445 F.Supp.3d 786 (2020)

UNITED STATES of America, EX REL. Frank SOLIS, Plaintiff,

v.

MILLENNIUM PHARMACEUTICALS, INC., Schering-Plough Corp., and Merck & Co., Defendants.

No. 2:09-cv-03010-MCE-EFB.

United States District Court, E.D. California.

Signed March 31, 2020.
Filed April 1, 2020.

789 *789 C. Brooks Cutter, John R. Parker, Jr., Cutter Law, P.C., Catherine J. Swann, Govt, United States Attorney's Office, Sacramento, CA, Jay D. Majors, U.S. Department of Justice, Washington, DC, for Plaintiff.

Sean Ashley Commons, Sidley Austin, LLP, Los Angeles, CA, James Marvin Perez, California Institute of Technology, Pasadena, CA, McGregor Scott, Orrick, Herrington & Sutcliffe LLP, Sacramento, CA, Paul Kalb, PHV, Pro Hac Vice, Sidley Austin LLP, Jonathan R. Ference-Burke, Ropes & Gray LLP, Washington, DC, John P. Bueker, PHV, Ropes & Gray LLP, Boston, MA, for Defendants.

MEMORANDUM AND ORDER

MORRISON C. ENGLAND, JR., UNITED STATES DISTRICT JUDGE.

This lawsuit was originally filed under seal on November 4, 2009, pursuant to the qui tam provisions of the Federal False Claims Act, 31 U.S.C. §§ 3729, et seq. ("FCA") The Defendants, who are pharmaceutical companies, include Millennium Pharmaceuticals, Inc., Schering-Plough Corp., and Merck & Co. ("Defendants" unless otherwise indicated). The so-called "Relator" plaintiff, Frank Solis, ("Relator" or "Plaintiff") a former sales employee who at various points worked for all three Defendants, claims that the companies fraudulently marketed and/or promoted the use of two drugs, Integrilin and Avelox. Relator alleges that Defendants promoted so-called "off label" uses for Integrilin not approved by the Food and Drug Administration ("FDA"). In so doing, according to Relator, Defendants "caused" physicians to improperly prescribe the drugs and to submit false claims to Medicare, Medicaid and TRICARE (United States Military Healthcare) for federal reimbursement which the government allegedly paid without knowing
790 the claims were ineligible for reimbursement. In addition, Relator alleges that Defendants paid illegal *790 kickbacks to entice physicians to prescribe the drugs. Following a three-year investigation, the United States and all twenty-four states named in the initial complaint chose not to intervene, and Relator's Complaint was subsequently unsealed on December 20, 2012.

Presently before the Court are Motions brought by Defendants Schering-Plough Corp. and Merck & Co., Inc, (collectively "Schering") and Defendant Millennium Pharmaceuticals, Inc. ("Millennium"). ECF Nos. 195, 199. Both Motions are brought pursuant to Federal Rule of Civil Procedure 12(b)(1)[1] and allege this Court lacks subject-matter jurisdiction over Relator's allegations, as set forth in his operative Third Amended Complaint ("TAC"). Defendants contend that Relator's Integrilin-related allegations as to both off-

label promotion and kickbacks are barred by the FCA's public disclosure bar (which divests federal courts of jurisdiction where the alleged fraud has already been publicly disclosed) since Relator cannot qualify as an "original source" as to those allegations. 31 U.S.C. § 3730(e)(4). In addition, by way of a separate Motion to Dismiss, Defendant Schering argues that Relator's allegations as to the improper promotion of Avelox also fail to state a viable claim under Rule 12(b)(6) or to allege fraud with the requisite particularity under Rule 9(b).

As set forth below, Defendants' Motions under Rule 12(b(1) are GRANTED because Relator has not shown he is an original source as to the allegations at issue. Because the Court consequently concludes that it has no jurisdiction over Relator's claims, Defendants' concurrently filed additional motions challenging the TAC are DENIED[2] as moot except for Defendant Schering's Motion to Dismiss under Rule 9(b), which is GRANTED since Relator's allegations with respect to the fraudulent promotion of Avelox remain insufficient. [3]

FACTUAL BACKGROUND

Integrilin helps reduce blood clots and thereby helps to prevent heart attacks and death in patients suffering from acute coronary syndrome ("ACS"). ACS is an umbrella term that covers a variety of diseases related to clotting in the coronary arteries that supply blood to the heart muscle, including unstable angina, mild heart attacks known as non-ST-segment elevation myocardial infarctions, and more severe heart attacks called ST-segment elevation myocardial infarctions ("STEMI"). Avelox, on the other hand, is an antibiotic approved by the FDA for treating adult patients with infections caused by a few susceptible strains of microorganisms.

With respect to Integrilin, FDA approval was first obtained in May 1998 by a company named COR Therapeutics, Inc. ("COR"), which thereafter promoted the drug along with Defendant Schering-Plough. In February of 2002, Defendant Millennium acquired COR and thereby obtained the right to co-promote
791 Integrilin. *791 In September of 2005, Defendant Millennium transferred its right to market Integrilin within the United States to Defendant Schering-Plough, thereby relinquishing any responsibility for the drug after a period of less than four years. Schering-Plough later merged with Merck in November of 2009 to form a new company, also known as Merck.

