

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

UNITED STATES OF AMERICA,	:	CIVIL ACTION
<i>ex rel.</i> DONALD R. GALMINES, et al.,	:	
Plaintiffs,	:	
	:	
v.	:	
	:	
NOVARTIS PHARMACEUTICALS	:	NO. 06-3213
CORPORATION,	:	
Defendant.	:	

MEMORANDUM

PRATTER, J.

JUNE 13, 2013

Qui tam Realtor Donald Galmines has sued Novartis Pharmaceuticals Corporation under the False Claims Act (FCA), 31 U.S.C. § 3729 et seq., and similar state statutes. Specifically, Mr. Galmines alleges that Novartis wrongfully marketed its prescription drug Elidel, thereby causing the submission of false claims to government healthcare systems, including Medicare and Medicaid. Novartis moves to dismiss the complaint pursuant to Federal Rules of Civil Procedure 12(b)(1), 12(b)(6), and 9(b). For the reasons that follow, the Court grants the motion in part and denies it in part.

I. Factual Background and Procedural History

A. Factual Allegations

In his complaint, Mr. Galmines alleges that Novartis employed him as a senior sales consultant in its Dermatology and Respiratory Division from 2001 through 2006. His position involved marketing and selling Elidel. The complaint further alleges that Novartis developed Elidel to treat the skin disease atopic dermatitis, and that Novartis sought Food and Drug Administration (FDA) approval for Elidel on December 15, 2000. In its New Drug Application (NDA), Novartis sought approval for the use of Elidel for patients older than three months of

age. However, the FDA's medical review of Elidel allegedly found that the drug posed safety risks to infants. On December 14, 2001, the FDA authorized the marketing of Elidel as a second-line treatment for atopic dermatitis in patients aged two and older.

Shortly after the FDA approved Elidel, Novartis allegedly began a marketing campaign to convince pediatricians and dermatologists to prescribe its drug to children under the age of two and as a first-line treatment, thereby contravening the limitations of the FDA's approval. As a sales consultant, Mr. Galmines was trained by Novartis personnel on how to convince doctors that Elidel was safe for such young children. Around the same time, Dr. Lawrence Eichenfield, a pediatric dermatologist affiliated with Novartis, made public statements supporting the view that infants could be treated with Elidel, while Dr. Alexander Kapp published a report asserting that Elidel was safe for children over three months old. Novartis allegedly funded this Kapp report, publicly touted it, and distributed copies of the report to sales personnel, including Mr. Galmines. Mr. Galmines's complaint also appears to allege that Novartis subsequently publicized other studies that promoted off-label uses of Elidel.

The complaint goes on to allege that after Elidel's product launch proved less successful than Novartis hoped, Novartis personnel allegedly encouraged and trained Mr. Galmines and other sales representatives to engage in off-label marketing of the drug by pushing sales to young children, portraying Elidel as a first-line treatment, and encouraging physicians to prescribe Elidel for chronic use. From 2004 to 2006, Novartis allegedly buttressed these efforts by producing visual aids that encouraged doctors to prescribe Elidel on a long-term basis and as a first-line treatment. On February 28, 2006, Karl Burnitz, Mr. Galmines's district manager, allegedly reprimanded Mr. Galmines for advising a physician to not prescribe Elidel to young infants.

On February 15, 2005, the FDA Advisory Committee held a hearing regarding the safety of Elidel for children. At the hearing, Dr. Marilyn Pitts of the FDA testified that 14% of Elidel prescriptions were written for children under the age of two. Dr. Carle Paul, Novartis's Elidel Medical Director, also testified, and stated that Novartis did not engage in off-label marketing of Elidel. Following the hearing, the FDA's Pediatric Committee recommended adding a warning to Elidel's approved labeling. The warning allegedly stated that Elidel should only be used for short periods of time, that it is only approved for patients who are unresponsive to other treatments, that it is not approved for children younger than two, that clinical trials of Elidel resulted in children younger than two having a higher rate of respiratory infections than those treated with a placebo, and that animal data shows that the risk of cancer increases with exposure to Elidel. Since the warning was issued, sales of Elidel have dropped substantially.

Mr. Galmines also alleges that Novartis used cash payments, gifts, and seminar sponsorships and opportunities to reward physicians who prescribed high volumes of Elidel. Mr. Galmines was allegedly instructed to pay doctors to speak at seminars where they would encourage the off-label use of Elidel. Additionally, according to Mr. Galmines, Novartis arranged payments to physicians for seminars that never actually took place. At the direction of Mr. Burnitz, Mr. Galmines also allegedly hosted and paid for \$1,000 dinners for physicians who prescribed high amounts of Elidel. Finally, Mr. Galmines was allegedly instructed to use "preceptorships," in which he followed a doctor for a few hours and paid that doctor, to reward such high-prescribing physicians.

B. Procedural History

Mr. Galmines filed his complaint in this matter under seal on July 21, 2006. The case remained under seal for an extended period of time while the United States decided whether to

intervene in the matter. The United States eventually declined to intervene, and the complaint was unsealed. On May 13, 2011, Novartis filed a 295-page motion to dismiss the complaint pursuant to Federal Rules of Civil Procedure 12(b)(1), 12(b)(6), and 9(b). In its motion, Novartis argued that the Court should dismiss the complaint because:

- The Court lacks subject-matter jurisdiction under the “first-to-file” rule.
- The Court lacks subject-matter jurisdiction due to the FCA’s public disclosure bar.
- Mr. Galmines fails to plead facts that adequately state a claim under the FCA.
- The complaint falls short of the specificity required by Rule 9(b).
- The Court should decline to exercise supplemental jurisdiction over Mr. Galmines’s state law claims.

