IN THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
BEAUFORT DIVISION

United States of America and The States of California and Illinois, *ex rel.* Scarlett Lutz and Kayla Webster, Plaintiffs/Relators, v. Laboratory Corporation of America Holdings, Defendant.	Civil Action No. 9:14-cv-3699-RMG **ORDER AND OPINION**

This matter is before the Court on Defendant Laboratory Corporation of America Holdings' ("LabCorp") partial motion to dismiss the fourth amended complaint ("FAC") under Federal Rules of Civil Procedure 9(b) and 12(b)(6). (Dkt. No. 60.) For the reasons below, LabCorp's motion to dismiss is granted in part and denied in part.

I. Background

Relators Scarlett Lutz and Kayla Webster ("Relators") filed a *qui tam* complaint in 2013 alleging violations of the False Claims Act ("FCA"), 31 U.S.C. § 3729 and multiple state statutes against LabCorp and other defendants. The claims against Defendant LabCorp were eventually severed from the claims against the other defendants. On June 26, 2018, the Relators filed their Fourth Amended Complaint, alleging that LabCorp violated the FCA through several fraudulent schemes impacting government health care programs, such as billing for medically unnecessary tests and paying kickbacks to physicians for ordering tests from LabCorp, and that it did so as part of a conspiracy with two other laboratories: Health Diagnostic Laboratory, Inc. ("HDL") and Singulex, Inc. ("Singulex"). In addition to claims under the FCA, Relators brought claims under the California Insurance Frauds Prevention Act ("CIFPA"), Cal. Ins. Code § 1871.7, and the

Illinois Insurance Claims Fraud Prevention Act ("ICFPA"), 740 Ill. Comp. Stat. Ann. 92/15, both of which allow interested persons to bring a *qui tam* suit for fraudulent claims submitted to private insurers. Neither the federal government nor any state government has decided to intervene in this *qui tam* action as of the date of this order.[1]

Defendant LabCorp now seeks the dismissal of most claims brought by the Relators. First, LabCorp argues that the FAC fails to state a cause of action against LabCorp for submitting claims for medically unnecessary tests. Second, LabCorp argues that Relators' claim for reverse false claims liability, Count II, is duplicative and fails to allege the claim with particularity, as required by Rule 9(b). Third, LabCorp argues that the Relators lack standing to bring claims under the CIFPA or ICFPA since they are not "interested persons" and, regardless, the claims fail under 9(b). Finally, LabCorp argues that the conspiracy claims fail under 9(b). LabCorp's motion does not seek dismissal of the claims based on alleged kickbacks paid to ensure that doctors referred and ordered lab tests. (Dkt. No. 60 at 3.) Relators oppose the motion. (Dkt. No. 63.)

II. Legal Standard

A. Motion to Dismiss

Rule 12(b)(6) of the Federal Rules of Civil Procedure permits the dismissal of an action if the complaint fails "to state a claim upon which relief can be granted." Such a motion tests the legal sufficiency of the complaint and "does not resolve contests surrounding the facts, the merits of the claim, or the applicability of defenses.... Our inquiry then is limited to whether the allegations constitute 'a short and plain statement of the claim showing that the pleader is entitled to relief.'" *Republican Party of N.C. v. Martin*, 980 F.2d 943, 952 (4th Cir. 1992) (quotation marks

[1] The United States expressly declined to intervene in the case. (Dkt. No. 30.) The Court draws no inference about the merits of the Relators' allegations based on the Government's decision not to intervene. *See U.S. ex rel. Berge v. Bd. of Trustees of the Univ. of Alabama*, 104 F.3d 1453, 1458 (4th Cir. 1997).

and citation omitted). In a Rule 12(b)(6) motion, the Court is obligated to "assume the truth of all facts alleged in the complaint and the existence of any fact that can be proved, consistent with the complaint's allegations." *E. Shore Mkts., Inc. v. J.D. Assocs. Ltd. P'ship,* 213 F.3d 175, 180 (4th Cir. 2000). However, while the Court must accept the facts in a light most favorable to the non-moving party, it "need not accept as true unwarranted inferences, unreasonable conclusions, or arguments." *Id.*