Relator Solis was a pharmaceutical sales representative for Millennium covering the Los Angeles area between July 2003 and September of 2005. At that time he transitioned to employment for Schering-Plough. Then, in November of 2009, after the Schering/Merck merger, he became a Merck sales representative. Relator was terminated by Merck on March 9, 2010.

Relator's operative TAC alleges that Defendants promoted improper uses of Integrilin, including its early use for STEMI patients, despite the fact that such early use is "extremely dangerous, off-label and fraudulent." TAC, ¶¶ 5, 11. Relator further claims that Defendants violated the so-called Anti-Kickback Statute ("AKS"), which prohibits a drug company from knowingly and willfully offering or paying remuneration to purchase goods or services for which payment may be made by a federal healthcare program. See 42 U.S.C. § 1320a-7(b)(2)(B). Relator alleges that Defendants violated the AKS by "funnel[ing] millions of dollars" in grants, honoraria, and meals to physicians in order to induce Integrilin prescriptions and to drive "off label" sales, all in violation of the AKS. See TAC, ¶¶ 7-8.[4]

While most of the TAC focuses on allegations pertaining to the use and promotion of Integrilin, Relator also includes more limited averments concerning Avelox, which Schering marketed and Relator claims he also promoted. Id. at ¶ 32. Those allegations are based solely on alleged kickbacks; no off-label claims pertaining to Avelox are asserted.

PROCEDURAL HISTORY

As indicated above, Relator's initial lawsuit was filed on November 4, 2009. After a three-year investigation, the United States and the twenty-four states named in the initial complaint chose not to intervene, and Relator's complaint was unsealed on December 20, 2012.

In response to earlier Motions to Dismiss filed on behalf of each of the Defendants, Relator filed a First Amended Complaint ("FAC") on June 27, 2013. The viability of Plaintiff's FAC was attacked through three separate motions. Defendant Schering filed a Motion to Dismiss for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1) on grounds that Relator's complaint was barred by the FCA's so-called "public disclosure" limitation. Defendant Millennium subsequently joined in that motion. Additionally, two other motions, one filed jointly by Schering and Merck and the other by Millennium, argued that the various causes of action pled in the FAC were substantively deficient in contravention of Rule 12(b)(6). By Memorandum and Order filed March 26, 2014 (ECF No. 105), this Court granted Defendants' Rule 12(b)(1) motion agreeing that the public disclosure bar applied to Relator's "combination use" allegations. Because Relator's FAC contained other allegations beyond combination use, however, including assertions pertaining to a completely different drug, Avelox, as well as allegations of fraud, improper billing, and
792 impermissible kickbacks, the Court permitted Relator to file a Second Amended Complaint *792 ("SAC") omitting the combination use allegations.[5]

Relator's SAC was also met by motions to dismiss. The Court again granted Millennium's motion to dismiss for lack of subject matter jurisdiction and denied as moot Millenium's concurrently filed dismissal request under Rules 12(b)(6) and 9(b). See March 26, 2015 Mem. and Order, (ECF No. 157) at 15. It held that both the kickback and off-label claims brought under federal law were substantially similar to allegations first raised in civil actions filed in 2007. Id. at 11-15. The Court further found that Relator was not an "original source" so as to escape the FCA's public disclosure bar as to those allegations because he "presented no evidence that he `had a hand' in the prior 2007 litigation." Id. at 15. Finally, the Court dismissed Relator's state law claims through application of the same analysis and because the Court declined to exercise supplemental jurisdiction over the state law claims in any event." Id. at 16. Although the Court denied Schering's initial motion under Rules 12(b)(6) and 9(b) challenging the SAC (Mar. 30, 2015 Mem. and Order, ECF No. 158), it ultimately dismissed Relator's claim against Schering following a subsequently filed Rule 12(b)(6) motion, ruling that the prior public disclosures were "equally applicable" to both Schering and Millennium, and that consequently Schering's dismissal was proper for the same reasons set forth in the Court's earlier March 26, 2015 Memorandum. Sept. 1, 2015 Mem. and Order, ECF No. 164.

Relators appealed from the Rule 12(b)(1) dismissal of his claims, and Defendants cross-appealed the Court's denial of their substantive motions to dismiss. On March 15, 2018, the Ninth Circuit affirmed in part and vacated in part, remanding the case with instructions. United States ex rel. Solis v. Millennium Pharm., Inc. ("Solis"), 885 F.3d 623 (2018). The Ninth Circuit affirmed this Court's determination that Relator's claims as to Integrilin were "substantially similar to those in ... prior public disclosures" and found that they were then precluded by the FCA's public disclosure bar unless Relator can show he qualified as an "original source" of the claims. Id. at 627. Although this Court had found that Relator did not so qualify, the Ninth

Circuit pointed out that intervening circuit law had in fact undercut the basis for that determination by repudiating an earlier recognized requirement that the Relator must have "had a hand" in the disclosure in order to qualify for the original source exception to the public disclosure bar. Id. at 628, citing United States ex rel. Hartpence v. Kinetic Concepts, Inc., 792 F.3d 1121, 1129 (9th Cir. 2015) (en banc). Consequently, the Ninth Circuit remanded for consideration of whether Relator had satisfied the original source test as articulated in Hartpence, which requires, in pertinent part, that Relator have "direct and independent knowledge" of the information on which his allegations are based in order to qualify as an additional source. Moreover, with regard to Relator's Avelox claims, while the Ninth Circuit rejected the notion that those claims had been previously disclosed, it nonetheless affirmed dismissal of the Avelox allegations under Rule 9(b), finding that Relator had failed to plead them with the requisite particularity. Id. at 629. The Ninth
793 Circuit's decision instructed *793 this Court to decide upon remand whether leave to amend should be permitted so as to give Relator another opportunity to make viable allegations concerning Avelox.

