IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA, *et al.*, *ex rel.* MATTHEW A. FITZER, M.D.,	*	
Plaintiffs,	*	
v.	*	**Civil Case No. 1:17-cv-00668-SAG**
ALLERGAN, INC., *et al.*	*	
Defendants.	*	

* * * * * * * * * * * * * * *

MEMORANDUM OPINION

Relator Matthew A. Fitzer ("Relator") filed an initial complaint against Defendant Allergan, Inc. ("Allergan"), under seal, in November, 2013, alleging that Allergan conducted an unlawful kickback scheme in violation of the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq*. ECF 1. In August, 2014, Relator filed an Amended Complaint adding Defendant Apollo Endosurgery, Inc. (individually, "Apollo" and collectively with Allergan "Defendants"). ECF 6. In February, 2021, after the United States declined to intervene, ECF 48, this Court unsealed the case, ECF 49, and Relator filed a Second Amended Complaint ("SAC"), ECF 77. Both Defendants moved to dismiss under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. ECF 80, 82. On September 10, 2021, this Court granted Defendants' motions and dismissed the SAC but allowed Relator 45 days to move for leave to amend. ECF 91, 92. Relator timely filed a motion for leave to amend on October 25, 2021, ECF 93, along with a proposed third amended complaint ("TAC"). ECF 94-2. On December 9, 2021, this Court granted Relator's motion for leave to amend. ECF 98, 99. Defendants now have both moved to dismiss the TAC, ECF 106, 107, Relator opposed those motions, ECF 112, and Defendants filed replies, ECF 116, 117. This

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Court has reviewed all of these filings and their attached exhibits. No hearing is necessary. Loc. R. 105.6 (D. Md. 2021). For the reasons set forth below, Defendants' motions will be granted and the TAC will be dismissed without prejudice. If Relator believes he can successfully amend the TAC, he will be given a final chance to seek leave to do so. If Relator fails to seek leave to file an amended complaint within 14 days of this opinion and its corresponding order, this Court's dismissal will convert to a dismissal with prejudice.

I. FACTUAL BACKGROUND

Defendants are two medical device companies that have, at different times, owned the LAP-BAND brand. ECF 100 ¶¶ 65, 69. The LAP-BAND is a surgically implanted device used for the treatment of obesity. *Id.* ¶ 119. Once implanted, the LAP-BAND fits around the stomach, allowing physicians to "adjust digestive function in a manner intended to reduce hunger and lessen the amount of food required to feel satisfaction." *Id.* ¶ 120.

At different times, both Defendants used the website www.lapband.com to advertise and market the LAP-BAND product. *Id.* ¶ 134. Among other features, the website included a physician locator tool that allowed potential patients to input their zip codes to identify bariatric surgeons in their area who could perform the surgery required to implant the LAP-BAND device. *Id.* ¶ 137. The locator would provide the prospective patient with a link to the local surgeons' websites and, for a period of time, their seminar schedules where patients could enroll in seminars and meet the surgeons listed on the website. *Id.* ¶¶ 137-38, 140-41.

Relator alleges that the website became a powerful tool for patients to find surgeons who could perform LAP-BAND surgery and, in turn, "provided constant exposure and flow of business to the included surgeons." *Id.* ¶ 150. Relator alleges that Defendants specifically marketed the physician locator (as opposed to the LAP-BAND product generally) and tried to "send patients to

the locator." *Id.* ¶ 143. Indeed, Relator alleges that his "former suitemate once attributed his entire practice to referrals from www.lapband.com." *Id.* ¶ 144.

Relator's claims stem from his theory that Defendants used the physician locator to conduct "an unlawful kickback scheme . . . by providing surgeons with valuable free advertising on [the website] in order to induce surgeons to recommend Defendants' LAP-BAND® medical device instead of alternative operations." *Id.* ¶ 2. Central to Relator's theory, he alleges that Defendants implemented a quota of LAP-BAND surgeries that a physician needed to perform per year to be included on the physician locator. *Id.* ¶ 15.

Relator is a bariatric surgeon qualified to perform all three of the major bariatric operations: gastric bypass, sleeve gastrectomy, and gastric band surgery. *Id.* ¶ 49. He learned about the LAP-BAND website and its physician locator at a practice development seminar in February, 2012. *Id.* ¶ 159-60. At the seminar, he was told that the website was "a very valuable promotional resource" and that he should contact Allergan if he was interested in being included. *Id.* ¶ 160. The next month, Relator met with an Allergan Account Manager and "asked to be included in the database for referrals by www.lapband.com." *Id.* ¶ 163-64. The Account Manager asked Relator some questions about "his decision-making process with regard to recommending a LAP-BAND® implant as opposed to other kinds of surgery[,]" and "what would make him decide to do a LAP-BAND® procedure and in what percentage of these cases he would be likely to do a LAP-BAND® implant." *Id.* ¶¶ 165-66. She also "encouraged Dr. Fitzer to track leads he received from the LAP-BAND® website and provided Dr. Fitzer with a 'LAP-BAND® Patient Log' spreadsheet to do so. She indicated that the patient tracker was provided for free to all LAP-BAND® surgeons." *Id.* ¶ 167. The Account Manager told Relator he would be "granted access to the website" and "added to the physician locator." *Id.* ¶ 169.

