IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, et al., ex rel. PEGGY RYAN,	:	CIVIL ACTION
Plaintiff,	:	
v.	:	No. 05-3450
ENDO PHARMACEUTICALS, INC.,	:	
Defendant.	:	

UNITED STATES OF AMERICA, et al., ex rel. MAX H. WEATHERSBY,	:	CIVIL ACTION
Plaintiff,	:	
v.	:	No. 10-2039
ENDO PHARMACEUTICALS, INC.,	:	
Defendant.	:	

UNITED STATES OF AMERICA, et al., ex rel. GURSHEEL S. DHILLON,	:	CIVIL ACTION
Plaintiff,	:	
v.	:	No. 11-7767
ENDO PHARMACEUTICALS, INC.,	:	
Defendant.	:	

MEMORANDUM

ROBERT F. KELLY, Sr. J. **JUNE 23, 2014**

Presently before this Court are the Government's "Memorandum on the Eligibility of Relators for a Share of Federal Settlement Proceeds," Plaintiff Peggy Ryan's "Motion to Determine that Relator Peggy Ryan is the Sole Relator Entitled to a Relator's Share Award," the Memorandums of Law in Support of their Eligibility to Receive a Relator's Share filed by

Plaintiff Max H. Weathersby and Plaintiff Gursheel S. Dhillon, and the Responses filed by all of the parties. For the following reasons, Ryan's Motion is Granted.

I. BACKGROUND

The current proceeding is the product of three separate *qui tam* actions brought against Defendants, Endo Health Solutions, Inc., and its subsidiary, Endo Pharmaceuticals, Inc. ("Endo") (collectively "Defendants")[1], for violations of the False Claims Act ("FCA") stemming from Endo's promotion of the drug Lidoderm for off-label uses.[2] (See Gov't's Memorandum on the Eligibility of Relators, at 1.) The individual parties who filed the *qui tam* actions are Peggy Ryan ("Ryan"), Max H. Weathersby ("Weathersby") and Gursheel S. Dhillon ("Dhillon")(collectively "Relators").[3] (Id.) All three actions generally allege that Endo promoted Lidoderm for uses that were not approved by the Food and Drug Administration nor medically accepted, thus causing false claims to be submitted to federal healthcare programs. (Id.)

Procedural History

Ryan was the first Relator to file a Complaint against Defendants on July 5, 2005. (See

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[1]Defendant Endo Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business in Chadds Ford, Pennsylvania. See Ryan Am. Compl. ¶ 5. Endo manufactures, markets and sells pharmaceuticals. Id.

[2]The Food and Drug Administration, pursuant to the Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301-97, has the authority to approve drugs for sale in interstate commerce, such approval is contingent on the manufacturer demonstrating that the drug is safe and effective for the specific intended uses. United States ex rel. Bergman v. Abbot Laboratories, No. 09-4264, 2014 WL 348583, at *7 (E.D. Pa. Jan. 30, 2014). In alleging "off-label" use, Relators are referring to the promotion and sale of Lidoderm for uses which the drug has not been proven safe and effective. Lidoderm is an adhesive patch that is applied to the skin and is approved only for the treatment of pain related to post-herpetic neuralgia ("PHN"), a complication that sometimes accompanies shingles. (See Gov't's Memorandum on the Eligibility of Relators, at 1.)

[3]The corresponding docket numbers for the three individual *qui tam* actions are as follows: Ryan, 05-cv-3450; Weathersby, 10-cv-2039; and, Dhillon, 11-cv-7767.

Ryan Compl.) She subsequently amended this Complaint on March 31, 2009. (See Ryan Am. Compl.) Overall, Ryan amended her Complaint three times between 2005 and 2011. Weathersby was the second Relator to file a Complaint on May 4, 2010. (See Weathersby Compl.) Weathersby has since amended his Complaint three times. The final Relator to file a Complaint was Dhillon on December 21, 2011.

At some point in 2010, when only Ryan and Weathersby had filed *qui tam* Complaints against Defendants, the Government disclosed the existence of the Complaints to each Relator. In 2012, after Dhillon filed his Complaint, the Government informed Dhillon of the other Relators, and revealed Dhillon's Complaint to Ryan and Weathersby. The following is a general synopsis of each Relator's individual Complaint.

Ryan's Qui Tam Complaint

At all times relevant to this litigation, Ryan worked as a sales representative for Endo. (Id.) On July 5, 2005, Ryan filed a *qui tam* Complaint alleging violations of the FCA by Defendants. (Id. at 3; see also Ryan Compl.) At this point in the litigation, the Complaint most relevant to this action is the Amended Complaint filed on March 31, 2009. In this Amended Complaint, Ryan alleged that Endo engaged in off-label promotion of Lidoderm, causing false reimbursement claims to be submitted to Medicaid and Medicare. (See Ryan Am. Compl.) Specifically, Ryan alleged that Endo: (a) instructed sales representatives to promote the drug for off-label uses; (b) did so, in part, by creating articles and studies touting the effectiveness of Lidoderm for off-label uses, which appeared to be the product of neutral third parties, but was actually funded and prepared by Endo; (c) did not seek FDA approval for off-label uses because

the Defendants wanted to maintain Lidoderm's "orphan drug" status,[4] which resulted in special tax incentives and exclusive status; and (d) paid kickbacks to induce physicians to prescribe Lidoderm. (Id.)

