

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.

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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 again moved to dismiss, ECF 106, 107, and this Court granted their motions on March 22, 2022 but allowed Relator 14 days to file a motion for leave to amend. ECF 118, 119. On April 5, 2022, Relator moved for reconsideration of this Court’s

decision to dismiss the TAC and, in the alternative, for leave to amend. ECF 120. On May 18, 2022, this Court denied Relator's motion for reconsideration, granted his leave to amend, and directed the Clerk's Office to docket the Fourth Amended Complaint ("FAC"). ECF 125, 126. Defendants have now moved to dismiss the FAC. ECF 130, 131. Relator has opposed those motions, ECF 136, and Defendants have each filed replies. ECF 138, 139. This 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 in part and denied in part. The FAC states a claim with respect to Counts 1, 2, and 9, but its other claims will be dismissed.

## **I. FACTUAL BACKGROUND**

### **A. Factual Background From the TAC**

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](http://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](http://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](http://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](http://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.

### **B. New Allegations in the FAC**

The FAC adds several new factual allegations aimed to shore up the deficiencies in the TAC. First, the FAC includes several allegations designed to show that surgeons on Defendants’ physician locator tool knew that they were listed on the locator and, therefore, knew that they were receiving free marketing (which Relator alleges was an unlawful kickback). The FAC alleges that surgeons “provided their profile information” and were “aware of the value of their free marketing” because Allergen sent them “email alerts showing leads generated from the locator” and “seminar sign-ups” and provided surgeons with “a lead tracker spreadsheet for surgeons to use on their own.” ECF 127 ¶¶ 8, 9, 168-69. The FAC also alleges that “[t]he surgeons’ information displayed on the locator was provided to Defendants by each physician[,]” and it includes an allegation that Defendants themselves represented to the public that the information on the locator tool was provided by the listed surgeons. *Id.* ¶¶ 153-56. As purported corroboration, Relator alleges that he was “asked by Allergan to complete” an informational form (similar to an exemplar form he includes in the FAC) “to obtain his LAP-BAND® locator listing in 2007 and 2012.” *Id.* ¶ 160-63. According to Relator, these “notices, postings, and communications make clear that physicians were active, knowing participants in the process of securing a listing on the locators operated by the Defendants.” *Id.* ¶ 173.

Second, the FAC contains new allegations intended to show that the claims for reimbursement listed in the claims tables in the FAC—which are for surgeries generically classified as “gastric banding procedures”—correspond to LAP-BAND surgeries rather than Realize band surgeries. The FAC includes additional allegations about the distinct training procedures that are required before a surgeon is eligible to perform LAP-BAND and Realize band surgeries. *Id.* ¶¶ 299-308. It also includes new allegations about the LAP-BAND’s market share

between 2010 and 2013. *Id.* ¶ 373 n.31. Relator also explains the “process of elimination” he conducted that led him to the conclusion that the surgeons listed in the claims tables “exclusively performed LAP-BAND®” surgeries. *Id.* ¶¶ 371-72. He explains that he began with a list of “all self-reported gastric-band surgeons from the American Society of Metabolic and Bariatric Surgeons” and then “determined which of those surgeons had listings on [www.lapband.com](http://www.lapband.com).” *Id.* ¶¶ 373-74. He then cross-referenced that list against the Realize band locator tool, and other publicly available websites to eliminate any surgeons who were Realize band certified. *Id.* ¶¶ 375-79. According to Relator, “some of the Medicare-claimant surgeons explicitly held themselves out as users only of the LAP-BAND® device.” *Id.* ¶ 379. Relator also describes a series of claims by Dr. Vito Bagnato in 2017 that he alleges must correspond to LAP-BAND surgeries because the Realize device was discontinued in 2016. *Id.* ¶¶ 381-82. Finally, Relator describes a conversation he had with Dr. Richard Diccico, who was listed on the locator in 2012 and 2013, during which Dr. Diccico told him “that he had only implanted about 10 Realize® bands total in his entire career[.]” *Id.* ¶ 388. Because Dr. Diccico received payment for 57 gastric band procedures performed in 2012 and 2013, Relator argues that “at least 47 of his Medicare claims during that year were for the LAP-BAND® device.” *Id.*

