

I. Background

Berkeley HeartLab, Inc. (“BHL”) is a California company that offers laboratory testing services for physicians treating patients with cardiovascular disease.² (Dkt. No. 501-5.) Defendant Latonya Mallory was the Lab Operations Manager for BHL from 2005 through September 2008. (Dkt. No. 501-4 at 3-4.) Defendant Robert Bradford Johnson was employed as a sales representative for BHL beginning in 2002. (Dkt. No. 501-6.) Defendant Floyd Calhoun Dent, III, was employed as a sales representative at BHL beginning in 2005. Johnson trained Dent to perform sales at BHL. (Dkt. No. 501-8; Dkt. No. 501-7 at 10.) Mallory left BHL in September 2008 and formed a new laboratory testing Company, Health Diagnostics Laboratory, Inc. (“HDL”), in November of that year. (Dkt. No. 501-4 at 5.) Mallory was President and CEO of HDL from 2008 through 2014.

In the latter half of 2009, Johnson, Dent, and Mallory arranged for HDL to retain Dent and Johnson to market its laboratory tests to physicians and physician practices. On January 4, 2010, Dent and Johnson incorporated BlueWave Healthcare Consultants, Inc. (“BlueWave”) as co-owners with 50% ownership each. (Dkt. No. 173-2 at 50-51; Dkt. No. 501-10 at 3-4.) BlueWave’s only clients were HDL and another laboratory called Singulex, Inc. (“Singulex”). All of BlueWave’s earnings derived from its sales agreements with HDL and Singulex. (Dkt. No. 501-7 at 26-27; Dkt. No. 501-10 at 21-22.)

II. The Complaint in Intervention

The Government has provided a lengthy summary of material undisputed facts with citations to the record describing several allegedly illegal marketing and business arrangements among BlueWave, HDL, and Singulex. (Dkt. No. 501-2 at 3-36.) Based on these activities, the

² Quest Diagnostics Inc. acquired BHL in 2011.

Government filed a Complaint in Intervention against BlueWave, Dent, Johnson (together, the “BlueWave Defendants”) and Mallory, alleging that they are liable for violations of the False Claims Act (“FCA”), 31 U.S.C. § 3729, *et seq.*, payment by mistake of fact, and unjust enrichment. (Dkt. No. 75.)

A. FCA Claims

Some of the Government’s FCA claims arise from Defendant Mallory’s alleged violation of the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b(b), through her participation in three separate schemes:

(1) P&H Fees: The Government alleges that Mallory and the BlueWave Defendants caused physicians to be paid process and handling fees to induce those physicians to order blood tests that were reimbursed by federal healthcare programs.

(2) Zero Balance Billing: The Government alleges that Mallory and the BlueWave Defendants caused Tri-Care co-payments and deductibles to be waived to induce physicians to order blood tests that were reimbursed by Tricare.

(3) Commission Payments: The Government alleges that, because the laboratories paid BlueWave commissions as an independent contractor for marketing their blood tests, those commissions were intended to induce physicians to order blood tests that were reimbursed by federal healthcare programs.

The Government alleges that each claim filed in connection with one of these three arrangements violates the AKS and “constitutes a false or fraudulent claim” under the FCA. *See* 42 U.S.C. § 1320a-7b(g). The Government’s fourth FCA claim is not based on an AKS violation:

(4) Medically Unnecessary Tests: The Government alleges that the BlueWave Defendants and Defendant Mallory induced physicians to order medically unnecessary

blood tests and caused claims for reimbursement for those tests to be submitted to federal healthcare programs.

B. Equitable Claims

Based on the conduct described above, the Government also claims: (1) that the Government paid Defendant Mallory based upon mistaken or erroneous understandings of material fact, and (2) that Defendant Mallory was unjustly enriched.

III. 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. The False Claims Act

The False Claims Act imposes civil liability on any person who “knowingly presents, or causes to be presented, to [the United States government] a false or fraudulent claim for payment or approval” or “knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.” 31 U.S.C. § 3729(a). A false or fraudulent claim includes false statements or fraudulent conduct that induce the contract for or extension of a government benefit. To prove a fraudulent inducement claim, 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).

IV. Discussion

A. False Claims Act

Defendant Mallory argues that she is entitled to summary judgment on the Government’s FCA claims because the Government has failed to create a genuine dispute of material fact about each of the four elements of an FCA claim.

