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

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United States of America, *et al.*, *ex rel.* Scarlett Lutz and Kayla Webster, Plaintiffs/Relators, v. Laboratory Corporation of America Holdings, Defendant. C/A No. 9:14-3699-RMG

ORDER AND OPINION

Before the Court is Defendant Laboratory Corporation of America Holdings' ("LabCorp") motion for summary judgment. (Dkt. No. 326.) For the reasons set forth below, the motion is denied.

I. <u>Background</u>

This is a *qui tam* action in which the United States of America declined to intervene. Relators allege that, from approximately early 2010 to mid-2014, LabCorp's in-office phlebotomists ("IOPs"), who are blood draw and processing technicians employed by LabCorp and stationed by LabCorp inside doctors' offices, drew blood from patients at the doctors' request and with knowledge that the doctors were receiving illegal kickbacks (referred to as processing and handling fees, or "P&H fees") from third-parties Health Diagnostic Laboratory and Singulex, Inc. (collectively, "HDL/S") in exchange for the doctors referring the blood that the IOP had drawn to be tested by HDL/S. Relators claim that LabCorp's was aware that the doctors were receiving kickbacks from HDL/S, as evidenced by, among other things, LabCorp' s 2013 and 2014 anonymous requests for Special Fraud Alerts from the Office of Inspector General ("OIG") on HDL's P&H payments. HDL/S billed the federal government for those lab tests under the patients' Medicare Part B coverage, which Relators allege were tainted by the kickback and therefore in violation of the Anti-Kickback Statute ("AKS"). Relators further allege that LabCorp drew blood to be tested by HDL/S if the doctors also referred blood to be tested by LabCorp. LabCorp then itself billed the federal government for that test, even though it had induced the referral and provided the blood test at no charge to the doctor. Although, in at least one region of LabCorp's business, LabCorp requested the doctors pay a \$5 blood draw fee. A blood draw for testing at two labs was done via a single venipuncture to the patient, referred to by LabCorp as a "courtesy draw" because the patient was spared from two venipunctures for two tests. (Dkt. No. 50.)

LabCorp previously moved to dismiss the portions of every claim predicated on allegedly medically unnecessary tests, as well as Count II for reverse false claims, Count III for violation of California law, and Count IV for violation of Illinois law. LabCorp did not move to dismiss the portions of claims predicated on violation of the AKS. The Court granted in part and denied in part LabCorp's motion, dismissing the portions of each claim predicated on medically unnecessary tests, as well as dismissing Count II, Count III and Count IV. (Dkt. No. 72.) The remaining claim is Count I, under which Relators allege that LabCorp violated the FCA in three ways: (1) knowingly causing HDL/S's false claims to be presented, § 3729(a)(1)(A); (2) knowingly presenting its own false claims, § 3729(a)(1)(A); and (3) conspiring with HDL/S to knowingly cause HDL/S to present false claims or to present its own false claims, § 3729(a)(1)(C). (Dkt. No. 50 ¶¶ 582-588.)¹

¹ Count I also alleges that LabCorp violated § 3729(a)(1)(B), which imposes liability on one who "knowingly makes, uses, or cause to be made, or used, a false record or statement material to a false or fraudulent claim." (Dkt. No. 50 ¶ 587.) As LabCorp states in its motion for summary judgment, "Relators principally seek liability under 31 U.S.C. § 3729(a)(1)(A), for the presentment of false claims, but also allege liability under 31 U.S.C. § 3729(a)(1)(B), for the use

II. Legal Standard

Summary judgment is appropriate if a party "shows that there is no genuine dispute as to any material fact" and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). A dispute is "genuine" if the evidence offered is such that a reasonable jury might return a verdict for the non-movant. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A fact is "material" if proof of its existence or non-existence would affect disposition of the case under applicable law. *See id.* Therefore, summary judgment should be granted "only when it is clear that there is no dispute concerning either the facts of the controversy or the inferences to be drawn from those facts." *Pulliam Inv. Co. v. Cameo Props.*, 810 F.2d 1282, 1286 (4th Cir. 1987).

