

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

United States of America, *et al.*,)
)
Plaintiffs,)
)
ex rel. Scarlett Lutz, et al.,)
)
Relators,)
v.)
)
Berkeley HeartLab, Inc., *et. al.*,)
)
)
Defendants.)
_____)

Civil Action No. 9:14-230-RMG

ORDER AND OPINION

This matter is before the Court on Defendants BlueWave Healthcare Consultants, Inc., Floyd Calhoun Dent, III, and Robert Bradford Johnson’s (collectively, “the BlueWave Defendants”) Motion for Summary Judgment on the claims in the Government’s Complaint in Intervention, Relator Chris Riedel’s non-intervened claims, and several of their affirmative defenses. (Dkt. No. 504.) For the reasons set forth below, the Motion for Summary Judgment is **GRANTED IN PART AND DENIED IN PART**. The Motion is **GRANTED** with respect to Relator Riedel’s Speaker Fee claim and **DENIED** as to all other claims and defenses.

The United States has filed a cross motion for Partial Summary Judgment against the BlueWave Defendants on Counts I and III of its Complaint in Intervention: (I) the presentation of false claims tainted by an illegal kickback scheme disguised by process and handling fees and (III) conspiracy to present those false claims. The Government has also moved for partial summary judgment on several of Defendants’ affirmative defenses. (Dkt. No. 501.) The Government’s Motion for Partial Summary Judgment is **GRANTED IN PART AND DENIED IN PART**. The Motion is **GRANTED** with respect to Defendants’ Fourth, Fifth, Sixth, Seventh,

Tenth, Twelfth, and Nineteenth affirmative defenses and **DENIED** with respect to all other claims and defenses.

I. Background

Berkeley HeartLab, Inc. (“BHL”) is a California company that offers laboratory testing services for physicians treating patients with cardiovascular disease. (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 Johnson was employed as a sales representative for BHL beginning in 2002. (Dkt. No. 501-6.) Defendant Dent 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 outlining the contours of several allegedly illegal marketing and business arrangements among BlueWave, HDL, and Singulex. (Dkt. No. 501-2 at 3-36.) Based on these activities, the Government filed a Complaint in Intervention against 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 Defendants’ alleged violation of the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b(b), through their participation in three separate schemes:

(1) P&H Fees: The Government alleges that 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 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 tainted by one of these three illegal kickback schemes 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 induced physicians to order medically unnecessary blood tests and submitted claims for reimbursement for those tests to federal healthcare programs.

B. Equitable Claims

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

C. Relator Riedel's Non-intervened Claims

Relator Riedel has brought two non-intervened claims. (Dkt. No. 286.) First, he claims that Singulex, HDL, and/or BlueWave paid physicians speaker fees to appear and teach at conferences to induce those physicians to order lab tests that were reimbursable by federal health care programs (the "Speaker Fee" arrangement). He also claims that Singulex, HDL, and/or BlueWave waived copayments and deductibles for private insurance carriers to induce physicians to order blood tests reimbursable by federal health care programs (the "Private Zero Balance Billing" scheme). Riedel's FCA claims are both premised on AKS violations.

The BlueWave Defendants argue that they are entitled to summary judgment on (1) all claims arising under the FCA brought by the Government and Relator Riedel; (2) the Government's equitable claims for payment by mistake of fact and unjust enrichment; and (3) Defendants' Second, Fourth, Fifth, Sixth, Seventh, Ninth, Tenth, Twelfth, Thirteenth, Fifteenth, and Nineteenth affirmative defenses.. (Dkt. No. 504-1.)

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

The BlueWave Defendants claim they are entitled to summary judgment on the Government's FCA claims because the Government has failed to create a genuine dispute of material fact about whether (1) they made false statements or engaged in a fraudulent course of conduct and (2) their statements or conduct were material to the Government's decision to pay any claims.

1. *False Statements or Fraudulent Course of Conduct*

The BlueWave Defendants argue that the Government has failed to create a genuine dispute of material fact about whether they made false statements or engaged in a fraudulent course of conduct because the Government has failed to point to evidence that (1) they had the requisite scienter to violate the AKS with regard to any of the alleged kickback schemes or (2) any test for which a claim was submitted to a federal health care program was medically unnecessary for a particular patient.

a. *Scienter to Violate the AKS*

Some of the Government's FCA claims are based on Defendants' alleged violation of the AKS through participation in three schemes described above, P&H Fees, Zero Balance Billing, and Commission Payments. 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.

