervene in the Original Complaint. On December 5, 2005, the Blair Complaint was voluntarily dismissed and subsequently unsealed in full.

On October 26, 2006, over OBP's objection, the district court allowed Duxbury's motion to amend the Original Complaint, and the next day, on October 27, 2006, both Relators filed a First

⁴ Duxbury asserts that the Blair Complaint had not been disclosed to him prior to the submission of the Information.

Amended Complaint (the "Amended Complaint"). The Amended Complaint added Relator McClellan as a party and alleged three counts, two of which are at issue on this appeal.⁵ (Am. Compl. ¶¶ 3, 227, 249, 270).

Count I alleges that, beginning in December 1992 to the present, OBP engaged in a scheme to provide kickbacks to health care providers "to induce them to prescribe ProCrit." (Id. ¶¶ 228-232). The kickbacks allegedly included "free ProCrit, off-invoice discounts and cash in the form of rebates, consulting fees, educational grants, payments to participate in studies or trials, and advisory board honoraria." (Id. ¶ 228). The Amended Complaint alleges that the kickbacks, among other things, "caused providers and hospitals to submit false claims for payment to Medicare for ProCrit." (Id. ¶¶ 229, 243-244).

Count III alleges that, beginning in 1997, OBP unlawfully promoted "[t]he administration of ProCrit at 40,000 units 1X per week to oncology patients," which "was not approved by the FDA." (Id. ¶¶ 131, 271, 273). Thus, the Amended Complaint alleges that OBP's "inflated dosing scheme was a substantial factor causing the submission of false claims for payment for ProCrit," insofar as OBP "caused providers and hospitals to administer ProCrit to

⁵ Count II of the Amended Complaint alleges that OBP engaged in a scheme to publish a fraudulently inflated AWP for Procrit. On June 27, 2007, the parties jointly stipulated to the dismissal of this count.

chemotherapy patients at 40,000 units 1X/week[], and in the absence of [OBP's] scheme they would have administered ProCrit at 10,000 IU 3X/week." (Id. ¶ 282).

C. The Dismissal of the Amended Complaint

On January 17, 2007, OBP moved to dismiss the Amended Complaint for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1) and, in the alternative, for failure to plead fraud with particularity under Federal Rule of Civil Procedure 9(b). On January 28, 2008, the district court allowed OBP's motion to dismiss with prejudice and entered judgment in OBP's favor. See United States ex rel. Duxbury v. Ortho Biotech Prods., L.P., 551 F. Supp. 2d 100 (D. Mass. 2008).

As to Count I, the district court first held that the kickback claims were "based upon" a "public disclosure," in this case the "allegations" contained in the MCC filed in the AWP MDL, which also alleged the use of illegal kickbacks. See id. at 105-08. The district court further held that Duxbury "qualifies as an original source" for the kickback claims, but only for those claims that occurred during his period of employment, 1992 through 1998, since "his direct knowledge of OBP's activities only extends to the time he was employed by the company." Id. at 109. Having established its subject matter jurisdiction, the court nevertheless dismissed the 1992 through 1998 kickback claims because the Amended

Complaint failed to plead the claims with sufficient particularity under Rule 9(b). Id. at 115-16.

As to the kickback claims from 1998 to the present, the district court held that McClellan did not qualify as an "original source," as the Amended Complaint did not sufficiently allege that McClellan offered information concerning the kickback claims to the government prior to the filing of the Original Complaint. Id. at 109-10. Relatedly, and in the alternative, the district court found that, even if McClellan qualified as an original source, his claims were barred by the "first-to-file" bar because he asserted his kickback claims after the filing of the Original Complaint. Id. at 110.

As to Count III, the court dismissed the claims concerning "off-label" promoting because they were barred by the "first-to-file" rule. Id. at 110-14. The district court first held that, even though Paragraphs 40 through 42 of the Original Complaint mentioned unlawful off-label promotion, the Original Complaint did "not provide the essential facts regarding a widespread scheme to promote off-label uses of Procrit." Id. at 114. Thus, the district court considered the Blair Complaint the "'first' complaint to allege claims based upon OBP's alleged off-label marketing of Procrit," and accordingly dismissed the off-label promoting claims in Count III of the Amended Complaint. Id.

As no claims survived, the district court dismissed the Amended Complaint with prejudice as to the Relators. Relators now appeal.

II. Discussion

The district court dismissed a portion of Count I and all of Count III for lack of subject matter jurisdiction. Thus, "[w]e review the district court's determination that it lacked subject matter jurisdiction de novo." Muskat v. United States, 554 F.3d 183, 194 (1st Cir. 2009). Subject matter jurisdiction in this case is based on the allegations contained in the Amended Complaint. See Rockwell, 549 U.S. at 473. Accordingly, "we take as true all well-pleaded facts in the [Amended Complaint], scrutinize them in the light most hospitable to the plaintiffs' theory of liability, and draw all reasonable inferences therefrom in the plaintiffs' favor." Fothergill v. United States, 566 F.3d 248, 251 (1st Cir. 2009); see also id. at 251 n.1 (noting that "[t]his standard applies to motions to dismiss for want of subject-matter jurisdiction that are adjudicated on the pleadings, in advance of jurisdictional discovery and without the taking of any evidence."). "[W]e may affirm an order of dismissal on any ground made apparent by the record (whether or not relied upon by the lower court)." Aguilar v. U.S. Immig. & Customs Enf., 510 F.3d 1, 8 (1st Cir. 2007).