"In determining whether a genuine issue has been raised, the court must construe all inferences and ambiguities in favor of the nonmoving party." *HealthSouth Rehab. Hosp. v. Am. Nat'l Red Cross*, 101 F.3d 1005, 1008 (4th Cir. 1996). The movant bears the initial burden of demonstrating that there is no genuine issue of material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Once the movant has made this threshold demonstration, the non-moving party must demonstrate specific, material facts that give rise to a genuine issue. *See id.* at 324. "Conclusory or speculative allegations do not suffice, nor does a 'mere scintilla of evidence'" in support of the non-moving party's case. *Thompson v. Potomac Elec. Power Co.*, 312 F.3d 645, 649 (4th Cir. 2002) (quoting *Phillips v. CSX Transp., Inc.*, 190 F.3d 285, 287 (4th Cir. 1999)).

of false records material to false claims. To the extent that Relators still pursue both theories, LabCorp's arguments apply equally to them." (Dkt. No. 327 n.4.) Relators' opposition does not address the § 3729(a)(1)(B) allegation. By declining to address the merits of this claim in response to a dispositive motion, Relators have waived the claim. *See, e.g., United States ex. rel. Holbrook v. Brink's Co.*, 336 F. Supp. 3d 860, 874 (S.D. Ohio 2018) (granting summary judgment where claim waived for lack of briefing).

III. Discussion

A. Violation of § 3729(a)(1)(A) by Knowingly Causing False Claims to be Presented by HDL/S

The FCA imposes liability on "any person who knowingly . . . causes to be presented, a false or fraudulent claim for payment or approval." § 3729(a)(1)(A). In other words, the "FCA also reaches claims that are rendered false by one party, but submitted to the Government by another." *United States ex rel. Rector v. Bon Secours Richmond Health Grp.*, No. 3:11-cv-0038, 2014 WL 1493568, at *9 (E.D. Va. Apr. 14, 2014). A corporation is a "person" under the statute. *Cook Cnty. v. United States ex rel. Chandler*, 538 U.S. 119, 126-27 (2003).

1. "Knowingly"

The FCA defines "knowingly" to "mean that a person, with respect to information, has actual knowledge of the information; or acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information; and require[s] no proof of specific intent to defraud." § 3729(b)(1). The purpose of this scienter requirement is to avoid punishing "honest mistakes or incorrect claims submitted through mere negligence." *United States ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co.*, 612 F.3d 724, 728 (4th Cir. 2010). "FCA claims require a relator to show only that the defendant had *knowledge* of the illegality of its actions, rather than *specific intent* to defraud." *United States ex rel. Oberg v. Penn. Higher Ed. Assistance Agency*, 912 F.3d 731, 735 (4th Cir. 2019) (emphasis in original). "Summary judgment is seldom appropriate in cases in which particular states of mind are decisive elements of [the] claim or defense, because state of mind is so often proved by inferences from circumstantial evidence and by self-serving direct evidence" and "knowledge is such a state of mind." *Magill v. Gulf & W. Indus.*, 736 F.2d 976, 979 (4th Cir. 1984). Moreover, "the issue of fraudulent intention is generally not amenable to resolution on summary judgment

[because] when evidence of intention is ambiguous, summary judgment simply cannot be awarded." United States ex rel. Bunk v. Gov't Logistics N.V., 842 F.3d 261, 276-77 (4th Cir. 2016) (internal citations omitted). But this does not mean that summary judgment is never appropriate on the element of knowledge. See, e.g., Dalton v. Cap. Assoc. Indus., 257 F.3d 409, 418 (4th Cir. 2001) (upholding summary judgment where, "[e]ven though summary judgment is seldom appropriate on whether a party possessed a particular state of mind, evidence that [defendant] acted willfully [was] wholly lacking"). "Therefore, in order for summary judgment to be appropriate, it must be clear that there is no issue of material fact as to whether [defendant] acted with the requisite mental state—here, scienter." Skibo on behalf of United States v. Greer Labs., Inc., 841 Fed. App'x 527, 532 (4th Cir. 2021).

Reviewing this record in a light most favorable to Relators, there are disputes of material fact as to whether LabCorp acted in reckless disregard to the falsity of the information. First, the record reflects that at least some doctors were paid P&H fees, such as where one doctor testified that she was paid before and while she referred tests to HDL/S. (Dkt. No. 362-23 at 8.) But LabCorp states that it "did not learn that possibility [of HDL/S paying doctors P&H fees] until mid-2012, when complaints increased." (Dkt. No. 327 at 15.) The record does reflect that by August 2012, LabCorp was aware that its IOPs had been drawing blood for doctors who were "getting paid by HDL" and "that HDL calls the fee a 'process and handling fee.'" (Dkt. No. 373-12 at 5.) But the record also reflects that, prior to mid-2012, LabCorp was aware that certain doctors who used LabCorp IOPs had increased their billing while referring tests to HDL/S. For instance, in January 2011 a LabCorp employee "discovered" that a doctor, whose billing had increased from \$7,000 in November to \$15,000 in December, had "also recently started doing HDL labs toward the end of December. [The doctor] told Mike and I that he is going to do