The BlueWave defendants claim that the Government has failed to create a genuine dispute of material fact about whether they had the requisite scienter to violate the AKS when they engaged in the payment of P&H Fees, Zero Balance Billing, and Commission Payments. The BlueWave defendants also claim that Relator Riedel has failed to create a genuine dispute of material fact about whether they had the requisite scienter to violate the AKS with regard to the payment of Speaker Fees. (Dkt. No. 504-1 at 6.)

Scienter – P&H Fees: Defendants claim that they relied on the advice of counsel¹ with respect to HDL’s and Singulex’s P&H Fee agreements with physicians and physician practices, that they relied on expert advice from consultants, and that their actions comported with industry practice. The Government has provided substantial evidence from which a reasonable juror could conclude that the BlueWave Defendants had the requisite scienter to violate to AKS by paying P&H Fees. For example, the Government points to evidence that Defendants had knowledge that their practice of paying P&H Fees was illegal or at least presented a substantial risk of running afoul of the AKS and failed to retain an attorney to evaluate the legality of their practice of

¹ For reasons set forth later in this order, Defendants are not entitled to summary judgment on their advice of counsel defense with respect to any claim.

paying P&H Fees until November 2013. The Government also points to evidence that even when the BlueWave Defendants received advice from their own counsel that their P&H Fee practice was prohibited, they continued to pay P&H Fees. (Dkt. No. 501-1 at 19-21.)

The parties disagree about the nature of Defendants' intent in light of the information available to them, and a jury must find the BlueWave Defendants possessed the requisite scienter to violate the FCA or conspire to violate the FCA by paying P&H Fees.² For this reason, neither the Government nor the BlueWave Defendants are entitled to summary judgment on Counts I and III of the complaint: (I) the presentation of false claims tainted by an illegal kickback scheme disguised by P&H fees and (III) conspiracy to present those false claims.

Scienter – Zero Balance Billing: The BlueWave Defendants claim that the Government and Relator Riedel have failed to create a dispute of material fact about whether they had the requisite scienter to violate the AKS when they engaged in Zero Balance Billing. (Dkt. No. 504-1 at 10.) The BlueWave Defendants claim that the Government points to no evidence that they were aware the practice of waiving co-pays and deductibles was unlawful, that their attorney and HDL's attorney reviewed HDL's Zero Balance Billing policy, and that they thought Tricare's co-payment and deductible policies were the same as Medicare's. They claim the Government has also failed to provide evidence that they engaged in Zero Balance Billing to induce referrals.

² The Government asserts that it is entitled to summary judgment on all claims tainted by P&H fees after November 14, 2013 because, as of that date, the Defendants "had been told on numerous occasions by multiple attorneys, including their own, that: (1) the Government would view the P&H fees as kickbacks; (2) P&H fees were a red flag for the United States; (3) Defendants were exposing themselves to criminal and civil liability in continuing to pay P&H; (4) "the P&H fee appears to be prohibited;" and (5) they should stop paying P&H fees. Also as of that date, they unquestionably knew they were the subjects of an ongoing federal investigation regarding the practice of paying P&H fees." (Dkt. No. 501-1 at 14.) The effect that various communications had on Defendants' scienter is a factual inquiry that must be submitted to a jury.

As with the payment of P&H Fees, the Government has pointed to evidence from which a reasonable juror could conclude that the BlueWave Defendants knowingly and willfully violated the AKS when they promoted and engaged in Zero Balance Billing for several years. For example, the Government has provided email evidence from which a reasonable juror could conclude that the BlueWave Defendants were on notice by early 2011 that their practice of Zero Balance Billing was illegal. This notice came from more than one source, including a BlueWave sales representative. (Dkt. No. 522 at 14-18.) A reasonable juror could also conclude from evidence the Government has provided about BlueWave's training materials that the purpose of Zero Balance Billing was to induce referrals. Sales representatives were instructed to highlight Zero Balance Billing when pitching HDL's services to physicians. (*Id.* at 17.)