To survive a motion to dismiss, the complaint must state "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Although the requirement of plausibility does not impose a probability requirement at this stage, the complaint must show more than a "sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009). A complaint has "facial plausibility" where the pleading "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

B. Pleading Fraud with Particularity – Rule 9(b)

A complaint alleging fraud "must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). However, "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *Id.* To meet this standard, the complaint must describe "the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." *U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008) (citations omitted). In other words, the complaint must describe the "who, what, when, where, and how of the alleged fraud." *Id.* (citations omitted).

Finally, "[a] court should hesitate to dismiss a complaint under Rule 9(b) if the court is satisfied (1) that the defendant has been made aware of the particular circumstances for which she

will have to prepare a defense at trial, and (2) that plaintiff has substantial pre-discovery evidence of those facts." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999). Rule 9(b) also requires a complaint to include "some indicia of reliability" to "support the allegation that an actual false claim was presented to the government." *Nathan*, 707 F.3d at 457 (citation omitted). A complaint provides the requisite indicia of reliability where "specific allegations of the defendant's fraudulent conduct necessarily [lead] to the plausible inference that false claims were presented to the government." *Id.*

III. Discussion

A. Claims Based on Medically Unnecessary Testing

Relators have not alleged that LabCorp encouraged any medically unnecessary testing, and therefore the Court grants the motion to dismiss all claims based upon this theory. Under 42 U.S.C. § 1395y(a)(1)(A), the federal government will not reimburse a Medicare claim unless the services at issue were "reasonable and necessary." It follows that "claims for medically unnecessary treatment are actionable under the FCA." *U.S. ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004). Relators allege that LabCorp improperly encouraged physicians to order medically unnecessary testing by informing at least one physician, Dr. Lloyd Miller, that LabCorp would only draw blood for free if the doctor also ordered testing from LabCorp and providing doctors with a space marked "other" on the LabCorp requisition form, causing doctors to order unnecessary and sometimes duplicative testing. (Dkt. Nos. 50 at ¶¶ 361 – 369; 63 at 13 – 14.) Relators also allege that LabCorp caused medically unnecessary testing by providing physicians with in-office phlebotomists who provided blood draws for blood samples referred to HDL and Singulex after LabCorp already knew they were engaged in fraud. (Dkt. Nos. 50 at ¶¶ 499 – 513; 63 at 12 –13.) LabCorp, however, argues that these claims are legally insufficient as

the Complaint alleges it was doctors, rather than LabCorp, that ordered the tests and LabCorp never certified the necessity of the tests. (Dkt. No. 60-1 at 9 – 13.)

In submitting a claim for reimbursement, "a laboratory generally may rely on that doctor's order in submitting a claim for reimbursement as medically necessary." *United States v. Bertram*, 900 F.3d 743, 750 (6th Cir. 2018). However, this rule is not universal, and there can still be a FCA violation where a laboratory "engage[s] in a scheme to encourage...physicians to order medically unnecessary tests...." *See United States ex rel. Groat v. Boston Heart Diagnostics Corp.*, 296 F. Supp. 3d 155, 165 (D.D.C. 2017). Here, Relators have not alleged that LabCorp encouraged any medically unnecessary testing. Instead, they have alleged that LabCorp incentivized doctors, such as Dr. Miller, to use its services by waiving a $5.00 fee for blood draws if a test is referred to them and making it easy to do so by including an "other field" to be used for tests to other laboratories. This claim alleges that LabCorp financially induced doctors to refer tests to LabCorp but does not allege that LabCorp encouraged specific tests for patients which were medically unnecessary. Similarly, while Relators allege that LabCorp knew that HDL offered above-market draw fees dating back to 2010, they do not allege that LabCorp knew that blood draws provided for HDL and Singulex were inherently medically unnecessary. (*See* FAC at ¶¶ 262 – 265.)