1. False Statements or Fraudulent Course of Conduct

Under 42 U.S.C. § 1320a-7b(g), “[A] claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the FCA].” The AKS prohibits a person from paying or receiving kickbacks to induce the

referral of an individual for services paid under a federal health care program. 42 U.S.C. § 1320a-7b(b)(1)-(2). A violation of the AKS occurs when a defendant: (1) knowingly and willfully; (2) offers or pays any remuneration, directly or indirectly; (3) to induce a person to refer individuals to the defendants for the furnishing of medical services; (4) paid for by Medicare. *United States ex rel. Mastej v. Health Mgmt. Assocs., Inc.*, 591 F. App'x 693, 705 (11th Cir. 2014). Under the AKS, the term “knowingly” “merely requires proof of knowledge of the facts that constitute the offense.” *Bryan v. United States*, 524 U.S. 184, 192-193 (1998); *Dixon v. United States*, 548 U.S. 1 (2006). The term “willfully” means that the defendant knew “that his conduct was unlawful,” knew he was acting “with a bad purpose,” or knew he was acting “with evil intent without justifiable excuse.” *Bryan*, 524 U.S. at 192-193.

Mallory argues that the Government has failed to point to evidence that she had the requisite scienter to violate the AKS with regard to any of the three alleged kickback schemes. Specifically, Mallory argues that there is no evidence that she knowingly and willfully designed any of the three arrangements (P&H Fees, Zero Balance Billing, or the Commission Payment Structure) for the purpose of inducing referrals. She says the evidence shows that she continuously sought out and relied on the advice of counsel to ensure that these arrangements were legal. (Dkt. No. 498-1 at 13-16.)

As with the BlueWave Defendants (Dkt. No. 693 at 7-10), the Government has provided evidence from which a reasonable juror could conclude that Defendant Mallory had the requisite scienter to violate the AKS when she incorporated the payment of P&H Fees, Zero Balance Billing, and Commission Payments into HDL's business model. For example, the record shows that Mallory received warnings from third party lawyers as early as December 2010 that the Government would consider HDL's P&H Fee practice to constitute illegal kickbacks and that

she continued to receive similar warnings from outside parties and her own lawyers through 2013 but did not discontinue the practice of paying P&H Fees. (Dkt. Nos. 501-53, 501-54, 501-58, 501-60, 501-64, 501-65.) The record also shows that Mallory was on notice as early as January 2011 that the practice of Zero Balance Billing presented significant legal risks and continued the practice. (Dkt. Nos. 522-10, 522-15.) Finally, the record shows that Mallory was on notice as early as August 2012 that her business relationship with BlueWave and its commission-based sales force “poses a high degree of risk with respect to the AKS.” (Dkt. No. 503-9 at 4.) There is therefore a genuine dispute of material fact about whether Defendant Mallory possessed the requisite scienter³ to violate the AKS by participating in these three arrangements.

The Government has also alleged that Mallory and the BlueWave Defendants violated the FCA by causing medically unnecessary tests to be presented for reimbursement while falsely representing that they met the standards for reimbursement. This FCA violation does not rest on an underlying AKS violation. 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).

³ The Government has also moved for summary judgment on Defendant Mallory’s Sixth affirmative defense that she cannot be liable for violations of the AKS based on the payment of P&H fees because the law is ambiguous. (Dkt. No. 501-1 at 35.) Mallory intends to argue that she did not have the requisite scienter to violate the AKS and the FCA when she participated in the P&H Fee arrangement because it was not clear that the payment of P&H fees was illegal. As discussed in this Court’s previous order with regard to the BlueWave Defendants’ defenses, this is a factual question that must be submitted to the jury. (Dkt. No. 693 at 23.) Likewise, as with the BlueWave Defendants, the Government is not entitled to summary judgment on its claims against Defendant Mallory based on P&H fees paid after 14, 2013 because a jury must consider whether she acted with the requisite scienter.

Mallory has not presented arguments unique from the BlueWave Defendants' about the Government's FCA claims based on medically unnecessary tests, and the Court determined in its previous order that the Government has provided evidence that creates at least a genuine dispute of material fact with regard to whether all Defendants are liable for the submission of claims for reimbursement for medically unnecessary tests. (Dkt. No. 693 at 10-11.)

2. *Scienter to Violate the FCA*

In addition to the scienter requirement under the AKS, the Government has the burden of proving that Mallory acted "knowingly" under the FCA, meaning with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information. 31 U.S.C. § 1320a-7b(g). Mallory claims the Government has failed to show that she acted with even the lowest level of culpability – reckless disregard – with respect to the alleged FCA violations. (Dkt. No. 498-1 at 16-19.)

