

As to those claims, Mallory wrongly suggests that there is no evidence (1) that the claims were submitted to or paid by the states, or (2) that the fraudulent conduct was material to or caused the states' payment of claims. Indeed, Lutz and Webster have provided Mallory and her defendants with gigabytes of Medicaid data that identifies the precise claims submitted to and the amounts paid by the plaintiff state governments. Moreover, the record is replete with evidence demonstrating both the materiality of the kickback scheme that Mallory and her co-defendants perpetrated and the causal link between that scheme and the payments made by plaintiff state Medicaid programs. For the following reasons, the Court should dismiss Mallory's motion for summary judgment.

II. UNDISPUTED FACTS

On February 6, 2013, Relators Lutz and Webster filed a *qui tam* complaint alleging that several corporate defendants (BlueWave Health Care Consultants, Inc. ["BlueWave"], Health Diagnostics Laboratory ["HDL"], and Singulex) and key individuals including Defendants Mallory, Floyd Calhoun Dent, III, and Robert Bradford Johnson were involved in a nationwide scheme to offer and pay kickbacks to physicians who ordered HDL and/or Singulex tests in violation of the federal False Claims Act ("FCA"), analogous state false claims acts, and California and Illinois insurance fraud statutes. On July 9, 2014, Lutz and Webster filed a First Amendment Complaint (the "Lutz-Webster FAC"), in which they named Mallory, Dent, and Johnson as defendants. Lutz and Webster then filed a Second Amended Complaint (the "Lutz-Webster SAC") on October 29, 2014. Dkt. No. 40-1. The Lutz-Webster SAC contains the same factual allegations that were raised in the original complaint and FAC. On April 4, 2016, Lutz and Webster filed a Third Amended Complaint (the "Lutz-Webster TAC") to reinsert claims under some state False Claims Act that were inadvertently omitted from the SAC. Dkt. No. 275. In all

other respects, the Third Amended Complaint is identical to the Lutz-Webster SAC.

For more than two years, from February 2013 until March 2015, the United States, with the assistance of Lutz and Webster, investigated the Lutz-Webster allegations, including those against Mallory. On March 31, 2015, the government filed a notice of its election to intervene in the matter against Mallory and other defendants. Dkt. No. 60. In its Complaint in Intervention, the government pleads that Mallory has violated § 3729(a)(1)(A), (B), and (C) of the federal False Claims Act, just as Lutz and Webster had alleged prior to the government's intervention. *Compare* Dkt. No. 40-1, ¶¶ 403-09 *with* Dkt. No. 75, ¶¶ 222-37.

While the United States has intervened in all of Lutz and Webster's claims against Mallory that arise under the federal False Claims Act, the plaintiff-states have declined to intervene in the claims that Mallory and her co-defendants violated the operative state False Claims Acts and private insurance statutes in California and Illinois. Thus, Lutz and Webster pursue these claims against Mallory, as well as Defendants Dent, Johnson, and BlueWave, as provided by state False Claims Acts and insurance law on a non-intervened basis.

During the discovery period, Lutz and Webster obtained from six Plaintiff states – Colorado, Florida, Illinois, Indiana, North Carolina, and Virginia – data sufficient to document each and every claim for an HDL laboratory test submitted to those state Medicaid programs. Lutz and Webster provided that data, along with business records affidavits for every state but Colorado, which has yet to provide an affidavit, to Defendants. *See* Exhibits 1-11.

III. LEGAL STANDARDS

A. Effect of Complaint in Intervention

The federal FCA permits the government to intervene, or decline to intervene, in a *qui tam* action filed by a relator-plaintiff.³¹ U.S.C. § 3730(b)(4). “If the government proceeds with the

action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action.” *Id.* § 3730(c)(1). Accordingly, “by automatic operation of the statute, the government’s complaint in intervention becomes the operative complaint as to all claims in which the government has intervened.” *United States ex rel. Sansbry v. LB & B Assocs., Inc.*, 58 F. Supp. 3d 37, 46-47 (D.D.C. 2014) (citing *United States ex rel. Feldman v. City of N.Y.*, 808 F. Supp. 2d 641, 648-49 (S.D.N.Y. 2011)).