Third, Relator attempts to bolster his allegations that the claims listed in the tables correspond to surgeries that were performed in either 2013 or 2014. He alleges that “[c]laims for reimbursement by the provider are generally required to be filed ‘no later than the close of the period ending 1 calendar year after the date of service.’” *Id.* ¶ 106 (quoting 42 C.F.R. § 424.44). Relator also alleges that the claims data listed in the FAC corresponds to surgeries performed during 2013-2014, regardless of when the claim for reimbursement was submitted. *Id.* ¶ 367-69. “For example, if a Part B provider performed a service on December 25, 2020, and submitted the

claim on January 5, 2021, the claim would be assigned to the 2020 CMS data set because the service rendered was in 2020.” *Id.* ¶ 369.

The FAC alleges other new allegations—like, for example, the percentage of bariatric surgeries covered by Medicare, *id.* ¶¶ 108, 115, the process by which a bariatric surgeon evaluates a patient for a specific bariatric surgery, *id.* ¶¶ 140-46, and the basis for Relator’s belief that Defendants’ physician locator tool was widely known among bariatric surgeons, *id.* ¶¶ 176, 179, 191. But the new allegations described in more detail above are Relator’s most direct efforts to allege *facts* in support of what were merely conclusory assertions in his prior pleadings.

## 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

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; 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 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).

While this Court dismissed the TAC for failure to state an FCA claim, this Court nonetheless held that the TAC adequately alleged that Defendants violated the AKS. ECF 118 at 7-8; *see also* ECF 98. With respect to the FCA allegations, however, this Court held that the TAC failed to state a claim because it did not adequately allege that any false claims were actually or necessarily presented to the government for reimbursement, and because it did not adequately allege the requisite causal link between the alleged AKS violation and the allegedly false claims. ECF 118. Defendants argue that the FAC fails to state a claim for those same reasons.<sup>1</sup>

### A. Presentment

“[T]here 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. This method of presentment requires “‘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). Second, a plaintiff can allege “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). If a relator seeks to allege presentment under the second avenue, Rule 9(b)’s particularity requirement requires “that plaintiffs connect the dots, even if unsupported by precise documentation, between the alleged false claims and government payment.” *Id.* at 199. In either case, while “significant detail” is required, “[a] court should hesitate to dismiss a complaint

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<sup>1</sup> Allergan also argues that the FAC should be dismissed for lack of subject matter jurisdiction because the first-to-file bar precludes Relator’s claims. This Court rejected this argument when Allergan made it in support of its motion to dismiss the SAC, ECF 91 at 6-10, and again after Allergan asked this Court to reconsider that decision when it moved to dismiss the TAC. ECF 118 at 9-10. This Court declines to explain, for the third time, why the first-to-file bar does not apply to Relator’s allegations.

under Rule 9(b) if the court is satisfied (1) that the defendant has been made aware of the particular circumstances for which she will have to prepare a defense at trial, and (2) that plaintiff has substantial prediscovery evidence of those facts.” *Harrison*, 176 F.3d at 784, 789.

Relator “focuses on the second method” of presentment, ECF 136 at 16 n.7, arguing that the FAC pleads “a pattern of conduct that would ‘*necessarily* have led[] to submission of false claims[.]’”<sup>2</sup> *Id.* at 197 (quoting *Nathan*, 707 F.3d at 457). Relator argues that the FAC addresses the deficiencies in the TAC “through particular allegations as to (1) why the surgeons listed in his two tables performed at least mostly, if not *only*, LAP-BAND surgeries during the relevant time period, and (2) the timing of the Medicare claims summarized in these tables, which represent dates of service in 2013 and 2014 respectively.” ECF 136 at 17.