Scienter – Commission Payments: The BlueWave Defendants claim that the Government has failed to create a genuine dispute of material fact about whether they had the requisite scienter to violate the AKS when they used a Commission Payment structure to market laboratory tests. The BlueWave Defendants claim that (1) they have denied having knowledge that they were acting unlawfully or wrongfully and (2) they relied on the advice of their counsel, Gene Sellers, to negotiate and draft the sales commission agreements. (Dkt. No. 504-1 at 7-8.) This Court determined in an earlier order that the BlueWave Defendants cannot use the advice of Mr. Sellers to shield them from liability for violating the AKS with their Commission Payment arrangement because Sellers did not advise or offer any legal advice to the BlueWave Defendants about the AKS. (Dkt. No. 310 at 10-11.)

Although Defendants deny that they intended to violate the AKS, the Government has provided evidence from which a reasonable juror could conclude that the Defendants acted with the requisite scienter to violate the AKS when they structured their business around Commission

Payments. For example, a reasonable juror could conclude that Defendants' communications with outside counsel about another federal kickback case based on illegal commission-based payments reflects knowledge that their own practice may have been illegal. (Dkt. No. 522-18.) A reasonable juror could also conclude that the BlueWave Defendants used independent contractors as sales representatives to shield themselves from liability for a commission-based payment structure because they knew the practice was illegal. (*Id.* at 18-19.)

Scienter – Speaker Fees: The BlueWave Defendants claim that Relator Riedel has failed to create a genuine dispute of material fact about whether they paid Speaker Fees in order to induce referrals, in violation of the AKS and the FCA. They also claim that Relator Riedel has failed to provide any evidence that the Speaker Fees were above fair market value. (Dkt. No. 504-1 at 11.) Relator Riedel has not filed any response to the BlueWave Defendants' motion for summary judgment, so the Court considers the Speaker Fee claim to be abandoned.

b. *Medically Unnecessary Tests*

The Government has also alleged that 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).

The BlueWave Defendants argue that the Government has failed to create a genuine dispute of material fact about whether all or some of the tests at issue were, in fact, medically unnecessary. Defendants claim, for example, that Dr. Trost, the Government's only expert witness to speak to the medical necessity of the tests, failed to identify a single medically

unnecessary test. This argument is an attempt to revisit this Court's prior order denying Defendants' motion to exclude the expert testimony of Dr. Trost. (Dkt. No. 585.) The Court has already considered Dr. Trost's opinion that the majority of the tests in the HDL and Singulex panels were not medically necessary and found his opinion was both reliable and relevant.

The Government has provided evidence that creates at least a genuine dispute of material fact with regard to whether at least some of the tests at issue were medically unnecessary. For example, Dr. Trost opined the HDL 2 and HDL-P tests offered by HDL and the Interleukin 6 and 17a tests offered by Singulex are medically unnecessary, and Dr. Robert Fishberg (Defendants' expert), did not disagree with Dr. Trost's conclusion that none of these tests were medically necessary. (Dkt. No. 522-30 at 3-8, 16-18; Dkt. No. 522-19.) Additionally, although both experts agree that HDL's CYP2C19 test should be used only for patients who are taking Plavix (clopidogrel) or for whom a physician is considering the use of Plavix (Dkt. No. 522-19 at 14; Dkt. No. 522-20 at 6), the Government has provided evidence from which a reasonable juror conclude that HDL ran CYP2C19 tests on over 1,000 patients – without physician authorization and without regard to whether the patients were taking or were likely to take Plavix – and submitted claims for reimbursement for those tests to federal health care programs. (Dkt. No. 522 at 27-19.) This evidence also suggests that the tests were not ordered by the beneficiary's treating physician, which alone indicates that they were not medically necessary. Under 42 C.F.R. § 410.32(a), "All [diagnostic laboratory] tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." Finally, Defendants' expert has not offered any opinion on

several tests that Dr. Trost opined were not medically necessary. (Dkt. No. 522-30 at 9-11, 13-15.)