These allegations stand in contrast to cases in which laboratories were leading doctors to order a specific, and unnecessary, testing regime. *See, e.g. United States ex rel. Groat v. Boston Heart Diagnostics Corp.*, 255 F. Supp. 3d 13, 29 (D.D.C. 2017), *amended on reconsideration in part*, 296 F. Supp. 3d 155 (D.D.C. 2017) (collecting cases) (denying request to dismiss where Defendant allegedly provided physicians with "pre-printed test requisition forms" that would "group together only a few medically justified tests with many medically unnecessary tests" and made "marketing statements as to the benefits of and scientific validation of its tests...."); *United*

States v. Berkeley Heartlab, Inc., 225 F. Supp. 3d 487, 500 (D.S.C. 2016) (Gergel, J.) (denying motion to dismiss where panels Defendants offered to physicians identified "particular genetic testing that is medically unnecessary for the vast majority of the population"); *U.S. ex rel. Downy v. Corning, Inc.*, 118 F. Supp. 2d 1160, 1166 (D.N.M. 2000) (denying motion to dismiss where laboratory combined unnecessary PAP test onto line for PSA test).

Here, by contrast, while LabCorp allegedly encouraged physicians to order LabCorp tests in general, and the Complaint still leaves the decision of which test to request to the ordering physician. Instead, the issue of whether LabCorp financially induced physicians to refer tests to LabCorp is covered under Relators' kickback claims, which is not at issue in this Order. Relators' claims alleging medically unnecessary tests are therefore dismissed.

B. Reverse False Claims

As this Court explained in a related case, "[t]he retention of proceeds provision of the FCA (often referred to as the 'reverse false claims' provision) imposes liability on anyone who 'knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.'" *United States v. Berkeley Heartlab, Inc.*, 247 F. Supp. 3d 724, 732 (D.S.C. 2017) *citing* 31 U.S.C. § 3729(a)(1)(G). In this context, an "obligation" includes "the retention of any overpayment." *Id. citing* 31 U.S.C. § 3729(b)(3).

Relators here allege that LabCorp received improper payments for claims it submitted that were tainted by violations of the anti-kickback statute. (FAC at ¶ 572.) Relators allege that, since these payments were made subject to an illegal kickback, LabCorp was required to return these payments. (*Id.* at ¶¶ 167 – 68, 590; Dkt. No. 63 at 14 – 16.) Relators argue that while these claims

are generally based on the same conduct that support their kickback claims, the reverse false claims causes of action are pled "in the alternative." (Dkt. No. 63 at 14.) However, it is well settled that "reverse false claims may not be based on the same conduct as a plaintiff's claims under 31 U.S.C. §§ 3729(a)(1)(A) and (a)(1)(B)." *United States ex rel. Branscome v. Blue Ridge Home Health Servs., Inc.*, No. 7:16CV00087, 2018 WL 1309734, at *5 (W.D. Va. Mar. 13, 2018) *citing Pencheng Si v. Laogai Research Found.*, 71 F. Supp. 3d 73, 97 (D.D.C. 2014). Therefore, as the Court previously explained, "[u]nder Plaintiff's interpretation 'just about any traditional false statement or presentment action would give rise to a reverse false claim action....'" *Berkeley Heartlab, Inc.*, 247 F. Supp. 3d at 733. Therefore, LabCorp's motion to dismiss Count II (the reverse false claims cause of action) is granted.