Mr. Galmines filed a 235-page opposition to the motion, to which Novartis responded with a reply brief. After oral argument, the parties also submitted supplemental briefs to the Court. Thus, it can be fairly said that the matter has been fully “prepared.”

On October 26, 2012, the Court dismissed Mr. Galmines’s complaint without prejudice due to his failure to sufficiently allege that he voluntarily provided information to the government in a timely manner. Mr. Galmines then filed a first amended complaint, which presents allegations as to how he informed the United States Attorney and various state government officials of his claims prior to filing his initial complaint. The first amended complaint includes counts under the False Claims Act and the laws of California, the District of Columbia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Nevada, Tennessee, and Virginia.

After Mr. Galmines filed the first amended complaint, Novartis again moved for dismissal under Rules 12(b)(1), 12(b)(6), and 9(b) and repeated the arguments presented in its

initial motion to dismiss. On January 14, 2013, Mr. Galmines responded to the second motion to dismiss. Two weeks later, Novartis filed a reply in support of its motion.

C. *Moyer* Complaint

On June 7, 2005, Gina Moyer and Judith Shelton, two former employees of Novartis, filed a 10-page complaint¹ in the Eastern District of Michigan and alleged that Novartis violated the FCA through its practices pertaining to a pair of drugs, Lamisil and Elidel. With regards to Elidel, the Michigan case relators alleged that Novartis received approval to market the drug as a treatment for atopic eczema, that subsequent research linked Elidel to lymphoma, and that Elidel was not to be used with occlusive dressings. Those relators also alleged that Novartis used kickbacks and false statements to doctors to implement “a scheme to increase the prescriptions for Elidel.”

According to the *Moyer* complaint, Novartis employees awarded “grant money” to physicians who prescribed Elidel. That complaint also alleged that Novartis gave cash payments, gift certificates, entertainment, and other benefits to doctors who prescribed large amounts of Elidel, and that these incentives greatly increased the use of Elidel.

The *Moyer* complaint also averred that Novartis engaged in off-label marketing of Elidel. As the Court will explain below, these allegations are central to the Court’s analysis here, and, thus, they are recounted in full as follows:

- In paragraph 12, the relators alleged that Novartis encouraged “off label use of Elidel *for treatment of psoriasis and seborrhea*” and “alternative off label uses of the drug.”
- In paragraph 13, the relators alleged that Novartis employees made false “statements regarding the relationship of the use of Elidel and the complication of lymphoma as well as off label detailing of Elidel *for treatment of psoriasis and/or seborrhea* and its use with occlusive dressings to increase potency[.]”

¹ Four of the pages addressed the relators’ retaliatory discharge claim and are thus irrelevant to the issues in this case.

- In Count 2, the relators set forth an abbreviated version of paragraph 13 and alleged that Novartis employees made “false statements regarding known complications of Elidel, off label uses for Elidel . . . and inappropriate administration of Elidel with occlusive dressings.” The relators also alleged that these statements induced physicians to prescribe Elidel at a higher rate.

The *Moyer* complaint contained no other allegations regarding the off-label marketing of Elidel.

II. Legal Standards

A. Rule 12(b)(1)

A district court can grant a motion to dismiss pursuant to Rule 12(b)(1) based on the legal insufficiency of a claim. *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1408 (3d Cir. 1991). In moving to dismiss a claim pursuant to Rule 12(b)(1), a party may challenge a court's jurisdiction either facially, i.e., based on the legal sufficiency of the claim, or factually, i.e., based on the sufficiency of jurisdictional fact. *Medtronic Vascular, Inc. v. Boston Scientific Corp.*, 348 F. Supp. 2d 316, 321 (D. Del. 2004).

Dismissal under a facial challenge is proper “only when the claim ‘clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or . . . is wholly insubstantial and frivolous.’” *Kehr Packages*, 926 F.2d at 1408-09 (quoting *Bell v. Hood*, 327 U.S. 678, 682 (1946)). In such a circumstance, the court must accept all well-pleaded allegations in plaintiff's complaint as true, and must view them in the light most favorable to the non-movant. *In re Kaiser Grp. Int'l Inc.*, 399 F.3d 558, 561 (3d Cir. 2005). However, a party asserting that the court has jurisdiction *always* bears the burden of showing that the case is properly before the court. *Packard v. Provident Nat'l Bank*, 994 F.2d 1039, 1045 (3d Cir. 1993) (citing *McNutt v. Gen. Motors Acceptance Corp.*, 298 U.S. 178, 189 (1936)).

Where subject-matter jurisdiction “in fact” is challenged, the trial court's very power to hear the case is at issue, and the court is therefore “free to weigh the evidence and satisfy itself as

to the existence of its power to hear the case.” *Mortensen v. First Fed. Savs. & Loan Ass’n*, 549 F.2d 884, 891 (3d Cir. 1977). In such an attack pursuant to Rule 12(b)(1), “no presumptive truthfulness attaches to plaintiff’s allegations . . . [and] [t]he party asserting subject-matter jurisdiction bears the burden of proving that it exists.” *See Church of Universal Bhd. v. Farmington Twp. Supervisors*, 296 F. App’x 285, 288 (3d Cir. 2008).

B. Rule 12(b)(6)

A Rule 12(b)(6) motion to dismiss tests the sufficiency of a complaint. Although Rule 8 of the Federal Rules of Civil Procedure requires only “a short and plain statement of the claim showing that the pleader is entitled to relief,” Fed. R. Civ. P. 8(a)(2), in order to “give the defendant fair notice of what the . . . claim is and the grounds upon which it rests,” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations and quotations omitted) (alteration in original), the plaintiff must provide “more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Id.* (citation omitted).