Defendants separately claim that the Government has failed to create a genuine dispute of material fact about whether they had the requisite scienter to violate the FCA by causing the presentment of medically unnecessary tests for reimbursement because some doctors believe the panels had value and “where there is a difference of opinion there can be no FCA” violation. (Dkt. No. 504-1 at 25.) Defendants cite several cases to support their argument that a scientific or medical disagreement precludes a finding that a defendant had the requisite scienter to violate the FCA. They then list all the doctors who have used the tests at issue and found them to be useful. But the relevant inquiry for FCA liability is whether the tests were medically necessary, not whether practitioners unanimously agree that they are absolutely devoid of any value. Further, evidence that some physicians find the tests to have some value is not at odds with Dr. Trost’s opinion that even though there is “observational evidence” linking the lipid panels at issue here with the increased risk of cardiovascular disease, “the routine clinical use of advance lipid testing of the HDL Inc. baseline and follow-up panels is not supported by published evidence.” (Dkt. No. 446-2 at 6-7.)

Even if there were a difference of opinion between the parties’ experts, it is the province of the jury to weigh the credibility of those opinions.³ “[T]o remove a plaintiff’s claims from the

³ Defendants also claim that because all the tests at issue have been assigned a Current Procedural Terminology (“CPT”) code, the Government has acknowledged that they are medically necessary. (Dkt. No. 504-1 at 26.) Defendants overstate the significance of CPT codes which are published by the American Medical Association and do not represent endorsement of any procedure or imply that the procedure is covered by a reimbursement policy. Many of the codes used by HDL and Singulex to claim reimbursement for the panels at issue were preexisting codes for commonly used laboratory processes. It is not the case, as Defendants appear to suggest, that they submitted to the AMA an entire panel of tests relevant to this litigation and that the AMA assigned that panel a reimbursement code.

jury simply because ‘a difference of opinion among experts’ exists would abrogate the jury’s responsibility to weigh the evidence and determine the credibility of witnesses.” *Brown v. Presbyterian Healthcare Servs.*, 101 F.3d 1324, 1334 n.9 (10th Cir. 1996) (citation omitted). For all of the reasons described above, 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.

2. Materiality

The BlueWave Defendants continue to argue that the Government has failed to show that they submitted material false claims 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. 504-1 at 28-30.) Defendants are not entitled to summary judgment on their materiality argument because the Government has provided evidence from which a reasonable juror could conclude that their AKS violations were material to the Government’s decision to pay claims.

A matter is material if: (1) a reasonable person would attach importance to it in determining a choice of action in the transaction, or (2) the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter in determining his choice of action, regardless whether a reasonable person would do so. *See Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 2002-03 (2016) (citations omitted). A federal court in the Southern District of New York had “no trouble concluding that compliance with the AKS is a ‘material’ condition of payment” because the AKS is “a felony offense punishable by up to five years in prison” – not a technical regulatory violation – and the

law now provides that a claim tainted by the AKS is a false or fraudulent claim for FCA purposes. *U.S. ex rel. Wood v. Allergan, Inc.*, No. 10- CV-5645 (JMF), 2017 WL 1233991, at *28 (S.D.N.Y. Mar. 31, 2017); *see also United States v. Am. at Home Healthcare & Nursing Servs., Ltd.*, No. 14-CV-1098, 2017 WL 2653070, at *8 (N.D. Ill. June 20, 2017) (rejecting post-*Escobar* materiality challenge in case alleging, inter alia, AKS violations) (internal citations omitted).

Contrary to their assertions, the BlueWave Defendants have not provided evidence which shows that the Government knew as of June 30, 2011 that any claims were *actually tainted* by an illegal kickback scheme. Defendants point to evidence which shows the Government was aware that some claims may have been tainted by kickbacks as early as June 30, 2011, but the record also shows that it took the Government years of investigation to determine whether any defendant had the requisite scienter to violate the AKS and, in turn, the FCA. The Government does not enjoy the luxury of refusing to reimburse health care claims the moment it suspects there may be wrongdoing. To this day, Defendants claim they did not have the requisite scienter to violate the FCA. All the evidence Defendants have put forth in support of their scienter cuts against their materiality argument that the Government was aware of AKS/FCA violations as early as 2011 but nonetheless continued to pay claims.

B. Equitable Claims

1. Mistake of Fact

The BlueWave Defendants argue that they are entitled to summary judgment on the Government's mistake of fact claim because the Government cannot show a mistake of a material fact. (Dkt. No. 504-1 at 36-37.) "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).