In addition to filing the first Complaint in this matter, Ryan also provided extensive assistance in the investigation of Defendants' fraudulent activities by serving as a confidential source in the Government's covert criminal investigation of Defendants over a several year period beginning in 2005. (See Ryan's Resp. to Gov't's Mem. on the Eligibility of Relators, Ex. A.) According to an affidavit submitted by Chris Mulhall ("Mulhall"), a Federal Bureau of Investigations ("FBI") agent who was at one time the supervisor in charge of all FBI health care fraud investigations in the Northern District of New York, the FBI initiated the investigation after being contacted by Ryan. (Id.) At this time, Ryan provided the FBI with evidence of intentional, illegal off-label sales of Lidoderm. (Id.) From 2005 through 2012, Mulhall states that Ryan worked closely with the FBI to develop the factual basis of the investigation which led to Defendants' agreement to plead guilty to a criminal mislabeling violation on February 25, 2014. (Id.) During the course of the investigation, Ryan provided the FBI with Defendants' off-label sales and training materials, and with over two hundred (200) hours of recorded conversations with employees of Defendants concerning off-label sales. (Id.) In addition, Ryan assisted the FBI and Health and Human Services ("HHS") in composing the initial subpoena for Defendants'

[4]Congress passed the Orphan Drug Act in 1983 to provide pharmaceutical manufacturers with an incentive to develop and test drugs for the treatment of rare diseases. See Baker Norton Pharm., Inc. v. U.S. Food and Drug Admin., 132 F. Supp. 2d 30, 31 (D.D.C. 2001). Obtaining "orphan drug" status provides incentives to the manufacturer in the form of tax breaks, assistance from the FDA in studying the drug, and, most importantly, seven years of non-patent marketing exclusivity. See 26 U.S.C. § 28; see also 21 U.S.C. § 360cc(a).

records[5], helped interpret the records, apprised the FBI of any developments and performed other tasks in furtherance of the investigation. (Id.)

Weathersby's Qui Tam Complaint

On May 4, 2010, Weathersby, who like Ryan was employed as a sales representative by Defendants, filed the second *qui tam* Complaint on behalf of the Untied States and various States including the District of Columbia. (See Weathersby Compl.) Weathersby's Complaint generally alleges that Defendants knowingly engaged in a scheme that disregarded federal laws and FDA regulations relating to prohibitions on sampling, illegal kickback schemes and off-label promotion, and improperly targeted physicians who do not treat PHN in order to promote the off-label use of Lidoderm.[6] (Id. at ¶ 8.) Weathersby claims that he is an original source of the off-label promotion allegations in this Complaint, and that these allegations are not based upon publicly disclosed information. (Id. at ¶ 16.) Since the filing of the Complaint in May 2010, Weathersby has amended the Complaint on three separate occasions with the last amendment occurring on December 21, 2012. (See Doc. Nos. 6, 14, 20.)

Dhillon's Qui Tam Complaint

On December 21, 2011, Dhillon, a physician living in Tennessee, became the final Relator when he filed a pro se *qui tam* action alleging that Defendants engaged in the off-label

[5]In January 2007, the Office of the Inspector General ("OIG") of HHS subpoenaed Defendants to produce Lidoderm marketing related documents. (See Gov't's Mem. on the Eligibility of Relators, at 3.)

[6]Although the Government intervened and settled the allegations relating to the off-label promotion, the Government declined to intervene on Weathersby's remaining claims against Defendants relating to alleged kickbacks, pricing violations, and retaliation. (See Gov't's Mem. on the Eligibility of Relators, at 2.) These claims were not resolved as part of the settlement agreement and remain pending. (Id.)

promotion of Lidoderm.[7] (See Dhillon Compl.) In general terms, Dhillon avers in the Complaint that Defendants engaged in a scheme to encourage the off-label use of Lidoderm, while criticizing competing products, by providing bonuses to sales representative who met or exceeded Lidoderm sales goals, and paying speakers to promote the use of Lidoderm for off-label uses. (Id. at ¶¶ 5-10.) Dhillon asserts that he learned this information first hand in his capacity as a physician. (Id. at ¶ 13.)

The Settlement Agreement

On February 21, 2014, the United States of America (the "Government") elected to intervene on behalf of the Relators for settlement purposes. (See Gov't's Notice of Election to Intervene, Feb. 21, 2014.) On this same day the Relators entered into a Settlement Agreement, whereby Defendants agreed to pay approximately $171.9 million to resolve the alleged FCA violations. (See Gov't's Mem. on the Eligibility of Relators, at 1.) Specifically, the Agreement settled the following claim:

> Endo knowingly promoted the sale and use of Lidoderm for conditions for which it had not been approved by the United States Food and Drug Administration including for use in connection with lower back pain and chronic pain, which were not medically-accepted indications (as defined in 42. U.S.C. § 1396r-8(k)(6)), and were not covered by Medicare, Medicaid, and other Federal Health Care Programs; and these prescriptions were paid for or reimbursed by Medicaid, Medicare, or other Federal Health Care Programs.
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> As a result of the foregoing conduct . . . Defendants knowingly caused false and fraudulent claims for Lidoderm to be submitted or caused Lidoderm purchases by Medicare, Medicaid, and other Federal Health Care Programs. The United States contends that engaging in the covered

[7]The Complaint was initially filed in the Middle District of Tennessee, but was transferred to this District.

> conduct gives rise to civil liability under the False Claims Act, 31 U.S.C. §§ 3729-3733, and/or the common law.

See Settlement Agreement.

At the time of settlement, all Relators agreed that the Settlement Agreement was fair, adequate and reasonable. (Id.) Specifically reserved at the time of the settlement was the issue of the Relators' entitlement to a share of the federal proceeds of the FCA settlement. (Id.) On March 7, 2014, we consolidated the cases solely with regard to the issue of the Relators' share pursuant to 31 U.S.C. § 3730(d)(1). (See Order Consolidating Cases, Mar. 7, 2014.) On April 11, 2014, the Government filed a Memorandum on the eligibility of the Relators to receive a share of the settlement proceeds. (See Gov't's Mem. on the Eligibility of Relators.) In this document, the Government did not advocate for any one Relator. (Id.) Rather, the Government set forth the relevant legal framework with the understanding that the individual Relators would respond with arguments supporting their individual eligibility to receive the award. (Id.) Within the permissible time period to respond, the Relators filed individual memorandums raising arguments for receiving either a portion of or the whole settlement award. The Government subsequently replied to these memorandums, and the Relators each responded in turn.

