

injections. *Id.* at ¶¶ 52–53. Both products are regulated by the United States Food and Drug Administration and satisfy the definition of a “drug” under the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, and a “biologic product” under the Public Health Service Act, 42 U.S.C. §§ 201 *et seq.* Compl. at ¶¶ 16–24.

On January 19, 2017, Relator filed this *qui tam* action against Defendant under seal in federal court pursuant to the procedures of the False Claims Act (“FCA”), 31 U.S.C. §§ 3729 *et seq.* Compl. Relator alleges that since at least February, 2014, Defendant secures reimbursement of its products by disguising illegal payments as charitable contributions to the Patient Access Network Foundation (“PAN”)—a copay and coinsurance assistance foundation—while manipulating the submission of patient assistance applications to ensure its contributions fund only patients seeking Defendant’s products. *Id.* at 1, ¶¶ 5, 42-43; ECF No. 66 (“Relator’s Mem in Opp’n”) at 2–3 (citing Compl. ¶¶ 115–159). Relator seeks to recover monies Defendant allegedly obtained illegally from federal health insurance programs through the sale of regenerative biomaterials, in violation of the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b, and thus in violation of § 3729(a)(1)(A) and (B) of FCA. Compl. at 1, ¶¶ 167–178.

On August 10, 2018, after the United States declined to intervene in the case, ECF No. 40, the Court unsealed the complaint for service on Defendant, ECF No. 43. On October 1, 2018, Defendant filed the pending motion to dismiss for failure to plead FCA violations with particularity under Fed. R. Civ. P. 9(b) and failure to state a claim upon which relief may be granted under Rule 12(b)(6). Mot. to Dismiss at 1. Additionally, Defendant contends dismissal is warranted because Relator’s claims are foreclosed by FCA’s public disclosure bar, 31 U.S.C. § 3730(e)(4). *Id.* On October 15, 2018, Relator filed a response in opposition to dismissal, ECF No. 66, and on October 22, 2018, Defendant filed a

reply thereto, ECF No. 67. On November 6, 2018, the United States, which is the real party in interest, filed a statement of interest,² ECF No. 68, to which Defendant responded on November 13, 2018, ECF No. 69. On January 2, 2019, Relator filed a supplemental response in opposition to dismissal with additional authority, ECF No. 73, to which Defendant replied on February 22, 2019, ECF No. 74. The matter is now ripe for the Court's consideration.

Legal Standards

I. AKS and FCA

AKS makes it a violation, *inter alia*, to “knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind” to induce the referral of business reimbursable under a federal health care program. 42 U.S.C. § 1320a-7b(b)(2). A person can violate AKS without knowing of AKS, or having the specific intent to violate the section. *Id.* § 1320a-7b(h). An AKS violation resulting in a federal health care payment automatically constitutes a false claim under FCA. *United States ex rel. Lutz v. United States*, 853 F.3d 131, 135 (4th Cir. 2017) (citing 42 U.S.C. § 1320a-7b(g)).

FCA provides civil liability against a person who, *inter alia*, “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval” (“false claims provision”) or “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim” (“false statements provision”). 31 U.S.C. §§ 3729(a)(1)(A)-(B). “Knowingly” means having “actual knowledge,” or acting “in deliberate ignorance of the truth or falsity of the

² In its statement of interest, “[t]he United States takes no position on the applicability of the public disclosure bar . . . [or] on whether Relator has sufficiently pleaded his allegations[.]” ECF No. 68 at 1-2. Rather, the United States presents arguments on three points relevant to examining Relator's complaint under Fed. R. Civ. P. 12(b)(6), and requests any dismissal under Fed. R. Civ. P. 9(b) or public disclosure bar grounds be without prejudice as to the Government. *Id.* at 5-15.

information” or “in reckless disregard of the truth or falsity of the information.” *Id.* § 3729(b)(1)(A). Proof of specific intent to defraud is not necessary to prove knowledge. *Id.* § 3729(b)(1)(B).

