IN THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA

United States of America, *et al.*, Plaintiffs, *ex rel.* Scarlett Lutz, *et al.*, Plaintiffs-Relators, v. Berkeley Heartlab, Inc., *et al.*, Defendants.	Civil Action No. 9:14-cv-00230-RMG (Consolidated with 9:11-cv-1593-RMG and 9:15-cv-2458-RMG) **ORDER and OPINION**

This matter is before the Court on defendant Latonya Mallory's motion for summary judgment of Relators Scarlett Lutz and Kayla Webster's Third Amended *Qui Tam* Complaint. (Dkt. No. 500.) Lutz and Webster have filed a response in opposition (Dkt. No. 519), and Mallory has filed a reply (Dkt. No. 529). For the reasons set forth below, Mallory's motion for summary judgment (Dkt. No. 500) is granted in part and denied in part.

I. Background

On February 6, 2013, Relators Lutz and Webster filed a *qui tam* complaint[1] alleging that several defendants including BlueWave Health Care Consultants, Inc. ("BlueWave"), Health Diagnostics Laboratory ("HDL"), Singulex, Inc., and several individuals including Defendants Mallory, Floyd Calhoun Dent, III, and Robert Bradford Johnson orchestrated a nationwide

[1] On July 9, 2014, Lutz and Webster filed a First Amendment Complaint in which they named Mallory, Dent, and Johnson as defendants. Lutz and Webster filed a Second Amended Complaint on October 29, 2014 with the same factual allegations raised in the original and First Amended Complaints. (Dkt. No. 40-1.) On April 4, 2016, Lutz and Webster filed a Third Amended Complaint reinserting claims under some state false claims acts that they inadvertently omitted from the Second Amended Complaint.

scheme to offer and pay kickbacks to physicians who ordered HDL and/or Singulex tests in violation of the federal False Claims Act ("FCA"), 42 U.S.C. § 3729, the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), various state false claims acts, and insurance fraud statutes in California and Illinois. Specifically, Relators allege the defendants' financial relationships with physicians provided financial incentives for the use of their laboratory services and resulted in billing private insurers for medically unnecessary testing services, in violation Section 1871.7(a) of the CIFPA, Cal. Ins. Code 1871.7(a), and Section 92/5(a) of the ILCFPA 740 Ill. Comp. Stat. § 92/5(a). (Dkt. No. 275 at 11). Relators also allege that defendants conspired to commit violations of the federal and state false claims acts. (Dkt. No. 275 at 10.)

Mallory filed this motion for summary judgment on June 23, 2017. (Dkt. No. 500.) The Court has since granted Relators' motion to dismiss many of their state law claims. (Dkt. No. 608.) Relators' remaining claims against Mallory arise under the false claims acts of Colorado, Florida, Illinois, Indiana, North Carolina, and Virginia and under insurance fraud statutes in California and Illinois. (Dkt. No. 595 at 1-2.) Mallory has moved for summary judgment on all of Relators' remaining state law claims. (Dkt. No. 500.)

II. Legal Standard

A. Summary Judgment

To prevail on a motion for summary judgment, the movant must demonstrate that there is no genuine issue of any material fact and that the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). The party seeking summary judgment has the burden of identifying the portions of the "pleadings, depositions, answers to interrogatories, any admissions on file, together with the affidavits, if any, which show there is no genuine issue as to any material fact that the moving party is entitled to judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The Court will construe all inferences and ambiguities against the movant

and in favor of the non-moving party. *U.S. v. Diebold, Inc.*, 369 U.S. 654, 655 (1962). The existence of a mere scintilla of evidence in support of the non-moving party's position is insufficient to withstand a motion for summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986). However, an issue of material fact is genuine if the evidence is such that a reasonable jury could return a verdict in favor of the non-movant. *Id.* at 257.

"When the moving party has carried its burden under Rule 56(c), its opponent must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). "In the language of the Rule, the nonmoving party must come forward with 'specific facts showing that there is a genuine issue for trial.'" *Id.* at 587. "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.'" *Id.* (quoting *First Nat'l Bank of Ariz. v. Cities Serv. Co.*, 391 U.S. 253, 289 (1968)).

B. False Claims Act

In order to establish a violation of the False Claims Act, a plaintiff must show that: (1) there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material to the government's decision to pay a claim; and (4) that caused the government to pay out money or to forfeit moneys due. *See United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008). The state false claims acts at issue here generally mirror the federal FCA. (Dkt. No. 275 at 42, explaining that "[t]he false claims acts of the sovereign States of North Carolina, California, Colorado, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Louisiana, Michigan, Minnesota, New Jersey, New York, Tennessee, Texas, Virginia, and Wisconsin generally mirror the federal FCA").