Following remand of the matter this Court held a Status Conference on April 4, 2019, at which time it directed Relator to file a TAC. Relator's TAC alleges causes of action for false claims based on the AKS (Counts One and Two), false claims for causing the submission of off-label billings (Counts Three and Four), and false claims for the fraudulent promotion of Integrilin (Count Five). Plaintiff's claims are all rooted in the federal FCA, but additional causes of action based on corresponding state law statutory provisions are also made on behalf of both California (Count Six) and twenty-seven other states (Counts Eight through Thirty-Two).[6]

Although counsel for Relator indicated during the Status Conference that the Avelox claims would not be pursued, the May 10, 2019, TAC continues to make Avelox related claims stemming from alleged kickbacks, albeit with a few additional allegations to remedy the earlier deficiencies identified by the Ninth Circuit. Relator also attempts to augment allegations pertaining to his own knowledge of Defendant's alleged fraudulent activities in order to shore up his claim that he qualifies as an "original source" of those allegations.

STANDARD

A. Dismissal under Rule 12(b)(1)

Federal courts are courts of limited jurisdiction and are presumptively without jurisdiction over civil actions. Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375, 377, 114 S.Ct. 1673, 128 L.Ed.2d 391 (1994). The burden of establishing the contrary rests upon the party asserting jurisdiction. Id. Because subject matter jurisdiction involves a court's power to hear a case, it can never be forfeited or waived. United States v. Cotton, 535 U.S. 625, 630, 122 S.Ct. 1781, 152 L.Ed.2d 860 (2002). Accordingly, lack of subject matter jurisdiction may be raised by either party at any point during the litigation, through a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(1). Arbaugh v. Y & H Corp., 546 U.S. 500, 506, 126 S.Ct. 1235, 163 L.Ed.2d 1097 (2006); see also Int'l Union of Operating Eng'rs v. Cnty. of Plumas, 559 F.3d 1041, 1043-44 (9th Cir. 2009). Lack of subject matter jurisdiction may also be raised by the district court sua sponte. Ruhrgas AG v. Marathon Oil Co., 526 U.S. 574, 583, 119 S.Ct. 1563, 143 L.Ed.2d 760 (1999). Indeed, "courts have an independent obligation to determine whether subject matter jurisdiction exists, even in the absence of a challenge from any party." Id.; see Fed. R. Civ. P. 12(h)(3) (requiring the court to dismiss the action if subject matter jurisdiction is lacking).There are two types of motions to dismiss for lack of subject matter jurisdiction: a facial attack, and a factual attack. Thornhill Publ'g Co. v. Gen. Tel. & Elec.

Corp., 594 F.2d 730, 733 (9th Cir. 1979). Thus, a party may either make an attack on the allegations of jurisdiction contained in the nonmoving party's complaint, or may challenge the existence of subject matter jurisdiction in fact, despite the formal sufficiency of the pleadings. Id.

When a party makes a facial attack on a complaint, the attack is unaccompanied by supporting evidence,
794 and it challenges jurisdiction based solely on the pleadings. Safe Air for Everyone v. Meyer, *794 373 F.3d 1035, 1039 (9th Cir. 2004). If the motion to dismiss constitutes a facial attack, the Court must consider the factual allegations of the complaint to be true, and determine whether they establish subject matter jurisdiction. Savage v. Glendale High Union Sch. Dist. No. 205, 343 F.3d 1036, 1039 n.1 (9th Cir. 2003). In the case of a facial attack, the motion to dismiss is granted only if the nonmoving party fails to allege an element necessary for subject matter jurisdiction. Id. However, in the case of a factual attack, district courts "may review evidence beyond the complaint without converting the motion to dismiss into a motion for summary judgment." Safe Air for Everyone, 373 F.3d at 1039.

In the case of a factual attack, "no presumptive truthfulness attaches to plaintiff's allegations." Thornhill, 594 F.2d at 733 (internal citation omitted). The party opposing the motion has the burden of proving that subject matter jurisdiction does exist, and must present any necessary evidence to satisfy this burden. St. Clair v. City of Chico, 880 F.2d 199, 201 (9th Cir. 1989). If the plaintiff's allegations of jurisdictional facts are challenged by the adversary in the appropriate manner, the plaintiff cannot rest on the mere assertion that factual issues may exist. Trentacosta v. Frontier Pac. Aircraft Ind., Inc., 813 F.2d 1553, 1558 (9th Cir. 1987) (quoting Exch. Nat'l Bank of Chi. v. Touche Ross & Co., 544 F.2d 1126, 1131 (2d Cir. 1976)). Furthermore, the district court may review any evidence necessary, including affidavits and testimony, in order to determine whether subject matter jurisdiction exists. McCarthy v. United States, 850 F.2d 558, 560 (9th Cir. 1988); Thornhill, 594 F.2d at 733. If the nonmoving party fails to meet its burden and the court determines that it lacks subject matter jurisdiction, the court must dismiss the action. Fed. R. Civ. P. 12(h)(3).