Relator was added to the physician locator in June, 2012. *Id.* ¶ 177. Despite immediately receiving an increase in patient interest attributable to the physician locator, *id.*, he experienced "problematic and unexplained gaps in service in his account[,]" *id.* ¶ 178, that he believes "resulted from Allergan's dissatisfaction with his LAP-BAND® productivity." *Id.* ¶ 179. A few months later, he was temporarily "locked out" of his www.lapband.com account. *Id.* ¶ 181-82. To Relator's knowledge, no LAP-BAND-only surgeons (surgeons who, unlike Relator, only perform LAP-BAND surgeries but not the other mainstream bariatric surgeries) experienced disruptions to their accounts. *Id.* ¶ 183-84.

In March, 2013, Relator was removed from the physician locator and was denied access to the website. *Id.* ¶ 188. Relator contacted his Allergan Account Manager who promised to investigate the matter. *Id.* ¶ 191-92. The two spoke on the phone two days later, and the Account Manager informed Relator that he had been removed from the physician locator because he "had not conducted at least 40 LAP-BAND® procedures in a year." *Id.* ¶ 197. The following day, Relator contacted Allergan's Vice President of Sales and informed him that, in Relator's view, the quota violated federal law, including the Anti-Kickback Statute ("AKS"). *Id.* ¶ 203. In the same email, Relator asked for a written explanation of Allergan's policy if Allergan would not agree to reinstate him on the physician locator. *Id.* ¶ 205. Relator later spoke on the phone with the Vice President of Sales, Mark Didio, who confirmed that only surgeons who performed 40 LAP-BAND surgeries per year were included on the website's physician locator. *Id.* ¶¶ 209-10. On the call, Relator alleges that he "explain[ed] to Mr. Didio how Allergan's conduct violated the [AKS]," and that the two "debate[d]" the validity of that accusation. *Id.* ¶ 211-12. Relator also alleges that he told Mr. Didio that he believed Allergan had implemented the quota scheme as a ploy to bolster declining sales and "prop up the LAP-BAND® long enough to sell it, to avoid the impending

write-down[,]" and that he "disputed Mr. Didio's sham explanation" that the scheme was related to quality of care. *Id.* ¶¶ 215, 222. According to Relator, "Mr. Didio did not deny it. His response to that accusation was silence." *Id.* ¶ 216. Moreover, Relator alleges that as a direct response to Dr. Fitzer's threats to speak with a qui tam attorney or the U.S. Attorney's Office about the quota scheme, Mr. Didio responded that "he needed to discuss the matter with Allergan's CEO." *Id.* ¶ 218. Finally, Relator alleges that Mr. Didio specifically refused to provide Dr. Fitzer with "documentation of the quota system in writing." *Id.* ¶ 219.

Relator has never been reinstated on the physician locator. *Id.* ¶ 194. Relator alleges that his own investigation revealed that "his expulsion . . . reflect[ed] a nationwide phenomenon[,]" and that "the physician locator only included approximately 21% of the surgeons who could perform the procedure." *Id.* ¶¶ 232-33.

As he allegedly explained to Mr. Didio, Relator alleges that Allergan's physician locator quota was designed to drive sales and prop up the LAP-BAND product at a time when its sales revenue was falling due to concerns about its efficacy and Allergan was looking to sell the LAP-BAND product line. *Id.* ¶¶ 240-50. Apollo purchased the LAP-BAND brand in or around December, 2013. *Id.* ¶ 69. "All three of the Allergan employees and executives who Dr. Fitzer communicated with about the quota transferred to Apollo in connection with the sale of the LAP-BAND® division." *Id.* ¶ 277. Apollo maintained a quota for inclusion on the physician locator through at least 2018. *Id.* ¶ 291.

II. LEGAL STANDARD

Under Rule 12(b)(6), a defendant may test the legal sufficiency of a complaint by way of a motion to dismiss. *See In re Birmingham*, 846 F.3d 88, 92 (4th Cir. 2017); *Goines v. Valley Cmty. Servs. Bd.*, 822 F.3d 159, 165–66 (4th Cir. 2016); *McBurney v. Cuccinelli*, 616 F.3d 393,

408 (4th Cir. 2010), *aff'd sub nom.*, *McBurney v. Young*, 569 U.S. 221 (2013); *Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th Cir. 1999). A Rule 12(b)(6) motion constitutes an assertion by a defendant that, even if the facts alleged by a plaintiff are true, the complaint fails as a matter of law "to state a claim upon which relief can be granted."