C. State Law Claims

Relators additionally bring claims under the CIFPA and ICFPA, California and Illinois laws that allow interested persons to bring a *qui tam* suit for fraud against private insurers. LabCorp argues that Relators lack standing to bring a *qui tam* suit for these claims as they are not "interested persons," as required by the statutes, since the Relators have no connection to LabCorp, California, Illinois, or any private insurers from those two states.[2] The FAC does not include any allegations that the Relators, both South Carolina residents, have any personal involvement with LabCorp, or any actions that took place in California or Illinois. (*See* FAC at ¶¶14, 47 – 57.) However, Relators propose that the Relators qualify as "interested persons" because "a potential relator qualifies as an interested person...as long as he or she is the original source of the

[2] The two statutes have largely identical language. The California statute, CIFPA, provides that "Any interested persons, including an insurer, may bring a civil action for a violation of this section for the person and for the State of California." Cal. Ins. Code § 1871.7. The Illinois statute, ICFPA, states that "An interested person, including an insurer, may bring a civil action for a violation of this Act for the person and for the State of Illinois." 740 Ill. Comp. Stat. Ann. 92/15.

information, and the lawsuit is not based on allegations previously disclosed in another proceeding or by the media." (Dkt. No. 63 at 21.) Because of its interest in the litigation, the California Department of Insurance ("CDI") submitted a Statement of Interest with Relators' Response, which argues that an "'interested person' who becomes a relator under the CIFPA does not need to have a direct interest in the litigation[,]" and instead anyone can qualify as a relator so long the facts underlying the claim are not already the subject of another case or the person is the original source of the information. (Dkt. No. 63-1 at 6 – 7.)

Relators and CDI's arguments would define the phrase "interested person" out of the statutes. Contrary to the Relators and CDI's arguments the phrase "interested person" in the statutes defines *who* may be a *qui tam* relator under the statute, making clear that only "*interested person*[*s*]...may bring a civil action for a violation of this section...." Cal. Ins. Code § 1871.7; 740 Ill. Comp. Stat. Ann. 92/15 (emphasis added). The fact, therefore, that a *qui tam* relator has "no personal right to recover the damages s[o]ught" and instead it is the "government entities" that are the real parties in interest does not affect who can serve as that *qui tam* relator in the first instance. (Dkt. No. 63 at 20.) Instead, that is determined by the text of the statute.

While the federal FCA states that a "[a] person may bring a civil action for a violation of section 3729," California and Illinois' statutes instead define who may serve as a *qui tam* relator by stating that the relator must be an "interested person[.]" *Id.*; 31 U.S.C. § 3730. There is little case law from either California or Illinois regarding who qualifies as an "interested person" under the statutes. However, an order from a trial court in Illinois, the Circuit Court of Cook County, addressed the issue. The court, looking to Merriam Webster's dictionary, stated that "'interested' is commonly defined as 'being affected or involved.'" *State ex rel. Zolna-Pitts v. ATI Holdings,*

Inc., No. 12CH27483, 2013 WL 3779568, at *3 (Ill. Cir. Ct. June 18, 2013) (citation omitted).[3] Applying this definition, the court held that the relator was not an interested person based on her being a participant in health insurance provided by Blue Cross Blue Shield of Illinois and Aetna because there was no allegation that "[the defendant] made any false claim to either insurer." *Id.* The court, however, held that the relator ultimately qualified as an "interested person" since she was a former employee of the defendant. *Id.*

Neither the Parties nor the CDI have identified any California decisions interpreting the meaning of "interested persons" under the CIFPA, and the Court similarly has been unable to locate any California decisions defining the phrase. However, California courts have interpreted the term "interested person" in other statutes to mean "a person having a direct, and not a merely consequential, interest in the litigation." *Associated Boat Indus. of N. Cal. v. Marshall*, 230 P.2d 379, 380 (1951), *disapproved of on other grounds by Envtl. Prot. Info. Ctr. v. Dep't of Forestry & Fire Prot.*, 50 Cal. Rptr. 2d 892 (Cal. Ct. App. 1996) (a party is an "interested person" if either "it or its members is or may well be impacted by a challenged regulation."). *See also Torres v. City of Yorba Linda*, 17 Cal. Rptr. 2d 400, 403–04 (Cal. Ct. App. 1993) ("'interested person'...is a person having a direct, and not a merely consequential, interest in the litigation."). These cases, both from Illinois and California, hold that an individual needs some greater connection to the litigation than merely being an original source or having a potential to gain a recovery from pursuing claims under the ICFPA or CIFPA. The court in *ATI Holdings, Inc.*, 2013 WL 3779568, made this clear when it rejected the argument that the relator was an "interested person" because