“A false or fraudulent claim includes false statements or fraudulent conduct that induce the contract for or extension of a government benefit.” *United States ex rel. Lutz v. Berkeley HeartLab, Inc.*, Civil Action No. 9:14-230-RMG, 2017 WL 5033652, at *3 (D.S.C. Oct. 31, 2017). The elements of a fraudulent inducement claim are: (1) “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.” *Id.* For the first element to be met, “the statement or conduct alleged must represent an objective falsehood.” *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376-77 (4th Cir. 2008)

“[T]here are two ways to adequately plead presentment” of a false claim. *United States ex rel. Grant v. United Airlines, Inc.*, 912 F.3d 190, 197 (4th Cir. 2018). First, a relator “can ‘allege with particularity that specific false claims actually were presented to the government for payment.’” *Id.* (quoting *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 457 (4th Cir. 2013)). The relator must, “‘at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.’” *Id.* (quoting *Wilson*, 525 F.3d at 379). “These facts are also referred to as the ‘who, what, when, where, and how of the alleged fraud.’” *United States ex rel. Cooley v. Carolina Wrecking, Inc.*, Civil Action No.: 2:17-0276-RMG, 2019 WL 236797, at *2 (D.S.C. Jan. 16, 2019) (quoting *Wilson*, 525 F.3d at 379). Second, the relator “can allege a pattern of conduct that would ‘necessarily have led[] to submission of false claims’ to the government for payment.” *Grant*, 912 F.3d at 197 (quoting *Nathan*, 707 F.3d at 457).

“The FCA may be enforced not just through litigation brought by the Government itself, but also through civil *qui tam* actions that are filed by private parties, called relators, ‘in the name of the Government.’” *Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*, 135 S. Ct. 1970, 1973 (2015) (quoting 31 U.S.C. § 3730)).

A. False Claims Provision

Regarding the false claims provision of FCA, “[c]ourts construe the phrase ‘false or fraudulent claim . . . broadly to reach all types of fraud, without qualification, which might result in financial loss to the Government.’” *Cooley*, 2019 WL 236797, at *2 (quoting *United States v. Triple Canopy, Inc.*, 775 F.3d 628, 634 (4th Cir. 2015), *vacated on other grounds*, 136 S. Ct. 2504 (2016) (mem.)).

B. False Statements Provision

For the purposes of FCA’s false statements provision, “‘material’” means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4). The false statement provision “does not require that the defendant itself ‘present’ the false claim to the government. Instead, this provision is satisfied where the defendant makes or uses a false record that is material to a false claim.” *Grant*, 912 F.3d at 200. The relator, however, “is still required to show that a false claim was submitted to the government.” *Id.*

C. Public Disclosure Bar

Unless opposed by the government, the public disclosure bar mandates dismissal of an FCA claim “if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed . . . in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party[.]” 31 U.S.C. § 3730(e)(4)(A). The bar, however, does not apply, if the relator is “an original source of the information.” *Id.* An original source is “an individual who either: (1) prior

to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.” *Id.* § 3730(e)(4)(B).

Once jurisdictional in nature, the public disclosure bar is now an affirmative defense. *United States ex rel. May v. Purdue Pharma L.P.*, 737 F.3d 908, 916 (4th Cir. 2013) (explaining the 2010 amendments to FCA eliminated the jurisdictional language of the public disclosure bar); *United States ex rel. Beauchamp v. Acadami Training Ctr., LLC*, 816 F.3d 37, 40 (4th Cir. 2016) (“Post-amendment, the public-disclosure bar is a grounds for dismissal—effectively an affirmative defense—rather than a jurisdictional bar.”). The bar is meant “to prevent “parasitic” *qui tam* actions in which relators, rather than bringing to light independently-discovered information of fraud, simply feed off of previous disclosures of government fraud.” *United States ex rel. May v. Purdue Pharma L.P.*, 811 F.3d 636, 642 (4th Cir. 2016) (quoting *United States ex rel. Siller v. Becton Dickinson & Co.*, 21 F.3d 1339, 1347 (4th Cir. 1994)).