To survive a motion to dismiss, the plaintiff must plead “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Specifically, “[f]actual allegations must be enough to raise a right to relief above the speculative level” *Twombly*, 550 U.S. at 555 (citations omitted). The question is not whether the claimant will ultimately prevail but whether the complaint is “sufficient to cross the federal court’s threshold.” *Skinner v. Switzer*, 131 S. Ct. 1289, 1296 (2011) (citation omitted). An assessment of the sufficiency of a complaint is thus “a context-dependent exercise” because “[s]ome claims require more factual explication than others to state a plausible claim for relief.” *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010) (citations omitted).

In evaluating the sufficiency of a complaint, the Court adheres to certain well-recognized parameters. For one, the Court “must only consider those facts alleged in the complaint and accept all of the allegations as true.” *ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 (3d Cir. 1994) (citing *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)); *see also Twombly*, 550 U.S. at 555 (stating that courts must assume that “all the allegations in the complaint are true (even if doubtful in fact)”); *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010) (“[A] court must consider only the complaint, exhibits attached to the complaint, matters of public record, as well as undisputedly authentic documents if the complainant's claims are based upon these documents.”). The Court also must accept as true all reasonable inferences that may be drawn from the allegations, and view those facts and inferences in the light most favorable to the non-moving party. *See Rocks v. City of Phila.*, 868 F.2d 644, 645 (3d Cir. 1989); *see also Revell v. Port Auth. of N.Y. & N.J.*, 598 F.3d 128, 134 (3d Cir. 2010). Nonetheless, the Court need not accept as true “unsupported conclusions and unwarranted inferences,” *Doug Grant, Inc. v. Greate Bay Casino Corp.*, 232 F.3d 173, 183-84 (3d Cir. 2000) (citations and quotations omitted), or the plaintiff’s “bald assertions” or “legal conclusions,” *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (citations and quotations omitted).

C. Rule 9(b)

“In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” Fed. R. Civ. P. 9(b). Pleading “particularity” does not require plaintiffs to “plead the date, place or time of the fraud, so long as they use an alternative means of injecting precision and some measure of substantiation into their allegations of fraud.” *Rolo v. City Investing Co. Liquidating Trust*, 155 F.3d 644, 658 (3d Cir. 1998) (citations omitted),

abrogation on other grounds recognized, Forbes v. Eagleson, 228 F.3d 471 (3d Cir. 2000).

While the purpose of Rule 9(b) is to provide notice of the precise misconduct alleged, courts should “apply the rule with some flexibility and should not require plaintiffs to plead issues that may have been concealed by the defendants.” *Id.* The Third Circuit Court of Appeals has cautioned against focusing exclusively on Rule 9(b)’s particularity language because such a focus is “too narrow an approach [that] fails to take account of the general simplicity and flexibility contemplated by the rules.” *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984) (citations and quotations omitted). Instead, the court should focus on whether the complaint “adequately describes the nature and subject of the alleged misrepresentation.” *Id.*

III. Discussion

A. Original Source Rule

In its motion to dismiss, Novartis argues that the Court lacks subject-matter jurisdiction over this action because of the FCA’s public disclosure bar, which states that “[n]o court shall have jurisdiction over an action under this section based upon the public disclosure of allegations . . . unless . . . the person bringing the action is an original source of the information.” *See* 31 U.S.C. § 3730(e)(4)(A).² The statute further defines “original source” as an individual who: (i) “has direct and independent knowledge of the information on which the allegations are based;” and (ii) has “voluntarily provided the information to the Government before filing an action under this section which is based on the information.” *See* 31 U.S.C. § 3730(e)(4)(B). The parties agree that Mr. Galmines must qualify as an “original source” in order to bring suit, but disagree as to whether he meets the twin requirements of the FCA’s original source rule.

² Although the Patient Protection and Affordable Care Act amended this portion of the FCA, the amendment is not retroactive. *See Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 283 n.1 (2010).

1. Information Provided to the Government

The FCA defines an “original source” as a person who “voluntarily provided . . . information to the Government before filing an action[.]” *See id.* Here, Mr. Galmines alleges that he provided information to the United States Attorney and various state officials before he filed this suit. Such an allegation brings Mr. Galmines within the statutory definition of “original source.” However, a split has developed among the circuit courts of appeal in which certain courts have departed from the plain language of the FCA in determining who may qualify as an original source.³ Novartis asks the Court to follow one set of these decisions to dismiss the case for lack of subject-matter jurisdiction.

The leading appellate decision that *Novartis* asks the Court to follow is *United States ex rel. McKenzie v. Bell South Telecommunications, Inc.*, 123 F.3d 935 (6th Cir. 1997). In *McKenzie*, the Sixth Circuit Court of Appeals held that “to be an original source, a relator must inform the government of the alleged fraud before the information has been publicly disclosed.” *Id.* at 942. The court reasoned that this requirement would effectuate the purpose of the 1986 amendments to the FCA by “discourag[ing] persons with relevant information from remaining silent and encourag[ing] them to report such information at the earliest possible time.” *See id.* at 943 (citations and quotations omitted). Additionally, two other circuit courts have gone beyond *McKenzie* and held that “there is an additional requirement that a *qui tam* plaintiff must meet in order to be considered an ‘original source,’ namely, a plaintiff also must have directly or indirectly been a source to the entity that publicly disclosed the allegations on which a suit is based.” *See United States ex rel. Dick v. Long Island Lighting Co.*, 912 F.2d 13, 16 (2d Cir. 1990); *see also Wang v. FMC Corp.*, 975 F.2d 1412, 1419-20 (9th Cir. 1992) (holding same).

³ The Third Circuit Court of Appeals has not weighed in on this circuit split.