Whether a complaint states a claim for relief is assessed by reference to the pleading requirements of Federal Rule of Civil Procedure 8(a)(2). That rule provides that a complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." The purpose of the rule is to provide the defendants with "fair notice" of the claims and the "grounds" for entitlement to relief. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555–56 (2007).

To survive a motion under Federal Rule of Civil Procedure 12(b)(6), a complaint must contain facts sufficient to "state a claim to relief that is plausible on its face." *Id.* at 570; *see Ashcroft v. Iqbal*, 556 U.S. 662, 684 (2009) ("Our decision in *Twombly* expounded the pleading standard for all civil actions[.]") (quotation omitted); *see also Willner v. Dimon*, 849 F.3d 93, 112 (4th Cir. 2017). However, a plaintiff need not include "detailed factual allegations" in order to satisfy Rule 8(a)(2). *Twombly*, 550 U.S. at 555. Further, federal pleading rules "do not countenance dismissal of a complaint for imperfect statement of the legal theory supporting the claim asserted." *Johnson v. City of Shelby, Miss.*, 574 U.S. 10, 11 (2014) (per curiam).

Nevertheless, the rule demands more than bald accusations or mere speculation. *Twombly*, 550 U.S. at 555; *see Painter's Mill Grille, LLC v. Brown*, 716 F.3d 342, 350 (4th Cir. 2013). If a complaint provides no more than "labels and conclusions" or "a formulaic recitation of the elements of a cause of action," it is insufficient. *Twombly*, 550 U.S. at 555. Rather, to satisfy the minimal requirements of Rule 8(a)(2), the complaint must set forth "enough factual matter (taken

as true) to suggest" a cognizable cause of action, "even if . . . [the] actual proof of those facts is improbable and . . . recovery is very remote and unlikely." *Twombly*, 550 U.S. at 556.

In addition to the plausibility standard set forth in *Twombly*, fraud-based claims are subject to heightened pleading requirements set forth in Federal Rule of Civil Procedure 9(b). Rule 9(b) requires a plaintiff to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). However, "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *Id.*

In reviewing a Rule 12(b)(6) motion, a court "must accept as true all of the factual allegations contained in the complaint" and must "draw all reasonable inferences [from those facts] in favor of the plaintiff." *E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, 637 F.3d 435, 440 (4th Cir. 2011) (citations omitted); *see Semenova v. MTA*, 845 F.3d 564, 567 (4th Cir. 2017); *Houck v. Substitute Tr. Servs., Inc.*, 791 F.3d 473, 484 (4th Cir. 2015); *Kendall v. Balcerzak*, 650 F.3d 515, 522 (4th Cir. 2011), *cert. denied*, 565 U.S. 943 (2011). However, a court is not required to accept legal conclusions drawn from the facts. *See Papasan v. Allain*, 478 U.S. 265, 286 (1986). "A court decides whether [the pleading] standard is met by separating the legal conclusions from the factual allegations, assuming the truth of only the factual allegations, and then determining whether those allegations allow the court to reasonably infer" that the plaintiff is entitled to the legal remedy sought. *A Soc'y Without a Name v. Virginia*, 655 F.3d 342, 346 (4th Cir. 2011), *cert. denied*, 566 U.S. 937 (2012).

III. ANALYSIS

Defendants raise multiple bases for dismissal. First, both Defendants argue that the TAC does not adequately allege an AKS violation. Although Defendants are correct to recognize that this Court's prior decision on Relator's motion to amend construed Relator's AKS allegations

under the far more lenient Rule 15 standard, for the same reasons explained in that decision, this Court now finds that the TAC's allegations are sufficient to state a plausible AKS violation under the Rule 12 standard.

Second, Apollo argues in its opening brief that the TAC must be dismissed because it pleads that Apollo complied with the AKS's referral services safe harbor. *See* ECF 106 at 16 ("Relator's AKS claims against Apollo fail because he pleads Apollo structured its activities to fit within an AKS safe harbor[.]"). Confusingly, however, Apollo later admits that, at most, the TAC only pleads Apollo's compliance with the safe harbor for "four of the five years Apollo owned the LAP-BAND®." *Id.* at 22. Then, in response to Relator's argument that the safe harbor is an affirmative defense that Relator need not plead around, Apollo appears to change course in its reply brief and argues that it "does not contend that it should prevail at this stage because Relator pleads Apollo's safe harbor compliance" but rather that Apollo was making the safe harbor argument to "add important context for the context-specific Rule 8 analysis." ECF 116 at 9. Whatever Apollo's argument is—and whether or not Relator is correct that the safe harbor is an affirmative defense—even assuming the TAC pleads Apollo's compliance for four of the five years it owned the LAP-BAND brand, that is not a basis for dismissal at this stage.