A court granting a motion to dismiss a complaint must then decide whether to grant leave to amend. Leave to amend should be "freely given" where there is no "undue delay, bad faith or dilatory motive on the part of the movant,... undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of the amendment...." Foman v. Davis, 371 U.S. 178, 182, 83 S.Ct. 227, 9 L.Ed.2d 222 (1962); Eminence Capital, LLC v. Aspeon, Inc., 316 F.3d 1048, 1052 (9th Cir. 2003) (listing the Foman factors as those to be considered when deciding whether to grant leave to amend). Not all of these factors merit equal weight. Rather, "the consideration of prejudice to the opposing party ... carries the greatest weight." Id. (citing DCD Programs, Ltd. v. Leighton, 833 F.2d 183, 185 (9th Cir. 1987)). Dismissal without leave to amend is proper only if it is clear that "the complaint could not be saved by any amendment." Intri-Plex Techs. v. Crest Group, Inc., 499 F.3d 1048, 1056 (9th Cir. 2007) (citing In re Daou Sys., Inc., 411 F.3d 1006, 1013 (9th Cir. 2005); Ascon Props., Inc. v. Mobil Oil Co., 866 F.2d 1149, 1160 (9th Cir. 1989) ("Leave need not be granted where the amendment of the complaint...constitutes an exercise in futility....").

B. Pleading Fraud Claims

Rule 9(b) requires that "in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. To meet the requisite particularity standards on a case like the present one, which asserts claims under the federal FCA, Relator's allegations must be accompanied by the "who,
795 what, when, where, and how of the misconduct charged." Ebeid ex rel. U.S. v. Lungwitz, *795 616 F.3d 993, 998 (9th Cir. 2010) (quoting Vess v. Ciba-Geigy Corp., U.S., 317 F.3d 1097, 1106 (9th Cir. 2003)). In the

Ninth Circuit, "it is sufficient to allege `particular' details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were also submitted." Ebeid, 616 F.3d at 998-99.

ANALYSIS

A. The "Public Disclosure" Bar: Initial Considerations

If a public disclosure has occurred and the Relator cannot qualify as an "original source" of the false claim allegations, this Court lacks jurisdiction under the FCA over the previously disclosed allegations. See Rockwell Int'l Corp. v. United States, 549 U.S. 457, 472-73, 127 S.Ct. 1397, 167 L.Ed.2d 190 (2007); United States ex rel. Meyer v. Horizon Health Corp., 565 F.3d 1195, 1199 (9th Cir. 2009). This "public disclosure" bar seeks to "strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits" in which "opportunistic plaintiffs who have no significant information to contribute of their own" seek to collect a share of the government's recovery. Graham Cnty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson, 559 U.S. 280, 295, 130 S.Ct. 1396, 176 L.Ed.2d 225 (2010).

By its Memorandum and Order filed March 26, 2014, (ECF No. 105) this Court determined that the statutory bar in effect at the time Relator's initial complaint was filed on November 4, 2009, governs here. As amended in 2006, that public disclosure bar precludes jurisdiction over a qui tam action "based upon" previously disclosed allegations, unless the party bringing the action qualifies as an "original source of the information already disclosed:

> No court shall have jurisdiction over an [FCA qui tam] action ... based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A) (2006) (emphasis added).

The 2006 statute goes on to define the term "original source" as follows:

> 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.

Id. at § 3730(e)(4)(B) (2006).

B. The Original Source Exception

As indicated above, by Memorandum and Order dated March 26, 2015, this Court determined that a public disclosure occurred. Therefore, Plaintiff can avoid the jurisdictional bar posed by public disclosure only upon a showing that he is an "original source" as defined by the statute and case law. A-1 Ambulance Ser., Inc. v. California, 202 F.3d 1238, 1243 (9th Cir. 2000) (under a two-part test, a court need only address the original source issue if it first determines a prior public disclosure has occurred). Relator bears the burden of establishing that he qualifies as an original source. See United States ex rel. Harshman v. Alcan Elec. &

Eng'g, Inc., 197 F.3d 1014, 1018 (9th Cir. 1999) (holding that a relator bears the burden of establishing
796 subject matter jurisdiction, including *796 whether he is an "original source" under the statute).

Ninth Circuit law makes it clear that to qualify as an original source, Relator must demonstrate (1) "direct and independent knowledge" of the information on which his allegations rest; and (2) that he "voluntarily provided" that information to the government before filing his action. Hartpence, 792 F.3d at 1128.[7] In order to show the requisite direct knowledge, Relator must demonstrate "firsthand knowledge of the alleged fraud, and that he obtained this knowledge through his `own labor unmediated by anything else.'" Harshman, 197 F.3d at 1020; United States ex rel. Aflatooni v. Kitsap Physicians Servs., 163 F.3d 516, 524-25 (9th Cir. 1999). Former employment with a defendant does not automatically make a Relator an original source with direct knowledge of fraudulent behavior alleged to have occurred while Relator was employed. See, e.g., United States ex rel. Bly-Magee v. Premo, 470 F.3d 914, 917 (9th Cir. 2006) (rejecting as insufficient mere fact of employment as executive director absent "specifics"); Harshman, 197 F.3d at 1021 (rejecting argument that "status as a member of the union" sufficed to show direct knowledge); United States v. Scan Health Plan, No. CV 09-5013, 2015 WL 12778776 at *7 and n. 9 (rejecting assertion that everything "learned during the course of [a relator's] employment ... constitutes `direct knowledge'" as "contrary" to "Ninth Circuit authority").