Mr. Galmines does not contend that his claim could survive a motion to dismiss if the Court followed any of the foregoing decisions. Rather, he argues that the Court should instead look to another line of cases best summarized by *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13 (1st Cir. 2009). In *Duxbury*, the First Circuit Court of Appeals interpreted the FCA according to its “plain and unambiguous terms” and held that the statute “only requires that a relator provide his or her information [to the government] prior to the filing of the qui tam suit.” *See id.* at 28. The court noted that such an interpretation comported with straightforward statutory definition of “original source,” and that if Congress had intended to “require relators to provide their information prior to the public disclosure, it easily could have done so.” *See id.* at 23 (citations and quotations omitted). Moreover, the court held that the legislative history of the FCA does not support interpreting “original source” in a manner that runs contrary to its statutory definition. *See id.* at 25.

Here, the Court will follow the *Duxbury* analysis and hold that Mr. Galmines may be an original source even though he did not provide information to the government before a public disclosure occurred. In so doing, the Court notes that three other courts of appeal that have reached the same result as *Duxbury*. *See United States ex rel. Davis v. D.C.*, 679 F.3d 832, 838-39 (D.C. Cir. 2012); *Minn. Ass’n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1050-51 (8th Cir. 2002); *United States ex rel. Siller v. Becton Dickinson & Co.*, 21 F.3d 1339, 1351 (4th Cir. 1994). Additionally, at least one court in this district has held that an original source merely needs to disclose information to the government before filing suit, noting that “the interpretation of the statute should be judged on what the statute states, not what some jurists may think the statute ought to have said.” *See United States ex rel. Merena v. Smithkline Beecham Corp.*, 114 F. Supp. 2d 352, 360 (E.D. Pa. 2000); *see also Allina*, 276 F.3d at 1050

(noting that the test adopted by *McKenzie* “has no textual basis in the statute”). The Court fully agrees with such observations and will not dismiss this action based on a judicially created requirement that lies outside the text of the False Claims Act.

2. Direct and Independent Knowledge

Novartis also argues that Mr. Galmines cannot qualify as an original source because he fails to plead that he “has direct and independent knowledge of the information on which [his] allegations are based.” *See* 31 U.S.C. § 3730(e)(4)(B). The parties appear to agree that Mr. Galmines has alleged “direct and independent knowledge” of Novartis’s off-label marketing and kickbacks. Novartis, however, contends that Mr. Galmines also must possess first-hand knowledge of the claims submitted to the government due to the alleged marketing and kickbacks. *See* Docket No. 43 at 40-42. In response, Mr. Galmines deems this argument a “patent red herring,” because he is claiming that Novartis *caused* the submission of false claims, not that Novartis submitted such claims itself. *See* Docket No. 45 at 39. After careful consideration of the arguments presented by both sides, the Court agrees with Mr. Galmines.

In *Rockwell International Corp. v. United States*, 549 U.S. 457 (2007), the Supreme Court addressed the original source rule and clarified that relators must have direct and independent knowledge of “the information upon which the relators’ allegations are based.” *Id.* at 470-71. This requirement does not mandate that a relator have independent knowledge of “all the relevant information” on which her allegations are based. *See United States ex rel. Stinson v. Prudential Ins. Co.*, 944 F.2d 1149, 1160 (3d Cir. 1991). However, a relator does need to “have direct and independent knowledge of the most critical element of its claims[.]” *See United States ex rel. Mistick PBT v. Hous. Auth.*, 186 F.3d 376, 388 (3d Cir. 1999) (Alito, J.) (citations and quotations omitted).

In its briefing, Novartis relies heavily on *Mistick*, a case where the relator claimed that “the defendants made false claims to the United States Department of Housing and Urban Development (HUD) for the cost of lead-based paint abatement work[.]” *See id.* at 379. The Third Circuit Court of Appeals held that the relator was “not an ‘original source’ because it did not have ‘direct and independent knowledge’ of the most critical element of its claims, *viz.*, that [a defendant] had made the alleged misrepresentations to HUD[.]” *See id.* at 388. The court subsequently stated that “a relator cannot be said to have ‘direct and independent knowledge’ . . . if the relator has no direct and independent knowledge of the allegedly fraudulent statements[.]” *See id.* at 389. Novartis argues that this latter statement in *Mistick* disqualifies Mr. Galmines from original-source status, because he fails to plead that he has firsthand or personal knowledge of fraudulent statements submitted to the government.

While *Mistick* would be controlling law if Mr. Galmines claimed that Novartis *made* false claims to the government, the Court must consider whether *Mistick* is distinguishable given the complaint’s allegation here that Novartis merely *caused*, that is, created the conditions that led inexorably to, the submission of false claims. Liability under the FCA does extend to the latter type of behavior, *see* 31 U.S.C. § 3729(a)(1), and several courts have held that a relator only needs to have firsthand knowledge of a false claim if he alleges that the defendant actually itself submitted the claim. For instance, in *United States ex rel. Colquitt v. Abbott Labs.*, 864 F. Supp. 2d 499 (N.D. Tex. 2012), a relator alleged that the defendants “knowingly caused the submission of false or fraudulent claims by promoting their stents for off-label use by healthcare providers[.]” *See id.* at 512. The court rejected the defendants’ argument that the relator must have direct and independent knowledge of the claims that providers submitted to the government, and instead held that the original-source rule merely required the relator to have

knowledge of the defendants' off-label marketing. *See id.* at 527; *see also United States ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 322-23, 333-34 (D. Mass. 2011) (holding that a relator who alleged "in great detail various means by which [the defendant] promoted off-label use of its biliary stents" had sufficient "direct and independent knowledge" to qualify as an original source); *United States ex rel. Underwood v. Genentech, Inc.*, 720 F. Supp. 2d 671, 679-80 (E.D. Pa. 2010) (Diamond, J.) (holding that a relator who alleges that a *third party* submitted false claims to the government need not identify a particular false claim in his complaint).