II. STANDARD OF LAW

Congress enacted the FCA for the purpose of protecting government funds and property from fraudulent claims. See Rainwater v. United States, 356 U.S. 590 (1958).[8] In essence, the

[8]The FCA was enacted in 1863 during the American Civil War to combat the "rampant fraud" being perpetrated by defense contractors against the government. United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co., 944 F.2d 1149, 1153 (3d Cir. 1991). Elaborating on the birth of the FCA, the United States Supreme Court noted that, "the False Claims Act was originally adopted following a series of sensational congressional investigations into the sale of provisions and munitions to the War Department. Testimony before Congress painted a sordid picture of how the United States had been billed for nonexistent or worthless goods, charged exorbitant prices for goods delivered,

FCA is an avenue "to provide for restitution to the government of money taken from it by fraud." United States ex rel. Marcus v. Hess, 317 U.S. 537, 551 (1943). The FCA accomplishes this goal by authorizing civil penalties against anyone who "knowingly presents or causes to be presented, a false or fraudulent claim for payment," and/or "knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A) & (B). The FCA allows civil suits to be brought by either the Government or by private plaintiffs in order to recover funds lost through false claims. 31 U.S.C. § 3730(a) & (b). A suit brought by a private plaintiff, known as a "relator," on behalf of the government is called a *qui tam* action.[9] When a relator brings a *qui tam* action, the Complaint is initially filed under seal and served upon the government, and the government may then elect to intervene and proceed with the action. 31 U.S.C. § 3730(a). If the government chooses not to intervene, the relator has the right to conduct the action on his or her own. 31 U.S.C. § 3730(c)(3). In either case, if a *qui tam* action results in a recovery, the proper relator is entitled to a share of the award. 31 U.S.C. § 3730(d). The amount received by the relator is apportioned according to a set of percentage ranges set forth in the FCA. Id. In addition, the relator is entitled to seek attorneys' fees, costs

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and generally robbed in purchasing the necessities of war. Congress wanted to stop this plundering of the public treasury. At the same time it is equally clear that the False Claims Act was not designed to reach every kind of fraud practiced on the Government." United States v. McNinch, 356 U.S. 595, 599 (1958).

[9]In Latin, the phrase *qui tam* is short for "*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. Atkinson v. Pa. Shipbuilding Co., 473 F.3d 506, 509 n. 1 (3d Cir. 2007) (quoting Vt. Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 765, 769 n.1 (2000)); see also Black's Law Dictionary (9th ed. 2009). Thus, a *qui tam* action permits private parties to bring suit to enforce the law on the Government's behalf and rewards successful plaintiffs with part of the recovery. United States ex rel. Zizic v. Q2Administrators, LLC, 728 F.3d 228, 231 n.1 (3d Cir. 2013) (quoting United States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 647 n.1 (D.C. Cir. 1994)).

and expenses from the defendant. Id.

III. DISCUSSION

At this stage in the proceeding, the sole issue to be decided by this Court is the Relators' entitlement to a share of the federal proceeds of the FCA settlement. See Settlement Agreement. The following is an overview of the Relators' arguments as to the legal issues to be decided in this Opinion regarding their rights pertaining to the settlement award.[10]

By Motion, Ryan seeks an Order by this Court determining: (1) that she is the first-to-file Relator, and (2) that she is the only Relator eligible for a Relator's share. (See Ryan Motion to Determine that She is the Sole Relator, at 2.) Arguing that she is the first-to-file a Complaint in this action, Ryan asserts that both Weathersby and Dhillon are barred from receiving any of the settlement. (Id.) In response, Weathersby and Dhillon separately raise similar arguments that they each are individually entitled to a Relator's share because they were in fact the first to a assert plausible claim for relief under the FCA. (See Weathersby Mem. of Law in Support of His Eligibility to Receive a Relator's Share, at 7; see also Dhillon Mem. of Law in Support of His Eligibility to Receive a Relator's Share, at 12.) At the heart of each argument is Weathersby and Dhillon's belief that Ryan's Amended Complaint failed to satisfy the heightened pleading standards of Rule 9(b). Therefore, both Relators assert that the first-to-file rule is inapplicable. If the Court does not agree, Weathersby argues that, in the alternative, not all of his FCA claims are precluded by the rule. (Id. at 20.)

Ryan next argues that Weathersby and Dhillon's claims are precluded by the public

[10]Due to the extensive briefing on the subject matter and the general disagreement between the parties as to the fruitfulness of mediation, we denied Weathersby's Request for Mediation on June 2, 2014. See Order Denying Request for Mediation, June 2, 2014.

disclosure ban. (See Ryan Motion to Determine that She is the Sole Relator, at 24.) Both Weathersby and Dhillon reject Ryan's contention, with each Relator arguing that the public disclosure bar is not applicable to their individual claims because each Relator qualifies as an "original source."

Dhillon raises two arguments that are unique from both Ryan and Weathersby's contentions. First, Dhillon's main argument is that "under contract law and prior precedent the only proper issue before the Court is the apportionment of the settlement proceeds among the Relators as provided in 31 U.S.C. § 3730(d)(1), as the government and the other parties to this action waived their right to argue dismissal of (the) *qui tam* complaints." (See Dhillon Mem. of Law in Support of His Eligibility to Receive a Relator's Share, at 5.) Second, Dhillon argues that both Ryan and Weathersby's Complaints are barred by the applicable statute of limitations and the doctrine of laches. (Id. at 18.)