To the contrary, courts have made it clear that a former employee does not qualify as an original source absent direct knowledge of instances where a defendant caused a false claim to be submitted. See, e.g., Harshman, 197 F.3d at 1021 (holding relator failed to satisfy his burden in proving original source status, explaining that that relator did "not allege that he played any role in submitting false claims to the government"); United States ex rel. Green v. Serv. Contract Educ. & Training Trust Fund, 843 F. Supp. 2d 20, 36 (D.D.C. 2012) (finding original source averments lacking where relator "ha[d] not pled that he observed first-hand the pay vouchers or supporting documentation allegedly submitted"). Relators must possess first-hand knowledge that "make[s] a genuinely valuable contribution to the exposure of the alleged fraud." United States ex rel Devlin v. California, 84 F.3d 358, 362 (9th Cir. 1996).[8] Moreover, particularly given the presumption against federal jurisdiction, conclusory allegations will not suffice. See. e.g., Bly-Magee, 470 F.3d at 917 (affirming dismissal despite "lengthy explanation of [relator's] involvement" and former employment where allegations made were "short of specifics"); United States ex rel. Casady v. Am. Int'l Grp., Inc., No. 10CV0431, 2013 WL 1702777 at * 5 (S.D. Cal. 2013) (finding no direct knowledge where allegations made only in a "conclusory fashion"); Scan Health Plan, 2015 WL 12778776 at * 6 (conclusory statements or allegations" insufficient for purposes of satisfying original source requirement). Instead, Relator must demonstrate facts that, if accepted as true, show that he is an original source by a
797 preponderance of the *797 evidence. Aflatooni, 163 F.3d at 525; United States ex rel. Hastings v. Wells Fargo Bank, N.A., No. CV 12-03624, 2014 WL 3519129 at * 7 (C.D. Cal. July 15, 2014); aff'd, 656 F. App'x 328 (9th Cir. 2016).

C. Whether Relator Qualifies as an Original Source

With this background in mind, the Court looks to what Relator claims he knew concerning the submission of fraudulent claims as a result of Defendants' purported misconduct. The focus must necessarily be on his knowledge concerning the improper claims themselves since that is the relevant inquiry: "the FCA `attaches liability, not to the underlying fraudulent conduct or to the government's wrongful payment, but to the claims for payment.'" United States ex rel. Kelly v. Serco, Inc., 846 F.3d 325, 333 (9th Cir. 2017) (quoting United states ex rel. Cafasso v. Gen. Dynamics C4 Sys., Inc., 637 F.3d 1047, 1055 (9th Cir. 2011). As the Ninth

Circuit has observed, "[i]t is not enough ... `to describe a [fraudulent scheme] in detail but then to allege simply and without any stated reason ... that claims requesting illegal payments must have been submitted.'" Id. at 1058 quoting United States ex rel. Clausen v. Laboratory Corp. of America, Inc., 290 F.3d 1301, 1311 (11th Cir. 2002).

Relator points to various steps taken by Defendants while he was employed as a sales representative to support the fraudulent practices he alleges. He claims he "lived through the fraud" by speaking with other sales employees as well as physician clients during the period of his employment with Defendants. Omnibus Opp., ECF No. 204: 3:27-4:1. As indicated above, however, the mere fact of employment is not enough absent direct knowledge of instances where a qui tam defendant caused a false claim to be submitted. Harshman, 197 F.3d at 1021. Nor can conversations with third parties establish direct knowledge. Moreover, while Relator points to his participation "in regular company training events" as well as "national and sales training conferences" at which he purportedly received "training, communications and feedback" geared towards his participation in the fraud he alleges," and while he claims those activities "clearly establish" a basis for his direct and independent knowledge of Defendants' sales scheme (see Omnibus Opp., 2:22-27), knowledge of a sales scheme is insufficient for purposes of qualifying as an original source unless Relator can also show that actual fraudulent claims were submitted as a result of the scheme. Mr. Solis has failed to set forth any such claims here. Finally, Relator's identification of aspirational business plans enumerating sales objectives for Integrilin use also do not suffice in the absence of any showing that those plans were actually executed, let alone that Relator had any role in such execution or caused any false claims to be sumitted as a result. See TAC, ¶¶ 68, 124.

Given the foregoing, this case is analogous to Aflatooni, where a former employer alleged that defendants submitted false claims to Medicare for treatment and services that were not performed or were unnecessary. 163 F.3d at 519-20, 525. The relator in that case simply claimed, much as Mr. Solis does here, that he was an original source simply "[b]y virtue of his position" as a treating physician at a facility operated by one of the defendants where he discovered that "over 50 percent of Medicare radiology claims" were missing information about the referring physician." Id. at 525. The Ninth Circuit found these allegations insufficient to qualify as an original source since the relator could not identify any specific patient charged for unnecessary medical services. Id. at 526. Without such information, the relator could not
798 demonstrate knowledge of the *798 defendant's "involvement in the submission of false Medicare claims." Id.