[3] The Court in *ATI Holdings* also noted that the ICFPA "was modeled after the California statute and the language of the two statutes is substantively identical." *Id.*

of her participation in health care plans in Illinois, a more concrete relationship to the submittal of false claims in Illinois than the Relators allege here.

Relators and CDI's proposed expansive definition of "interested person" is unpersuasive. First, the proposed definition is taken from language contained in § 1871.7(h), which states that a person may not bring an action if the "allegations or transactions" are already the subject of a lawsuit or enforcement action in which the state is a party or where the information was already publicly disclosed unless the person was "an original source of the information." Cal. Ins. Code § 1871.7(h). While this section provides an important limit on who can serve as a *qui tam* relator, it does nothing to define the phrase "interested person" included in § 1871.7(e).

Relators and CDI also point to two cases to argue for their more expansive definition of "interested person." The first, *People ex rel. Strathmann v. Acacia Research Corp.*, 148 Cal. Rptr. 3d 361, 370 (2012), stated that "Strathmann is an 'interested person' bringing this action as a qui tam relator. 'A qui tam relator is essentially a self-appointed private attorney general, and his recovery is analogous to a lawyer's contingent fee.'" *Id.* (citations omitted). Relators argue this language indicates that Strathmann was an "interested person by virtue of his status as a *qui tam* relator." (Dkt. No. 63 at 26.) This, however, puts the cart before the horse, as the phrase "interested person" defines who may be a *qui tam* relator. Furthermore, in *Strathmann*, the relator was a former employee. *Id.* at 366. *People ex rel. Alzayat v. Hebb*, 226 Cal. Rptr. 3d 867 (Ct. App. 2017), a case relied on extensively by CDI, is similarly unhelpful. The court in *Alzayat*, a case determining whether certain claims under CIFPA are barred by the California workers' compensation statute, clearly holds that CIFPA "does not mandate that the relator has suffered his or her own injury." *Id.* at 889. However, a direct injury to Relators is not at issue here and

otherwise, *Alzayat*, involving a relator who was an employee of the defendant, provides no guidance on the definition of "interested person."

This opinion does not seek to define for California or Illinois precisely the contours of who qualifies as an "interested person" under their state laws. However, based on case law in Illinois and California, something more than merely being a source of the information or standing to gain from any ultimately recovery is required to qualify as an "interested person" under the statutes. The FAC does not allege that Relators have any contacts, were employed or were in any other way affected by or involved in the submission of allegedly false claims and/or kickback tainted claims in California or Illinois. Therefore, it is clear that the Relators here are not "interested persons" under those statutes. The Relators therefore do not have standing to bring claims under the CIFPA and ICFPA, and the Court grants LabCorp's motion to dismiss Count III (CIFPA) and Count IV (ICFPA).[4]

D. Conspiracy Claims

To state a cause of action for conspiracy under the FCA, "[t]he complaint must allege the existence of an agreement to violate the FCA and at least one act performed in furtherance of that agreement." *Berkeley Heartlab, Inc.*, 225 F. Supp. 3d at 501 *citing* § 3726(a)(1)(C). LabCorp argues that Relators fail to state a claim for conspiracy since Relators fail to allege "*any* agreement with HDL or Singulex regarding phlebotomy services, much less any agreement concerning the submission of false claims." (Dkt. No. 60 at 23). LabCorp is incorrect, and Relators properly pled a conspiracy claim under the FCA with the particularity requirements of 9(b).