Defendants argue the FAC does not fix either of these flaws. According to Defendants, Relator’s new allegations about why the claims data in the tables correspond to LAP-BAND surgeries, rather than Realize band surgeries, are insufficient to negate the possibility that some or all of the claims correspond to Realize band surgeries. *Id.* at 23; ECF 130 at 18-19. Defendants argue that the investigative method Relator used to eliminate surgeons who performed Realize band surgeries was unreliable, *see* ECF 139 at 15; ECF 130 at 18-19, and they argue that Relator’s

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<sup>2</sup> To the extent he argues that he meets the first method of presentment—pleading actual claims that were submitted—this Court disagrees. He does not plead the time of any claim (only the year of service); he does not plead what any surgeon obtained through his or her false claims (rather, he pleads average reimbursement amounts per surgeon per year); and, despite his allegations about why he *thinks* the claims reflected in the tables likely correspond to claims for reimbursement for LAP-BAND surgeries, he merely pleads that these claims were submitted under a generic code for gastric banding procedures, meaning that some or all of them could have been claims for reimbursement of Realize band procedures. As this Court understands the presentment test under *Nathan* and *Grant*, pleading actual claims requires pleading *actual claims*, not merely deducing that claims were likely submitted based on average reimbursements per year for claims that *might* correspond to LAP-BAND surgeries.

allegations about the LAP-BAND’s overwhelming market share during the relevant time period are no substitute for factual allegations that the claims referenced in the FAC, in fact, correspond to LAP-BAND surgeries. ECF 139 at 17-18. As support for that assertion, Allergan relies on a case from the Eleventh Circuit holding that a relator “cannot ‘rely on mathematical probability to conclude that [a defendant] surely must have submitted a false claim at some point.’” *Helmlly v. Bethany Hospice and Palliative Care of Coastal Ga., LLC*, 853 F. App’x 496, 502 (11th Cir. 2021) (quoting *Carrel v. AIDS Healthcare Found., Inc.*, 898 F.3d 1267, 1277 (11th Cir. 2018)).

On the other hand, Relator argues that “a 90% market share makes it a certainty that the tables contain at least a *majority* of LAP-BAND claims.” ECF 136 at 20. That may or may not be true, but Relator does not provide any information in the FAC about the size of the gastric banding market—namely, how many gastric band surgeries were performed in 2013 and 2014—that would allow this Court to verify that assertion.<sup>3</sup>

Generally, this Court agrees with Defendants. First, Relator’s investigative process of eliminating surgeons who may have performed Realize band surgeries in addition to LAP-BAND surgeries during the relevant time period has proven less than reliable, even at this early pre-discovery stage. While this Court must still assume the allegations in the FAC to be true, the

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<sup>3</sup> It is also worth noting more generally that Relator has been concerningly inconsistent about his level of certainty that the claims referenced in the data tables of each iteration of his complaint in fact correspond to LAP-BAND surgeries. First, he was sure that all the claims referenced in the tables *only* corresponded to LAP-BAND surgeries because the listed surgeons were not Realize band certified and, therefore, they *exclusively* performed LAP-BAND surgeries. ECF 77 ¶¶ 214-15. Then, he realized that at least one surgeon was Realize band certified after all, and it appears as though Allergan may have found a few more. ECF 131-1 at 20-21. And now, he commits only that the “vast majority, if not all” of the claims correspond to LAP-BAND surgeries. ECF 136 at 18. This is still a motion to dismiss, so this Court must assume the truth of Relator’s allegations (although not those that are demonstrably false), but Relator should be far more discerning about his representations to this Court in the future. If he is certain of something, he is of course free to represent that. But Relator now finds himself in the precarious position of having admitted that representations he made both in his pleadings and in numerous briefs were demonstrably false.

certifications a surgeon lists on the internet, or the physician locator websites a surgeon appears on, are not reliable proxies for the types of surgeries that surgeon *actually* performed during particular periods of time. Relator's burden is to allege that false claims were "*necessarily*" presented. As this Court has explained in prior opinions, that is a purposefully difficult burden. And it simply cannot be satisfied by asking this Court to infer that because a particular surgeon did not appear on the Realize band locator in 2013 or 2014, and because that surgeon's listing on other public websites did not say that he or she was Realize band certified, that, therefore, all of the gastric banding procedures he or she performed in 2013 or 2014 must have been LAP-BAND surgeries.

To be clear, Relator may very well be right—it seems logical that surgeons who were not publicly holding themselves out as Realize band certified in 2013 or 2014 probably were not performing Realize band surgeries in those years. While that inference seems reasonable enough as a matter of common sense, it falls far short of alleging with particularity that any of the claims represented in the tables, in fact, correspond to LAP-BAND surgeries. Without any certainty that these claims correspond to LAP-BAND surgeries in the first place, they do not demonstrate that any false claims were "*necessarily*" presented.