Also on point is United States ex rel. Meyer v. Horizon Health Corp., 565 F.3d 1195 (9th Cir. 2009). There the Ninth Circuit found that two nurses did not qualify as original sources where they had no "direct access" to the fraudulent invoices occasioned by a patient who allegedly could not benefit from the care for which charges were being submitted. Id. at 1205. In upholding dismissal under Rule 12(b)(1), the Ninth Circuit held that there was "an important distinction" between "kn[owing] about alleged fraud" and demonstrating "direct and independent knowledge of [defendants'] alleged fraudulent billing ..." Id. at 1202. As Defendant Millenium points out, "not all knowledge equates to "direct and independent" knowledge sufficient to qualify as an original source." Def. Millennium's Mot., ECF No. 195, 9:11-12.

It is therefore clear that the Relator in this case cannot simply rely upon the fact of his employment and must instead point to specific facts demonstrating his direct and independent knowledge of fraudulent behavior. He has failed to do so. Turning first to his off-label allegations, Relator makes no real attempt to show his own involvement in the fraudulent scheme so as to show his direct and independent knowledge of the scheme, let alone whether he had knowledge of actual claims submitted because of the fraud. Indeed, his best argument is that Schering's Medical Science Liaison ("MSL") provided letters and material which

summarized publicly available studies about off-label use of Integrilin in combination with other drugs. TAC, ¶¶ 51-58. Relator claims that MSL letters also provided physicians with reprints of scientific studies published in medical journals between 2001 and 2008 that discussed improper off-label "early use of Integrilin." See id. at 77-79. He does not allege, however, that he had any personal role in preparing those letters, and he does not even identify any specific doctors to which they were directed.

Moreover, even assuming Plaintiff had the requisite direct and independent knowledge of these activities, he concedes that is was only later studies published in 2009 that called into question the reasoning of that prior research. Consequently, the alleged "falsity" of those earlier studies was, at best, only apparent in hindsight. This is insufficient. "[A]n actual false claim is the sine qua non of a[n FCA] violation." Cafasso, 637 F.3d at 1055. Importantly, with respect to dissemination of false information after the 2009 studies were published, only two paragraphs contend that such practices, continued, and both of those allegations are made only on "information and belief,"[9] probably because Relator ceased his employment with Defendants in March of 2010, shortly after the 2009 studies were published.

Additionally, whether a use is on- or off-label is not dispositive of whether Medicare properly reimburses providers in any event; the salient issue is instead whether treatment is "reasonable and necessary for the diagnosis or treatment" of an illness." 42 U.S.C. § 1395y(a)(1)(A). Relator's TAC, however, sweepingly alleges that "bills for Integrilin ... were ineligible for reimbursement under Medicaid and Medicare because
799 the drugs were used for *799 off-label purposes." TAC ¶ 45. As Defendants point out, that is incorrect. The FDA itself has "long recognized that in certain circumstances, new (off-label) uses are appropriate, rational, and accepted medical practices." Schering Mot., ECF No. 200, 12:2-6, citing Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices, 63 Fed. Reg. 31,143, 31,153 (June 8, 1998) (codified at 21 C.F.R. pts. 16, 99). The FDA accordingly protects certain off-label use by physicians as "not merely legitimate but important to the practice of medicine." Carson v. Depuy Spine, Inc., 365 F. App'x 812, 815 (9th Cir. 2010). There must be allegations that distinguish between bona fide prescribing decisions for off-label use and improper use. U.S. ex re. Rost v. Pfizer, 253 F.R.D. 11, 16-17 (D. Mass. 2008) (alleging off labels marketing as criminal "is not sufficient, without more, to plead a false claims act violation").

Relator's TAC is silent as to this crucial distinction, since he seemingly characterizes all off-label use and promotion as fraudulent. He assumes that Defendants' off-label promotion of Integrilin, for example, would necessarily "cause hospitals to submit false claims to Medicare, Medicaid, and TRICARE." Omnibus Opp., 6:23-25. That sweeping characterization cannot carry the day. Without showing direct and independent knowledge of an actual false claim being made as a result of such activities, Relator cannot qualify as an original source. Speculation that a false claim "must have been submitted" as a result of Defendant's activities cannot suffice.

In addition to these off-label allegations, Relator thus further alleges that Defendants provided kickbacks to physicians in connection with Integrilin and Avelox. In support of his sweeping allegation that Defendants "illegally provided monetary and other incentives for physicians who were willing to prescribe the drugs" (TAC, ¶ 15), Relator primarily points to meals allegedly paid for by Defendants, as well as some speaker fees and travel expenses provided to those physicians. Relator exhaustively lists at least twenty separate and specific meals which he claims were kickbacks to doctors prescribing Integrilin and Avelox.

Again, however, Relator does not identify payments that were actually intended to, or did, induce doctors to prescribe Integrilin. At most, Relator alleges that the "dramatic increase in Integrilin prescriptions at hospitals with a large number of Medicare and Medicaid patients that Defendants specifically targeted

creates a highly plausible inference that the government reimbursed claims that were the direct results of kickbacks, or were influenced by improper marketing." ECF No. 204 at p.15. However, Relator provides no factual support for that conclusory statement. Indeed, nowhere does the TAC allege that attendees at the events hosted by Defendants were actually asked, or agreed, to use Integrilin as a quid pro quo. Relator fails to identify even a single claim submitted by anyone who attended the meals hosted by Defendants. Indeed, the TAC fails to, at the very least, specifically allege that those meals themselves had any concrete effect on physicians' prescribing practices for Integrilin. To the contrary, Relator concedes that the physicians who attended those meals had already prescribed Integrilin extensively before the meals alleged.