Defendants' additional arguments require more in-depth analysis. Both Defendants argue that the TAC fails to state a claim because it does not include particularized allegations that any false claims were actually presented for reimbursement and because it fails to allege the requisite causal link between the alleged AKS violation (*i.e.* the physician locator scheme) and the allegedly false claims. Allergan also asks this Court to reconsider its holding that the first-to-file bar does not preclude Relator's claims. Because the first-to-file bar is a jurisdictional issue, this Court will discuss it first before turning to the issues of presentment and causation.

a. First to File Bar

This Court declines Allergan's invitation to reconsider its holding that the first-to-file bar does not preclude Relator's suit. As Relator argues, Allergan's request amounts to an untimely motion for reconsideration. Even if it were timely, Allergan presents no new facts or legal developments that would affect this Court's ruling and, instead, merely attempts to relitigate an issue that was decided in Relator's favor. As this Court previously explained, the *Schwartz* case involved an entirely different fraud scheme than the one Relator alleges here. ECF 91 at 8-10. While Allergan is correct that, under the same material elements test, that conclusion is not dispositive, Allergan ignores the fact that this Court went on to explain that, "[t]he mere fact that the amended complaint in *Schwartz* referenced Allergan's use of the LAP-BAND website to drive sales is not a sufficient overlap to put the Government on notice of the fraud Relator alleges here[.]" *Id.* at 10. As this Court also held, Relator here is not "using insignificant factual variations to allege what is essentially the same fraudulent scheme already made known to the government." *Id.* (quoting *United States ex rel. Carter v. Halliburton Co.*, 710 F.3d 171, 181 (4th Cir. 2013)). Despite Allergan's focus on the fact that different courts have used different words to express the applicable legal standard, in this Court's view, the amended complaint in *Schwartz* did not equip the government to investigate Relator's claims,[1] nor did it allege a "greater fraud" that included Relator's claims "within [its] scope,"[2] nor did it "fully subsume[]" Relator's claims.[3] Allergan's untimely motion to reconsider is denied.

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[1] *United States ex rel. Carson v. Manor Care, Inc.*, 851 F.3d 293, 303 (4th Cir. 2017).

[2] *United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 122 (D.C. Cir. 2015); *United States ex rel. Chovanec v. Apria Healthcare Grp. Inc.*, 606 F.3d 361, 364-65 (7th Cir. 2010).

[3] *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 238 (3d Cir. 1998).

In an attempt to circumvent the 14-day deadline for motions to reconsider, Allergan also invokes Federal Rule of Civil Procedure 54(b) as grounds for its request for reconsideration. Allergan has not come close to meeting the standard for revision of an interlocutory order under Rule 54(b). *See Carlson v. Boston Scientific Corp.*, 856 F.3d 320, 325 (4th Cir. 2017) ("[A] court may revise an interlocutory order under the same circumstances in which it may depart from the law of the case: (1) a subsequent trial producing substantially different evidence; (2) a change in applicable law; or (3) clear error causing manifest injustice.") (quotations and alterations omitted). This Court's September 10, 2021 order will therefore stand as to the applicability of the first-to-file bar.

b. False Claims Act Allegations

To state a claim under the FCA, a relator must plead 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;[4] and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a 'claim')." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 788 (4th Cir. 1999).

These elements must be pled with particularity under Federal Rule of Civil Procedure 9(b). *Id.* at 783-84. Under Rule 9(b), a plaintiff "'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 [the person] obtained thereby.'" *United States ex rel. Owens v. First*

[4] Apollo also argues that the TAC does not adequately allege materiality. ECF 39-40. But the question whether the TAC adequately alleges materiality (at least the way Apollo argues it) appears coextensive with the question whether it alleges that any false claims "result[ed] from" an AKS violation. Because "compliance with the AKS is a 'material' condition of payment[,]" the relevant question simply becomes whether the TAC adequately alleges that any claims "result[ed] from" AKS violations. *United States ex rel. Wood v. Allergan, Inc.*, No. 10-CV-5645 (JMF), 2017 WL 1233991, at *28 (S.D.N.Y. Mar. 31, 2017), *rev'd on other grounds* 899 F.3d 163 (2d Cir. 2018).