III. Discussion

A. Intervened Federal FCA Claims

The United States has intervened in all of Lutz and Webster's claims against Mallory that arise under the federal FCA. Because the Government bears responsibility for prosecuting those claims under 31 U.S.C. § 3730(c)(1), the Court will consider Mallory's arguments about those claims in its order on Mallory's motion for summary judgment on claims in the Government's Complaint in Intervention. (Dkt. No. 498.)

B. Non-Intervened State Law Claims

1. False Claims

Mallory argues she is entitled to summary judgment on Lutz and Webster's non-intervened state claims because Relators have provided no evidence that (1) Mallory's conduct and statements were material to states' or private insurers' decisions to pay claims; (2) states or private insurers actually paid claims submitted by HDL or Singulex; or (3) Mallory's conduct caused the states or private insurers to pay claims. (Dkt. No. 500-1.)

a. Materiality

Mallory argues that her alleged state false claims act violations were not material to states' or private insurers' decisions to pay because the federal government continued to pay claims despite having knowledge of Mallory's conduct. (Dkt. No. 500-1 at 3.) This assertion concerns the federal government's knowledge and continued payment of claims, so it is not relevant to the materiality of individual states' decisions to pay claims submitted by HDL or Singulex.

Mallory also argues that the alleged kickback scheme was not material to states' decisions to pay claims even if it was technically illegal. (Dkt. No. 519 at 8-9.) Mallory notes that on March 23, 2010, the federal AKS was amended to state that "a claim that includes items

or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim." 42 U.S.C. § 1320a-7b(g), *as amended by* the Patient Protection and Affordable Care Act, Pub. L. no. 111-148, 124 Stat. 119 (2010), effective January 1, 2011. Mallory claims that the corresponding statutes in North Carolina, Colorado, Florida, Illinois, Indiana, and Virginia do not include the same explicit notification that claims tainted by illegal kickbacks are false claims. (Dkt. No. 529 at 5.) The Court does not agree with Mallory's premise that the 2010 amendment to the federal AKS made compliance with the AKS material to FCA violations and is persuaded that the 2010 amendment was simply a clarification of existing law. *See U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 54 (D. Mass. 2011).

In any event, commonsense and the weight of analogous[2] authority considering the materiality of AKS violations within the context of the federal FCA suggests that evidence that claims are tainted by an illegal kickback scheme in which providers are bribed for referrals would be material to a state's decision to pay claims. *See, e.g., United States ex rel. United Health Group, Inc.*, 659 F.3d 295, 313 (3d Cir. 2011); *United States ex rel. Nevyas v. Allergan, Inc.*, 2015 WL 4064629, at *4 (E.D. Pa. Jul. 2, 2015); *United States ex rel. Gale v. Omnicare, Inc.*, 2013 WL 3822152, at *5 (N.D. Ohio Jul. 23, 2013); *United States ex rel. Fry v. The Health Alliance of Greater Cincinnati*, 2008 WL 5282139, at *33 (S.D. Ohio Dec. 18, 2008); *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 615-16 (N.D. Ill. 2003). A violation of the anti-kickback statute is not a technical violation of the law.

Finally, as the question of materiality is both fact-intensive and context-specific and the Court finds that there is at least a genuine dispute of material fact here, the question should be presented to a jury. *See Westmoreland*, 812 F. Supp. 2d at 46.

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[2] As explained above, the state false claims acts at issue here generally mirror the federal FCA.

b. Payment

Mallory claims there is no evidence that any state or private insurer disbursed or forfeited money and that Lutz and Webster both testified that they had no personal knowledge of any HDL or Singulex claims that were presented to and paid by state Medicaid programs or private insurers with patients residing in California or Illinois. (Dkt. No. 500-1 at 4.) Lutz and Webster claim that the law does not require them to have personal knowledge of presentment and payment but allows them to rely on claims data showing presentment and payment of claims. Lutz and Webster have subpoenaed HDL's claim submissions to Medicaid programs in Colorado, Florida, Indiana, Illinois, North Carolina, and Virginia (Dkt. No. 619 at 6) and produced that data to Mallory in May and June 2016.[3] (Dkt. No. 519, Exhibits 1-11.) This data shows that HDL submitted and was reimbursed by state Medicaid programs for laboratory testing services.

c. Causation

With regard to causation[4], Mallory argues that the Relators cannot rely on statistical sampling to prove liability or damages but instead must show a direct link between defendants' financial arrangements and each of the allegedly false claims submitted to state governments. Mallory claims that rejecting statistical sampling in favor of subjecting each claim to analysis and cross examination is "crucial" in this case because not all of the physicians or physician practices that had a P&H agreement with HDL actually received P&H fees. (Dkt. No. 500-1 at 6.)