Federal courts consider a variety of factors to determine whether a defendant acted with reckless disregard, including "(1) the defendant's adherence to custom or industry practice; (2) the defendant's existing knowledge or expertise; (3) any legal advice the defendant received; (4) any professional or expert advice the defendant received; (5) the defendant's disclosure of its conduct to the government; (6) the existence of any guidance or authority from an administrative agency or court; (7) the reasonableness of the defendant's actions, positions, or interpretations; and (8) the defendant's motive." James Wiseman, *Reasonable, but Wrong: Reckless Disregard and Deliberate Ignorance in the False Claims Act After Hixon*, 117 Colum. L. Rev. 435, 450-51 (2017).

As discussed earlier in this order, there is a genuine dispute of material fact about whether Mallory had the requisite scienter to violate the AKS. For FCA violations based on AKS violations, Mallory says the Government must separately establish that she acted with the

requisite scienter under the FCA. However, in this case Mallory's arguments as to why she did not act with the requisite scienter under the FCA essentially mirror the arguments she made about scienter under the AKS: that she relied on the advice of counsel, that she adhered to industry practice, and that the Government knew about the conduct but continued to reimburse claims. For the same reasons that a reasonable juror could conclude Mallory had the requisite scienter to violate the AKS, a reasonable juror could conclude that she had the requisite scienter to violate the FCA.

Mallory has not presented arguments unique from the BlueWave Defendants' about the Government's FCA claims based on medically unnecessary tests, and the Court determined in its previous order that the Government has presented evidence sufficient to create a genuine dispute of material fact about whether Defendants knowingly or with reckless disregard for the truth caused claims for medically unnecessary laboratory tests to be submitted to federal healthcare programs for the reimbursement. (Dkt. No. 693 at 12-13.)

3. Materiality

Defendant Mallory argues that the Government has failed to show that she is liable under the FCA because the Government continued to pay claims after it learned some facts about the conduct in this case as early as June 30, 2011. (Dkt. No. 498-1 at 8-10.) For the same reasons outlined in this Court's order on the BlueWave Defendants' Motion for Summary Judgment (Dkt. No. 693 at 13-14), Defendant Mallory is not entitled to summary judgment on her materiality argument.

4. Causation

To prove a fraudulent inducement claim, a plaintiff must show that Defendant's false or fraudulent course of conduct 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). Mallory says the Government has failed to create a genuine dispute of material fact about causation because it has failed to show that the physician or physician practices that had P&H Fee agreements with HDL actually received P&H Fees. (Dkt. No. 498-1 at 10-13.) She also argues that the Government's damages expert, Eric Hines, incorrectly assumes that if one physician in a practice received P&H fees, all the claims from that practice were tainted by kickbacks. Mallory argues that the Government must establish causation with respect to each false claim and cannot rely on statistical sampling. (*Id.*) The Court has addressed Mallory's causation argument in a previous order and determined that there is a genuine dispute of material fact about how many of the claims submitted to healthcare programs were tainted by the alleged kickback schemes, and this question must be submitted to the jury. (Dkt. No. 634 at 6-7.)

B. Conspiracy to Violate the FCA

The Government has also alleged that the BlueWave Defendants and Defendant Mallory conspired to violate the FCA. Defendant Mallory argues that she is entitled to summary judgment on the Government's conspiracy claim because the Government cannot demonstrate that (1) Mallory conspired with one or more persons to get a false or fraudulent claim allowed or paid by the United States; (2) one or more conspirators performed any act to effect the object of the conspiracy; (3) Mallory willfully joined that conspiracy; and (4) the United States has suffered damages as a result of the false or fraudulent claim. (Dkt. No 498-1 at 20-21); *United States ex rel. Mikes v. Straus*, 84 F. Supp. 2d 427, 432 (S.D.N.Y. 1999); *United States ex rel. Miller v. Bill Harbert Intern. Const., Inc.*, 608 F.3d 871, 901 (D.D.C. 2010).

"To state a claim under the FCA for conspiracy, a plaintiff must plead that the alleged conspirators agreed to make use of a false record or statement to achieve the end of getting the government to pay a claim." *United States v. Toyobo Co. Ltd.*, 811 F. Supp. 2d 37, 50 (D.D.C. 2011); *see also United States ex rel. Reagan v. East Texas Medical Center Regional Healthcare*

System, 274 F. Supp. 2d 824, 857 (S.D. Tex. 2003) (“the essence of a conspiracy under the FCA is an agreement between two or more persons to commit fraud. . . . Courts agree that, to establish the existence of a civil conspiracy, a plaintiff must present evidence to show a meeting of the minds of two or more persons on the object or course of action.”)