The district court dismissed the remaining portion of Count I under Federal Rule of Civil Procedure 9(b) for failure to plead fraud with sufficient particularity. We similarly "review de novo the district court's dismissal order for failure to comply with Rule 9(b)." United States ex rel. Gagne v. City of Worcester, 565 F.3d 40, 45 (1st Cir. 2009).

A. Count I

The Relators contend that the district court erred in dismissing the kickback claims contained in Count I, which the court dismissed, in part, based on the "public disclosure" bar, and, in part, based on Rule 9(b).

"The threshold question in a False Claims Act case is whether the statute bars jurisdiction." Rost, 507 F.3d at 727. The district court's dismissal of the kickback claims turns on the "public disclosure" bar, set forth at 31 U.S.C. § 3130(e)(4). It provides:

(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 [General] 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 Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4)(A) & (B) (emphasis added).

As we discussed in Rost, analysis of the "public disclosure" bar "requires several inquiries":

(1) whether there has been public disclosure of the allegations or transactions in the relator's complaint;

(2) if so, whether the public disclosure occurred in the manner specified in the statute;

(3) if so, whether the relator's suit is "based upon" those publicly disclosed allegations or transactions; and

(4) if the answers to these questions are in the affirmative, whether the relator falls within the "original source" exception as defined in § 3730(e)(4)(B).

507 F.3d at 728. On appeal, the Relators do not challenge the district court's holding that the kickback claims contained in Count I are "based upon the public disclosure of allegations . . . in a . . . civil . . . hearing," in this case the allegations of illegal kickbacks contained in the MCC filed in the AWP MDL. Thus, we turn our attention to the fourth question, whether the Relators fall within the "original source" exception as defined in § 3730(e)(4)(B).

1. The "Provided" Language in the Original Source Exception

On appeal, OBP and the United States, appearing as an amicus, propose an alternative ground to affirm the dismissal of Count I. Under the FCA, an "original source" is defined as:

an individual who has [1] direct and independent knowledge of the information on which the allegations are based and [2] has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4)(B) (emphasis added). In determining whether the Relators qualified as original sources, the district court held that "[t]he plain language of the FCA only requires the relator to provide his information to the government prior to filing his action," and that "[t]his unambiguous statutory language must guide the court's interpretation." Duxbury, 551 F. Supp. 2d at 109.

Both OBP and the United States argue that this was error, and contend that 31 U.S.C. § 3730(e)(4)(B) requires a relator to provide the information to the government before the public disclosure itself, not just before the filing of the relator's suit. As there is no allegation in the Amended Complaint that either McClellan or Duxbury provided any information concerning their kickback claims to the government prior to the public disclosure of the kickback allegations in the AWP MDL, both OBP and the government contend that we can affirm the dismissal of the kickback claims on this alternative ground. As explained in more

detail below, and after a careful analysis of the FCA, we disagree, and conclude that the district court's interpretation is the correct one.

We have not addressed the meaning of "provided the information to the Government before filing an action" under § 3730(e)(4)(B), but the issue has divided the courts. The Fourth Circuit, consistent with the district court, has held that § 3730(e)(4)(B) "requires only that the relator . . . voluntarily provide the information to the government before filing his qui tam action." United States ex rel. Siller v. Becton Dickinson & Co., 21 F.3d 1339, 1351 (4th Cir. 1994) (emphasis in original). The Second and Ninth Circuits have outlined a second approach, holding that the relator "must have directly or indirectly been a source to the entity that publicly disclosed the allegations on which a suit is based." United States ex rel. Dick v. Long Island Lighting Co., 912 F.2d 13, 16 (2d Cir. 1990); see also United States ex rel. Wang v. FMC Corp., 975 F.2d 1412, 1419 (9th Cir. 1992). The D.C. and Sixth Circuits have taken a third approach that stakes out a middle ground, holding that "an 'original source' must provide the government with the information prior to any public disclosure," but not requiring the relator to be the cause of the public disclosure. United States ex rel. Findley v. FPC-Boron Employees' Club, 105 F.3d 675, 690 (D.C. Cir. 1997); see also United States ex rel. McKenzie v. BellSouth Telecomms., Inc., 123 F.3d 935, 942-43

(6th Cir. 1997). OBP and the United States urge us to take this middle approach.

Although we are about to travel a well-trodden path, our first step remains the same. "Our first step in interpreting a statute is to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case." Robinson v. Shell Oil Co., 519 U.S. 337, 340 (1997). "The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." Id. at 341.

By its terms, the "original source" exception only requires the relator to "provide[] the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. § 3730(e)(4)(B). Section 3730(e)(4)(B) does not impose any other timing requirement. Nor does § 3730(e)(4)(A). Thus, like the Fourth Circuit and the district court below, we conclude that the plain terms of § 3730(e)(4)(B) begin and end the matter. See Robinson, 519 U.S. at 340 ("Our inquiry must cease if the statutory language is unambiguous and 'the statutory scheme is coherent and consistent.'" (quoting United States v. Ron Pair Enters., Inc., 489 U.S. 235, 240 (1989))).

The government argues that the language of § 3730(e) (4)(B), when read in context, supports its view. Following the D.C. Circuit, the government points to the meaning of the terms "original source" itself, contending that a "source" is defined as "[t]he originator or primary agent of an act, circumstance, or result." Black's Law Dictionary 1522 (9th ed. 2009) (using the example "she was the source of the information."). Thus, a source cannot "originat[e]" information that has been publicly disclosed. The D.C. Circuit similarly found significance in "Congress's decision to use the term 'original source' rather than simply incorporating subparagraph (B)'s description into subparagraph (A)." Findley, 105 F.3d at 691.