Our analysis logically begins with Ryan's contention that because she was the initial filer of a *qui tam* Complaint against Defendants, she is the only Relator eligible for a Relator's share. In order to reach this conclusion, Ryan must demonstrate that her Amended Complaint was sufficiently pleaded, and that Weathersby and Dhillon's claims are precluded by either the First-to-File rule or the public disclosure ban. See Foglia v. Renal Ventures Mgmt., LLC, No-12-4050, 2014 WL 2535339 (3d Cir. June 6, 2014)(setting forth the requisite pleading standard under Rule 9(b) for FCA claims); see also 31 U.S.C. § 3730(b)(5) & (e)(4).

A. Sufficiency of Ryan's Complaint

Weathersby and Dhillon argue that Ryan's Amended Complaint fell short of the pleading requirements and, therefore, did not assert a plausible claim. These arguments require the Court

to discern the sufficiency of Ryan's Amended Complaint. We note from the outset that the pleading standard applicable to FCA claims was an area of much uncertainty within this Circuit until recently. The Federal Rules of Civil Procedure usually require only that a plaintiff present "a short and plain statement" of his or her claim. See Fed. R. Civ. P. 8(a). However, the Rules demand that "in alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake," though malice, intent, knowledge, and other conditions of a person's mind may be alleged generally. Fed. R. Civ. P. 9(b). Since FCA claims inherently involve some "false" or "fraudulent" conduct, it seems appropriate that some level of more particularized pleading is required. See Id.; see also LaCorte, 149 F.3d 227, 234 (3d Cir. 1998) (implying that some degree of specificity should apply in FCA cases).

The Circuits are split as to the degree of specificity required in alleging FCA claims. The Fourth, Sixth, Eighth and Eleventh Circuits require that a plaintiff must show "representative samples" of the "alleged fraudulent conduct, specifying time, place, and content of the acts and the identity of the actors." See United States ex rel. Noah Nathan v. Takeda Pharm. N. Am., Inc., 707 F.3d 451, 455-56 (4th Cir. 2013), *cert. denied*, 2014 WL 1271321 (U.S. Mar. 31, 2014); United States ex rel. Bledsoe v. Cmty. Health Sys., Inc., 501 F.3d 493, 510 (6th Cir. 2007); United States ex rel. Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 557 (8th Cir. 2006); United States ex rel. Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301, 1308, 1312 (11th Cir. 2002). The First, Fifth and Ninth Circuits have taken a slightly different approach holding that Rule 9(b) only requires a plaintiff to allege "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." United States ex rel. Duxbury v. Ortho Biotech Prods., LP, 579 F.3d 13, 29 (1st Cir. 2009); United

States ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009); Ebeid ex rel. United States v. Lungwitz, 616 F.3d 993, 998-99 (9th Cir. 2010).

Until recently, the Court of Appeals for the Third Circuit ("Third Circuit") had not entered the fray and declared the level of specificity required under Rule 9(b) in pleading an FCA *qui tam* action. See United States ex rel Underwood v. Genentech, Inc., 720 F. Supp. 2d 671, 672 (E.D. Pa. 2010) (noting the silence on the issue). However, recently in Foglia v. Renal Ventures Mgmt., LLC, No-12-4050, 2014 WL 2535339 (3d Cir. June 6, 2014), the Third Circuit rejected the stricter standard applied by the Fourth, Sixth, Eighth and Eleventh Circuits reasoning that requiring "representative samples" would be "one small step shy of requiring production of actual documentation with the complaint, a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates." 2014 WL 2535339, at *6-7 (quoting Grubbs, 565 F.3d at 190). Instead, the Court adopted the more lenient standard utilized in the First, Fifth and Ninth Circuits, finding that it adequately satisfies Rule 9(b)'s purpose of giving the defendants fair notice of the claims against it. See Id. at *8.

In applying this standard, the Foglia Court asserted that a plaintiff's claim must be accompanied by "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." Id. at 11 (citing Grubbs, 565 F.3d at 190). "Describing a mere opportunity for fraud will not suffice. Sufficient facts to establish 'a plausible ground for relief' must be alleged." Id. at 12 (citing Fowler v. UPMC Shadyside, 578 F.3d 203, 211 (3d Cir. 2009)). Adhering to the framework of Foglia, we now examine the essentials of Ryan's claim.

Generally, Ryan alleges that Defendants knowingly marketed and promoted the off-label

use of the drug Lidoderm in violation of federal and state laws and regulations. In doing so, Ryan asserts that Defendants intentionally and knowingly undertook a course of conduct that would lead to the submission of thousands of ineligible Medicaid and Medicare claims for Lidoderm prescriptions. In the Amended Complaint, Ryan describes a scheme undertaken by Defendants to promote the off-label use of Lidoderm through the creation of fraudulent studies, by directing the sales force to advocate such applications, and by targeting and encouraging physicians through a system of kickbacks to prescribe the drug for such uses. These claims do not ring hollow as Ryan illustrates in greater detail the Defendants' actions in furtherance of the scheme in the following paragraphs of her Amended Complaint.

Ryan avers that Defendants sought to exploit a loophole in the FDA rules, which allows drug manufacturers to distribute publications created by neutral third parties to describe the off-label uses of drugs, by fraudulently creating articles, studies, publications and programs touting the effectiveness of Lidoderm for such uses under the guise of being created by neutral third parties. (Ryan's Am. Compl. ¶ 19.) However, these studies were actually financed and directed by Defendants. (Id.) Specifically, Ryan cites to two pilot studies released in 2004 that suggested that Lidoderm was effective in treating lower back pain and osteoarthritis. (Id. ¶ 20.)