II. Federal Rule of Civil Procedure 12(b)(6)

“A motion filed under Rule 12(b)(6) challenges the legal sufficiency of a complaint . . . considered with the assumption that the facts alleged are true[.]” *Francis v. Giacomelli*, 588 F.3d 186, 192 (4th Cir. 2009) (citations omitted). The Court measures the legal sufficiency by determining whether the complaint meets the Rule 8 standards for a pleading. *Id.* Rule 8 requires, in pertinent part, that a claim for relief contain a “statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a). “Each allegation must be simple, concise, and direct.” Fed. R. Civ. P. 8(d)(1).

When reviewing a motion under Rule 12(b)(6), the Court must “accept all well-pleaded allegations in the plaintiff’s complaint as true and draw[] all reasonable factual inferences from those facts in the plaintiff’s favor[.]” *Edwards v. City of Goldsboro*, 178 F.3d 231, 244 (4th Cir. 1999). However, the Court need not accept as true allegations that are contradicted by exhibits to the complaint. *Veney v. Wyche*, 293 F.3d 726, 730 (4th Cir. 2002) (citation omitted). To survive a Rule 12(b)(6) motion to dismiss, the plaintiff’s “[f]actual allegations must be enough to raise a right to relief above the speculative level.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). “[O]nce a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint.” *Id.* at 563. A complaint need not assert “detailed factual allegations”; however, it must contain “more than labels and conclusions, and a formulaic recitation of the elements of a cause of action” will not suffice. *Id.* at 555 (citations omitted). Furthermore, “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). A claim has “facial plausibility” where the pleading “allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.*

III. Federal Rule of Civil Procedure 9(b)

In addition to the plausibility standard of *Iqbal*, Rule 9(b) heightens the pleading standard for FCA claims by requiring a party alleging fraud to “state with particularity the circumstances constituting fraud[.]” Fed. R. Civ. P. 9(b); *see Grant*, 912 F.3d at 196 (citing *Nathan*, 707 F.3d at 455–56) (“Claims arising under §§ 3729(a)(1)(A) and (B) of the FCA are fraud-based claims that must satisfy Rule 9(b)’s pleading standard.”). “Rule 9(b)’s particularity requirement serves as a necessary counterbalance to the gravity and quasi-criminal nature of FCA liability.” *Grant*, 912 F.3d at 197

(quotation marks and citation omitted). This requirement ““does not permit a [FCA] plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government.”” *Id.* at 196 (quoting *Nathan*, 707 F.3d at 457). The complaint must ““provide some indicia of reliability’ to support the allegation that an actual false claim was presented to the government.”” *Id.* at 197 (citing *Nathan*, 707 F.3d at 457). Failure to plead plausible allegations of submission of a false claim means the relator “has not alleged all the elements of a claim under the [FCA].” *Nathan*, 707 F.3d at 456 (citation omitted). Without such allegations, “a relator not only fails to meet the particularity requirement of Rule 9(b), but also does not satisfy the general plausibility standard of *Iqbal*.” *Id.* at 457 (citations omitted).

Discussion

Defendant moves to dismiss the complaint under Rules 12(b)(6) and 9(b) for failure to allege particularized facts plausibly showing an FCA violation and under the FCA’s public disclosure bar. ECF No. 65-1 (“Def’s Mem. in Supp. of Mot. to Dismiss”) at 6. With respect to Rules 12(b)(6) and 9(b), Defendant asserts that: (1) Relator fails to state an FCA claim by failing to allege a false or fraudulent claim and neglecting to show that Defendant caused any false claim to be submitted; (2) Relator fails to state a claim under § 3729(a)(1)(B) by failing to allege a false statement or record; and (3) all claims related to the FEHBP fail as a matter of law. *Id.* at 12-22. With respect to the public disclosure bar, Defendant contends that: (1) Relator’s allegations about Defendant’s payment of kickbacks for EpiFix had previously been publicly disclosed; and (2) Relator is not an original source. *Id.* at 23-30. The Court examines each of these contentions. The Court first analyzes Relator’s allegations with respect to FEHBP and his FCA claim for false statements or records under 31 U.S.C.