HDLs on his pts to get a base-line Cardiac Status. Then he will do NMRs and Lipid Cascades on all follow-ups thereafter. We have a LCA IOP at this account." The internal response to this message was, "If we are drawing the lab, we are fine with drawing the lab," and that "[t]he account is getting \$20-\$30 per patient for the draw-process." (Dkt. No. 366-29 at 3.) However, the record also reflects that a different doctor testified that in her office, the IOP would only draw blood for LabCorp's own testing, after which a different phlebotomist would physically takeover the venipuncture to draw additional blood for other labs to test. (Dkt. No. 362-23 at 8.) Even if some doctors had a non-LabCorp phlebotomist takeover the venipuncture for non-LabCorp testing, the record reflects that LabCorp considered this practice inappropriate when it, for instance, noted that "because we believe that [a doctor's practice] is being reimbursed by HDL for the draws, we cannot be providing that service for them whether the needle is in the arm already or not." (Dkt. No. 372-10 at 2.) This record, therefore, reflects a dispute of material fact as to whether LabCorp had actual knowledge that HDL/S was paying P&H fees to the doctors for whom LabCorp knew its IOPs were drawing blood to be tested by HDL/S.

As an initial matter, LabCorp argues that there is scant evidence that its IOPs actually drew blood for the kickback-receiving doctors. For instance, out of twenty-one doctors deposed, twelve testified that there was no LabCorp IOP in his or her practice and six testified that there was an IOP, but the IOP did not draw blood to be tested by HDL/S. (Dkt. No. 327 at 9.) But by that count, there are allegedly three kickback-receiving doctors who may or did have a LabCorp IOP in their practice that may or did draw blood for HDL/S tests. Similarly, one doctor testified that in his own practice, he would sometimes ask a staff phlebotomist to draw blood for an HDL/S test if the "LabCorp technician was tied up . . . and then vice versa, there may be a case where my staff was tied up . . ." (Dkt. No. 362-13 at 4.)

LabCorp notes that after its compliance department investigated and became aware of the practice of IOPs drawing blood for doctors who were paid P&H fees by HDL/S, certain LabCorp divisions stopped drawing blood for HDL/S testing, required doctors to certify that they were not receiving P&H fees, or instituted a \$5 draw fee on the doctor. For instance, the record reflects that LabCorp's Divisional Compliance/Safety officer in Dublin, Ohio instituted a certification protocol. But the record is not clear that all LabCorp divisions curtailed their practice of drawing blood for HDL/S testing for doctors known to be receiving P&H fees from HDL/S. Moreover, regarding the \$5 draw fee, there is a material dispute of fact as to whether that constituted compensation for the blood draw, thereby rebutting any inference that LabCorp was providing the blood draw for free in exchange for a LabCorp test referral, or whether the \$5 alternatively constituted LabCorp diverting a portion of the doctors' P&H fee to itself.

Last, it is undisputed that in February 2013 and 2014, LabCorp requested the OIG issue a Special Fraud Alert identifying HDL's payment of P&H fees as a potential violation of the AKS. LabCorp made these requests anonymously, through outside counsel, and therefore omitted mention to the OIG of its own role in drawing the blood sent to HDL for testing. (Dkt. No. 369-16 at 2.) LabCorp contends that the Special Fraud Alert requests merely indicate that it attempted to curb HDL's kickback-paying practice, perhaps without sacrificing its own separate relationship with the kickback-receiving doctors. Regardless of what intention the jury infers from this evidence, its existence creates a genuine dispute of material fact as to whether and when LabCorp knew HDL paid kickbacks to doctors whom LabCorp knew used IOPs to draw the blood. As one doctor testified, he decided to change labs after he determined on his own that the P&H fees were inappropriate, not because LabCorp notified him that P&H fees are inappropriate. (Dkt. No. 362-13 at 6.)