The Court agrees with the foregoing distinctions. If a defendant's off-label marketing caused a *third party* to submit false claims to the government, then a relator may qualify as an original source even if she lacks "direct and independent knowledge" of the act of submission of those claims. This holding comports fully with *Mistick*, because Mr. Galmines has "direct and independent knowledge of the most critical element of [his] claims." *See Mistick*, 186 F.3d at 388. In *Mistick*, the most critical element of the relator's claim was that the defendants submitted a false claim *directly* to the government. Here, however, the centerpiece of Mr. Galmines's claim is Novartis's off-label marketing and kickback scheme. Given that Mr. Galmines has direct and independent knowledge of that scheme, and bearing in mind that Third Circuit appellate precedent does not require Mr. Galmines to have firsthand knowledge of "all the relevant information" on which his allegations are based, *see Stinson*, 944 F.2d at 1160, the Court holds that Mr. Galmines is an original source and that the FCA's public disclosure bar does not prohibit his suit.

B. First-to-File Rule

Section 3730(b)(5) of the FCA states that "when a person brings an action under this subsection, no person other than the Government may . . . bring a related action based on the

facts underlying the pending action.” 31 U.S.C. § 3730(b)(5). Novartis argues that this “first-to-file rule” bars Mr. Galmines’s claims, because he filed suit after Gina Moyer and Judith Shelton – two former employees of Novartis – brought a *qui tam* action against Novartis that also related to Elidel. The parties agree that *United States ex rel. LaCorte v. Smithkline Beecham Clinical Laboratories, Inc.*, 149 F.3d 227 (3d Cir. 1998), sets forth the controlling law on this issue.

In *LaCorte*, the Third Circuit Court of Appeals held that “if a later allegation states all the essential facts of a previously-filed claim, the two are related and section 3730(b)(5) bars the later claim, even if that claim incorporates somewhat different details.” *Id.* at 232-33. In other words, the first-to-file rule prohibits a subsequent suit if the “material elements of [its] claim are the same as those [of a prior action].” *See id.* at 235; *see also id.* at 235 n.6 (noting that the first-to-file rule applies if “later complaints allege the same material elements as claims in the original lawsuits”).

After setting forth the applicable standard for interpreting § 3730(b)(5), the Third Circuit Court of Appeals held in *LaCorte* that all the claims in the case before it were barred by the first-to-file rule because “they merely repeat[ed] preexisting causes of action.” *See id.* at 235. Three aspects of the court’s decision are particularly noteworthy. First, *LaCorte* determined the applicability of the first-to-file rule by comparing the allegations of the original and later complaints. *See id.* at 235 n.6. Second, the court separately analyzed each claim of each relator to determine whether a particular claim was barred by the first-to-file rule. For instance, after the court held that the first-to-file rule barred a relator’s claim that the defendant billed the government for unnecessary differentials, the court did not assume that § 3730(b)(5) also precluded that relator’s remaining claims. *See id.* at 235-36. Third, the court repeatedly held that the first-to-file rule applies if a later claim “merely echoes the [prior complaint’s] broader

allegation,” *see id.* at 236, or if a prior complaint “fully subsumes all the material elements” of a later claim, *see id.* at 238.

Applying *LaCorte* here, the Court finds that the first-to-file rule bars Mr. Galmines from bringing a claim under the FCA based on alleged kickbacks. A comparison of the *Moyer* complaint with the instant complaint shows that both pleadings allege that Novartis provided various rewards to physicians who prescribed high amounts of Elidel. While Mr. Galmines’s allegations offer more detail than those of the *Moyer* relators, the first-to-file rule “bars [a] later claim, even if that claim incorporates somewhat different details.” *See id.* at 232-33. Therefore, the Court lacks subject-matter jurisdiction over Mr. Galmines’s kickback allegations.⁴

As for Mr. Galmines’s allegations of off-label marketing, the Court must reach a different conclusion. As stated above, the *Moyer* complaint alleged that Novartis promoted the use of Elidel *for the treatment of psoriasis and seborrhea*.⁵ Mr. Galmines, however, makes almost no allegations about these diseases. Instead, his complaint primarily alleges that Novartis engaged continuously in the off-label marketing of Elidel for the treatment of *atopic dermatitis*.⁶ Given the differences between Mr. Galmines’s complaint and the *Moyer* complaint, Mr. Galmines’s complaint does not share “all the essential facts of [the] previously-filed claim,” but rather pertains to a different off-label promotion scheme. *See LaCorte*, 149 F.3d at 232-33. Moreover, the Court notes that the primary purpose of a *qui tam* complaint is to provide the government

⁴ In reaching this holding, the Court finds that whether the *Moyer* complaint satisfied the pleading requirements of Rule 9(b) is inapposite, because the plain language of § 3730(b)(5) does not include an exception for situations in which a first-filed complaint is pled with insufficient particularity.

⁵ While paragraph 18 of the *Moyer* complaint did not expressly allege that off-label marketing pertained to psoriasis or seborrhea, this paragraph merely summarized earlier allegations in the complaint, which repeatedly pled that Novartis’s off-label marketing related to these two diseases.

⁶ Atopic dermatitis is an itchy inflammation of the skin, while psoriasis is a disease that causes cells to build up on the surface of the skin. Seborrheic dermatitis is a skin disorder that mainly affects the scalp.

notice of the need to investigate a particular scheme. *See United States ex rel. Folliard v. Synnex Corp.*, 798 F. Supp. 2d 66, 71 (D.D.C. 2011). No reasonable reading of the *Moyer* complaint would have informed the government of the need to investigate whether Novartis was marketing Elidel as a first-line treatment or for use in young infants, because the *Moyer* complaint never alleged that such marketing occurred. Therefore, the Court finds that the first-to-file rule does not bar Mr. Galmines’s claim that Novartis violated the FCA through its alleged off-label marketing.