The same is true of Relator's market share allegations. Relator argues that the LAP-BAND's 90% market share in 2013 makes it a "*certainty*" that the majority of claims reflected in the tables correspond to LAP-BAND surgeries.<sup>4</sup> ECF 136 at 20. Again, this Court does not doubt the likelihood of Relator's assertions—if Relator's market share statistics are accurate, it seems very likely that many, if not all, of the surgeries represented in the tables were LAP-BAND

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<sup>4</sup> That is only true, of course, if the total number of surgeries reflected in the tables exceeds 10% of the total number of gastric banding surgeries performed in 2013.

surgeries. But the standard is that he must show that Defendants' conduct "*necessarily*" led to the presentment of false claims. *Grant*, 912 F.3d at 197. Alleging that something is likely true, or even that something is almost certainly true, is not the same as alleging that something is *necessarily* true. Relator's market share allegations clearly make it more likely that he is correct that the claims reflected in the FAC's data tables correspond to LAP-BAND surgeries. But even taking those allegations as true, they do not demonstrate that any false claims were "necessarily" presented for reimbursement. *See Helmlly*, 853 F. App'x at 502. These uncertainties prevent this Court from concluding that Defendants' conduct "necessarily" led to the presentment of false claims because they leave this Court unable to conclude, with certainty, that any of the claims in fact relate to LAP-BAND surgeries.

What neither Defendant adequately addresses, however, are Relator's new allegations about Dr. Bagnato and Dr. Diccico. Relator alleges that Dr. Bagnato (who appeared on the locator in at least 2014 and 2017) submitted 12 claims for reimbursements of LAP-BAND implantations in 2017, one year after Ethicon discontinued the Realize band. ECF 127 ¶ 382. And he alleges that Dr. Diccico—who was listed on the locator in 2012 and 2013—submitted 57 requests for reimbursements for gastric banding procedures between 2012 and 2013. *Id.* ¶ 388. Dr. Diccico apparently "told Dr. Fitzer personally that he had only ever implanted about 10 Realize® bands total in his entire career[.]" *Id.*

Defendants do little to challenge these allegations. They both argue that Relator does not plead that Dr. Bagnato or Dr. Diccico knew that they appeared on the physician locator. ECF 130 at 19; ECF 131-1 at 28-29. Apollo also argues that Relator's allegations demonstrate that Dr. Diccico never appeared on the locator after Apollo acquired the LAP-BAND from Allergan in 2014. ECF 138 at 11 n.4. Likewise, Allergan argues that Dr. Bagnato's claims were allegedly

submitted long after it sold the LAP-BAND business to Apollo. ECF 139 at 17. Apollo also argues that Relator fails to plead that Dr. Bagnato submitted false claims because Relator acknowledges that “Apollo did not maintain a quota in 2017.”<sup>5</sup> *Id.*

Defendants’ timing arguments appear correct: the claims Dr. Bagnato allegedly submitted in 2017 were not submitted while Allergan was operating the physician locator, and, similarly, the claims Dr. Diccico allegedly submitted in 2012 and 2013 were not submitted while Apollo was operating the locator. But Defendants’ other arguments—both regarding the physicians’ level of knowledge of the locator and about whether Apollo maintained a quota in 2017—relate more to the issue of causation (which will be addressed below) than they do to the issue of presentment.

Ultimately, if this Court assumes the allegations about Dr. Bagnato and Dr. Diccico to be true as this Court must, those allegations lead to the conclusion that both doctors necessarily submitted claims in at least 2012 and 2013 (Dr. Diccico), and 2017 (Dr. Bagnato), for LAP-BAND surgeries performed in those years. Because those claims are *per se* false if Relator manages to prove they “result[ed] from” Defendants’ alleged AKS violations, Relator’s allegations are sufficient to plead presentment, even under the Fourth Circuit’s demanding standard. *United States ex rel. Lutz v. Mallory*, 988 F.3d 730, 741 (4th Cir. 2021) (a violation of the AKS “automatically constitutes a false claim under the False Claims Act.”). (And as explained below, while Relator has a long road ahead to *prove* that those claims resulted from Defendants’ AKS violations, he has at this stage adequately alleged causation.) Accordingly, while the claims tables in the FAC still fail to plead either specific false claims or “a pattern of conduct that would ‘necessarily have led[] to submission of false claims[,]’” Relator’s allegations about Dr. Bagnato

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<sup>5</sup> Apollo will have the chance to prove its timing, but the FAC alleges (as did prior iterations of the complaint) that “Apollo maintained a form of the quota through at least 2018.” ECF 127 ¶ 340.



and Dr. Diccico's claims meet this bar.<sup>6</sup> *Grant*, 912 F.3d at 197 (quoting *Nathan*, 707 F.3d at 457) (emphasis in original).