B. Summary Judgment

Summary judgment is appropriate only when, no material facts are in dispute and the movant is entitled to judgment as a matter of law. Fed.R. Civ. P. 56(a); *Carlson v. Boston Scientific Corp.*, 856 F.3d 320, 324 (4th Cir. 2017). In considering a motion for summary judgment, the court will not “weigh the evidence and determine the truth of the matter.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986). “If a movant asserts that a fact cannot be disputed, it must support that assertion either by ‘citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials’; or ‘showing. . . that an adverse party cannot produce admissible evidence to support the fact.’” *Jeter v. Palmetto Health*, 2012 WL 6522093, at *2 (D.S.C. Nov. 14, 2012), *report and recommendation adopted in part sub nom. Jeter v. Palmetto Health Internal Med. Ctr.*, 2012 WL 6521454 (D.S.C. Dec. 14, 2012), *aff’d sub nom. Jeter v. Palmetto Health*, 515 F. App’x 234 (4th Cir. 2013).

IV. ARGUMENT

Defendant Mallory devotes most of the memorandum in support of her motion for summary judgment to attacking (1) claims into which the United States has intervened, or (2) allegations into which the United States has intervened and which apply with equal force to Lutz and Webster's non-intervened claims.¹ While Lutz and Webster believe all of these arguments lack merit, they yield, as they must, to the United States, which is primarily responsible for litigating the aspects of the case into which it has intervened. 31 U.S.C. § 3730(c)(1); *see also Feldman*, 808 F. Supp. 2d at 648 (if government partially intervenes, "a relator may retain standing to prosecute those aspects of his or her complaint as to which the government has not intervened"). Accordingly, Lutz and Webster incorporate by reference the United States' response to Mallory's Motion for Summary Judgment of the Intervenor's Complaint (Dkt. No. 498).

As to Lutz and Webster's non-intervened state claims, Mallory argues that (1) her conduct and statements were not material to the states or private insurers' decisions to pay claims; (2) there is no evidence that the states or private insurers paid HDL or Singulex claims; and (3) there is no evidence that Mallory's conduct caused the states or private insurers to pay claims. Each of these arguments fails.

¹ Included in category one are Mallory's arguments that her purported False Claims Act and Anti-Kickback Statute violations were immaterial to, or did not cause, the federal government's decision to pay claims, Dkt. No. 500-1 at 3-7; and that she did not conspire with her co-defendants to violate the federal False Claims Act; *id.* at 9-10. Category two comprises Mallory's arguments that her statements and conduct were not objectively false, *id.* at 7-9; and that she did not knowingly submit false claims, *id.* at 9. Indeed, as to the last of these arguments, she merely incorporates by reference the relevant section of her Memorandum in Support of Summary Judgment of the Intervenor's Complaint. *Id.* at 9.

A. Contrary to Mallory's assertion, there is irrefutable evidence that state-government healthcare programs disbursed money to pay tainted claims for HDL laboratory tests.

Mallory argues that Lutz and Webster – relators with personal knowledge of Mallory's conduct and its impact on a physician's practice in South Carolina, a non-plaintiff state – lack personal knowledge that claims were presented to or paid by any of the plaintiff state Medicaid programs. Dkt. No. 500-1 at 4. But the law does not require that Lutz or Webster personally know that the plaintiff states, in which they neither live nor work, disbursed money for claims for HDL laboratory tests. Instead, Lutz and Webster are entitled to seek claims data demonstrating that both presentation and payment occurred. In this matter, Lutz and Webster subpoenaed and obtained data for claims for HDL tests submitted to and paid by Medicaid programs in Colorado, Florida, Indiana, Illinois, North Carolina, and Virginia.² They produced the data to Mallory and her co-defendants in three installments – the first was received by counsel on May 12, 2017, the second on June 1, 2017, and the third on June 13, 2017. Exhibits 1-6. This data establishes the precise claims for HDL laboratory tests, as identified by operative Current Procedural Terminology codes, that were submitted to and paid by the state Medicaid programs. It also provides the date of submission, the related prescriber identifiers, and other information from which defendants, including Mallory, could verify the claims. *Id.* Additionally, Lutz and Webster have received – and, again, produced to defendants – business records affidavits detailing the data collection process from all of the aforementioned states besides Colorado.³ Exhibits 7-11. Thus, Lutz and Webster have established that Colorado, Florida, Illinois, Indiana, North Carolina, and Virginia have been presented with and paid claims for HDL laboratory tests.