Furthermore, Ryan alleges that Defendants have utilized a marketing strategy whereby its sales force would promote the off-label use of Lidoderm to physicians. (Id. ¶ 21.) Ryan specifically notes that Defendants directed company sales representatives who were attending a company sales conference to inform physicians of Lidoderm's ability to treat carpal tunnel syndrome, osteoarthritis, low back pain and several other off-label conditions. (Id.) In an effort to aid the sales force, Defendants provided the representatives with literature and publications

promoting Lidoderm's off-label uses. (Id. ¶¶ 21-22.)

In addition, Ryan states that Defendants utilized a system of kickbacks in order to encourage physicians to prescribe Lidroderm for unapproved uses. (Id. ¶ 23.) Ryan states that "high prescribers" of Lidoderm for off-label purposes were given honorariums to present at medical conferences and round table dinners. (Id.)

Finally, Ryan utilizes statistical sales data to further support her claims that Defendants promoted the off-label use of the drug Lidoderm in violation of federal and state laws and regulations. For instance, though the number of patients suffering from PHN has remained relatively constant, net sales of Lidoderm increased by 73% to $309.2 million in 2004. (Id. ¶ 24.) Since 2004, the net sales of Lidoderm has more than doubled, and in 2007 reached $705.6 million, which equaled 65% of Defendants' total net sales for the year. (Id.)

It is evident from the preceding recitation of the allegations in Ryan's Amended Complaint that we are not faced with a "close case" like the Third Circuit encountered in Foglia. See Foglia, 2014 WL 2535339, at *13. Rather, the in depth allegations detailed in Ryan's Amended Complaint depict "more than a mere opportunity for fraud." Id. at *11 (citing Fowler, 578 F.3d at 211). Ryan's Amended Complaint has not only set forth "particular details of a scheme to submit false claims," but has additionally supported them with solid evidence that would allow for a "strong inference" that false claims were actually submitted. Id. (citing Grubbs, 565 F.3d at 190). Accordingly, we find that Ryan satisfies the standard set forth by the Third Circuit in Foglia.

B. Implications of the First-to-File Rule

In order to prevent the filing of duplicative suits, the False Claims Act contains a first-to-

file rule, whereby the earliest initiator of a suit reigns supreme over subsequent claimants. See 31 U.S.C. § 3730(b)(5); see also LaCorte, 149 F.3d at 233. Specifically, 31 U.S.C. § 3730(b)(5) states, "[w]hen a person brings an action under this subsection, 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). Based on the unambiguous nature of the statute, the Third Circuit rejected the notion that § 3730(b)(5) applies only to *qui tam* actions arising from facts identical to those underlying the previous suit. See LaCorte, 149 F.3d at 232-233 (stating that "§ 3730(b)(5)'s plain language is conclusive; the statute speaks of a 'related action,' not an identical one"). Instead, the Court found that the plain language of the statute mandates a far broader application of the first-to-file bar. Id. (finding § 3730(b)(5) to be unambiguous, thereby, requiring each word be given its ordinary meaning). The Court found that "related claims," which trigger the bar, include "a later allegation (that) states all the essential facts of a previously filed claim . . . even if that claim incorporates somewhat different details." Id. (holding "the phrase 'related action based on the facts underlying the pending actions,' clearly bars claims arising from events that are already the subject of existing suits"). Finally, employing a broad interpretation of 31 U.S.C. § 3730(b)(5) comports with the competing goals of the rule - preventing opportunistic suits, while at the same time, encouraging that citizens act as whistleblowers. Id. at 233. Narrowly defining "facts underlying the pending action as identical facts" would frustrate the Government's ability to recover fraudulently obtained funds because an individual's incentive to bring a *qui tam* action would decrease where multiple relators could expect to share in the recovery. Id. at 234. Furthermore, "such duplicative claims do not help

reduce fraud or return funds to the federal fisc,[11] since once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds." Id.

In light of our finding that Ryan's Amended Complaint was sufficiently pleaded and now that the contours of § 3730(b)(5) have been defined, we proceed to compare the claims set forth by Weathersby and Dhillon with the claims of the original relator, Ryan, to see whether any of the subsequent Relators' claims survive.[12] Based upon the following rationale, we find that Weathersby and Dhillon fail to raise any claims that were unique from the claims raised previously by Ryan. Therefore, Weathersby and Dhillon are prohibited from asserting such claims by the bar of the first-to-file rule, 31 U.S.C. § 3730(b)(5). Consequently, we find that Ryan is the sole Relator eligible for the settlement award.

Relator Weathersby

A side-by-side analysis of Ryan and Weathersby's Complaints evidences that the claims are in fact related, thereby barring Weathersby's claims. See 31 U.S.C. 3730(b)(5). Weathersby argues that he is in essence the first filer of allegations on five claims, as they "do not appear anywhere in the Ryan First Amended Complaint." (See Weathersby Mem. of Law in Support of His Eligibility to Receive a Relator's Share, at 20.) We examine each of Weathersby's claims in comparison to the claims raised by Ryan.

Weathersby argues that the first-to-file bar should not preclude his claims that Defendants

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[11]Fisc is a rarely used meaning a state or royal treasury. See Merriam-Webster Dictionary 2014.

[12]Specifically, we will compare Ryan's Amended Complaint filed on March 31, 2009, with Weathersby's Complaint filed on May 4, 2010, and Dhillon's Complaint filed on December 21, 2011. We note that Dhillon's Complaint appears to have been filed in the U.S. District Court for the Middle District of Tennessee on February 3, 2011. However, for the purposes of this analysis the dates are not dispositive.

used "flawed clinical studies supporting off-label uses, while it concealed its own more robust, negative clinical trials demonstrating Lidoderm worked no better than (and in some cases, worse than) a placebo in treating off-label conditions," and Defendants' use of off-label consensus medical guidelines. (See Id. at 20-21.) However, these claims merely reiterate in slightly different terms Ryan's claim that Defendants engaged in a scheme to promote off-label uses of Lidoderm through the publication and dissemination of fraudulent studies. Accordingly, the claims are precluded by 31 U.S.C. § 3730(b)(5).