The Government has provided evidence from which a reasonable juror could conclude that all Defendants entered into agreements with respect to the payment of P&H Fees, Waiver of Copayments and Deductibles, and Commission Payments. (Dkt. No. 502-1, Defendants’ sales agreement including provisions for P&H Fees, Payment of Commissions, and Waiver of Copayments and Deductibles). From this evidence, combined with the other evidence already discussed in this Order, a rational trier of fact could conclude that (1) Mallory willfully entered those agreements with Dent and Johnson; (2) Defendants’ actions under those contractual agreements contributed to FCA and AKS violations; and (3) the Government suffered damages when it reimbursed the false claims.

With respect to the Government’s fourth FCA claim, Defendants’ contractual agreements do not include provisions for encouraging physicians to order medically unnecessary tests. However, a reasonable juror could conclude based on email communications in the record that Mallory and the BlueWave Defendants together agreed to run medically unnecessary test panels retroactively on existing patient samples. (*See* Dkt. No. 522-27 (emails between Mallory and Dent) and Dkt. No. 693 at 10-13 (the Court’s previous discussion of medically unnecessary testing).)

C. Equitable Claims - Mistake of Fact and Unjust Enrichment

The Government has also alleged that Defendant Mallory is liable in equity because (1) the Government paid her based upon mistaken or erroneous understandings of material fact and (2) she was unjustly enriched. To prevail on a claim for payment by mistake of fact, the

government must show that a federal health care program made “payments under an erroneous belief which was material to the decision to pay.” *U.S. ex rel. Roberts v. Aging Care Home Health, Inc.*, 474 F. Supp. 2d 810, 819 (W.D. La. 2007) (quoting *United States v. Mead*, 426 F.2d 118, 124 (9th Cir. 1970)). “The government by appropriate action can recover funds which its agents have wrongfully, erroneously, or illegally paid.” *United States v. Medica-Rents Co.*, 285 F.Supp.2d 742, 776 (N.D. Tex. 2003) (internal quotation and citations omitted). A claim for unjust enrichment “may be maintained as a general rule whenever the defendant has money in his hands which belongs to the plaintiff, and which in equity and good conscience he ought to pay to the plaintiff.” *Maisha v. Univ. of N.C.*, 641 F. App’x 246, 251-52 (4th Cir. 2016) (internal quotations and citations omitted). “[T]hree elements encompass the equitable remedy of unjust enrichment and quasi-contract: the plaintiff must show that (1) he had a reasonable expectation of payment, (2) the defendant should reasonably have expected to pay, or (3) society’s reasonable expectations of person and property would be defeated by nonpayment.” *United States v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 2016 WL 7851459, at *9 (D.S.C. 2016) (quoting *Provident Life & Acc. Ins. Co. v. Waller*, 906 F.2d 985, 994–95 (4th Cir. 1990)).

Defendant Mallory argues that she is entitled to summary judgment on the Government’s equitable claims because there is no evidence that payments were made to Mallory or that she obtained a personal benefit as a result of the alleged misconduct. Mallory argues that it is not sufficient for the Government to argue that she received benefits in her role as CEO of HDL “in the form of salary, bonuses, travel and other reimbursement and shareholder disbursements.” (Dkt. No. 498-1 at 22-24.) She further argues that HDL may have used the alleged wrongful payments for other purposes, including, for example, to pay the government pursuant to its

settlement agreement, to pay its attorneys, and to pay the salaries of other HDL employees and officers.

Mallory relies primarily on *United States v. Fadul*, No. CIV. A. DKC 11-0385, 2013 WL 781614 (D. Md. Feb. 28, 2013). In *Fadul*, the Government moved for summary judgment on FCA claims and the same two equitable claims at issue here. The district court determined that “the Government is entitled to obtain repayment from anyone ‘into whose hands the mistaken payments flowed,’ including third parties who did not directly receive the mistaken payments but nonetheless participated somehow in the transaction and ‘received benefits as a result’ thereof.” *Id.* at *13 (quoting *Mead*, 426 F.2d at 124-25). Nonetheless, the court ultimately determined that the Government had not shown that the Defendant, Dr. Fadul, was personally liable in equity for payments the Government made to his company, Cardio Vascular Center (“CVC”), based on the mistake of fact. CVC was a limited liability company that provided mobile diagnostic services for nursing home patients. Dr. Fadul owned CVC, was the operating officer of CVC, and was the sole member of the LLC. The Court cited two reasons for its decision: (1) CVC used billing software that automatically added reimbursement codes for services that had not actually been performed, and it was not clear from the record to what extent Dr. Fadul was actually involved with billing; and (2) the Government failed to present evidence that Dr. Fadul actually received a personal benefit from the billing practice, and the court would not assume that he did based solely on his position at the head of CVC. The district court distinguished its decision from another district court’s decision that an officer of a healthcare corporation was individually liable because the officer personally signed the false certifications and received benefits in the form of an increased salary. *See U.S. ex rel. Roberts v. Aging Care Home Health, Inc.*, No. CIV.A. 02-2199, 2008 WL 2945946, at *7 (W.D. La. July 25, 2008) (defendant personally liable for