The parties do not address how the Court should proceed if it finds that some, but not all, of Mr. Galmines’s allegations are “based on the facts underlying [*Moyer*].” *See* 31 U.S.C. § 3730(b)(5). However, the claim-by-claim analysis adopted by *LaCorte* indicates that Mr. Galmines’s off-label marketing claim should proceed even if the first-to-file rule bars his kickback allegations from moving forward. *See LaCorte*, 149 F.3d at 235-36; *see also United States ex rel. Merena v. Smithkline Beecham Corp.*, 205 F.3d 97, 102 (3d Cir. 2000) (Alito, J.) (“[W]hen it is asserted that a later-filed complaint contains claims that are based on the facts underlying certain claims in a pending multi-count complaint, the court must conduct a claim-by-claim analysis in order to determine if section 3730(b)(5) applies.”). Therefore, the Court holds that it has subject-matter jurisdiction over Mr. Galmines’s claim that Novartis violated the FCA through off-label marketing, but dismisses Mr. Galmines’s kickback allegations with prejudice.⁷

⁷ Although Mr. Galmines lumps his kickback claim together with his off-label marketing claim in Count 1 of his complaint, “courts must analyze the jurisdictional status of each reasonably discrete claim of fraud in a *qui tam* action and do so based on a review of the substance of the complaint, not just how it may be formally structured.” *See United States ex rel. Boothe v. Sun Healthcare Grp., Inc.*, 496 F.3d 1169, 1177 (10th Cir. 2007). Therefore, the Court may conclude that it has subject-matter jurisdiction over some, but not all, of Count 1 of the first amended complaint. Under such circumstances, it would be within the Court’s case management powers and duties to order the relator to prepare and file a further amended complaint to take into account the Court’s ruling here.

C. Rule 12(b)(6)

In addition to arguing that the Court lacks subject-matter jurisdiction over Mr. Galmines's claims, Novartis seeks to dismiss the complaint under Rule 12(b)(6). Novartis presents four reasons that the Court should dismiss the first amended complaint under Rule 12(b)(6). First, Novartis contends that the Court should dismiss the complaint because Mr. Galmines fails to "specifically allege how claims pharmacies submitted to the Government for off label uses of Elidel were false or fraudulent[.]" *See* Docket No. 43 at 48. Although the parties' arguments on this point are somewhat jumbled, in the final analysis the Court starts with the proposition that "claims may be false if they claim reimbursement for services or costs that . . . are not reimbursable[.]" *United States v. R&F Props. of Lake Cnty., Inc.*, 433 F.3d 1349, 1356 (11th Cir. 2005); *see also United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 51 (D. Mass. 2001) ("Defendant does not dispute that an off-label prescription submitted for reimbursement by Medicaid is a false claim within the meaning of the FCA."). Moreover, the first amended complaint plausibly suggests that at least some of the claims submitted to government healthcare programs for Elidel prescriptions were not reimbursable, because it also alleges that these programs do not pay for drugs that are "not prescribed for a medically accepted indication," and that at least 1.2 million Elidel prescriptions were written off-label in a manner that put the health of the children receiving those prescriptions at risk. Therefore, Mr. Galmines has sufficiently pled that false claims for Elidel prescription reimbursements were submitted to the government.

Second, Novartis argues that the first amended complaint fails to allege that Novartis "caused" the submission of any false claims, because doctors made independent medical decisions to prescribe Elidel for off-label uses. This argument is, of course, reminiscent of the

“original source” analysis above, albeit on a different issue. Under *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3d Cir. 2004), causation exists for a FCA claim if a defendant’s conduct is a “substantial factor” behind the submission of a false claim to the government. *See id.* at 244. In *Franklin*, the district court applied this “substantial factor” test in a FCA case where the relator alleged that the defendant engaged in off-label marketing of pharmaceuticals. *See Franklin*, 147 F. Supp. 2d at 52. The court held that the alleged marketing was a “substantial factor” behind the submission of false claims because, “when all reasonable inferences are drawn in favor of the Relator, the participation of doctors and pharmacists in the submission of false . . . claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud.” *See id.* at 52-53. Here too, the first amended complaint plausibly suggests that doctors wrote off-label Elidel prescriptions because of Novartis’s marketing, and that Novartis’s actions thus played a substantial and foreseeable role in the submission of false claims.

Third, Novartis contends that the first amended complaint fails to allege that Novartis’s conduct played a material role in government decisions to pay for Elidel prescriptions. Essentially, Novartis argues that government healthcare programs will reimburse “*medically necessary* off-label uses” of drugs, and that its off-label marketing thus did not necessarily have a material impact on government payment decisions. *See* Docket No. 43 at 53 (emphasis supplied). However, the first amended complaint pleads facts which suggest that the off-label use of Elidel is medically *risky*, not that it is medically *necessary*. Given these allegations, the first amended complaint sufficiently pleads that Novartis’s off-label marketing materially affected government reimbursements. *Cf. Franklin*, 147 F. Supp. 2d at 53 (“The fact that such prescriptions are for an off-label use is material because . . . the government would not have paid the claims if it had known of the use for which they were being submitted.”).