More generally, Allergan relies on the Fourth Circuit's very recent opinion in *United States ex rel. Nicholson v. MedCom Carolinas, Inc.*, 42 F.4th 185 (4th Cir. 2022). In that case, the relator alleged a kickback scheme involving "the sale of skin grafts to the VA by commission-based salespeople who were paid based on how much they sold." *Id.* at 189. In the Fourth Circuit's words, though, "[f]rom there, the details g[o]t hazy fast." *Id.* While relator's "outline [was] clear, there [was] considerable ambiguity and confusion about the specifics." *Id.* at 191. It was unclear how the relator knew any of the information he alleged, and, with respect to one prominent example, "No first names were used; no location was given (which VA hospital, where in the country?); the payment amount [was] vague, somewhere on the border between guess and estimate; and [the relator] [did] not link that sale to the general kickback scheme[.]" *Id.* It was also unclear how many MedCom entities were allegedly involved in the scheme, who the commission-based salespeople worked for, and who paid their commissions. *Id.* At one point, the Fourth Circuit describes one of Nicholson's allegations as sounding "like a neighbor's conversation only half overheard through the walls." *Id.* at 196. After describing these egregious deficiencies, the Fourth Circuit concluded that "[t]he unknowns swamp the knowns. And while there is discussion of some payment, there is no discussion of the most important detail: a

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<sup>6</sup> Relator may ultimately seek reasonable discovery to prove that the claims reflected in the table are, in fact, false claims. See *United States ex rel. Rigsby v. State Farm Fire & Casualty Co.*, 794 F.3d 457, 467 (5th Cir. 2015) ("In cases of fraud, Rule 9(b) has long played that screening function, standing as a gatekeeper to discovery, a tool to weed out meritless fraud claims sooner than later.' . . . 'Rule 9(b) is not meant to supplant discovery.'") (first quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 18, 185 (5th Cir. 2009) then quoting Richard L. Marcus et al., *Civil Procedure: A Modern Approach* 187 (6th ed. 2013)). But those claims are not what gets the FAC past the gatekeeping function of Rule 9(b).

submitted false claim. This story simply does not give us any confidence that Nicholson ‘has substantial pre-discovery evidence of [these] facts.’” *Id.* (quoting *Harrison*, 176 F.3d at 784) (alteration in original).

While the *Nicholson* case helpfully discusses the standards for pleading presentment in the Fourth Circuit, its facts are not comparable. Simply put, there is no serious confusion about what Relator alleges here. And his fact-based allegations are supported by “pre-discovery evidence,” even if much of it is pulled from publicly available sources. *Harrison*, 176 F.3d at 784. These fact-based allegations of the scheme generally, coupled with allegations that (assuming they are true) Dr. Bagnato and Dr. Diccico “necessarily” submitted claims for LAP-BAND surgeries that they performed while they were listed on both Allergan’s and Apollo’s physician locators, are enough to adequately allege presentment.

## **B. Causation**

### **i. Applicable Standard**

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). The parties dispute the applicable standard of causation this text imposes. However, in analyzing Relator’s prior pleadings, this Court looked to “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); *see* ECF 118 at 16-18. 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.” *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 100 (3d Cir. 2018). “‘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.