[4] The Court also refuses to withhold ruling on the motion to dismiss the CIFPA claim since the CDI is still investigation the Relators' allegations. (Dkt. No. 63 at 21.) The CDI clearly has standing to bring a claim under the CIFPA, § 1871.7(d), but that is unrelated to whether the Relators here have standing as "interested persons" under the statute.

LabCorp identified the details of the alleged agreement with HDL, notably a discussion on March 1, 2013, where LabCorp and HDL executives discussed the "mutually beneficial" issue of the use of LabCorp's phlebotomists, and a July 21, 2014, "Memorandum of Understanding between HDL, Inc. and LabCorp" circulated between the companies' executives which discussed "LabCorp's assistance in providing phlebotomy services...." (FAC at ¶¶ 397 – 398, 421.) Similarly, the FAC alleges that LabCorp had extensive knowledge of HDL's violations of the FCA, including a kickback scheme with physicians, both before and after the alleged agreement, and that LabCorp acted in furtherance of the agreement by continuing to provide blood draw services for HDL referred tests. (*Id.* at ¶¶ 287 – 324, 388, 423.) Regarding Singulex, the FAC alleges that "[b]y 2012, LabCorp entered into a contract with Singulex to perform some of the tests in the Singulex panel," which allegedly was related to the blood draws since it "provided LabCorp with a direct benefit from drawing Singulex samples for referring physicians." (*Id.* at ¶ 436.) The FAC alleges that by 2013 LabCorp and Singulex "were collaborating to provide testing for employee health plans...." (*Id.* at ¶ 441.) LabCorp also allegedly knew of Singulex's alleged kickback scheme with physicians both before and after entering its contract and collaboration with Singulex. (*Id.* at ¶¶ 262 – 265, 277, 288.) Finally, the FAC alleges that both before and after these alleged agreements, LabCorp continuously drew blood for tests that were referred to Singulex. (*Id.* at ¶¶ 433, 445 – 446.) The FAC therefore alleges that LabCorp entered into an agreement and continued to draw blood even after knowing about the allegedly illegal kickback scheme.

Here, the FAC includes allegations of specific agreements entered into between LabCorp and both Singulex and HDL regarding blood draw services which caused false claims to be submitted. Regardless, the FAC also unmistakably alleges that LabCorp knew of the Singulex and HDL's kickback scheme with physicians and continued to draw blood for tests referred to Singulex

and HDL. By doing so, the FAC also alleges that LabCorp shared the two laboratories' specific intent to submit false claims and/or kickback tainted claims to government programs. *See U.S. ex rel. DeCesare v. Americare in Home Nursing*, No. 1:05CV696, 2011 WL 607390 (E.D. Va. Feb. 10, 2011) (holding conspiracy was properly pled where complaint alleged defendant "kn[ew], as of the first letter, that it may be participating in an illegal referral network, such that its continuing to do so afterwards constituted its assent to the other parties' allegedly illegal agreement."). Therefore, at this stage, Relators sufficiently pled their conspiracy claim under the FCA.

E. Amended Complaint

In their Response, Relators requested leave to amend their complaint. If Relators wish to amend their complaint, they should file a separate motion under Rule 15(a)(2), attaching the proposed amended complaint, and identify why "justice so requires."

IV. Conclusion

For the foregoing reasons, the Court **GRANTS IN PART** and **DENIES IN PART** Defendant LabCorp's partial Motion to Dismiss. (Dkt. No. 60.) The Motion is **GRANTED** as to claims regarding medically unnecessary tests, the cause of action for reverse false claims liability (Count II), and the causes of action under California law (Count III) and Illinois law (Count IV), and those claims are **DISMISSED**. The Motion is **DENIED** as to Relators conspiracy claim.[5]

AND IT IS SO ORDERED.

Richard Mark Gergel
United States District Court Judge

January 15, 2019
Charleston, South Carolina

[5] This order does not affect Relators' kickback related claims, which were not a subject of LabCorp's Motion to Dismiss.