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 United States has provided evidence which creates at least a genuine dispute of material fact about whether it paid the claims at issue under the erroneous belief that (1) Defendants had not tainted the claims with kickbacks and (2) that the underlying tests had been ordered by the beneficiaries’ treating physicians. For reasons also discussed earlier in this Order⁴, the Government’s mistaken belief that a test was ordered by the beneficiary’s treating physician is material to its decision to pay. *See Mead*, 426 F.2d at 124 (Government’s erroneous belief that defendants had complied with the applicable regulations was material to its decision to pay).

2. Unjust Enrichment

The BlueWave Defendants claim they are entitled to summary judgment on the Government’s unjust enrichment claim because the Government received the benefit that it paid for – in this case, blood tests for Medicare and Tricare participants. (Dkt. No. 504-1 at 37.) Defendants use the same argument to support their Fifteenth affirmative defense, that there can be no unjust enrichment if the Government received what it paid for.

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

⁴ Under 42 U.S.C. § 1395y(a)(1)(A), the Government will not reimburse Medicare claims for services that are not “reasonable and necessary.” Under 42 C.F.R. § 410.32(a), any tests “not ordered by the physician who is treating the beneficiary are not reasonable and necessary.”

(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)).

Under 42 U.S.C. § 1395y(a)(1)(A), the federal government will not reimburse Medicare claims for services that are not “reasonable and necessary.” The Government therefore intends to reimburse claims to cover reasonable and necessary medical services for health care program participants. The Government has provided evidence from which a reasonable juror could conclude that the BlueWave Defendants submitted claims and received reimbursement for medically unnecessary tests. It is difficult to fathom a clearer case of unjust enrichment if the Government’s FCA claims are substantiated. However, neither party is entitled to summary judgment on the Government’s unjust enrichment claim and Defendants’ Fifteenth affirmative defense because the Court declines to grant summary judgment on any FCA claim by which Defendants were allegedly unjustly enriched.

C. Affirmative Defenses

1. Advice of Counsel

The BlueWave Defendants claim that they relied in good faith on the advice of counsel with respect to the Commission Payment agreements and P&H Fee agreements so are entitled to summary judgment on those claims. (Dkt. No. 504-1 at 38.)

To prevail on an advice of counsel defense, the BlueWave Defendants must establish by a preponderance of the evidence that they: (1) sought the advice in good faith; (2) provided full

and accurate information to their attorneys; (3) reasonably relied on the advice; and (4) faithfully followed that advice. *United States v. Butler*, 211 F.3d 826, 833 (4th Cir. 2000); *see also U.S. ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 381 (4th Cir. 2015) (“to establish the advice-of-counsel defense, the defendant must show the (a) full disclosure of all pertinent facts to counsel, and (b) good faith reliance on counsel’s advice”) (quotations omitted); *United States v. Newport News Shipbldg., Inc.*, 276 F. Supp. 2d 539, 565 (E.D. Va. 2003) (same); *United States v. United Med. & Surgical Supply Corp.*, 989 F.2d 1390, 1403 (4th Cir. 1993) (“Good faith reliance on the advice of counsel is not a complete defense to an allegation of willful misconduct, but is merely one factor a jury may consider when determining [the defendant’s] state of mind.”).

As to the Commission Payment agreements with HDL and Singulex, the BlueWave Defendants claim that they relied on the advice of attorney Gene Sellers. (Dkt. No. 504-1 at 39.) The BlueWave Defendants further claim that they are entitled to an advice of counsel defense because HDL and Singulex relied on counsel to negotiate and draft the sales commission agreements. As to the P&H Fee agreements, Defendants claim they relied on attorney Gregory Root’s (counsel for BHL during their tenure at BHL) opinion that P&H Fees were legal, a letter drafted by HDL’s attorneys, and a 2012 legal opinion from LeClair Ryan attorney Michael Ruggio to HDL which stated that P&H fees paid to physicians were lawful if they did not exceed fair market value. Defendants also claim that Jonathan Wolin, counsel and corporate compliance officer for BHL, informed them that the payment of P&H fees was legal.⁵

This Court determined in an earlier order that the BlueWave Defendants cannot use the advice of Mr. Sellers to shield them from liability for violating the AKS with their Commission

⁵ Although the BlueWave Defendants appear to assert an advice of counsel defense based on communications from the law firm Mintz Levin and from attorney Kung, they clarified in their reply that they were not seeking to rely on the advice of these attorneys for their advice of counsel defense. (Dkt. No. 534 at 3.)