As this Court explained in its opinion on Relator’s motion for reconsideration, this causation standard is, ultimately, an evidentiary burden that applies at the summary judgment stage. ECF 125 at 12-13. But that burden informs what Relator must allege at the pleading stage in order to state a claim that the allegedly false claims that were presented resulted from Defendants’ alleged AKS violations. *Id.*

Since this Court issued its decisions dismissing the TAC and denying Relator’s motion for reconsideration, the Eighth Circuit rejected the *Greenfield* causation standard and held that when a relator seeks to prove an AKS-based FCA claim, the relator “must prove that a defendant would not have included particular ‘items or services’ *but for* the illegal kickbacks.” *United States ex rel. Cairns v. D.S. Medical LLC*, --- F.4th ----, 2022 WL 2930946, at \*6 (8th Cir. July 26, 2022) (quoting 42 U.S.C. § 1320a-7b(g)) (emphasis added). The *Cairns* decision created a circuit split on this issue, and the Fourth Circuit has not yet weighed in.

This Court declines to adopt the but-for cause standard endorsed by *Cairns*. The *Cairns* court began, as courts must, with the text of the AKS. *Id.* at \*4. It had “little trouble concluding that, in common and ordinary usage, the participle phrase ‘resulting from’ . . . expresses ‘a but-for causal relationship.’” *Id.* The court cited the dictionary as support for its interpretation, and it relied on several Supreme Court cases that have reached similar interpretations in different contexts. *Id.* Specifically, the court relied heavily on the Supreme Court’s opinion in *Burrage v. United States*, 571 U.S. 204 (2014), which held that the phrase “results from” in the Controlled Substances Act requires “but-for” causation. But the *Burrage* Court also indicated that the interpretation of that phrase might not be as clear-cut as the *Cairns* court suggests it is. Indeed, the Court explained that “[w]here there is no textual *or contextual* indication to the contrary, courts regularly read phrases like ‘results from’ to require but-for causality.”<sup>7</sup> *Id.* at 212 (emphasis added). And here, there are contextual indications to the contrary. As the *Greenfield* court explains in detail, the legislative history of the 2010 amendments to the AKS indicates that Congress intended to make it easier, not harder, to bring (and ultimately prove) FCA claims predicated on violations of the AKS. *Greenfield*, 880 F.3d at 96-97. The Third Circuit also explained that Congress intended to avoid the “incongruous” result where “but-for” causation

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<sup>7</sup> While certainly not the primary basis for its decision, the *Burrage* Court recognized that the rule of lenity supported its defendant-favored interpretation of the phrase “results from.” *Burrage*, 571 U.S. at 216 (“Especially in the interpretation of a criminal statute subject to the rule of lenity, we cannot give the text a meaning that is different from its ordinary, accepted meaning, and that disfavors the defendant.”) (internal citation omitted). Although the Court emphasized that its interpretation of “results from” comported with that phrase’s “ordinary, accepted meaning[.]” the Court’s nod to the rule of lenity is notable because that rule never applies unless a statute is ambiguous. *Moskal v. United States*, 498 U.S. 103, 107 (1990) (“We have repeatedly ‘emphasized that the touchstone of the rule of lenity is statutory ambiguity.’”) (quoting *Bifulco v. United States*, 447 U.S. 381, 387 (1980)). In other words, if the Supreme Court had come to its interpretation with as “little trouble” as the *Cairns* court did, the rule of lenity would not have had any conceivable application. *Cairns*, 2019 WL 2930946, at \*4.

would be required to prove an AKS-based FCA case, but a defendant could be convicted criminally under the AKS itself on proof of less than “but-for” causation. *Id.* This Court, therefore, finds the Third Circuit’s reasoning in *Greenfield* more persuasive than the Eighth Circuit’s analysis in *Cairns* and, accordingly, declines to adopt Defendants’ preferred “but-for” cause standard.

## ii. FAC’s Allegations

As this Court explained in its opinion denying Relator’s motion for reconsideration, the TAC did not adequately allege causation for a number of reasons:

[Relator] did not adequately allege that the purportedly false claims on which he relied were related to LAP-BAND surgeries; he did not adequately allege that anyone was subject to an unlawful referral, primarily because he did not provide any temporal information about when any referrals were made, when any procedures took place, or when any claim was submitted; and he did not adequately allege that any of the providers listed in the claims tables were aware of the alleged kickback.

ECF 125 at 14. Aside from the last item in that list, this Court has addressed each of those shortcomings above and explained why, with Relator’s knew allegations—especially those about the claims submitted by Dr. Bagnato and Dr. Diccico—the FAC rectifies them. Defendants maintain, however, that the FAC still does not adequately allege that any of the relevant surgeons knew they were listed on the physician locator tool.