Kuwaiti General Trading & Contracting Co., 612 F.3d 724, 731 (4th Cir. 2010) (citation omitted). In more colloquial terms, this requirement has been described as imposing a duty to plead the "who, what, when, where, and how" of the alleged fraud. *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008). "Rule 9(b)'s particularity requirement serves as a necessary counterbalance to the gravity and 'quasi-criminal nature' of FCA liability." *United States ex rel. Grant v. United Airlines Inc.*, 912 F.3d 190, 197 (4th Cir. 2018).

i. Presentment

As the elements above demonstrate, the FCA requires a relator to allege that false claims were, in fact, submitted to the government for payment. The Fourth Circuit has held in an AKS-based FCA case that, "the critical question is whether the defendant caused a false claim to be presented to the government, because liability under the [FCA] attaches only to a claim actually presented to the government for payment, not to the underlying fraudulent scheme." *United States ex rel. Nathan v. Takeda Pharmaceuticals North America, Inc.*, 707 F.3d 451, 456 (4th Cir. 2013). The Fourth Circuit found that Rule 9(b),

> 'does not permit a False Claims Act 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.' Rather, Rule 9(b) requires that 'some indicia of reliability' must be provided in the complaint to support the allegation that an actual false claim was presented to the government.

Id. at 456-57 (quoting *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002)).

The Fourth Circuit clarified this requirement in 2018, when it held that "there are two ways to adequately plead presentment under Rule 9(b). First, a plaintiff can 'allege with particularity that specific false claims actually were presented to the government for payment.'" *Grant*, 912 F.3d at 197. To succeed under this pleading standard the complaint must allege, "'at a minimum

. . . 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 *Kellogg Brown & Root, Inc.*, 525 F.3d at 379). The second method does not require detailed allegations of a specific false claim that was presented but, rather, "a pattern of conduct that would '*necessarily* have led[] to submission of false claims[.]'" *Id.* (quoting *Nathan*, 707 F.3d at 457) (emphasis in original). Under this theory of presentment, "Rule 9(b)'s heightened pleading standard requires that plaintiffs connect the dots, even if unsupported by precise documentation, between the alleged false claims and government payment." *Id.* at 199. The TAC does not sufficiently allege either theory of presentment.

First, the TAC does not allege with any particularity that "specific false claims actually were presented to the government for payment." *Grant*, 912 F.3d at 197. Relator argues that two tables included in the TAC suffice to demonstrate that specific false claims were presented. Those two tables purport to show Medicare claims data for procedures performed by several doctors who appeared on the physician locator in 2013 when Allergan owned the LAP-BAND and in 2014 when Apollo owned it. ECF 100 ¶¶ 315-20.

Relator argues that these tables "identify 18 surgeons by name, provider numbers, and states of practice and list the precise number of LAP-BAND procedures for which they filed claims with Medicare during the applicable year and for which they were reimbursed." ECF 112 at 29. As Relator explains in the TAC, though, these tables represent "a sample of providers" who submitted claims using the code 43770, which corresponds to "Laproscopy, surgical, gastric restrictive procedure; placement of adjustable gastric band (gastric band and subcutaneous port components)." ECF 100 ¶ 316. Relator goes on to explain that, "[t]he submission of a Medicare claim containing code 43770, therefore, necessarily means that an adjustable gastric band

procedure was performed, which means that at least one unit of either (1) the LAP-BAND® device or (2) the REALIZE® device [a LAP-BAND competitor] was used during the operation." *Id.* ¶ 317. Although Relator asserts that the surgeons included in the tables were not qualified to perform REALIZE band surgeries, neither the TAC nor any of Relator's briefing has explained or provided any factual basis for that conclusion. To the contrary, Relator has alleged that "[t]here is no important difference between procedures using the REALIZE® band and the LAP-BAND®" and that "[p]lacement of the two bands is procedurally very similar." *Id.* ¶ 259. While it is certainly possible that Relator is correct in his assertion that these physicians were, for some reason, not qualified to implant the REALIZE band, Relator's conclusory assertion of that fact falls far short of Rule 9(b)'s particularity requirement. Relator argues that this Court "should resist the call for weighing the[se] allegations at this stage[,]" ECF 112 at 30, but this Court is not weighing allegations—the TAC simply provides nothing other than Relator's say-so to support his conclusion that the listed claims submitted under code 43770 correspond to LAP-BAND surgeries. In the absence of any fact-based allegations to support that claim, this Court cannot assume the truth of Relator's conclusory assertion that the tables represent claims related to LAP-BAND surgeries rather than REALIZE band surgeries.