Payment arrangement because Sellers did not advise or offer any legal advice to the BlueWave Defendants about the AKS. (Dkt. No. 310 at 10-11.)

Both Root and Wolin gave advice about BHL's practice of paying P&H fees of \$11.50, while the BlueWave Defendants paid P&H fees of \$17. Defendants cannot rely on advice from these attorneys about P&H fees because they did not provide either one with full disclosure of the pertinent facts: the value of the P&H fees they were paying was pertinent to any assessment of the legality of those fees.

The BlueWave Defendants argue that they are entitled to rely on the advice of counsel for HDL and Singulex with regard to both their Commission Payment and P&H Fee practices, including, for example, attorneys from LeClair Ryan (Michael Ruggio and Dennis Ryan) who provided advice to HDL and attorneys for Singulex who they say reviewed the Commission Payment agreements. Because the BlueWave Defendants did not seek any of this advice on their own, they are forced to advance a new theory that they should be allowed to rely on HDL and Singulex's counsel because they acted as agents of both laboratories. (Dkt. No. 504-1 at 40.) The sales commission agreements refer to BlueWave individuals as independent contractors. The BlueWave Defendants refer only to a Navigant report that describes them as agents of the laboratories for the purposes of HHS/OIG guidelines. (Dkt. No. 504-1 at 40.) With this limited information, the Court is unable to determine at this time whether the BlueWave Defendants may rely on the advice of counsel for HDL and Singulex because they were acting as agents of these entities so will make this determination at trial. Defendants will not be entitled to a jury instruction on their advice of counsel defense for any claim unless they present evidence to support each element of the defense at trial. For the reasons stated above, the Court declines to

grant summary judgment for the Government on the BlueWave Defendants' advice of counsel defense (their Second affirmative defense).

2. *Good Faith*

The BlueWave Defendants claim that they are entitled to summary judgment because they acted in good faith (their First affirmative defense), and acting in good faith is a defense to alleged AKS or FCA violations. (Dkt. No. 504-1 at 41-45.) Defendants' argument that they acted in good faith is based on all the other arguments they have already advanced, including, for example, that they relied on the advice of counsel and experts, that the AKS is ambiguous, and that their actions comported with industry practice. For all the reasons discussed throughout this order, the BlueWave Defendants are not entitled to summary judgment on their good faith defense because a reasonable juror could find that they acted with the requisite intent to violate the FCA and that they did not act in good faith.

3. *Duty to Mitigate*

For their Thirteenth affirmative defense, the BlueWave Defendants argue that they are entitled to summary judgment because the Government failed to mitigate its damages in connection with its equitable claims for unjust enrichment and payment by mistake of fact. (Dkt. No. 504-1 at 34.) This Court ruled in a prior order that the Government may have a duty to mitigate damages in connection with its equitable claims. (Dkt. No. 428 at 11-12.) Defendants are not entitled to summary judgment on this affirmative defense because there is a genuine dispute of material fact about when the Government had sufficient knowledge of the alleged violations (including knowledge that Defendants acted with the requisite scienter) to trigger any duty it may have had to mitigate its damages. Defendants intend to argue at trial that they did not

have the requisite scienter to violate the FCA⁶ at any time up to trial. Defendants apparently intend to argue in the alternative that if they did have the requisite scienter to violate the FCA, the Government had sufficient evidence of their scienter as of June 2011 to trigger any duty to mitigate.

4. Laches

The BlueWave Defendants claim they are entitled to the defense of laches because the Government had knowledge about the facts underlying its complaint by June 30, 2011, but waited several years to file suit in order to allow damages to grow to astronomical amounts. They claim that the government has provided no reason why it could not file suit earlier and cannot seriously contend that the delay did not prejudice the BlueWave Defendants. (Dkt. No. 504-1 at 35-36.)