However, we decline to rely upon the plain meaning of the terms "original source" when the statute defines the term at § 3730(e) (4) (B). It is only "[w]hen a word is not defined by statute" that we "construe it in accord with its ordinary or natural meaning." See Smith v. United States, 508 U.S. 223, 228 (1993). In addition, we decline to attribute significance to Congress's use of the terms "original source" rather than engraft the definition found at § 3730(e) (4) (B) into § 3730(e) (4) (A). Section 3730(e) (4) (A) sets forth two exceptions to the "public disclosure" bar, (1) when the relator is an "original source" and (2) when "the action is brought by the Attorney General." Thus, setting forth the definition of one of these exceptions in a

separate subparagraph, rather than shoehorning it into § 3730(e)(4)(A), avoids unnecessary confusion and does not imply anything further. Finally, had Congress intended to retain the plain meaning of "original source" and require relators to provide their information prior to the public disclosure, "it easily could have done so." See Rost, 507 F.3d at 729 (rejecting argument that, for purposes of the meaning of "public disclosure," "equates the government with the public").

Typically, we end our review when "the plain language of a statute unambiguously reveals its meaning, and the revealed meaning is not eccentric." United States v. Meade, 175 F.3d 215, 219 (1st Cir. 1999) (noting that, in such circumstances, "courts need not consult other aids to statutory construction"). OBP and the government, however, argue that such an eccentricity would result.

Both OBP and the government primarily argue that interpreting the "provided" language in § 3730(e)(4)(B) by its plain terms would conflict with the intent of Congress. See United States v. Am. Trucking Ass'n, 310 U.S. 534, 542 (1940) ("In the interpretation of statutes, the function of the courts is . . . to construe the language so as to give effect to the intent of Congress."). Specifically, they argue that reading § 3730(e)(4)(B) by its plain terms would permit relators to bring suit based upon fraud that was already publicly disclosed, so long as the relator

had "direct and independent knowledge" of the fraud. For example, a relator who learns about fraud against the government in the Huffington Post would be permitted to bring a qui tam suit "based upon" that "public disclosure" if she has "direct and independent knowledge" of the fraud and provides that information to the government before filing suit, literally the day before filing. The same would be true if the "public disclosure" resulted from a long-standing government investigation, where a relator would be entitled to bring suit so long as he or she had "direct and independent" knowledge of the public disclosure.

The D.C. Circuit concluded that, although the FCA provides financial incentives to provide information about fraud to the government, "[o]nce the information has been publicly disclosed, however, there is little need for the incentive provided by a qui tam action." Findley, 105 F.3d at 691. The Sixth Circuit discusses this point in more detail, holding that requiring a relator to disclose his or her information to the government prior to the public disclosure at issue advances the twin goals of (1) alerting the government to potential fraud and (2) creating incentives to do so as early as possible. McKenzie, 123 F.3d at 942-43. As put by the Sixth Circuit,

[T]his approach furthers Congress's . . . goal in amending the FCA: "[T]o prevent 'parasitic' qui tam actions in which relators, rather than bringing to light independently discovered information of fraud, simply feed off of previous disclosures of public fraud."

Siller, 21 F.3d at 1347. Anyone who alerts the government and is a "true whistleblower" deserves any reward that may be obtained by pursuing a qui tam action under the FCA. However, the individual who sits on the sidelines while others disclose the allegations that form the basis of her complaint should not be able to participate in any award. This would be contrary to the purpose of the statute.

Id. at 943; see also Wang, 975 F.2d at 1419 ("Qui tam suits are meant to encourage insiders privy to a fraud on the government to blow the whistle on the crime. In such a scheme, there is little point in rewarding a second toot."). Thus, both OBP and the government argue that requiring the relator to provide his or her information before the public disclosure corrects this problem and ensures that only productive suits are filed, that is, those suits in which a "true whistleblower" alerts the government of fraud not publicly disclosed.

After careful consideration of the arguments in favor of adopting the middle approach, we conclude that honoring the plain and unambiguous meaning of § 3730(e)(4)(B) would not conflict with the intent of Congress. Our decision is supported by our own review of the "language, structure, and history" of § 3730(e)(4)(B) and the "public disclosure" bar. See Rost, 507 F.3d at 728-29 (reviewing the language, structure and history of the terms "public disclosure" in rejecting interpretation that conflicted with the plain meaning of the statute). As we have just discussed the

language of § 3730(e)(4)(B), we turn to the structure and history of the statute.

i. Structure

The structure of the FCA mitigates many of the concerns that lead the D.C. and Sixth Circuits to adopt the middle approach and, in fact, demonstrates that the middle approach has the potential to prohibit productive suits. As an initial matter, the "first-to-file" rule already provides potential relators significant incentive not to sit on the sidelines. As we discuss in more detail below, "a goal behind the first-to-file rule" is to provide incentives to relators to "promptly alert[] the government to the essential facts of a fraudulent scheme." United States ex rel. Lujan v. Hughes Aircraft Co., 243 F.3d 1181, 1188 (9th Cir. 2001). It is unclear why a relator would wait for a public disclosure and risk another relator bringing suit.