Weathersby's remaining three claims relate to Defendants' marketing of Lidoderm for off-label uses. Specifically, Weathersby asserts that Defendants distributed free samples to induce Lidoderm off-label prescribing; directed its sales force to focus promotional efforts on physicians that specialize in the treatment of conditions other than PHN, and utilized quotas and bonuses to encourage its sales force to promote sales to physicians who do not use Lidoderm on-label. (Id.) Once again, Weathersby's claims overlap the preexisting cause of action filed by Ryan, which previously set forth that Defendants directed their sales force to promote the off-label uses of Lidoderm to physicians and provided the force with materials to further this end. Though Weathersby's allegations may be stated in a slightly different manner, they are precluded because they echo the allegations previously raised in Ryan's Amended Complaint. See LaCorte, 149 F.3d at 232-33 (where the claims are related, section 3730(b)(5) bars the later claim, even if that claim incorporates somewhat different details).

Relator Dhillon

Although Dhillon, who is now represented by counsel, neglected to explicitly assert that any of his claims would survive the first-to-file rule, we undertake to examine his Complaint in

the absence of such argument. Comparing the Complaints of Ryan and Dhillon is difficult due to the fact that Dhillon was acting *pro se* when filing the Complaint, and it is challenging to ascertain his claim. Upon review, we interpret Dhillon's Complaint to raise one relevant claim. However, this claim fails to provide any unique essential facts relating to the Defendants' fraudulent acts.

Dhillon generally asserts that Defendants encouraged its employees to promote Lidoderm for off-label purposes. Specifically, Dhillon contends that Defendants, "routinely rewarded its representatives with trips and gifts," and held dinner meetings with company provided speakers who would attest to the off-label uses of Lidoderm. (See Dhillon Compl., at 2.) In support of this contention, Dhillon points to the tremendous amount of sales of the drug in comparison to the relatively low number of cases of PHN, and asserts that this information was "widely known throughout the company and was routinely discussed by management and sales personnel." Id. As stated above in reference to Weathersby, we find no meaningful distinction between this claim and the claims raised previously by Ryan and Weathersby. Due to this fact and Dhillon's Complaint being filed chronologically last, this claim is barred by 31 U.S.C. § 3730(b)(5).[13]

[13]In addition, Dhillon asserts that Defendants acted to subvert an internal investigation into the off-label use of Lidoderm by firing employees that testified truthfully and confiscating additional evidence. We interpret this to be an anti-retaliation claim, which is not pertinent to the issues before this Court because the Settlement Agreement relates only to the off-label marketing of Lidoderm, as the Government declined to intervene on Dhillon's retaliation claim. Moreover, anti-retaliation claims are not addressable under § 3729 of the False Claims Act because they do not articulate conduct prohibited under the statute. See 31 U.S.C. § 3729 (delineating conduct actionable under the False Claims Act). Rather, Congress enacted a "whistleblower" provision at 31 U.S.C. § 3730(h) of the False Claims Act, which allows *qui tam* plaintiffs to attain remuneration for personal injury suffered in retaliation for lawful actions taken by employees. However, in this case, Dhillon's retaliation claim is precluded because he is not an employee of Defendants. See 31 U.S.C. § 3730(h) (requiring filer to be an "employee").

C. The Public Disclosure Bar

Since we have concluded that Ryan is the sole, proper Relator due the settlement award, it is not necessary to address the application of the public disclosure bar in this case. However, this ground has been raised by all the parties in this dispute. Therefore, we will briefly discuss its application.

The public disclosure bar of the FCA divests a court of jurisdiction over *qui tam* suits based on allegations or transactions that have been publicly disclosed in certain sources, including the news media and reports generated by federal investigations, unless the person bringing the action is an original source of the information. See 31 U.S.C. § 3730(e)(4)[14]; see also Zizic, 728 F.3d at 231-32.

The Government produced a number of news articles, which originated prior to the filing of Complaints by either Weathersby or Dhillon.[15] These articles qualify as public disclosures from news media under the plain language of 31 U.S.C. § 3730(e)(4).[16]

Next, we must ascertain whether the *qui tam* actions originated by Weathersby and

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[14]The Patient Protection and Affordable Care Act ("PPACA"), Pub.L. No. 111–148, § 10104(j)(2), 124 Stat. 119, 901–02 (2010), amended the FCA's public disclosure bar. However, since the amendment is not retroactively applicable, we will discuss the pre-PPACA version of the public disclosure bar in this case. See Zizic, 728 F.3d at 232 f.3.

[15]These articles include the following: a 2006 Business Week article discussing the off-label marketing of Lidoderm; several news articles on the January 2007 subpoena served on Endo by the Inspector General of the U.S. Department of Health and Human Services (HHS); 2007 news articles on the Government investigation into off-label uses of Lidoderm from various sources including "The Motley Fool," the Philadelphia Inquirer, The Pharmaceutical Business Review, Reuters, Medical Marketing and Media, Drugs.com, and Newsinferno.com. (See Gov't's Mem. of Eligibility, at 15-16.)

[16]We note that the Government additionally presents evidence from Endo's 2007 SEC 10-k filing revealing that it had received the subpoena from HHS. Under 31 U.S.C. § 3730(e)(ii), the 10-k filing qualifies as a public disclosure as a federal report, and the subpoena qualifies under the federal investigation provision. See 31 U.S.C. § 3730(e)(ii).