Fourth, Novartis argues that the first amended complaint fails to state a claim for conspiracy under 31 U.S.C. § 3729(a)(3). In his briefing, Mr. Galmines argues that his kickback allegations provide a tenable basis for his conspiracy claim. However, the Court lacks subject-matter jurisdiction over the kickback allegations under the first-to-file rule, and the allegations remaining in the first amended complaint cannot support a conspiracy claim after the kickback scheme is removed. Therefore, the Court dismisses this claim with prejudice.⁸

D. Rule 9(b)

Novartis's final argument with respect to Mr. Galmines's federal claim is that the first amended complaint fails to plead fraud with particularity as required by Rule 9(b). In support of this argument, Novartis contends that Mr. Galmines has failed to "identify a single false claim for Elidel reimbursement" or a "single specific instance of off-label promotion" by Novartis to a particular physician, and that the first amended complaint does not allege how Novartis's off-label marketing caused doctors to alter their medical judgment and prescribe Elidel. The Court finds that the court persuasively addressed this type of Rule 9(b) argument in *United States ex rel. Underwood v. Genentech, Inc.*, 720 F. Supp. 2d 671 (E.D. Pa. 2010).

In *Underwood*, a pharmaceutical company filed a Rule 9(b) motion to dismiss a *qui tam* complaint alleging that it used off-label marketing and kickbacks to induce physicians to prescribe its drug. *See id.* at 674, 679. Like Novartis, the defendant in *Underwood* argued that the complaint failed to satisfy Rule 9(b) because it did not "identify a false claim actually submitted to the Government." *Id.* at 678. The court rejected this argument and held that a relator could not reasonably "be required to identify[,] at the pleading stage[,] a specific false claim submitted to the Government by a third party[.]" *See id.* at 679. Instead, a relator may

⁸ Novartis also argues that the first amended complaint's kickback allegations fail to state a claim under Rule 12(b)(6). However, the Court need not address this argument because the first-to-file rule bars Mr. Galmines from bringing a claim based on alleged kickbacks.

“use an alternative means of injecting precision and some measure of substantiation into [his] allegations of fraud” so that a defendant will have sufficient notice of its alleged misconduct. *See id.* at 679-80 (quoting *Rolo v. City Investing Co. Liquidating Trust*, 155 F.3d 644, 658 (3d Cir. 1988)). The court then held that the relator satisfied this standard by including detailed allegations regarding kickbacks in his complaint and by alleging that thousands of off-label prescriptions were written for the drug in question. *See id.* at 680.

Here, as in *Underwood*, Mr. Galmines has injected precision into his off-label marketing allegations by pleading a myriad of details about how such marketing occurred. The first amended complaint details with specificity how Novartis trained its personnel to engage in off-label marketing, how it equipped those personnel with reports and visual aids to support such marketing, how it used medical experts to promote the off-label use of Elidel, and how Mr. Galmines was reprimanded when he declined to market Elidel for such uses. These allegations, together with the first amended complaint’s allegation that at least 1,218,000 off-label prescriptions were written for Elidel, “are sufficiently specific both to inform [Novartis] of the ‘precise misconduct’ charged, and to make it unlikely that [Mr. Galmines] has commenced this action in bad faith.” *See id.* at 680. Therefore, the Court will not dismiss the first amended complaint under Rule 9(b). *See id.*; *see also United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) (“[T]o plead with particularity the circumstances constituting fraud for a False Claims Act § 3729(a)(1) claim, a relator’s complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.”).

E. State Law Claims

Finally, the Court addresses whether to dismiss the claims that Mr. Galmines brings under the laws of California, the District of Columbia, Louisiana, and Massachusetts, as well as the claims brought under Indiana, Virginia, and Nevada law. Novartis argues that the first four jurisdictions in this group require a relator to file his or her claim in state court, and that Mr. Galmines fails to plead that he has filed an action in any of these four jurisdictions. Upon reviewing the statutes cited by Novartis, the Court agrees that they do indicate that a relator must file suit in state court. *See* Cal. Gov't Code § 12652(c)(2) (“A complaint filed by a private person under this subdivision **shall** be filed in superior court[.]”) (emphasis added); D.C. Code § 2-381.03(b)(2) (“A complaint filed by a qui tam plaintiff pursuant to this subsection **shall** be filed in the Superior Court[.]”) (emphasis added); La. Rev. Stat. Ann. § 46:439.1(A) (“A private person may institute a civil action in the courts of this state”); Mass. Gen. Laws ch. 12, § 5C(2) (authorizing *qui tam* actions “in superior court”). Moreover, Mr. Galmines neither discusses these specific statutes nor contends that he has filed suit in the courts of the foregoing states. Therefore, the Court dismisses first amended complaint’s claims under the laws of California, the District of Columbia, Louisiana, and Massachusetts with prejudice.⁹

⁹ On November 12, 2011, several states, including the District of Columbia, Massachusetts, Nevada, and Virginia, filed a submission with the Court which requested (without citation to supporting authority) that “the Court refrain from reaching state-specific issues” in ruling on Novartis’s first motion to dismiss, and that the Court “solicit the written consent” of the states before dismissing the complaint. *See* Docket No. 53 at 2. Although these states have been served with Novartis’s second motion to dismiss, they have not renewed their arguments as to whether the Court should refrain from reaching state-specific issues or solicit their written consent before acting in this case. Moreover, Novartis notes correctly that the states’ argument as to their consent is based on § 3730(b)(1), a statutory provision that is apposite when a relator dismisses a claim voluntarily, not when a court dismisses a claim upon a defendant’s motion. *See United States ex rel. Shaver v. Lucas W. Corp.*, 237 F.3d 932, 934 (8th Cir. 2001).