Moreover, the Supreme Court's recent decision in Rockwell, which interpreted the "direct and independent" knowledge requirement of the public disclosure bar, substantially undercuts the conclusion by the D.C. and Sixth Circuits that "little incentive" is necessary for suits brought after a public disclosure. In addressing the meaning of the "direct and independent knowledge" requirement of the "original source" exception in § 3730(e)(4)(B), the Rockwell Court also addressed the meaning of the term "information" found in both § 3730(e)(4)(A) and

§ 3730(e)(4)(B). It held that "information" for purposes of both subparagraphs refers to the "information underlying the allegations of the relator's action," not the information underlying the public disclosure. Rockwell, 549 U.S. at 472. The Court noted:

Section 3730(e)(4)(A) bars actions based on publicly disclosed allegations whether or not the information on which those allegations are based has been made public. 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. at 471-72 (emphasis added).

Rockwell clarifies that the information that the original source has "direct and independent knowledge" of does not have to be the same as the information upon which the public disclosure is based. Thus, a public disclosure concerning governmental fraud resulting from a Huffington Post article may be based on

information that is different (to use the example in Rockwell, "what a confidential source told a . . . reporter about insolid pondcrete") than the information a relator may have in support of the same fraud ("that a defective process would inevitably lead to insolid pondcrete"). See id. The same would be true of an ongoing governmental investigation, where the information upon which the government's public disclosures are based may be different from the information that the relator has in his possession.

But as a result of that clarification, Rockwell strongly suggests that situations can arise where the information upon which the public disclosure is based may be unavailable (such as a reporter protecting a source) or be of little value (if based on rumors), while a relator may have different information of the publicly disclosed fraud (such as eyewitness testimony, documents, etc.) of great significance. This has substantial plausibility when the public disclosure is based on the "news media," where sources may fear to come forward to serve as witnesses but others with "direct and independent knowledge" may be so willing. Although in such a situation, the relator, in a technical sense, is not a "true whistleblower," we disagree that such a relator does not "deserve[] any reward that may be obtained by pursuing a qui tam action under the FCA." See McKenzie, 123 F.3d at 942-43. Thus, the approach taken by D.C. and Sixth Circuits has the potential to bar productive suits.

ii. History

The history of the "public disclosure" bar and the "provided" language under § 3730(e)(4)(B) also does not require us to deviate from the plain meaning. The legislative history of the "public disclosure" bar has been well rehearsed by this and other circuits. See, e.g., Praver, 24 F.3d at 324-26; see also Findley, 105 F.3d at 679-81. We only discuss legislative history relevant to our inquiry here.

The "provided" language in § 3730(e)(4)(B) was specifically enacted to "'correct[]" the holding of United States ex rel. Wisconsin v. Dean." Findley, 105 F.3d at 691; see also Siller, 21 F.3d at 1354; FMC Corp., 975 F.2d at 1419 ("Seeking only to 'correct' opinions like Dean, Congress permitted one who publicly disclosed the information to bring a qui tam suit."). Dean was a 1984 Seventh Circuit decision decided prior to the 1986 amendments that resulted in the current "public disclosure" bar. The case concerned a previous jurisdictional bar, adopted in 1943, that barred relator suits "'based upon evidence or information in the possession of the United States . . . at the time such suit was brought.'" Findley, 105 F.3d at 680 (omission in original) (quoting Act of December 23, 1943, 57 Stat. 608, recodified in 31 U.S.C. § 3730(b)(4) (1982) (superseded)). The 1943 jurisdictional bar provided no exception for when "the relator was the source of that information," although such an exception was proposed. Id.

"In Dean, the Seventh Circuit was faced with the question of whether the State of Wisconsin should be allowed to act as a qui tam relator in a Medicaid fraud action where the State, in accordance with the federal regulations, had already reported the fraud to the federal court." Praver, 24 F.3d at 325 (citing United States ex rel. Wisconsin v. Dean, 729 F.2d 1100, 1102-04 (7th Cir. 1984)). The Dean court answered in the negative, stating that "[i]f the State of Wisconsin desires a special exemption to the False Claims Act because of its requirement to report Medicaid fraud to the federal government, then it should ask Congress to provide that exemption." 729 F.2d at 1106.

Congress obliged, and in 1986 Congress amended the FCA to "'encourage more private enforcement suits.'" Findley, 105 F.3d at 680 (quoting S. Rep. No. 93-345, at 23-24 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5288-89); see also Rost, 507 F.3d at 730 (same). As emphasized by the Sixth Circuit, one goal of the amendments was to "prevent 'parasitic' qui tam actions in which relators, rather than bringing to light independently discovered information of fraud, simply feed off of previous disclosures of fraud." McKenzie, 123 F.3d at 943 (quoting Siller, 21 F.3d at 1347).

But two additional changes are relevant here. The first was to abolish the "government knowledge" regime entailed by the 1943 jurisdictional bar, which Congress concluded "proved too restrictive of qui tam actions, resulting in the under-enforcement

of the FCA." Rost, 507 F.3d at 729. Congress replaced the "government knowledge" regime with one, as shown by the "public disclosure" bar, focused on the "public disclosure of information given to the government." Id. As put by the D.C. Circuit, "Congress thus changed the focus of the jurisdictional bar from evidence of fraud inside the government's overcrowded file cabinets to fraud already exposed in the public domain." Findley, 105 F.3d at 684. To replace the "government knowledge" bar, Congress "'broadened the universe of potential [qui tam] plaintiffs, with only four exclusions' enumerated in § 3730(e)." Rost, 507 F.3d at 730 (quoting United States ex rel. LeBlanc v. Raytheon Co., 913 F.3d 17, 19 (1st Cir. 1990)).