payments made by mistake of fact when he served as CFO of the healthcare organization, received a salary of between \$105,000 and \$148,000, and was at one point a 50% shareholder of the organization).

For reasons stated throughout this and other orders, the Government has presented evidence from which a reasonable juror could conclude that Defendant Mallory was responsible for the conduct underlying the alleged FCA violations because the violations were the result of contracts she entered with the BlueWave Defendants that were integral to HDL's business structure. As was the case in *Roberts*, the Government has provided substantial evidence that Defendant Mallory benefitted personally from the mistaken payments. She was a 15% shareholder of HDL and received millions of dollars in salary, bonuses, and discretionary distributions. (Dkt. Nos. 522-34, 522-35.) The Government has also presented evidence that the benefits Mallory received constitute a portion of the mistaken payments and unjust enrichment to which the Government is entitled because Medicare payments made up approximately 30% of HDL's reimbursements. (Dkt. No. 522-29 at 6-7.)

In the Order on the BlueWave Defendants' Motion for Summary Judgment, the Court addressed the substance of Defendant Mallory's other arguments with regard to these equitable claims, including the argument (the subject of her Tenth affirmative defense) that she cannot be liable based on the theory of unjust enrichment because the Government received the benefit of the medical services it paid for. (Dkt. No. 693 at 15-16.) For the same reasons stated in that Order, the Government is not entitled to summary judgment on Mallory's Tenth affirmative defense because the Court declines to grant summary judgment on any FCA claim by which Defendant Mallory was allegedly unjustly enriched.

D. Affirmative Defenses

In its Partial Motion for Summary Judgment, the Government seeks summary judgment on several of Defendant Mallory's affirmative defenses. (Dkt. No. 501.)

1. *Duty to Mitigate*

The Government has moved for summary judgment on Defendant Mallory's Eighth affirmative defense which is based on the Government's duty to mitigate damages. For the reasons outlined in this Court's Order on the BlueWave Defendants' Motion for Summary Judgment (Dkt. No. 693 at 3), the Government is not entitled to summary judgment on Defendant Mallory's mitigation defense.

2. *Laches*

The Government has moved for summary judgment on Defendant Mallory's Seventh affirmative defense which is based on the doctrine of laches. For reasons stated in this Court's Order on the BlueWave Defendants' Motion for Summary Judgment (Dkt. No. 693 at 20), the Government is entitled to summary judgment on Defendant Mallory's Seventh affirmative defense as a matter of law.

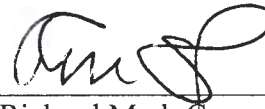
3. *Legal and Contractual Remedies*

The Government has moved for summary judgment on Defendant Mallory's Third affirmative defense that the Government's equitable claims are barred because the FCA is an adequate remedy at law and her Fourth affirmative defense that the Government's equitable claims are barred because express contracts cover the dispute. (Dkt. No. 504-1 at 32-34.) For the reasons outlined in this Court's Order on the BlueWave Defendants' Motion for Summary Judgment (Dkt. No. 693 at 21-22), the Government is entitled to summary judgment on Defendant Mallory's Third and Fourth affirmative defenses.

V. **Conclusion**

For the reasons set forth above, Defendant Mallory's Motion for Summary Judgment (Dkt. No. 498) is **DENIED**. The Government's Motion for Partial Summary Judgment (Dkt. No. 501) is **GRANTED IN PART** with respect to Defendant Mallory's Third, Fourth, and Seventh affirmative defenses and **DENIED IN PART** with respect to all other claims and defenses.

AND IT IS SO ORDERED.



Richard Mark Gergel
United States District Court Judge

October 21, 2017
Charleston, South Carolina