Laches is “a defense developed by courts of equity” to protect defendants against “unreasonable, prejudicial delay in commencing suit.” *SCA Hygiene Prod. Aktiebolag v. First Quality Baby Prod., LLC*, 137 S. Ct. 954, 960 (2017). The defense fails with regard to the United States’ equitable claims⁷ for unjust enrichment and payment by mistake of fact because the doctrine of laches does not prevent the Government from bringing suit to protect the public fisc. As the Fourth Circuit has explained, this rule reflects “the ‘great principle of public policy’ protecting the public interest from official negligence.” *U.S. ex rel. Siller v. Becton Dickinson & Co.*, 21 F.3d 1339, 1346 (4th Cir. 1994); *see also United States v. Jones*, 532 F. App’x 321, 322 (4th Cir. 2013) (“As a general rule laches or neglect of duty on the part of officers of the

⁶ Both equitable claims are essentially premised on the illegality of FCA violations.

⁷ To the extent Defendants intended to assert laches as a defense to the Government’s FCA claims, the parties do not dispute that the United States filed its FCA claims within the applicable statute of limitations, and “‘in the face of a statute of limitations enacted by Congress, laches cannot be invoked to bar legal relief.’” *SCA Hygiene*, 137 S. Ct. at 960 (quoting *Petrella v. MGM, Inc.*, 134 S. Ct. 1962, 1974 (2014)).

Government is no defense to a suit by it to enforce a public right or protect a public interest.” (quotation marks omitted)). The Government is entitled to summary judgment on Defendants Twelfth affirmative defense as a matter of law.

5. Legal and Contractual Remedies

The BlueWave Defendants argue that they are entitled to summary judgment on the Government’s equitable claims because the FCA is an adequate remedy at law. (Dkt. No. 504-1 at 32.) As this Court previously decided, “[b]ecause the FCA did not expressly abrogate the Government’s ability to bring actions such as payment by mistake and unjust enrichment, the Government may bring equitable or common law claims in the alternative.” (Dkt. No. 268 at 16.)

The BlueWave Defendants also argue that because express contracts control the dispute here, claims in equity cannot lie against BlueWave. *See United States v. Savannah River Nuclear Sols., LLC*, No. 16-00825, 2016 WL 7104823, at *26 (D.S.C. Dec. 6, 2016). They claim that the dispute in this case is covered by enrollment agreements, provider agreements, and reassignment of Medicare and Tricare benefits agreements between HDL and Singulex and the government for Medicare and Tricare reimbursements or the individual physicians and the government. BlueWave attached a “handful of contracts between the actual physician practices and the Government” to its pleading and claims the “[G]overnment’s real dispute is whether HDL, Singulex, or the physicians breached its obligations to Medicare and Tricare under their reimbursement contracts.” (Dkt. No. 534 at 22.)

The Government has alleged that the BlueWave Defendants are directly liable for violations of the FCA, and strictly contract-based claims would not afford the Government an adequate remedy against the BlueWave Defendants. Further, as the Government noted, the United States was allowed to proceed with its common law claims in *Tuomey* because “the challenged payments in that case were not alleged to have been disallowed by an enforceable

express contract but, instead, were alleged to have been fraudulent specifically because they were for reimbursement for services rendered pursuant to contractual relationships that violated federal law.” *Savannah River Nuclear Sols.*, 2016 WL 7104823, at *27 (citing *Tuomey*, 675 F.3d at 398-400).

For the reasons stated above, as there is no genuine dispute of material fact for a jury to consider on these two issues, the Government is entitled to summary judgment on the BlueWave Defendants’ Fourth and Fifth affirmative defenses concerning the availability of legal and contractual remedies.

6. *Fifth and Fourteenth Amendments*

The BlueWave Defendants argue that the AKS violates the due process protections of the Fifth and Fourteenth Amendments to the U.S. Constitution because it is vague and overbroad. (Dkt. No. 504-1 at 12-18.) For example, Defendants claim that many essential terms in the AKS and its corresponding regulations (e.g. “remuneration” and “refer”) are not defined (*Id.* at 13). The Court is not aware of any decision by a federal court finding that the AKS is void for vagueness, and federal courts have consistently rejected such vagueness challenges to the AKS. *See, e.g., United States v. Williams*, 218 F. Supp. 3d 730, 740- 41 (N.D. Ill. 2016) (“Myriad courts have previously considered vagueness challenges to the Anti-Kickback Statute and rejected them, largely on the basis that the requirement of willfulness—knowledge that the act is unlawful—mitigates any vagueness concerns.”) (collecting cases). Although some terms in the AKS are not expressly defined, this does not render the statute unconstitutional. *See, e.g., United States v. Patel*, 17 F.Supp.3d 814, 825-30 (N.D. Ill. 2014) (applying principles of statutory interpretation to determine the meaning of the term “refer,” as that term is used in the AKS).