The second was to reinstate the "original source" exception proposed, but not adopted, in 1943, so as to avoid the situation in Dean where a potential relator who provided information to the government was not barred from bringing a qui tam suit. It is this second change that the "provided" language sought to remedy, by allowing individuals to maintain suit and "provide their information to the government." As put by the Fourth Circuit:

To "correct" Dean only required that Congress adopt language that would ensure that a plaintiff who had provided his information to the government would not be barred from bringing a qui tam action on the ground that the government already possessed the information. This it did in section 3730(e)(4)(B), by providing that a plaintiff

who produces his independently-obtained information to the government is excepted from section 3730(e)(4)(A)'s jurisdictional bar.

Siller, 21 F.3d at 1354.

The second additional change provides a direct justification of the "provided" language in § 3730(e)(4)(B), but it is the first that has been glossed over. Both the D.C. Circuit and the Sixth Circuit have focused on the concern with "parasitic" suits, concluding that any such suit brought after a "public disclosure" was necessarily "parasitic." As noted above, we question that conclusion. But we also note that the 1986 amendments equally sought to end a regime that resulted in the "under-enforcement" of the FCA, one that rested too much on government notice to prevent fraud. As we have noted, Congress "amended the statute to 'encourage more private enforcement suits.'" Rost, 507 F.3d at 730 (quoting S. Rep. No. 93-345, at 23-24). Although we have recognized that a "public disclosure" regime has the benefit, one lacking in a "government notice" regime, of providing "public pressure" on the government to act, see Rost, 507 F.3d at 730, there also may arise situations when even that is not enough, and the government would benefit from suits brought by relators with substantial information of government fraud even though the outlines of the fraud are in the public domain.

The D.C. Circuit was quite explicit that its approach "may on occasion prevent qui tam lawsuits that may not be truly

'parasitic.'" Findley, 105 F.3d at 685. However, we have rejected readings of the "public disclosure" bar that "would create a new exclusion not articulated in the text" which would discourage "productive private enforcement." See Rost, 507 F.3d at 730. In Rost, we rejected an interpretation of "public disclosure" under § 3730(e)(4)(A) to include self-disclosures made by a private party only to government agencies without further disclosure, as it would "reinststate exactly what Congress eliminated -- the 'government knowledge' bar." Id. Although the reading urged here would not return us to the "government notice" regime, it is overbroad so as to prohibit cases that are "productive private enforcement suits." Thus, just as we eschewed reading an exclusion in Rost that did not have textual support and resulted in discouraging "productive private enforcement," we similarly decline to do so here.

We conclude by emphasizing that we are cognizant of our institutional role and the limits of our competence in interpreting the FCA. As noted by the Fourth Circuit, in criticizing the approaches taken by the Second and Ninth Circuit:

It strikes us as especially inappropriate (not to mention frighteningly treacherous) to attempt, as these courts have done, to distill from such broad, generalized objectives, the answers to the kind of specific statutory questions that we herein address; fine calibrations are just not possible through the use of such crude instruments. This is particularly so in this context, given that, although we can perhaps divine from these abstract purposes a congressional intention to balance the need to encourage qui tam actions

against the need to prevent parasitic suits, we can discern virtually nothing as to precisely how Congress ultimately believed it achieved that balance. If the language of law is to have any meaning at all, then surely it must prevail over the kind of speculation that is entailed in such an enterprise as these courts have undertaken.

Siller, 21 F.3d at 1354-55. We agree. The FCA has many moving parts, so that any attempt by us to move one may upset others. Given the difficulty in determining the right "balance," we conclude that the better approach is to rely upon the plain and unambiguous language of § 3730(e)(4)(B) in the absence of any clear direction to do otherwise.

Thus, we reject OBP's and the government's contention that § 3730(e)(4)(B) requires an "original source" to provide his or her information before the public disclosure at issue. Instead, we will honor the plain and unambiguous terms of the statute, and hold that § 3730(e)(4)(B) only requires that a relator provide his or her information prior to the filing of the qui tam suit.

2. McClellan

The Relators contend that the district court erred in holding that McClellan failed to qualify as an original source. We disagree. As an initial matter, the Amended Complaint alleges that "Relator McClellan does not bring any new legal claims against [OBP], but rather adds additional supporting facts to the legal claims previously made [in the Original Complaint]." (Am. Compl. ¶ 28). Thus, the district court correctly concluded that McClellan

was required, in order to qualify as an "original source," to provide his information prior to the filing of the Original Complaint, rather than the Amended Complaint. See Duxbury, 551 F. Supp. 2d at 109.

Although the Amended Complaint alleges that "[b]oth Relators have direct and independent knowledge of information on which the allegations are based, and have provided such information to the United States before filing suit, as required by 31 U.S.C. § 3730(e)(4)," (Am. Compl. ¶ 16), the district court noted that Duxbury "proffered no support for this conclusory allegation" and the district court refused to "reasonably infer it," as "Duxbury did not move to add McClellan as a relator until October 2006." Id. at 110. We agree.

McClellan counters that we are required to "take as true all well-pleaded facts in [the] complaint[]" and "draw all reasonable inferences therefrom in [his] favor." See Fothergill, 566 F.3d at 251. However, we are under no obligation to credit McClellan's conclusory allegations, which simply parrot the elements of the statute. See Rodríguez v. SK & F Co., 833 F.2d 8, 8 (1st Cir. 1987) (per curiam) (affirming dismissal for lack of subject matter jurisdiction where "the plaintiff has failed to allege grounds upon which to support either his conclusory allegation of diversity jurisdiction or federal question jurisdiction."); cf. Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949

(2009) (in reviewing a motion to dismiss for failure to state a claim, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.").