§ 3729(1)(B). The Court next turns to FCA’s public disclosure bar and finally analyzes Defendant’s arguments Relator’s complaint should be dismissed under Federal Rules of Civil Procedure 12(b)(6) and 9(b).

I. FEHBP Claims

Relator alleges that by violating AKS, Defendant caused false claims to be submitted to two programs: Medicare and FEHBP. Compl. at ¶¶ 168, 172–178. Defendant contends Relator’s claims as to FEHBP fail as a matter of law because the AKS does not apply to that program. Def.’s Mem. in Supp. of Mot. To Dismiss at 21-22. In response, Relator concedes that because AKS does not apply to FEHBP, those claims cannot proceed and must be dismissed.³ Relator’s Mem. in Opp’n at 5. Accordingly, the Court grants Defendant’s motion to dismiss with respect to Relator’s FEHBP-based claims.

II. False Statements Claim

Defendant advances the Court should dismiss Relator’s claim under FCA’s false statements provision because Relator fails to allege Defendant made or used any false statements or false records material to a false or fraudulent claim. Def’s Mem in Supp. of Mot. To Dismiss at 21. As noted by Defendant in its reply, ECF No. 67 at 13, Relator fails to address this argument in his Memorandum in Opposition.

The Court recognizes it could consider Relator to have conceded his cause of action under

³ The Court agrees that AKS expressly does not apply to FEHBP. *See* 42 U.S.C. §§ 1320a-7b(b)(2), (f)(1) (emphasis added) (providing that AKS applies to unlawful remuneration provided in connection with a “Federal health care program,” defined in relevant part as “any plan or program that provides health benefits, whether directly, through insurance, or otherwise, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of Title 5)”); 5 U.S.C. §§ 8901 et seq. (providing for FEHBP); *see also* Office of Personnel Mgmt., *Healthcare*, <https://www.opm.gov/healthcare-insurance/healthcare/> (last visited May 3, 2019) (“[T]he FEHB Program is exempt from the application of [AKS].”).

FCA's false statements provision. *See Campbell v. Rite Aid Corp.*, Civil Action No. 7:13-cv-02638-BHH, 2014 WL 3868008, at * 2 (D.S.C. Aug. 5, 2014) ("Plaintiff failed to respond to [Defendant's] argument regarding causes of action 1 and 2, and the Court can only assume that Plaintiff concedes the argument."); *Stenlund v. Marriott Int'l, Inc.*, 172 F. Supp. 3d 874, 887 (D. Md. 2016) ("In failing to respond to this argument, Plaintiff concedes the point."); *Kissi v. Panzer*, 664 F. Supp. 2d. 120, 123 (D.D.C. 2009) ("Because the plaintiff's opposition fails to address the defendants' arguments, the Court may treat the defendants' motion [to dismiss] as conceded."). However, a violation of AKS resulting in a federal health care payment constitutes a per se false claim under FCA, *Lutz*, 853 F.3d at 135 (citing 42 U.S.C. § 1320a-7b(g)), and - as analyzed in Section IV below - the Court holds Relator has adequately pled an AKS violation resulting in a federal health care payment. Accordingly, at this juncture, the Court will deny Defendant's motion to dismiss as to Relator's false statements provision claim.