The tables also omit other important information about the purported claims, like the dates on which the relevant procedures were performed and the dates on which each claim was submitted for reimbursement. *See United States ex rel. Dugan v. ADT Sec. Servs. Inc.*, No. DKC-2003-3486, 2009 WL 3232080, at *14 (D. Md. Sept. 29, 2009) ("Rule 9(b) requires a Plaintiff to allege with particularity the dates of the supposed fraudulent conduct."). Without this information, this Court is left unable to determine whether the purported claims listed in the TOC are actual, representative, false claims. *Grant*, 912 F.3d at 197. Relatedly, as will be discussed in more detail

below, without this information, the TOC fails to provide any causal link between the physician locator and these claims. Accordingly, the TOC fails to allege with particularity that "specific false claims actually were presented to the government for payment." *Id.*

Second, and for similar reasons, the TAC does not allege that Defendants engaged in "a pattern of conduct that would '*necessarily* have led[] to submission of false claims" to the government for payment." *Id.* (quoting *Nathan*, 707 F.3d at 457) (emphasis in original). Relator argues he meets this standard because the TAC alleges that Defendants engaged in a successful and fraudulent scheme to incentivize surgeons to perform LAP-BAND surgeries, and then, at some unspecified time, those surgeons submitted claims for reimbursement using a generic Medicare code that corresponds to gastric banding procedures. ECF 112 at 32. For the reasons explained above, though, these allegations describe a scheme that "*could* have led to presentment" but not one that "*necessarily* led to a false claim being submitted[.]" *Grant*, 912 F.3d at 200 (emphasis in original).

Relator notes that the Fourth Circuit in *Nathan* cited *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13 (1st Cir. 2009), which held that the relator there had satisfied Rule 9(b)'s strictures even though he had not identified specific false claims. ECF 112 at 31-32. But that case undermines, rather than strengthens, Relator's argument because the allegations in *Duxbury* were far more particularized than the allegations in the TAC. There, the relator alleged that the defendants were providing unlawful kickbacks to promote the sale of its drug Procrit. *Duxbury*, 579 at 16. As the First Circuit explained, the complaint did more than "suggest fraud was possible." *Id.* at 29-30. The First Circuit highlighted one particular allegation that one defendant "received more than $5,000 of free commercially packaged ProCrit . . . so that [the defendant] could submit the free product for reimbursement to Medicare under the false and

fraudulent certification that the provider had paid for the product. . . . [The defendant] was reimbursed by Medicare for the free commercially packaged ProCrit[.]" *Id.* at 30. With respect to another defendant, the relator alleged "that the hospital submitted approximately 4,800 claims a month for Medicare reimbursement based upon [the alleged] unlawful kickbacks." *Id.* Even then, the First Circuit characterized its finding that the allegations satisfied Rule 9(b) as a "close call." *Id.* Ultimately, though, it held that unlike in a prior First Circuit case "where the allegations gave rise to only speculation as to whether the alleged scheme caused the filing of false claims with the government, Duxbury has alleged facts that false claims were in fact filed by the medical providers he identified, which further supports a strong inference that such claims were also filed nationwide." *Id.* In other words, as the First Circuit explained, the complaint alleged, "'factual . . . evidence to strengthen the inference of fraud beyond possibility.'" *Id.* (quoting *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007)) (alteration in original).

Moreover, while Relator is correct that the Fourth Circuit cited the *Duxbury* decision in *Nathan*, it also quoted the First Circuit's decision in *Rost* as support for its holding that Rule 9(b) requires more than speculative allegations that would require a court to infer that false claims were submitted. *Nathan*, 707 F.3d at 460. Specifically, the Fourth Circuit quoted the First Circuit's explanation that in *Rost*, the complaint merely speculated that false claims had been submitted because, "'[i]t may be that physicians prescribed [the drug] for off-label uses only where the patients paid for it themselves or when the patients' private insurers paid for it.'" *Id.* (quoting *Rost*, 507 F.3d at 733) (alterations in original).

The TAC's allegations here are much closer to the speculative allegations that were determined insufficient in *Rost* and *Nathan* than the more concrete, fact-based, allegations in *Duxbury* that did not require the district court to assume the truth of the relator's unsupported

inferences. Indeed, Relator here asks this Court to make the same kinds of inferences that the First Circuit held were impermissible in *Rost* and that the Fourth Circuit held were impermissible in *Nathan*. Relator asks this Court to blindly accept his conclusory assertions that because several surgeons submitted reimbursement requests at unspecified times, for surgeries that took place at unspecified times, using a Medicare code that is not specific to LAP-BAND procedures, that false claims were *necessarily* submitted for reimbursement. These are exactly the kind of unsupported inferences the Fourth Circuit has held do not meet Rule 9(b)'s standard in the context of AKS-based FCA claims.