2. "Causes"

The FCA imposes liability on a corporation that "causes" a false claim to be presented. § 3729(a)(1)(A). The phrase "causes" is not defined by the statute; it is interpreted to reflect ordinary tort principles of proximate causation. See, e.g., United States ex rel. Sikkenga v. Regence BlueCross BlueShield of Utah, 472 F.3d 702, 714 (10th Cir. 2006) (noting that the "approach [that] is useful in analyzing causation under § 3729 [] provides a familiar test—that of proximate causation—to determine whether there is a sufficient nexus between the conduct of the party and the ultimate presentation of the false claim to support liability under the FCA") (abrogated on other grounds by Cochise Consultancy, Inc. v. United States ex rel. Hunt, 139 S.Ct. 1507 (2019)); United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 244 (3d Cir. 2004) (applying "ordinary causation principles from negligence law in determining responsibility under the FCA"); United States v. Mallory, 988 F.3d 730 (4th Cir. 2021) (finding district court's jury instructions proper, which included: "In order to find a defendant's conduct caused claims to be submitted, you must determine that the conduct was a substantial factor in the claim being presented to the United States and that it was foreseeable to the defendant that the claim would be presented"); United States ex rel. Wuestenhoefer v. Jefferson, 105 F. Supp. 3d 641, 681 (N.D. Miss. 2015) ("The causation standard employs traditional notions of proximate causation[.]") (citing Sikkenga, 472 F.3d 702 (10th Cir. 2006)); United States ex rel. DeCesare v. Americare In Home Nursing, 757 F. Supp. 2d 573, 589 (E.D. Va. 2010) (applying ordinary causation principles of proximate causation). "And under that inquiry [of proximate causation], where a necessary and foreseeable result of the defendant's actions is the filing of a false claim with the government, the FCA applies." United States ex rel. DeCesare, 757 F. Supp. 2d at 589. "Under federal law an act will be deemed a proximate cause of a result if the act is a 'substantial factor in

the sequence of responsible causation, and if the [result] is reasonably foreseeable or anticipated as a natural consequence." *United States ex rel. Wuestenhoefer*, 105 F. Supp. 3d at 681 (quoting *Hecht v. Commence Clearing House, Inc.*, 897 F.2d 21, 23-24 (2d Cir. 1990)). "In a False Claims Act, to establish causation a relator must show an 'affirmative act' going beyond 'mere passive acquiescence."" *Id.* at 681.

The questions before the Court is whether, on this record construed in a light favorable to Relators, a reasonable factfinder could conclude that LabCorp's conduct—specifically, LabCorp IOPs drawing blood for doctors to refer to HDL/S for testing when LabCorp knew those doctors were receiving P&H fees from HDL/S for the test—was a substantial factor in HDL/S presenting the resulting claim, and whether it was also foreseeable to LabCorp that HDL/S would present the claim. The answer to both is yes.²

First, there is record evidence that LabCorp IOPs did in fact draw the blood that doctors referred to HDL/S for testing in exchange for their P&H fee (as well, as discussed, as evidence that LabCorp was aware that its IOPs were drawing that blood, and was aware that those doctors were being paid a P&H fee by HDL/S). (Dkt. No. 366-29 at 3.) LabCorp contends that no reasonable factfinder would conclude it was a substantial factor in HDL/S's false claim submissions because some doctors have testified that they would have ordered the blood to be drawn for HDL/S tests regardless of whether it was drawn by a LabCorp IOP or some other phlebotomist. (Dkt. No. 327 at 26 n.7.) Whether the doctor would have proceeded with drawing blood to have tested at HDL/S in the absence of an IOP is inapposite. The issue is instead whether the record supports finding that IOPs did draw the blood, which, as discussed, the record

² LabCorp argues that it cannot be liable for any claims that HDL/S submitted in which a LabCorp IOP did not draw the blood. The Court agrees. Indeed, Relators' theory of causation for violation of § 3729(a)(1)(A) is that LabCorp caused HDL/S to submit false claims by providing the blood draws.

does reflect. Second, a reasonable fact finder could also conclude that it was foreseeable to LabCorp that HDL/S would present claims for reimbursement for those tests. LabCorp does not point to any record evidence to show this fact is not in dispute, and it is reasonable to find that LabCorp would have anticipated that HDL/S would seek to be reimbursed for testing on blood drawn by an IOP. *See, e.g., In re Enron Corp. Secs., Derivative & Erisa Litig.*, 762 F. Supp. 2d 942, 974 (S.D. Tex. 2010) (applying proximate causation and noting that "[a]ll that is required is that the injury be of such a general character as might reasonably have been anticipated[.]") (internal quotation marks omitted). For instance, the record reflects that starting in at least February 2012, LabCorp internally assessed HDL as a possible investment or acquisition target—such as when LabCorp executives discussed that, "[w]hile some of HDL's tactics may be distasteful to us," its projected 2012 revenue was \$250 million. (Dkt. No. 346-15 at 2-3.) From this, the fact finder could reasonably conclude that LabCorp was aware of HDL's business practices, including its P&H payments, and therefore that it was foreseeable to LabCorp that HDL would submit claims for reimbursements on tests that are tainted by those kickbacks.