III. Public Disclosure Bar

Because it could be dispositive of the remaining claims, the Court next turns to FCA's public disclosure bar. Defendant advances FCA's public disclosure bar applies to prevent the instant lawsuit because Relator's claims were previously disclosed, and Relator does not qualify as an original source. Def's Mem in Supp. of Mot. to Dismiss at 22-30. Relator responds the public disclosure bar does not apply here because the alleged previous public disclosure did not occur in a hearing to which the Government was a party, and the previous disclosure was not substantially the same as the instant claims. Rel's Mem. in Opp'n. at 17-21. Defendant replies the prior disclosure qualified as a public disclosure, the relator in that case was the Government's agent, and the allegations in that case are substantially the same as those in the instant case. ECF No. 67 at 5-8. Accordingly, Defendant

advances Relator’s claims should be dismissed under FCA’s public disclosure bar. *Id.*

As noted above, absent Government objection, FCA’s public disclosure bar requires the Court to dismiss an FCA claim “if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed . . . in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party.” 31 U.S.C. § 3730(e)(4)(A). The prior public disclosure alleged to be applicable here is a *qui tam* FCA case filed in 2014 against MiMedx in the United States District Court for the District of Columbia, *United States ex rel. Montecalvo v. MiMedx Group, Inc.*, No: 1:14-cv-01260-RCL (D.D.C. 2014).⁴ Def’s Mem. in Supp. of Mot. to Dismiss at 23.

Montecalvo constitutes a civil hearing within the meaning of the public disclosure bar. *Siller*, 21 F.3d at 1350 (4th Cir. 1994) (“Given the fluidity in the meaning of the term ‘hearing,’ and the fact that we can discern no reason why Congress might have intended otherwise, we agree with our sister Circuits (albeit somewhat reluctantly) that an entire civil proceeding can constitute a ‘hearing’ for purposes of section 3730(e)(4)(A).”). Further, relator Montecalvo was the Government’s agent for the purposes of the public disclosure bar. *See Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 764, 772 (2000) (noting an FCA *qui tam* relator “is simply the statutorily designated agent of the United States, *in whose name* (as the statute provides, see 31 U.S.C. § 3730(b)) the suit is brought[.]”); *United States ex rel. Gilbert v. Va. Coll.*, 305 F. Supp. 3d 1315, 1321-25 (N.D.Ala. 2018) (finding *qui tam* relators are agents of the Government for the purposes of FCA’s public disclosure bar); *but see United States v. Medtronic, Inc.*, 327 F. Supp. 3d 831, 842 (E.D. Pa.. 2018) (holding in the context of the public disclosure bar, “a *qui tam* relator is not the government’s agent.”) .

⁴ The Court can properly take judicial notice of *Montecalvo*. *See Papasan v. Allain*, 478 U.S. 265, 268 (1986) (“Although this case comes to us on a motion to dismiss under Federal Rule of Civil Procedure 12(b), we are not precluded in our review of the complaint from taking notice of items in the public record[.]”)

The Court finds, however, the *Montecalvo* suit and the instant lawsuit are not substantially related, and thus the public disclosure bar does not apply. A prior public disclosure and the instant claims are substantially the same if the earlier disclosure puts the Government on notice of wrongdoing such that the Government could have started an investigation. *United States ex rel. Black v. Health & Hosp. Corp. of Marion Cty.*, 494 Fed. App'x 285, 294 (4th Cir. 2012); *Citynet, LLC on behalf of the United States v. Frontier W.Va., Inc.*, Civil Action No. 2:14-15947, 2018 WL 1582527 at *20 (S.D. W. Va. Mar. 30, 2018) (noting the Fourth Circuit has not had occasion to define substantially the same under the post-2010 FCA, and collecting cases showing substantially the same under the public disclosure bar means similar enough that the Government was on notice of wrongdoing and could choose to pursue action against the defendant).