We also refuse to "reasonably infer" McClellan's allegation concerning disclosure. On appeal, McClellan points to a single allegation in the Original Complaint that he "had over 400 Patient Trial Cards in his possession in one time." (Compl. ¶ 39). This allegation does not support an allegation that he provided his information about the kickback claims prior to the filing of the Original Complaint. McClellan also points to the Information, which was provided to the government after the filing of the Original Complaint. The Information provides significant detail concerning the Relators' off-label promotion claims, not its kickback claims, and thus the Information also provides no support for his allegation that he provided his information prior the filing of the Original Complaint.

For the above reasons, we hold that the district court did not err in holding that McClellan did not qualify as an "original source" under § 3730(d)(1), and thus affirm the dismissal of those kickback claims attributable to McClellan. Accordingly, we do not need to address the district court's alternative ground

for dismissing the claim, that those kickback claims attributable to Duxbury are barred by the "first-to-file" rule.

3. Duxbury

We finally address the dismissal of Duxbury claims under Rule 9(b). Duxbury seeks reversal. We agree.

In applying Rule 9(b), the district court held that the rule "requires relators to 'provide details that identify particular false claims for payment that were submitted to the government.'" Duxbury, 551 F. Supp. 2d at 114 (quoting Rost, 507 F.3d at 731) (emphasis added). This was error. In Rost, we noted a distinction between a qui tam action alleging that the defendant made false claims to the government, and a qui tam action in which the defendant induced third parties to file false claims with the government. 507 F.3d at 732 (noting that latter action is "in a different category" than former).⁶ In the latter context, we held that a relator could satisfy Rule 9(b) by providing "factual or statistical evidence to strengthen the inference of fraud beyond

⁶ Although this distinction resembles the distinction between "subsection (a)(1)" claims, which have a presentment requirement, and "subsection (a)(2)" claims, which do not, see Gagne, 565 F.3d at 44-45, our analysis in Rost applied equally to both (a)(1) and (a)(2) claims. See Rost, 507 F.3d at 731-32 (noting that relator there asserted both (a)(1) and (a)(2) claims); see also id. at 733 (rejecting a claim that (a)(2) claims should be treated differently, noting that "[o]ur analysis -- which recognizes the role played by third parties other than Pfizer in submitting claims and making statements to the government -- undermines Rost's § 3729(a)(2) argument as well"). Here, as in Rost, Duxbury asserts both (a)(1) and (a)(2) claims. (See Am. Compl. Count I).

possibility" without necessarily providing details as to each false claim. Rost, 507 F.3d at 733; see also United States ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009) (holding that FCA claims under Rule 9(b) "may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.").

Similar to this case, Rost concerned allegations that "false claims were allegedly submitted by doctors who were allegedly induced and seduced by defendants into prescribing Genotropin for off-label uses to their patients, including federally insured patients." Id. at 732. We acknowledged that "Rost's complaint amply describes illegal practices in which Pfizer allegedly engaged." Id. However, "[a]s presently pled, the complaint d[id] not sufficiently establish that false claims were submitted for government payment in a way that satisfies the particularity requirement." Id. at 733. We noted:

It may well be that doctors who prescribed Genotropin for off-label uses as a result of Pharmacia's illegal marketing of the drug withstood the temptation and did not seek federal reimbursement, and neither did their patients. It may be that physicians prescribed Genotropin for off-label uses only where the patients paid for it themselves or when the patients' private insurers paid for it. Rost did not plead enough to satisfy the concerns behind Rule 9(b).

Id.

Here, as in Rost, Duxbury does not allege that OBP itself submitted false claims to the government, but that, through OBP's illegal kickbacks, false claims to the Medicare Program were filed by medical providers for reimbursement of Procrit purchases. However, unlike in Rost, Duxbury does more than "suggest fraud was possible." Id. at 733. Duxbury sets forth allegations of kickbacks provided by OBP that resulted in the submission of false claims by eight healthcare providers in the Western United States: (1) St. Joseph's Hospital in Tacoma, Washington (Am. Compl. ¶ 211a); (2) Rainier Oncology of Puyallap, Washington (Am. Compl. ¶ 211b); (3) Memorial Clinic in Olympia, Washington (Am. Compl. ¶ 211c); (4) Western Washington Cancer Treatment Center (Am. Compl. ¶ 211d); (5) Mid Columbia Kidney Center in Kennewick, Washington (Am. Compl. ¶ 211e); (6) St. Peter's Hospital in Olympia, Washington (Am. Compl. ¶ 211f); (7) Memorial Clinic Oncology Group in Washington (Am. Compl. ¶ 211g); (8) Swedish Hospital in Seattle, Washington (Am. Compl. ¶ 211h). As to each, Duxbury provides information as to the dates and amounts of the false claims filed by these providers with the Medicare program. One such allegation is instructive:

In 1997-98 Western Washington Treatment Center in Olympia, Washington received more than \$5,000 of free commercially packaged ProCrit from [OBP] under the direction of Robert Ashe so that Western Washington could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product.

[OBP] intended the free commercially packaged ProCrit to be a "cash equivalent" "kickback" to Western Washington in order to induce the provider to purchase ProCrit and to administer ProCrit at the "off-label" once a week dosing regimen. Western Washington was reimbursed by Medicare for the free commercially packaged ProCrit. As a result, [OBP] knowingly caused the presentation by Western Washington of these false claims to the United States Government.

(Am. Compl. ¶ 211d). Duxbury provides more specifics with respect to other medical providers. As to St. Joseph's Hospital, Duxbury alleges that the hospital submitted "approximately 4,800 claims a month for Medicare reimbursement" based upon OBP's unlawful kickbacks. (Am. Compl. ¶ 211a).