The BlueWave Defendants also complain that the AKS fails to define a standard for the inducement of referrals and that the appropriate test is the primary purpose test. (Dkt. No. 504-1

at 13.) This Court has already ruled that the AKS is violated if one purpose of the payment was to induce or reward referrals. (Dkts. No. 368 at n.3; Dk. No. 310 at 10.)

Finally, the BlueWave Defendants used this opportunity to seek reconsideration of this Court's prior decision on the admissibility of Kathleen McNamara's expert opinion about the fair market value of P&H Fees by recycling arguments from prior pleadings. (*Compare* Dkt. No. 448 at 6-12 *with* Dkt. No. 504-1 at 14-17.) The Court has already ruled on those arguments so refers the parties to its August 21, 2017 Order denying Defendants' motion to exclude the expert testimony of Kathy McNamara. (Dkt. No. 603.)

The Government is entitled to summary judgment on Defendants' Tenth affirmative defense that the AKS is unconstitutional under the Fifth and Fourteenth Amendments. Nonetheless, to the extent that Defendants wish to argue and present evidence at trial that they cannot be liable under the AKS because it is ambiguous (the substance of their Ninth affirmative defense) they will be able to do so at trial.

7. First Amendment

The BlueWave Defendants argue that they are entitled to summary judgment on the Government's FCA claims based on allegedly illegal Commission Payments because the Government's theory is based on an unconstitutional interpretation of the AKS: "Under the government's interpretation of the AKS, no independent contractors may speak to physicians in aid of lab test marketing. The government considers any such speech a per se violation of the AKS. Such interpretation violates the First Amendment because it is a speaker and content based ban on truthful speech." (Dkt. No. 504-1 at 18-21.) The BlueWave Defendants argue that the Government's interpretation of the AKS restricts any speech by any independent contractor for the marketing of blood tests. They claim this restriction is speaker based because it applies only

to independent contractors, not employees or other individuals. They claim that the restriction is content-based because it only restricts marketing speech.

Defendants have misrepresented the Government's theory of liability. Under the AKS, "whoever" knowingly and willfully solicits, receives, offers, or pays remuneration to induce Medicare referrals – whether an independent contractor or not – violates the statute unless an AKS exception or safe harbor applies. 42 U.S.C. § 1320a-7b(b)(1)-(2). The statute creates safe harbors for (a) employees, 42 C.F.R. § 1001.952(i) or (b) independent contractors pursuant to personal services agreements, *id.* § 1001.952(d), and the BlueWave Defendants do not claim that they are eligible for any safe harbor.

The BlueWave Defendants describe the Government's theory of liability as a blanket restriction on independent contractors speaking about blood tests, but the Government only claims Defendants are liable because they knowingly and willingly offered and paid remuneration to induce referrals. The Government's theory of liability targets speech only insofar as the speech constitutes an offer to pay kickbacks, and speech "used as an integral part of conduct in violation of a valid criminal statute" is not protected by the First Amendment. *United States v. Stevens*, 559 U.S. 460, 471 (2010) (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 498 (1949)); *see also Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 557 (1980) ("[F]or commercial speech to come within [the First Amendment], it at least must concern lawful activity . . ."). For these reasons, the Government is entitled to summary judgment on Defendants' Nineteenth affirmative defense.

V. **Conclusion**

For the reasons set forth above, the BlueWave Defendants' Motion for Summary Judgment (Dkt. No. 504) is **GRANTED IN PART** with respect to Relator Riedel's Speaker Fee claims and **DENIED IN PART** as to all other claims.

The Government's Motion for Partial Summary Judgment (Dkt. No. 501) is **GRANTED IN PART** with respect to Defendants' Fourth, Fifth, Sixth, Seventh⁸, Tenth, Twelfth, and Nineteenth 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 23, 2017
Charleston, South Carolina

⁸ Defendants Sixth and Seventh defenses were pleading defenses including failure to state a claim and failure to plead fraud with particularity. The Court has already ruled on these issues in its orders on the BlueWave Defendants' motions to dismiss. (Dkt. Nos. 268, 390.) Defendants have not raised new arguments on these issues on the Government's Partial Motion for Summary Judgment.