Paying for a client's meals in order to strengthen business relationships is, in and of itself, hardly an unusual sales strategy. Relator consequently provides no indicia, much less reliable indicia, that could give
800 rise to a strong inference that claims for Integrilin were submitted to the government *800 as a result of an unlawful quid pro quo arrangement between Defendants and any of the medical professionals attending the events they hosted. More specifically, Relator makes no showing that he played any independent role either in formulating a fraudulent promotion scheme or, more critically, in knowing that the scheme actually resulted in false claims. Without such showing Relator cannot qualify as an original source. He simply cannot sweepingly assert that such activities must necessarily have resulted in false claims when none have been identified. As the court in Aflatooni made clear, Relator must point to "information, as opposed to speculation" concerning the submission of false claims. Aflatooni, 163 F.3d at 526. Given the many opportunities the Court has granted Relator, he apparently cannot do so.

Like the relators in Meyer and Aflatooni, the Relator here has not identified even a single instance of a false claim for reimbursement allegedly caused by Defendants. As in Aflatooni, Relator does not provide "the name of any [M]edicare patient who was allegedly charged for" an Integrilin prescription purportedly caused by off-label promotion or kickbacks allegedly received from Defendants. Id. at 526. And, as in Meyer, Relator does not allege that he ever personally observed "allegedly fraudulent billing" by a physician due to such off-label promotion or kickbacks. 565 F.3d at 1198-99, 1202. While Relator does set forth conclusory allegations that the TAC rests "entirely upon [his] personal observations" and that those allegations "were not learned through external public disclosures" (TAC, ¶ 33), he offers little beyond such broad and unsubstantiated declarations to support his claims. That is insufficient. See Bell Atl. Corp v. Twombly, 550 U.S. 544, 545, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007) (holding mere "labels and conclusions" or "a formulaic recitation of a cause of action's elements" as insufficient).

To reiterate, there is "an important distinction" between "kn[owing about alleged fraud" and demonstrating "direct and independent knowledge of `defendants' allegedly fraudulent billing", which is necessary to qualify as an original source. Meyer, 565 F.3d at 1198-1292 (overturned on other grounds by Hartpence, supra); see also Aflatooni, 163 F.3d at 525. Relator must do more than simply provide a "lengthy explanation of [his] involvement" while employed by Defendants; he must supply specifics to prove his direct and independent knowledge of actual false claims. Bly-Magee, 470 F.3d at 917. Instead here, Relator provides no specifics about his purported direct and independent knowledge of actual false claims for reimbursement. His bid for original source status accordingly still falls short.

This is four times in over ten years that Relator has been given the opportunity to plead these fundamental jurisdictional facts, but he still has been unable to do so. As such, the TAC is DISMISSED without leave to amend because it is "fatally short of specifics" as to how Relator has direct and independent knowledge of false claims allegedly caused by Defendants. Bly-Magee, 470 F.3d at 917; see also Casady, 2013 WL 1702777 at *5.

B. Avelox Allegations

To reiterate, the Ninth Circuit affirmed dismissal of Relator's claims pertaining to Avelox on grounds that they were not pled with the requisite specificity to survive challenge under Rule 9(b), which requires claims grounded in fraud to be pleaded with particularity. That court explained that because "FCA claims are subject to Federal Rule of Civil Procedure 9(b)," a relator "must state with particularity `the who, what, when, where, and how *801 of the misconduct alleged.'" Solis, 885 F.3d at 628. Application of this heightened Rule 9(b) pleading standard is particularly justified in FCA cases "because the FCA is geared primarily to encourage insiders to disclose information necessary to prevent fraud on the government." Ebeid, 616 F.3d at 999. In order to satisfy that exacting standard, then, a relator must set out "what is false or misleading about a statement, and why it is false." Id. at 998.

801

As previously stated, once the matter was remanded to this Court, a status conference was held to address, among other things, whether or not to afford Relator the opportunity to amend in order to rectify that shortcoming. Although counsel for Relator indicated in open court that he no longer intended to pursue allegations pertaining to Avelox, amendment was nonetheless permitted with respect to Relator's alleged status as an original source of fraudulent allegations levied against Defendants.

The TAC as filed ran counter to Relator's representations inasmuch as it continued to include averments that Avelox was improperly marketed by Defendants through the use of the same kickbacks identified above with respect to Integrilin. While the Court would be within its authority to disregard any Avelox allegations under these circumstances, because substantive examination of the TAC shows squarely that the deficiencies identified by the Ninth Circuit have still not been rectified, dismissal of the Avelox claims is nonetheless warranted in any event.

The TAC fails to meaningfully add to its allegations pertaining to Avelox so as to address the Ninth Circuit's concerns. Although the Ninth Circuit found that Relator violated Rule 9(b) in failing to either "identify a single claim" submitted pursuant to Defendants' alleged scheme or to set forth "reliable indicia supporting a strong inference that such claims were submitted" (Solis, 885 F.3d at 629), Relator makes virtually no attempt to augment his allegations beyond a new one-sentence-long paragraph and exhibit. TAC, ¶ 146, Ex. 52. The new sentence contained in the TAC simply avers that a "sales spreadsheet from 2004 tracked 18,794,263 California patients who were covered by Medicaid or Medicare Part D plans in order to determine the effectiveness of Defendants' efforts to put Avelox on Medicaid and Medicare formularies (Exhibit 52)." Id.