By design, Rule 9(b) imposes strict pleading requirements. And the Fourth Circuit has repeatedly acknowledged the "practical challenges" that Rule 9(b) presents in FCA cases "in which a relator may not have independent access to records such as prescription invoices, and where privacy laws may pose a barrier to obtaining such information without court involvement." *Id.* at 458; *Grant*, 912 F.3d at 196. Those barriers may make it difficult for Relator to adequately plead his claims. But "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 196 (quoting *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 (11th Cir. 2006)). In light of that heightened pleading requirement, the TAC does not adequately allege that false claims were *necessarily* submitted for reimbursement.

ii. Causation

In 2010, Congress amended the AKS to provide that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). Allergan argues the AKS's "resulting from" language imposes

a but-for causation standard, whereas Relator argues that it only requires an AKS violation to be the proximate cause of a false claim.

Allergan relies on *Burrage v. United States*, in which the Supreme Court held that the phrase "results from" imposed a but-for cause requirement under the Controlled Substances Act. 571 U.S. 204, 210-11 (2014). According to Allergan, then, an FCA violation only "results from" an AKS violation if the false claim would not have been submitted "but-for" the AKS violation. By contrast, under Relator's preferred standard, a claim violates the FCA if the AKS violation was the proximate cause of the false claim—if it was "a substantial factor in the sequence of responsible causation, and if the [claim was] reasonably foreseeable or anticipated as a natural consequence" of the AKS violation. ECF 112 at 37 (quoting *United States ex rel. Wuestenhoefer v. Jefferson*, 105 F. Supp. 3d 641, 681 (N.D. Miss. 2015)).

Courts around the country have struggled to define the standard of causation that is required to prove an FCA claim based on an AKS violation. While the Fourth Circuit has not addressed this question, no court has adopted Allergan's preferred but-for cause standard. *See United States ex rel. Fesenmaier v. Cameron-Ehlen Group, Inc.*, No. 13-cv-3003 (WMW/DTS), 2021 WL 101193, at *10 (D. Minn. Jan. 12, 2021) (collecting cases rejecting the but-for cause standard and noting that, like here, "Defendants cite *no* case in which a court has held that an AKS violation must be the but-for cause of a false claim.") (emphasis in original). But courts have also rejected the attempt Relator makes to stretch the proximate cause standard to categorically include any and all claims "tainted" by an AKS violation. *See United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 100 (3d Cir. 2018).

Instead, several courts have "articulated a 'middle of the road' approach." *United States v. Teva Pharmaceuticals USA, Inc.*, No. 13 Civ. 3702 (CM), 2019 WL 1245656, at *24 (S.D.N.Y.

Feb. 27, 2019). Under that approach, "a kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient." *Greenfield*, 880 F.3d at 100. "'A link is required, but it is less than' showing that the bribe succeeded in producing the prescription." *Teva Pharmaceuticals*, 2019 WL 1245656, at *24 (quoting *Greenfield*, 880 F.3d at 98). As the United States District Court for the District of Massachusetts explained:

> [A] claim is false if it seeks reimbursement for a prescription that was not provided in compliance with the Anti-Kickback Statute, regardless of whether the claim was the result of a *quid-pro-quo* exchange or would have been submitted even absent the kickback. *See Greenfield*, 880 F.3d at 96. Relators need not show that a *quid pro quo* exchange occurred, or that the physicians would not have prescribed Defendant's medication but for the kickbacks. It is sufficient to show that Defendant paid kickbacks to a physician for the purpose of inducing the physician to prescribe specific drugs, and that the physician then prescribed those drugs, even if the physician would have prescribed those drugs absent the kickback.

United States ex rel. Bawduniak v. Biogen Idec, Inc., No. 12-cv-10601, 2018 WL 1996829, at *3 (D. Mass. Apr. 27, 2018). "In other words, Relators need only show that the [defendants'] referral . . . actually sat in the causal chain." *Teva Pharmaceuticals*, 2019 WL 1245656, at *24.

Relator has not met this burden for several reasons. First, as explained above, the allegations in the TAC do not adequately allege that the purportedly representative claims were, in fact, related to LAP-BAND surgeries. Second, even if these claims were related to LAP-BAND surgeries, the allegations do not link them to any "particular patient" who was "exposed to an illegal recommendation or referral[.]" *Greenfield*, 880 F.3d at 100. Third, and relatedly, while the TAC alleges that the physicians in the claim charts "appeared on Defendants' physician locator tool in 2013" and/or 2014, ECF 100 ¶¶ 319-20, the TAC does not provide any information about when the relevant procedures took place and when each claim was submitted. Without that information, the TAC's allegations that a surgeon appeared on the locator in 2013 or 2014, and

submitted a claim for reimbursement at some unidentified time, do not allege that "a particular patient [was] exposed to an illegal recommendation or referral and [that] a provider submit[ted] a claim for reimbursement pertaining to that patient." *Greenfield*, 880 F.3d at 100. As just one example of the numerous gaps in the TAC's allegations, it leaves open the possibility that, even if the listed surgeons appeared on the locator in 2013 or 2014, some or all of their claims were related to patients who underwent LAP-BAND surgery, or who were advised to elect LAP-BAND surgery, before the relevant surgeon was listed on the locator. The TAC's allegations, therefore, do not sufficiently allege that any particular referral "actually sat in the causal chain" between the alleged AKS violation and the allegedly false claim. *Teva Pharmaceuticals*, 2019 WL 1245656, at *24.