² Lutz and Webster have thus far been unable to obtain claims data from the remaining plaintiff states.

³ Lutz and Webster expect to have the Colorado business records affidavit well in advance of the July 21, 2017, deadline prescribed by the Court. Dkt. No. 418.

B. Defendants' scheme to provide illegal inducements to physicians in exchange for referring patients for laboratory testing was material to the states' decisions to pay claims.

For starters, Mallory focuses the materiality inquiry on her individual conduct. Both Lutz and Webster and the United States have alleged that Mallory and her co-defendants Dent and Johnson conspired to develop a kickback scheme, where HDL offered, through its marketing agents Dent and Johnson,⁴ processing and handling (“P&H”) fees to physicians to induce them to refer patients for laboratory testing at HDL and Singulex. Indeed, Mallory, Dent, and Johnson conspired to create this scheme in 2009, before BlueWave was incorporated. Dkt. No. 504-10 (Dent Dep. Tr.) at 8-10; 504-17 (Johnson Dep. Tr.) at 25, 30-34. Thus, Lutz and Webster need not show that Mallory’s individual conduct was material to the states’ decisions to pay claims (though, as a developer of the scheme and the signor of the checks for P&H fees, it surely was). Rather, the operative question is whether the P&H scheme – the fraudulent course of conduct developed and undertaken by Mallory, Dent, and Johnson – was material to the government’s decision to pay claims.

The materiality element is satisfied here because compliance with the anti-kickback statute is a material condition of payment. The federal anti-kickback statute (“AKS”) prohibits the knowing and willful solicitation and receipt of “any remuneration. . . in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program.” 42 U.S.C. § 1320a-7b(b)(1)(A). In 2010, Congress amended the AKS, through the Patient Protection and Affordable Care Act, to make clear that “a claim that includes items or

⁴ Dent and Johnson later formed BlueWave, through which they marketed HDL and Singulex tests.

services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act].” *Id.* at 42 U.S.C. § 1320a-7b(g).

Consistent with the plain language of the AKS, courts have uniformly held that compliance with the statute is a material condition of payment. *E.g.*, *United States ex rel. United Health Group, Inc.*, 659 F.3d 295, 313 (3d Cir. 2011); *United States ex rel. Nevyas v. Allergan, Inc.*, 2015 WL 4064629, at *4 (E.D. Pa. Jul. 2, 2015); *United States ex rel. Gale v. Omnicare, Inc.*, 2013 WL 3822152, at *5 (N.D. Ohio Jul. 23, 2013); *United States ex rel. Fry v. The Health Alliance of Greater Cincinnati*, 2008 WL 5282139, at *33 (S.D. Ohio Dec. 18, 2008); *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 615-16 (N.D. Ill. 2003).

That view persists even after the U.S. Supreme Court’s decision in *Universal Health Services, Inc. v. United States ex rel. Escobar*, --- U.S. ----, 136 S.Ct. 1989 (2016), which clarified that the materiality inquiry focuses on the likely behavior of the target of the false statement or fraudulent conduct, *i.e.*, the government. *Id.* at 2002-03. In *United States ex rel. Wood v. Allergan, Inc.*, 2017 WL 1233991 (S.D.N.Y. Mar. 31, 2017), the U.S. District Court for the Southern District of New York assessed the effect of alleged kickbacks under the *Escobar* framework and had “no trouble concluding that compliance with the AKS is a ‘material’ condition of payment.” *Id.* at *28. An AKS violation, per the court, “is a far cry from an ‘insubstantial’ regulatory violation.” *Id.* Rather, it is a felony offense punishable by up to five years’ imprisonment. *Id.* (citing 42 U.S.C. § 1320a-7b). Moreover, “the law now provides explicitly that ‘a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim.’” *Id.* (quoting 42 U.S.C. § 1320a-7b(g)).