As Defendant Schering points out, however, whether or not Avelox was placed on a hospital's formulary still says nothing about whether actual "claims were submitted." ECF No. 200, 19:3-5, citing Solis, 885 F.3d at 629. Indeed, Solis had already rejected Relator's allegations pertaining to formularies as insufficient to show that actual claims were submitted, since "[b]eing `on formulary' merely means that the drug is available to be used or prescribed" and does not prove in itself that actual false claims were submitted. Id. Consequently, Relator's claims pertaining to Defendant's promotion of Avelox still fail to satisfy Rule 9(b) standards, and Defendant Schering's Motion to Dismiss on that basis will be granted.

CONCLUSION

For all the reasons stated above, the Motions to Dismiss submitted by Defendants Millennium and Schering asserting lack of subject matter jurisdiction under Rule 12(b)(1), ECF Nos. 195 and 199, are GRANTED.

Because Relator has not met his burden of proof in showing that he was an original source of allegations made pertaining to Integrilin, the public disclosure bar applies and prevents Relator from maintaining any of the three causes of actions rooted in the federal FCA.

802 *802 In addition, although Relator goes on to assert some additional claims predicated on the false claim laws of some twenty-seven states, because those claims also hinge on the same false claim analysis set forth above, they too fail. Moreover, even were the state law claims to have some viability apart from the merits of the federal FCA claims, which the Court believes they do not, in the absence of any predicate federal claim the Court declines to exercise supplemental jurisdiction over the state law claims in any event.

Because the Court does not believe that the jurisdictional infirmities of Relator's claims against Defendants can be rectified through further amendment, no additional leave to amend will be permitted. Relator has already had three opportunities to correct the fatal deficiencies in his pleadings, including a trip to the Ninth Circuit. That is enough.

Defendant Schering's Motion to Dismiss pursuant to Rules 12(b)(6) and 9(b) (ECF No. 200) is also GRANTED to the extent that the TAC fails to state any claims pertaining to Avelox with the particularity required for claims sounding in fraud. Since the TAC makes virtually no attempt to remediate the deficiencies of its predecessor with respect to the promotion of Avelox, no further leave to amend will be permitted.

The remainder of Defendant Schering's Motion to Dismiss (ECF No. 200) is DENED as moot. In addition, since the Court concludes that it lacks jurisdiction over Relator's claims pertaining to Integrilin in the first instance, Defendants' other motions challenging the substance of Relator's claims are moot. Defendant Millennium's Motion to Dismiss (ECF No. 196), as well as Defendants' Joint Motion to Strike (ECF No. 197), and Motion to Dismiss under California's Anti-SLAPP statute (ECF No. 198) are accordingly DENIED on that basis.

Since this now concludes the Court's handling of this matter, the Clerk of Court is directed to close the file.

IT IS SO ORDERED.

[1] All further references to "Rule" or "Rules" are to the Federal Rules of Civil Procedure unless otherwise noted.

[2] Those Motions include Motions to Dismiss brought by Defendants Millennium, Schering-Plough and Merck to dismiss pursuant to Rules 9(b) and 12(b)(6) (ECF Nos. 196, 200); a Joint Motion to Strike portions of the TAC under California's so-called "anti-SLAPP" statute, Cal. Code Civ. Proc. § 425.16 (ECF No. 198) brought by both Defendants; and a Motion to Strike portions of the TAC pursuant to Rule 12(f) (ECF No. 197), also brought by both Defendants.

[3] Having determined that oral argument was not of material assistance, the Court ordered this matter submitted on the briefs in accordance with Local Rule 230(g).

[4] Off-label use of a drug occurs when it is used either for a purpose not approved by the FDA, of where non-indicated dosing regimens for the drug are promoted.

[5] Because the Rule 12(b)(6) motions challenged the sufficiency of the FAC's allegations at a point when the question of the Court's jurisdiction over this qui tam action had not yet been determined, and since the parameters of a SAC without the combination use allegations would likely be far different than its predecessor, the Court denied those motions without prejudice to being renewed following submission of the SAC.

[6] In his TAC, Relator drops some states (New Hampshire and Wisconsin) and adds others (Colorado, Connecticut, Maryland, Minnesota, North Carolina, and Washington)

[7] Defendants do not dispute, for purposes of these motions, that Relator provided information to the government before filing this action. See Schering Mot., ECF No. 199, p. 10, n. 6; Millennium Mot., ECf No. 195, p. 7, n.2.

[8] While Hartpence abrogated earlier decisions finding that to qualify under the original source exception, a Relator also had to show that he "had a hand" in the original disclosure, it did not change the "direct and independent knowledge" component of the exception and earlier caselaw remains viable as to that component.

[9] See TAC, ¶ 65 ("On information and belief, Defendants' promotion of Integrilin off-label as an early treatment for ACS patents and as an off-label treatment for STEMI patients continue to this day."); Id. at ¶ 100 ("[U]pon information and belief, Merck continues to promote Integrilin for off-label use in off-label patient populations in the same manner as set forth in this Complaint today.").