Montecalvo and the case at bar are similar in some ways. Like the instant case, *Montecalvo* is based upon Defendant's marketing and sales of EpiFix. *Compare* Compl. ¶¶ 51-53 with *Montecalvo*, ECF No. 1 ("Compl.") ¶ 4. Like this case, *Montecalvo* includes claims MiMedx violated AKS, and thus violated FCA. *Compare* Compl. ¶¶ 1, 167-78 with *Montecalvo* Compl. ¶¶ 19, 111, 117-29, 176, 196-212. Further, some of the specific allegations in the two complaints appear quite similar. *See* Def's Mem. In Supp. of Mot. to Dismiss at 25-27 (comparing allegations in the instant complaint to those in the *Montecalvo* complaint). The crux of the instant case, however, is that Defendant coordinated its charitable contributions to PAN to ensure its money funded purchases of Defendant's products. *See* Compl. ¶¶ 42-47. The *Montecalvo* complaint mentions PAN only once. *Montecalvo* Compl. ¶ 121(c). The PAN-related allegation in *Montecalvo* reads: "Moreover, on information and belief, Mr. Moore routinely uses the Patient Access Network ('PAN') Foundation, an organization that pays co-payments, by logging into the 'PAN Portal' as if he represents the medical provider and puts

patients through who may not be eligible for coverage.” *Id.* Despite the similarities between Relator’s complaint and *Montecalvo*’s complaint, the Court holds *Montecalvo*’s claim would not have put the Government on notice of the complicated scheme alleged in the instant case in which Relator claims Defendant illegally funded purchase of its own products by filtering money through PAN. For that reason, Relator’s case is not substantially similar to *Montecalvo*, and thus the public disclosure bar does not apply.

Assuming *arguendo* all elements of the public disclosure bar were met, it still would not apply because Relator is an original source. Even when otherwise applicable, the public disclosure bar does not apply when the relator is an “original source,” 31 U.S.C. § 3730(e)(4)(A), defined as, *inter alia*, a person “who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing” an FCA action. *Id.* § 3730(e)(4)(B). Relator has knowledge independent of that contained in *Montecalvo*. As noted above, Relator’s allegations are substantially different from Montecalvo’s PAN-related claim. Further, while Montecalvo was employed with a MiMedx competitor, *Montecalvo* Compl. ¶¶ 2-3, Relator was a MiMedx sales representative, Compl. ¶ 5. As a MiMedx insider, Relator would have an independent basis for his knowledge. Additionally, because Relator’s independent information is significant and could change decisions made regarding the allegations of wrongdoing, Relator’s information materially adds to that disclosed in *Montecalvo*. *See United States ex rel. Advocates for Basic Legal Equality, Inc. v. U.S. Bank, N.A.*, 816 F.3d 428, 431 (6th Cir. 2016 (quoting *Black’s Law Dictionary* 1124 (10th ed. 2014)) (“Materiality in [the public disclosure] setting requires [Relator] to show it had information ‘[o]f such a nature that knowledge of the item would affect a person’s decision making,’ is ‘significant,’ or is ‘essential.’”) Finally, Relator voluntarily provided his

information to the Government prior to filing this action. Compl. ¶ 4.

Accordingly, because the allegations in the instant case are not substantially similar to those in *Montecalvo*, or alternatively because Relator is an original source, FCA's public disclosure bar does not apply to the instant case. For those reasons, the Court will deny Defendant's motion to dismiss as to FCA's public disclosure bar.

IV. Federal Rules of Civil Procedure 12(b)(6) and 9(b)

Defendant argues the Court should dismiss Relator's complaint for failure to adequately plead as required under Federal Rules of Civil Procedure 12(b)(6) and 9(b). Def's Mot to Dismiss at 1. Relator avers he has adequately pled his complaint such that dismissal is unwarranted. Rel's Mem. in Opp'n. at 2. In the alternative, Relator seeks leave to amend his complaint. *Id.* at 17 n.4.