Mallory concedes that the state False Claims Acts of Colorado, Florida, Indiana, Illinois, North Carolina, and Virginia mirror the federal FCA; thus, authority analyzing the federal FCA

generally applies with equal force to the state FCAs. Dkt. No. 500-1 at 3. All of those states besides Colorado have anti-kickback statutes that are identical in substance to the federal AKS. *See* Fla. Stat. Ann. § 68.802; 305 Ill. Comp. Stat. Ann. § 5/8A-3(b); Ind. Code § 12-15-24-2; N.C. Gen. Stat. § 108A-63(g)-(j); Va. Code. Ann. § 26-20-4. In the absence of case law to the contrary, this Court should hold that whether claims submitted to the plaintiff states are tainted by kickbacks is material to the government’s determination regarding whether to remit payment.⁵

C. Mallory’s causation arguments have no bearing here, as there is no dispute that Defendants paid P&H fees and Lutz and Webster have provided data for the claims for which they seek damages.

Mallory first contends that Lutz and Webster “paint too broad a stroke” by alleging that “because the defendants violated the [AKS] in their *quid pro quo* arrangements, any and all claims submitted to . . . states. . . for laboratory testing, *regardless of how patients came to be customers of the defendants*, violated the FCA.”⁶Dkt. No. 500-1 at 5 (emphasis added). Mallory misrepresents Lutz and Webster’s position. The record leaves no question as to how the patients became HDL customers: Mallory and her co-defendants Dent and Johnson concocted and executed a marketing scheme to offer illegal P&H payments to physicians who referred clients for testing at HDL. *See, e.g.*, Dkt. No. 498-4 (HDL P&H agreement); 504-6 (HDL position statement on P&H fees); 504-10 (Dent Dep. Tr.) at 14. Viewed most charitably to Mallory and

⁵ Mallory argues that the federal government reimbursed the kickback-tainted claims after it learned of Mallory’s non-compliance with the AKS. Dkt. No. 500-1 at 3. As this contention relates to the intervened federal FCA claims against Mallory and her co-defendants, Lutz and Webster yield to and incorporate by reference the United States’ response. Of relevance to the *non-intervened* aspects of the Lutz-Webster complaint, Mallory takes no position regarding the states’ decision to pay Medicaid claims – nor could she, as neither she nor her co-defendants have taken discovery from the plaintiff states on that issue.

⁶ Again, Mallory conflates the federal FCA claims, in which the United States has intervened, and the state law claims, which Lutz and Webster are prosecuting on behalf of the states. Lutz and Webster’s response focuses on these non-intervened state law claims.

her co-defendants, the evidence creates a genuine issue of material fact as to whether HDL's offer of P&H fees caused the submission of false claims to state governments.

United States v. Medco Health Systems, Inc., 223 F. Supp. 3d 222 (D.N.J. 2016) does not support Mallory's position. There, the plaintiff alleged that Medco's contributions to the Hemophilia Association of New Jersey, made with the intent to induce referrals, violated the AKS and, thus, the FCA. *Id.* at 223. The court granted Medco's motion for summary judgment, finding that the plaintiff had provided no evidence any of the patients for which claims were submitted to and paid by the government had been referred by the Hemophilia Association of New Jersey. *Id.* at 228-29. The focus in that case, then, is the identity of the referring entity. There is no similar proof problem here. The record establishes that HDL paid P&H fees to physicians who referred patients to HDL for laboratory testing, and that HDL submitted claims for the tests it ran to government healthcare programs. As noted above, Lutz and Webster have obtained and provided to defendants the relevant Medicaid claims data for Colorado, Florida, Illinois, Indiana, North Carolina, and Virginia. That data precisely identifies each referring provider.

That claims data also renders inapposite Mallory's argument regarding statistical sampling. Dkt. No. 500-1 at 6-7. Lutz and Webster have not identified a small number of claims and then extrapolated from that discrete set to prove liability or a larger amount of damages. Instead, they have provided to Mallory and her co-defendants each and every claim that supports their damages arguments. Mallory's reliance on *United States ex rel. Michaels v. Agape Senior Community, Inc.*, 848 F.3d 330, 341 (4th Cir. 2017) is therefore misplaced.

V. **CONCLUSION**

For the foregoing reasons, this Court should deny Mallory's Motion for Summary Judgment of Relators Scartlett Lutz and Kayla Webster's Third Amended Qui Tam Complaint.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 7, 2017 I filed the foregoing on the Court's Electronic Filing System which forwarded an electronic copy to all counsel of record.

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