Dhillon were "based upon" allegations set forth in the aforementioned public disclosures. "A '*qui tam* action is 'based upon' a qualifying disclosure if the disclosure sets out either the allegations advanced in the *qui tam* action or all of the essential elements of the *qui tam* action's claims.'" United States ex rel. Feldstein v. Organon, Inc., 364 F. App'x. 738, 742 (3d Cir. 2010) (quoting United States ex rel Mistick PBT v. Hous. Auth. of City of Pittsburgh, 186 F.3d 376, 388 (3d Cir. 1999)). However, the allegations asserted in the relator's complaint need not be "actually derived from" the publicly disclosed allegations to be considered as "based upon." Id. (quoting Atkinson, 473 F.3d at 519). Rather, they "need only be 'supported by' or 'substantially similar to' the disclosed allegations and transactions." Id. Where there is a "substantial identity" between the public disclosure and the allegations in the relator's complaint, a substantial similarity exists. Id. (quoting United States ex rel. Poteet v. Medtronic, Inc., 552 F.3d 503, 514 (6th Cir. 2009)).

Finally, because the disclosures predate the filing of individual *qui tam* actions by Weathersby and Dhillon, the Court will have to dismiss these actions for lack of jurisdiction unless either party can show that they were an original source. See 31 U.S.C. § 3730(e)(4)(B). An "original source" is 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 . . . which is based on the information." Id. In this context, the word "information" refers to the facts on which the relator's allegations are based, not the facts on which the publicly disclosed allegations or transactions of fraud are based. Zizic, 728 F.3d at (citing Rockwell Int'l Corp. v. United States, 549 U.S. 457, 470–72 (2007)).

It is evident from Dhillon's Complaint that the basic nature of his barebones allegations

qualify as "based upon" the allegations set forth in the public disclosures. Moreover, Dhillon is not an original source because he did not have any direct and/or independent knowledge as is required to escape the public disclosure bar. Thus, the public disclosure bar is triggered as to Dhillon's claims. The determination of whether the bar applies in Weathersby's case is much closer, but we find that the bar is not applicable. Upon review of Weathersby's Complaint, it is apparent that his claim is not "based upon" the allegations set forth in the public disclosures. Rather, as a sales representative employed by Defendants, Weathersby had direct and independent knowledge of Defendant's transgressions. Accordingly, we find that Weathersby's knowledge of Defendants' fraudulent conduct was not attributable to the public disclosures. See United States ex rel. Paranich v. Sorgnard, 396 F.3d 326, 338 (3d Cir. 2005).

D. Dhillon's Argument that Contract Law Applies

Attacking the other Relators' claims in a different manner, Dhillon argues that, at this post-settlement stage in the proceedings, contract law applies, and the only proper issue before the Court is the apportionment of settlement proceeds under 31 U.S.C. § 3730(d)(1). (See Dhillon Resp. at 2.) However, Dhillon neglects to cite to any instance where contract law prevailed over the specific provisions of the FCA in determining who to properly award in a *qui tam* action.[17] Instead, we are left to wade through an assortment of confusing and conclusory

[17]The only case Dhillon cites for the general proposition that contract law applies to the interpretation of *qui tam* settlement agreements is Simonian v. Irwin Industrial Tool Co., No. 10-1260, 2011 WL 147717 (N.D. Ill. Jan. 18, 2011). However, this case is distinguishable as it was a *qui tam* action under 35 U.S.C. § 292 for false marking patent infringement. Actions under § 292 are distinctive in that government intervention is severely restricted. See Hollander v. Ranbaxy Laboratories Inc., 804 F. Supp. 2d 344, 352 (E.D. Pa. 2011) (noting the differences between the FCA and § 292). Furthermore, Simonian was not decided within this Circuit, and therefore, is not precedential. See Camesi v. University of Pittsburgh Medical Center, 729 F.3d 239, 246 f.2 (3d Cir. 2013) (stating that decisions from outside this Circuit are not precedential within the Third Circuit).

contentions. Using our best efforts to interpret Dhillon's assertions, we find the arguments are without merit.

Dhillon raises several arguments that involve the interplay between 31 U.S.C. § 3730(d)(1), which permits the receipt of an award by a successful *qui tam* plaintiff, and the first-to-file rule and the public disclosure ban, which destroy a plaintiff's ability to recover such an award. Dhillon contends that these components are "irrelevant" because "no provision of the contract reserves any party the right to dismiss or challenge the Relator's right to a share of the proceeds." Id. at 3. We do not agree.

Dhillon's arguments posit that § 3730(d)(1) exists in a vacuum severed from the body of the FCA. However, it is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme. Davis v. Michigan Dept. of Treasury, 489 U.S. 803, 809 (1989). While Dhillon correctly concludes that the FCA provides for a "whistleblower" to receive an award for *qui tam* actions under § 3730(d)(1), Dhillon's argument incorrectly excludes the FCA's provision that this reward is contingent on the "whistleblower" qualifying as the first-to-file under §3730(b)(5) and not being proscribed by the public disclosure ban.[18] Without providing any relevant judicial precedent, Dhillon asks the Court to take a blind eye to the preclusion provisions of the FCA, and solely focus on the award. We do not believe Congress intended these components to act in isolation, and therefore, deny Dhillon's arguments to the contrary.

[18]As stated previously, the public disclosure ban divests the court of jurisdiction and mandates dismissal "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed" by any of several sources enumerated by statute. See 31 U.S.C.A. § 3730(e)(4)(A); see also United States ex rel. Repko v. Guthrie Clinic, P.C., 490 F. App'x 502, 504 (3d Cir. 2012).

Next, we reject Dhillon's contention that, under general contract principles, the Government, by assenting to paragraph 7 of the Settlement Agreement,[19] waived the right to challenge the awarding of the funds to the Relators. We are perplexed by this argument as paragraph 7 pertains solely to the reservation of claims by the Government. At this juncture in the proceedings, where the Court is solely focused on which party receives the award, the Government has not advocated on behalf of any one Relator. Rather, the Government has filed briefs to aid the Court in adjudicating which Relator is the proper recipient of the settlement award.