Finally, this case is different in one important respect from the other AKS-based FCA cases discussed above that have analyzed the causation standard. In all these other cases, it was beyond dispute that the relevant providers were aware that they had been provided with the alleged kickback. *Greenfield*, 880 F.3d at 91-94 (provider allegedly donated to defendants in exchange for marketing); *Fasenmaier*, 2021 WL 101193, at *3-7 (providers were allegedly taken on vacations, trips on private airplanes, golf trips, hunting trips, ski trips, and provided with meals); *Teva Pharmaceuticals*, 2019 WL 1245656, at *1 (providers were allegedly "bribed with speaker fees, expensive meals, and alcohol in exchange for prescribing" defendants' multiple sclerosis and Parkinson's disease drugs); *Bawduniak*, 2018 WL 1996829, at *1 (defendant allegedly gave providers sham consulting and speaker program arrangements in order to increase prescriptions of defendants' multiple sclerosis drugs).

Here, however, the TAC leaves open the possibility that the providers were never aware of their listing on the physician locator. To be sure, Relator alleges that he "attended a practice

development seminar in February 2012" at which *he* was told that "he should contact [Allergan] if he wished to be included." ECF 100 ¶ 160. Relator also alleges that the benefits of inclusion on the physician locater were "substantial" and that his former suitemate "attributed his entire bariatric practice to www.lapband.com referrals." *Id.* ¶ 22. But these allegations do not support Relator's argument in his briefing that all of the surgeons listed in the claims tables had "affirmatively requested to be included" and were, therefore, "susceptible to Defendants' quota[.]" ECF 112 at 29. The fact that Dr. Fitzer was told to request inclusion on the locator says nothing about whether any other physician affirmatively requested to be included or was otherwise aware of his or her listing on the locator. In fact, the TAC does not allege that any of the surgeons listed in the tables of representative claims—or any surgeons other than Relator and his former suitemate—ever knew that the locator existed or that they were listed on it. While this Court recognizes that if the physician locator tool was as powerful of a marketing tool as Relator alleges, he may be right to speculate that, as a general matter, it is likely that listed surgeons would have been aware of their listing. But the TAC is subject to Rule 9(b), and, in this Court's view, that standard precludes this Court from simply taking Relator's unsupported word for it. In the absence of any fact-based allegations that the relevant providers were aware that they had received the alleged remuneration, this Court cannot conclude that the TAC adequately alleges that any "referral . . . actually sat in the causal chain[,]" *Teva Pharmaceuticals*, 2019 WL 1245656, at *24, much less that any "particular patient [was] exposed to an illegal recommendation or referral[.]" *Greenfield*, 880 F.3d at 100. While this Court is mindful that Relator need not allege a full-scale bribery scheme involving some sort of *quid-pro-quo*, an AKS violation cannot be causally related to a claim for reimbursement if the provider was never aware of the alleged kickback in the first place.

c. Dismissal

For the reasons explained above, the TAC fails to state a claim and must be dismissed.[5] Both Defendants argue that this Court's dismissal should be with prejudice because, given the length of this case and the number of prior amendments, any attempt to amend the TAC would be futile. This Court understands Defendants' concerns that, while not Relator's fault, this case has been pending for more than eight years despite never moving past a motion to dismiss. However, because this Court is dismissing the TAC on different grounds than it dismissed the SAC and because amendment is not, at this point, technically futile, this Court will give Relator one final opportunity to plead a viable claim. If Relator believes he can successfully amend, he is directed to file a motion for leave to file a fourth amended complaint within 14 days.

IV. CONCLUSION

For the reasons set forth above, Defendants' motions to dismiss, ECF 106, 107, will be GRANTED and the TAC will be DISMISSED without prejudice. Relator is directed to file any motion for leave to file another amended complaint within 14 days. If Relator does not do so, this Court's dismissal will convert to a dismissal with prejudice. A separate order follows.

Dated: March 22, 2022

/s/
Stephanie A. Gallagher
United States District Judge

[5] The parties appear to agree (correctly) that the viability of Relator's state law claims rise and fall with his federal FCA claim. Accordingly, for the same reasons explained above, Relator's state law claims must be dismissed.