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[3] Relators had not obtained the Colorado business records at the time of briefing but represented that they expected to have those records by July 21, 2017. (Dkt. No. 519 at 6.)

[4] Mallory weaves this argument throughout her motion for summary judgment.

The Government took great care to ensure that its damages expert isolated only those claims that could be directly linked to P&H fees paid to physicians. (Dkt. No. 522 at 24-26.) The Relators do not appear to have exerted the same effort to show which physicians who ordered HDL tests actually received P&H payments. (Dkt. No. 529 at 4.) Mallory claims that in excess of 40% of HDL's customers did not receive P&H payments at all. (Dkt. No. 529 at 4.) The Court reads this as a tacit admission that the majority of HDL's customers did receive P&H fees. Moreover, Relators have provided defendants with documentation of all claims submitted by HDL to the six states[5] during the relevant period, and that documentation identifies each referring provider. Despite having this information, Mallory does not argue that all of the claims HDL submitted to state Medicaid programs were ordered by referring physicians who did not receive P& H fees. The Court concludes that at least some of the claims HDL submitted to state Medicaid programs were linked to tests ordered by physicians who received P&H fees from HDL.[6] There is clearly a genuine dispute of material fact about how many of the claims submitted to the state healthcare programs were tainted by the alleged kickback scheme, and this question must be submitted to the jury. *See U.S. ex rel. Pogue v. Diabetes Treatment Centers of Am.*, 565 F. Supp. 2d 153, 161 (D.D.C. 2008) (denying summary judgment on claims arising out of referrals by medical directors when relators did not provide those patients' Medicare forms because ascertaining the number of false claims submitted and thus, the appropriate amount of damages, is a question for the fact finder).

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[5] Relators represented that the Colorado data would be made available to Defendants in July 2017.

[6] The parties do not appear to dispute that at least one or some of the relevant state claims are linked to physicians who received P&H fees from HDL.

C. Conspiracy Claims

Relators have alleged and provided evidence to show that Mallory and her co-defendants Dent and Johnson conceived and executed a marketing scheme to offer illegal P&H payments to physicians who referred clients to HDL for testing. *See, e.g.,* Dkt. No. 498-4 (HDL P&H agreement); 504-6 (HDL position statement on P&H fees); 504-10 (Dent Dep. Tr.) at 14. This evidence creates at least a genuine dispute of material fact about whether defendants' marketing scheme caused the submission of false claims and about whether Mallory is liable under a conspiracy theory. A rational trier of fact could conclude that the evidence presented shows that (1) Mallory willfully entered an agreement with Dent and Johnson with the goal of obtaining reimbursement for false claims; (2) one conspirator performed an overt act to execute that scheme; and (3) the state governments suffered damages when they reimbursed false claims.

D. Claims Arising Under Insurance Statutes in California and Illinois

Mallory argues that Relators have submitted no evidence showing that HDL or Singulex submitted (or were reimbursed for) claims to private insurers with clients in California or Illinois in violation of either state's insurance statutes. Relators did not argue in their brief that they have such evidence. (Dkt. No. 519.) For this reason, Relators have created no genuine dispute of material fact about whether Mallory violated the insurance statues in Illinois or California, and Mallory is entitled to summary judgment on these claims.

IV. Advice of Counsel

Mallory has separately argued that she did not have the requisite scienter to violate any state false claims act because the record shows that she consulted attorneys and asked for guidance about the P&H practice. There is substantial evidence in the record that creates a genuine dispute of material fact about whether Mallory had the requisite scienter to violate the

state false claims acts. The court will discuss this issue in more depth in its order ruling on Defendants' motion for summary judgment on the Government's FCA claims.

V. Conclusion

For the reasons set forth above, Latonya Mallory's motion for summary judgment (Dkt. No. 500) is granted with regard to Lutz and Webster's claims arising under insurance statutes in California and Illinois. Mallory's motion for summary judgment is denied as to all other claims.

AND IT IS SO ORDERED.

Richard Mark Gergel
United States District Court Judge

August 24, 2017
Charleston, South Carolina