LabCorp's motion for summary judgment on Count I's claim for violation of § 3729(a)(1)(A) by knowingly causing HDL/S to present false claims is denied.

B. Violation of § 3729(a)(1)(A) by Knowingly Presenting False Claims

The FCA imposes liability on one who "knowingly presents . . . a false or fraudulent claim for payment." § 3729(a)(1)(A). Relators allege that LabCorp provided free blood draws to the doctors whom it knew were receiving kickbacks from HDL/S (the "courtesy draws"), in exchange for the doctors referring a blood test to LabCorp. Relators allege that LabCorp's free blood draw service constituted an inducement to the doctors, in exchange for which the doctors

gave LabCorp the testing referral, on which LabCorp then submitted its claim. (Dkt. No. 50 ¶¶ 550-557.)

As to the scienter element, Relators argue that LabCorp's "courtesy draws" were illegal inducements reflecting that LabCorp was aware of the kickback scheme between HDL/S and the doctors for whom LabCorp drew blood. For instance, in January 2010, LabCorp knew that an IOP "was approached by the office to draw Lipomeds for Health Diagnostic Laboratories in Richmond, VA, he was instructed by the office not to charge a draw fee for this patient. The patient also had labwork to go to LabCorp, [the LabCorp rep] instructed him to put a draw fee like usual on the order that was coming to LabCorp and that would take care of the draw for Health Diagnostics as well." (Dkt. No. 396-24 at 2.) LabCorp contends that because there was no governing law or regulation identifying courtesy draws generally as improper, and because its own corporate policy had long provided for courtesy draws, there is no material dispute of fact that courtesy draws in these instances were not unlawful inducements.³ The fact finder could reasonably find the record indicates that courtesy draws for doctors were merely a pre-existing policy intended to protect patients from two venipunctures. Or, the fact finder could reasonably conclude that these particular courtesy draws, for these doctors whom LabCorp knew were receiving P&H fees, were cooped by LabCorp to induce doctors to make testing referrals. As one doctor testified that, "as long as we were utilizing their lab," he understood "it was okay for

³ LabCorp's 1998 "Responsibilities of Patient Service Technicians" states: "LabCorp does not offer professional courtesy testing to its clients . . . based on the federal government's position that providing free or deeply discounted laboratory testing to health care providers, their families, or their employees may be construed as an unlawful inducement," but when a patient service technician "draws a specimen that will be sent to LabCorp for testing, he or she may draw an additional specimen that may be tested by another laboratory," which is done "for the convenience of the patient, so that he or she is not subjected to multiple draws; however, specimens may not be collected solely for other laboratories or the physician's in-office laboratory without the prior approval of the corporate compliance department or the law department." (Dkt. No. 328-1 at 54-55.)

the LabCorp IOP to draw blood, some of which that would go to, for example, HDL and some of which would go to LabCorp." (Dkt. No. 362-13 at 4.) LabCorp was also aware that another doctor, as LabCorp described, "was very up front about getting paid the collection fee"—to the extent that one LabCorp employee assessed, "I don't see her stopping either." (Dkt. No. 367-10 at 2.)

LabCorp's motion for summary judgment on Count I's claim for violation of § 3729(a)(1)(A) by knowingly presenting false claims is denied.

C. Violation of § 3729(a)(1)(C) by Conspiring with HDL/S to Violate the FCA

The FCA imposes liability on one who "conspires to commit a violation of subparagraph (A)[.]." § 3729(a)(1)(C). Subparagraph (A), as discussed, imposes liability on one who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." § 3729(a)(1)(A). Under the FCA, "there can be no liability for conspiracy where there is no underlying violation of the FCA." *Pencheng Si v. Laogai Research Fdtn.*, 71 F. Supp. 3d 73, 89 (D.D.C. 2014). The Court has already determined that this record, construed in a light most favorable to Relators, contains genuine disputes of material fact as to whether LabCorp knowingly caused HDL/S to present false claim and knowingly presented its own false claims. The remaining question here, therefore, is whether the record also reflects a dispute of material fact as to whether LabCorp conspired with HDL/S to do so.