Although a close call, Duxbury's claims satisfy Rule 9(b) under this "more flexible standard." See Gagne, 565 F.3d at 46. Although Duxbury does not identify specific claims, he has alleged the submission of false claims across a large cross-section of providers that alleges the "the who, what, where, and when of the allegedly false or fraudulent representation." See Rodi v. So. New England Sch. of Law, 389 F.3d 5, 15 (1st Cir. 2004) (quotation omitted); see also Rost, 507 F.3d at 731 (noting that Rule 9(b) requires a plaintiff to allege "'the time, place, and content of an alleged false representation.'" (quoting Doyle v. Hasbro, Inc., 103 F.3d 186, 194 (1st Cir. 1996))). In particular, Duxbury has identified, as to each of the eight medical providers (the who), the illegal kickbacks (the what), the rough time periods and

locations (the where and when), and the filing of the false claims themselves.

Moreover, as to his (a)(2) claims, Duxbury has also alleged facts with respect to the medical providers he identifies that support his claim that OBP intended to cause the submission of false claims. See Allison Engine, 128 S. Ct. at 2126 (holding that an action under subsection (a)(2) requires a relater to allege "that the defendant intended that the false record or statement be material to the Government's decision to pay or approve the false claim"); see also Gagne, 565 F.3d at 47 (affirming dismissal of an (a)(2) claim under Rule 9(b) where "[r]elators fail to connect the only falsity or fraud for which they provide any detail").

With respect to Western Washington, Duxbury alleges that "Washington received more than \$5,000 of free commercially packaged ProCrit from [OBP] . . . so that Western Washington could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product," and that "Western Washington was reimbursed by Medicare for the free commercially packaged ProCrit." (Am. Compl. ¶ 211d) (emphasis added). The same is true of the other medical providers. See, e.g., id. ¶ 211a ("[OBP] intentionally failed to report these payments to the US Government in order to keep secret the profit spread between the rate upon which Medicare reimbursed medical providers like St. Joseph's for ProCrit."); id. ¶ 211b ("Ranier

Oncology . . . was provided more than \$20,000 of free commercially packaged ProCrit from [OBP] . . . under the guise of running an unlawful mini-trial so that Rainier Oncology could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product."); id. ¶ 211c ("Memorial Clinic . . . was provided approximately \$15,000 of free commercially packaged ProCrit from [OBP] so that Memorial Clinic could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product."); id. ¶ 211e ("Mid Columbia Kidney Center . . . submitted claims to Medicare and was subsequently reimbursed by Medicare approximately \$75,000 for the administering of ProCrit to Mid Columbia Kidney Center patients. . . . [OBP] provided Mid Columbia Kidney Center with an 'off-invoice' rebate of 5-8% for the purchase of ProCrit. [OBP] intentionally failed to report those 'off-invoice' rebates in order to keep secret the 'profit spread' between the actual acquisition cost to the Provider and the Medicare reimbursement rate so that the Providers could benefit from the spread."); id. ¶ 211f ("St. Peter's Hospital . . . submitted claims to Medicare for approximately two million dollars of ProCrit. St. Peter's contract with [OBP] provided St. Peter's with an 'off-invoice' rebate of 14% for the purchase of ProCrit. [OBP] intentionally failed to report to the U.S. Government these 'off-label' rebates

in order to keep secret the 'profit spread' between the actual acquisition cost to the Provider and the Medicare reimbursement rate so that the Providers could benefit from the spread."); id. ¶ 211g ("Memorial Clinic Oncology Group . . . purchased \$750,000 of ProCrit. Memorial Clinic Oncology Group's agreement with [OBP] provided Memorial Clinic Oncology Group with an 'off-invoice' rebate of 5% for the purchase of ProCrit. [OBP] intentionally failed to report to the US Government the 'off-invoice' rebates in order to keep the 'profit-spread' between the actual acquisition cost to the Provider and the Medicare reimbursement rate so that the Providers could benefit from the spread."); id. ¶ 211h ("Swedish Hospital . . . was given cash in the form of a so-called 'unrestricted educational grant' in the amount of approximately \$15,000 [which was a kickback]. Provider subsequently purchased over \$100,000 of ProCrit of which approximately 50% was submitted for Medicare reimbursement.").

Unlike in Rost, where the allegations gave rise to only speculation as to whether the alleged scheme caused the filing of false claims with the government, Duxbury has alleged facts that false claims were in fact filed by the medical providers he identified, which further supports a strong inference that such claims were also filed nationwide. We thus have allegations of "factual . . . evidence to strengthen the inference of fraud beyond possibility." Rost, 507 F.3d at 733.

Although we find that the factual evidence alleged here of the submission of false claims caused by OBP at a cross-section of medical providers, is sufficient in this context, "[w]e decline to draft a litigation manual full of scenarios" of what allegations would be sufficient for purposes of Rule 9(b). LeBlanc, 913 F.2d at 20 (discussing "original source" exception). "Suffice it to say that we limit our holding to the facts." Id. Accordingly, we conclude that Duxbury's allegations pass muster for purposes of Rule 9(b).