Finally, Dhillon argues that under the express terms of the Settlement Agreement, the parties had agreed that Ryan, Weathersby and Dhillon were collectively "Relators," and as such, were each entitled to a portion of the Relator's Share. This argument fails for multiple reasons. As an initial matter, Dhillon neglects to specify where in the Settlement Agreement there is any language that supports this conclusion. Furthermore, Dhillon's unfounded perception of the

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[19]Paragraph 7 of the Settlement Agreement, which refers to the reservation of claims by the Government, in its entirety states, "Notwithstanding the releases given in paragraph 2 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
b. Any criminal liability;
c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
e. Any liability based upon obligations created by this Agreement;
f. Any liability for express or implied warranty claims or other claims for defective and deficient products or services, including quality of goods and services;
g. Any liability for failure to deliver goods or services due;
h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; or
i. Any liability of individuals."

See Settlement Agreement, ¶ 7.

Settlement Agreement contradicts the express provisions and purpose of the FCA. At §3730(b)(5), the FCA contains a first-to-file rule, which provides that "[w]hen a person brings an action under this subsection, 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 underlying purpose of this rule is "to provide incentives to relators to 'promptly alert the government to the essential facts of a fraudulent scheme.'" United States ex rel. Wilson v. Bristol-Myers Squibb, Inc., No. 13-1948, 2014 WL 1688934, at *4 (1st Cir. Apr. 30, 2014) (quoting United States ex rel. Duxbury v. Ortho Biotech Products, L.P., 579 F.3d 13, 24 (1st Cir. 2009)). In context of this objective, it is apparent that allowing multiple relators to share in the recovery for the same claim would drastically decrease the incentive for a "whistleblower" to promptly bring a *qui tam* action. See LaCorte, 149 F.3d at 234. The logical conclusion from the FCA's inclusion of the first-to-file rule is that Congress intended only one relator to prevail for each claim. Here, Ryan filed first, and the allegations raised in her Amended Complaint encompassed all of the underlying FCA infringing conduct perpetrated by Defendants that formed the basis for the Settlement Agreement. Therefore, the claims raised by Weathersby and Dhillon are precluded, and Ryan is the sole Relator eligible to receive the award. See 31 U.S.C. § 3730(b)(5).

E. Dhillon's Statute of Limitations and/or Laches Argument

Dhillon also argues that Ryan's and Weathersby's claims are barred by the applicable statute of limitations and/or the doctrine of laches because they did not move forward with their actions as individuals after the Government failed to do so within three years and sixty days. (See Dhillon Resp. at 18.)

Dhillon's laches argument fails for two reasons. First, "laches generally does not apply when a claim is brought at law, that is only for monetary damages." United States ex rel. Spay v. CVS Caremark Corp., No. 09-4672, 2013 WL 1755214, at *9 (E.D. Pa. Apr. 24, 2013) (quoting United States ex rel. Kusner v. Osteopathic Med. Ctr. of Phila., No. 88–9753, 1996 WL 287259, at *6 (E.D. Pa. May 30, 1996)). Because the FCA does not provide for injunctive or other equitable relief and the Complaints in this action seek only monetary damages, laches cannot apply. Id. Second, where a claim is subject to a statute of limitations, laches usually is not applicable. Id. (finding that the FCA's six year statute of limitations precludes laches from barring an otherwise timely claim). Thus, we hold that Dhillon's attempt to employ the doctrine of laches to be inappropriate in this case.

Furthermore, the statute of limitations does not bar Ryan's suit. Under the FCA, "a civil action under § 3730 may not be brought . . . more than 6 years after the date on which the violation of § 3729 is committed." 31 U.S.C. 3731(b)(1). Lidoderm first became available in September of 1999, and Ryan filed her initial Complaint on July 5, 2005. (See Ryan Compl. ¶ 15.) Under the unlikely assumption that a false claim was filed on the earliest possible date, September 1, 1999, the statute of limitations would have allowed Ryan to file her Complaint on or until September 1, 2005. Ryan filed her initial Complaint on July 5, 2005, which clearly falls within the applicable statute of limitations.

IV. CONCLUSION

For the aforementioned reasons, we hold that Ryan is the sole Relator eligible to receive a share of the award pursuant to 31 U.S.C. § 3730(d)(1). Our conclusion relies upon the recent Third Circuit decision in Foglia, and serves to promote the intent of the FCA. Furthermore, as a

practical matter, we believe this result is further justified by the extensive role Ryan played in procuring the settlement with Defendants. (See Ryan's Resp. to Gov't's Mem. on the Eligibility of Relators, Ex. A.) The FBI investigation was initiated after Ryan filed the first Complaint in 2005. Id. This occurred five years before Weathersby filed the next Complaint. After alerting the FBI, Ryan played an instrumental role in the investigation until the Settlement Agreement was reached in 2014. Id. Overall, the primary purpose of a *qui tam* complaint is to provide the Government notice of the need to investigate a particular scheme. United States ex rel. Galmines v. Novartis Pharmaceuticals Corp., 2013 WL 2649704, at *10 (E.D. Pa. June 13, 2013) (citing United States ex rel. Folliard v. Synnex Corp., 798 F. Supp. 2d 66, 71 (D.D.C. 2011)). In this case, Ryan supplied the Government with the initial notification of Defendants' fraudulent activities and then proceeded to go to extraordinary lengths to provide further information to aid the Government in prosecuting the FCA action. In light of this contribution and the legal justifications presented by Ryan, it is our holding that Ryan is the sole Relator eligible to receive the settlement award.

An appropriate Order follows.