Novartis also seeks to partially dismiss the first amended complaint's claims under the false claims acts of Indiana and Virginia, ostensibly because those statutes do not have a retroactive effect and were passed after some of the alleged false claims in this matter had already been submitted. Mr. Galmines does not dispute these arguments, but instead contends that Novartis is making "an argument to limit damages that should be determined at a later time." *See* Docket No. 45 at 79. However, Mr. Galmines offers no citation in support of this assertion, and the Court finds that Novartis may use a motion to dismiss to partially bar his claims under the laws of Indiana and Virginia. *See United States ex rel. Bogart v. King Pharms.*, 410 F. Supp. 2d 404, 406 (E.D. Pa. 2006) (granting a motion to dismiss a claim under the New Mexico Medicaid False Claims Act because the claim accrued before the statute was enacted); *see also Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1385 n.1 (3d Cir. 1994) (noting that a Rule 12(b)(6) motion may be used to dismiss a claim based on the statute of limitations if "the complaint facially shows noncompliance with the limitations period and the affirmative defense clearly appears on the face of the pleading") (citations omitted). Therefore, the Mr. Galmines may not bring claims under Indiana and Virginia law to the extent that those claims predate the statutes under which he has filed suit.

Finally, Novartis notes that Nevada's false claims statute appears to codify the original-source rule adopted by the Second and Ninth Circuit Courts of Appeal. *See* Nev. Rev. Stat. § 357.100(2)(c) (defining an original source as a person whose "information provided the basis or caused the making of the investigation, hearing, audit or report that led to the public disclosure"). Mr. Galmines neither mentions this aspect of Nevada law nor disputes that he cannot qualify as

an original source under Nevada's statutory definition of that term. The Court thus dismisses the first amended complaint's claim under Nevada law with prejudice.¹⁰

IV. Conclusion

For the foregoing reasons, the Court grants in part and denies in part Novartis's motion to dismiss. Mr. Galmines may bring suit against Novartis under the FCA based on his off-label marketing allegations, and he also may pursue his claims under the laws of Hawaii, Illinois, Indiana, Michigan, Tennessee, and Virginia. However, Mr. Galmines may not base his FCA claim on his kickback allegations, and his claims under 31 U.S.C. § 3729(a)(3) and the laws of California, the District of Columbia, Louisiana, Massachusetts, and Nevada, as well as any claims accruing before the passage of the false claims acts of Indiana and Virginia, are dismissed with prejudice.

An Order consistent with this Memorandum follows.

BY THE COURT:

S/Gene E.K. Pratter
GENE E.K. PRATTER
United States District Judge

¹⁰ Although Novartis also argues that the first amended complaint's California and District of Columbia claims should be dismissed for this same reason, the Court need not address this argument because it has already dismissed these claims for the reasons discussed above.

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

UNITED STATES OF AMERICA,	:	CIVIL ACTION
<i>ex rel.</i> DONALD R. GALMINES, et al.,	:	
Plaintiffs,	:	
	:	
v.	:	
	:	
NOVARTIS PHARMACEUTICALS	:	NO. 06-3213
CORPORATION,	:	
Defendant.	:	

ORDER

AND NOW, this 13th day of June, 2013, having reviewed the briefing submitted in this matter, as well as the contentions of the parties set forth at oral argument, it is hereby ORDERED that the Defendant's Second Motion to Dismiss (Docket No. 62) is GRANTED IN PART and DENIED IN PART. The Relator may bring suit under the False Claims Act (FCA) based on his off-label marketing allegations, and also may bring claims against Novartis under the laws of Hawaii, Illinois, Indiana, Michigan, Tennessee, and Virginia. However, the Relator cannot base his FCA claim on his kickback allegations, and his claims under 31 U.S.C. § 3729(a)(3) and the laws of California, the District of Columbia, Louisiana, Massachusetts, and Nevada, as well as any claims accruing before the passage of the false claims acts of Indiana and Virginia, are dismissed with prejudice.

It is FURTHER ORDERED that the Relator shall file a second amended complaint that comports with this Order by no later than June 21, 2013. The Defendant shall answer this complaint by July 5, 2013.

It is FURTHER ORDERED that an **INITIAL PRETRIAL CONFERENCE** in this matter will be held on July 15, 2013 at 2:00 p.m. with the Honorable Gene E.K. Pratter in the

United States Courthouse, 601 Market Street, Philadelphia, PA 19106 in Chambers, Room 10613.

Attached is the Court's Notice concerning Scheduling and Discovery Policy and a Conference Information Report which you are required to complete and forward to the Court **at least three business days prior** to the day of the conference. You are also required to comply with the provisions of F.R.C.P. 26(f) regarding a conference of the parties and submission of a report outlining a proposed case management plan. For example, if the parties agree to exceed the standard number of interrogatories or depositions as provided in the Federal Rules of Civil Procedure they are to stipulate to such a change in their Rule 26(f) report, which shall be provided to the Court **at least three business days prior** to the day of the conference. *Neither Report should be docketed.*

If trial counsel in this case is on trial in a court of record at the scheduled time of the conference, another attorney in trial attorney's office, who should be familiar with the case, is required to appear at the conference. Do not send unknowledgeable substitutes. The conference will be continued to another date only in exceptional circumstances. Requests for phone conferences will not be routinely granted.

Counsel are advised to review and follow Judge Pratter's General Pretrial and Trial Procedures which are posted on <http://www.paed.uscourts.gov>. Counsel may call Chambers at the number listed below to request a hard copy of the Procedures Memorandum.

In the event counsel sends any fax to Chambers after 5:00 p.m. on weekdays or any time on the weekends, counsel must also leave a voice mail message on the Court's direct telephone number (267-299-7350).

Counsel are also advised that the Court expects all counsel to be registered on the ECF system of this District Court. All official filings submitted to the Clerk of the Court must be filed directly by the filing attorney on to ECF. The Court's orders, opinions and other docketed materials will be filed on to ECF and notice thereof will be communicated to counsel either by ECF or ordinary first-class mail. Requests to be excused from ECF registration must be made in writing directly to Judge Pratter.

BY THE COURT:

S/Gene E.K. Pratter
GENE E.K. PRATTER
United States District Judge