As a preliminary matter, the Court will deny Relator's request for leave to amend his complaint. Fed. R. Civ. P. 15(a)(2) directs: "[t]he court should freely give leave [to amend] when justice so requires." Leave to amend a pleading should be denied only under limited circumstances, such as when the amendment would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or the amendment would be futile. *Foman v. Davis*, 371 U.S. 178, 182 (1962). Here, Relator does not elaborate as to what amendments he would make to the complaint, but instead generally requests leave to amend. Leave to amend is properly denied where the requested leave to amend is not accompanied by a motion to amend or a proposed amended complaint. *See Cozzarelli v. Inspire Pharms., Inc.*, 549 F.3d 618, 630-31 (4th Cir. 2008) (finding no abuse of discretion where district court denied leave to amend when plaintiffs requested leave to amend in a response but did not file a motion to amend or a proposed amended complaint). Accordingly, in the absence of a motion to amend accompanied by a proposed amended complaint, Relator's request for leave to amend is

denied.

Regarding Defendant's motion to dismiss Relator's FCA causes of action for failure to comply with Federal Rules of Civil Procedure 12(b)(6) and 9(b), the Court agrees with Relator: the FCA causes of action have been adequately pled at this stage in the proceeding. AKS prohibits, *inter alia*, "knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind" to induce referral of business reimbursable under a federal healthcare program. 42 U.S.C. § 1320a-7b(b)(2). "An AKS violation that results in a federal health care payment is a per se false claim under the FCA." *Lutz*, 853 F.3d at 135 (citing 42 U.S.C. § 1320a-7b(g)). To state a cause of action under the provisions of FCA at issue here, Relator must show: (1) a false statement or fraudulent conduct; (2) carried out with the required level of knowledge; (3) which influenced the Government's decision to pay a claim; and (4) the Government paid out or forfeited money. *Lutz*, 2017 WL 5033652, at *3 (D.S.C. Oct. 31, 2017).

Relator here alleges a scheme where Defendant would encourage sales representatives to identify patients of Defendant's medical provider clients who would be eligible for PAN funding to cover Medicare coinsurance and copays and prepare PAN applications for them. Compl. ¶¶ 42, 115-178. Defendant would then make charitable contributions to and fund PAN in an amount correlated with the number of patients Defendant had identified who would be seeking PAN funding. *Id.* Defendant would next have its sales representatives, who had been told to hold applications until the PAN funds were funded, rush to submit applications. *Id.* The net result of this activity, Relator alleges, was Defendant funding sales of its own products by - in essence - laundering money through PAN. *Id.* ¶¶ 42-43.

Relator sufficiently alleges an AKS violation because he claims Defendant knowingly and

willfully paid a remuneration, here Medicare coinsurance and copays, indirectly via its correlated charitable contribution funding of PAN, to induce patients on Medicare to purchase Defendant's Products. An AKS violation resulting in a federal Medicare payment is a per se false claim under FCA. *Lutz*, 853 F.3d at 135 (citing 42 U.S.C. § 1320a-7b(g)). Further, Relator has shown the elements necessary to state a cause of action under FCA. Relator alleges: (1) Defendant fraudulently correlated its charitable contributions to PAN with applications for PAN funding to ensure its products were purchased; 2) Defendant engaged in this activity knowingly; (3) this activity influenced purchase of Defendant's products; and (4) these actions necessarily would have caused the Government to pay out money, *see Grant*, 912 F.3d at 197 (quoting *Nathan*, 707 F.3d at 457) (noting a Relator can show presentment of a false claim under FCA by "alleging a pattern of conduct that would 'necessarily have led [] to submission of false claims' to the government for payment."). Accordingly, the Court holds Relator has sufficiently pled his FCA causes of action, and he has pled them with sufficient particularity, at this stage of the proceedings. For those reasons, the Court will deny Defendant's motion to dismiss pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b).

Conclusion

For the foregoing reasons, the Court **GRANTS IN PART AND DENIES IN PART** Defendant's motion to dismiss. ECF No. 65. Defendant's motion to dismiss is **GRANTED** as to Relator's FEHBP claims, and **DENIED** as to Relator's remaining claims. Relator's FEHBP claims are **DISMISSED WITH PREJUDICE**.

IT IS SO ORDERED.

Florence, South Carolina
May 15, 2019

s/ R. Bryan Harwell
R. Bryan Harwell

Chief United States District Judge