Thus, we hold that the kickback claims attributable to Duxbury, from the years 1992 through 1998, satisfied Rule 9(b). As the district court has jurisdiction over these claims since Duxbury established himself as an "original source," we reverse the dismissal of these claims.⁷

B. Count III

The Relators contend that the district court erred in dismissing the "off-label" promotion claims contained in Count III. The district court relied upon the "first-to-file" bar, which

⁷ OBP urges other alternative grounds for affirming the dismissal of the Duxbury kickback claims. We deal with them briefly. OBP first claims the statute of limitations bars most of Duxbury's kickback claims. As the district court has not addressed the issue, we leave it to the district court to address it in the first instance. OBP also argues that the district court abused its discretion in permitting Duxbury to serve the Original Complaint outside the 120-month window mandated by Federal Rule of Civil Procedure 4(m) and D. Mass. Local Rule 4.1(b). We identify no abuse of discretion.

provides that "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 Blair Complaint, filed nearly a year before the Amended Complaint, also alleged a similar "off-label" promotion claim. Accordingly, the district court examined whether the Original Complaint, filed a month before the Blair Complaint, sufficiently alleged an "off-label" claim to be considered the first-filed complaint for purposes of the "first-to-file" bar. Duxbury, 551 F. Supp. 2d at 110-11. After carefully considering the allegations contained in both complaints, the district court concluded that, despite some similarities, the Original Complaint did "not provide the essential facts regarding a widespread scheme to promote off-label uses of Procrit." Id. at 114 (emphasis added). We agree.

As the Ninth Circuit has noted, "a goal behind the first-to-file rule" is to provide incentives to relators to "promptly alert[] the government to the essential facts of a fraudulent scheme." Lujan, 243 F.3d at 1188. All courts that have addressed the issue have interpreted § 3730(b)(5) to bar "a later allegation [if it] states all the essential facts of a previously-filed claim" or "the same elements of a fraud described in an earlier suit." United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 232-33 (3d Cir. 1998) (emphasis added); see also United States ex rel. Hampton v. Columbia/HCA Healthcare

Corp., 318 F.3d 214, 217-18 (D.C. Cir. 2003) (holding that "§ 3730(b)(5) bars any action incorporating the same material elements of fraud as an action filed earlier" and "reject[ing] another possible test, one barring claims based on 'identical facts.'"); Lujan, 243 F.3d at 1188-89 (following LaCorte, and rejecting an "identical facts" test). Under this "essential facts" standard, § 3730(b)(5) can still bar a later claim "even if that claim incorporates somewhat different details." LaCorte, 149 F.3d at 232-33. We take the same approach.

The Relators contend that the Original Complaint, in particular, Paragraphs 40 through 42, allege all of the "essential facts" of the off-label promotion scheme. As the district court found, there are significant similarities between the "off-label" promotion allegations contained in those paragraphs and the allegations in the Blair Complaint. Both allege that OBP did not have FDA approval for "a dosing regimen of 40,000 units once per week." (Compare Original Compl. ¶¶ 40(c), 41; Blair Compl. ¶¶ 22-27). Both allege that OBP promoted this dosage in order to "increase . . . payments for each Medicare Beneficiary receiving Procrit for treatment." (See Original Compl. ¶¶ 40(c), 41; Blair Compl. ¶¶ 22-27). And both allege that the higher dosage resulted in the filing of false claims with the government. See Duxbury, 551 F. Supp. 2d at 113 (noting these similarities).

However, the Original Complaint and Blair Complaint differ in one crucial respect. As recognized by the district court, the Blair Complaint contained a number of allegations that discuss, in significant detail, OBP's promotion of the "off-label" use, and alleged such "promotion" efforts as

- (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. at 113 (citing Blair Compl. ¶¶ 27, 28-79). By contrast, Paragraphs 40 through 42 of the Original Complaint only allege one method by which OBP promoted the "off-label" use of Procrit, the use of "clinical trials," and, in particular, an unnamed "Phase IV Study" that "resulted in Medicare Part B paying for 40,000iu/week of Procrit in cancer chemotherapy patients instead of 30,000iu/week -- an increase in 33% in payments for each Medicare Beneficiary receiving Procrit for treatment of their chemotherapy related anemia." (Compl. ¶ 40(c)). As this allegation fails to encompass the other allegations contained in the Blair Complaint concerning OBP's "off-label" promotion, it fails to allege the "essential facts" of the "off-label" promotion scheme contained in the Blair Complaint. In fact, the Original Complaint nowhere refers to a

"off-label" promotion scheme. Thus, we conclude that the Original Complaint cannot trump the Blair Complaint for purposes of the "first-to-file" rule.

On appeal, the Relators argue that the Information, which the Relators provided to the DOJ in response to its inquiries concerning the allegations contained in the Original Complaint, provided further allegations that covered the "essential facts" contained in the Blair Complaint. We have previously held that, in reviewing a dismissal for lack of jurisdiction, "we need not confine our jurisdictional inquiry to the pleadings, but may consider those other materials" in the district court record. Aguilar, 510 F.3d at 8. We decline to do so here. The "first-to-file" rule is "exception-free," Lujan, 243 F.3d at 1187, and does not permit us to consider the Information, which was provided after the filing of the Blair Complaint.⁸ Had Duxbury wanted to include the allegations contained in the Information, he had his opportunity to do so when he filed the Original Complaint seven months earlier.

For the above reasons, the district court did not err in dismissing Count III.

⁸ We also note that the Information was produced after the Blair Complaint was made available to the Relator Duxbury, although the Relators contend that Duxbury had not yet received the Information.

III. Conclusion

For the foregoing reasons, we affirm the dismissal of all claims except those kickback claims attributable to Duxbury. For these latter claims, we reverse the dismissal and remand for further proceedings consistent with this opinion.

Affirmed in part, Reversed in part and Remanded.