"[T]o prove a false claim under FCA section $3729(a)(1)(C) \dots$, a relator must show that the defendant agreed with another to commit a violation of FCA sections (a)(1)(A) [or] (B) \dots and committed an overt act in furtherance of the violation." *United States v. Catholic Health Sys. of Long Island, Inc.*, No. 12-cv-4425-MKB, 2017 WL 1239589, at *8 (E.D.N.Y. Mar. 31, 2017) (reviewing claim on summary judgment and noting that "although the wording of the sections [§ 3729(a)(1)(C)] changed slightly, there was no substantive difference between the 1994 and 2009 version of the statute for these sections" as a result of the 2009 Fraud Enforcement Recovery Act). "Conspire' in this context requires a meeting of the minds 'to defraud the Government." *United States v. LifePath Hospice, Inc.*, 2016 WL 5239863, at *8 (M.D. Fla. Sept. 22, 2016) (citing *Allison Engine Co., Inc. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)). Such a meeting of the minds could be evidenced by LabCorp's knowledge that it may be participating in an illegal referral network, coupled with its assent to HDL/S's and the doctors' illegal agreement, via its own continued participation. *See United States ex rel. Decesar*, 2011 WL 607390, at *7. The question, then, is whether this record reflects any dispute of fact as to an illegal agreement between HDL/S and the doctors, and as to LabCorp's continued participation in their referral network with knowledge of their agreement. The Court finds that it does.

As discussed, the record reflects that HDL/S paid certain doctors P&H fees in exchange for referring testing to HDL/S, such as one doctor has testified that she herself was paid. (Dkt. No. 362-23 at 8.) There is also record evidence that LabCorp was aware that the doctors were paid P&H fees, such as when Cigna notified LabCorp in 2011 of, as LabCorp described it, "a ton of leakage to HDL" because specific doctors—whom LabCorp noted were "being paid by HDL a handling fee between \$15.00 and \$25.00 and are unwilling to give this revenue stream up" were referring testing to out-of-network HDL/S instead of to in-network LabCorp. (Dkt. No. 370 at 2-3.) There is also record evidence that, nonetheless, LabCorp IOPs continued to draw blood for doctors whom LabCorp knew were referring tests to HDL/S in exchange for P&H fees, such as when LabCorp apparently continued to draw blood for HDL/S testing after a LabCorp senior vice president flagged in September 2012 the potential "major compliance problem when the doctor gets 25 bucks for a draw we do" because that "potentially puts them at primary risk and us also." (Dkt. No. 369-1 at 2.) On the other hand, in August 2012 LabCorp noted that "when a venipuncture fee is billed it includes the processing and handling of the specimen" and that LabCorp's compliance department is "not willing to participate in this scheme as we believe it crosses the anti-kickback statutes." (Dkt. No. 373-12 at 4.) From this record, therefore, there remain material disputes of fact as to whether LabCorp assented to HDL/S's referral scheme by continuing to provide IOP blood draws for blood tested by HDL/S in exchange for its own testing referrals.

LabCorp's motion for summary judgment on Relators' claim that it conspired to violate the FCA with HDL/S is denied.

D. HDL/S Claims in which the *BlueWave* jury rejected liability

LabCorp argues that the *BlueWave*, 9:14-0230-RMG jury determined that these same claims were not violations of the AKS and, therefore, that Relators cannot here argue that these claims do violate the AKS to underpin the allegation that violated the FCA. "Collateral estoppel precludes relitigation of an issue decided previously in judicial or administrative proceedings provided the party against whom the prior decision was asserted enjoyed a full and fair opportunity to litigate that issue in an earlier proceeding." *In re McNallen*, 62 F.3d 619, 624 (4th Cir. 1995). The issue here is whether, when and on how many occasions LabCorp's IOPs drew blood while knowing that the blood would be tested by HDL/S and knowing that the doctors received a kickback from HDL/S for referring the test. That issue was not decided by the jury in *BlueWave*.

IV. Conclusion

For the foregoing reasons, LabCorp's motion for summary judgment (Dkt. No. 326) is denied.

AND IT IS SO ORDERED.

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<u>s/ Richard Mark Gergel</u> Richard Mark Gergel United States District Judge

June 15, 2021 Charleston, South Carolina