The TAC failed to allege that any of the physicians in the claims tables knew that they were listed on the locator tool primarily because its allegations about how physicians obtained a listing on the locator were limited to Relator’s own experience. ECF 118 at 19-20. The FAC, however, contains many more details about how Defendants communicated with both physicians and the public about the locator. And those allegations are not limited to Relator’s experience alone. As explained above, the FAC alleges that surgeons “provided their profile information” and were “aware of the value of their free marketing” because Allergen sent “them email alerts showing

leads generated from the locator” and “seminar sign-ups” and provided surgeons with “a lead tracker spreadsheet for surgeons to use on their own.” ECF 127 ¶¶ 9, 168-69. Both Defendants allegedly represented to the public that the information in surgeons’ listings was provided by the listed surgeons themselves. *Id.* ¶¶ 153-56. Indeed, Relator alleges that at least some of that information would not have been available from any other source. *Id.* ¶ 165. Relator also includes a screenshot of a physician locator sign-up form that was used by Apollo for both its Orbera device (a separate Apollo product) and the LAP-BAND. *Id.* ¶ 160. The form itself makes clear that this was a widely used form for surgeons who requested inclusion on the locator. *Id.*

Although Defendants argue that the FAC does not specifically allege that Dr. Baganto and Dr. Diccio themselves knew about their own listings on the physician locator, these new allegations are sufficient to allege that both Defendants made it their practice to interface with surgeons both while surgeons were requesting to be listed on the locator, and while they were listed. Assumed true, then, these allegations link the alleged AKS violation to the allegedly false claims because they demonstrate that at least two surgeons—both of whom would necessarily have been aware of their listings on the locator—submitted claims for reimbursement for LAP-BAND surgeries performed during the same years in which they were listed on the locator. Accordingly, these allegations, coupled with the more detailed allegations of presentment, are sufficient to allege that these surgeons’ LAP-BAND referrals “sat in the causal chain” between the free marketing Defendants provided them through the locator tool (the allegedly unlawful remuneration that undergirds the alleged AKS violation) and the allegedly false claims.<sup>8</sup> *Teva Pharmaceuticals*, 2019 WL 1245656, at \*24.

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<sup>8</sup> Much is made in the parties’ briefing about the import of the quota that Defendants allegedly imposed as an eligibility requirement for surgeons to remain on the locator. Allergan, for example, argues that “Relator tries to abandon his reliance on the quota as the supposed cause of LAP-

### C. State Law Claims

In this Court’s opinion dismissing the TAC, this Court noted in a footnote that “[t]he parties appear to agree (correctly) that the viability of Relator’s state law claims rise and fall with his federal FCA claim.” ECF 118 at 21 n.5. Relator argues that is now “law of the case” and should not be reconsidered. ECF 136 at 29. But this Court was construing a different complaint that made the same allegations against all surgeons who allegedly submitted false claims. Thus, for purposes of the TAC, it was true that the viability of Relator’s state law claims depended on the viability of his federal claims. But the allegations are different now, and while the FAC states a claim with respect to the claims for reimbursement allegedly presented by Dr. Bagnato and Dr. Diccico, it does not state a claim with respect to those presented by any of the surgeons listed in the claims tables.

The FAC alleges that Dr. Bagnato submitted claims using a Georgia state code. ECF 127 ¶ 382. And while the TAC alleged that Dr. Diccico submitted claims using a Florida state code, Relator inexplicably removes that allegation from the FAC. *Compare* ECF 100 ¶ 324 *with* ECF

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BAND® claims. He now insists that he can adequately plead causation (and thus falsity) by alleging that surgeons knew they had a locator listing.” ECF 139 at 20. Allergan confuses the issues here. The quota is certainly relevant to this case—particularly insofar as Relator alleges that it demonstrates Defendants’ intent to use the physician locator tool as a mechanism to drive referrals of the LAP-BAND. To the extent Relator uncovers in discovery that physicians were aware of the quota, that awareness may also factor into the causation element of proving that false claims “resulted from” Defendants’ alleged AKS violations. But the causation analysis—at least at this stage—does not depend on Relator’s ability to allege that any physicians were aware of the quota. In this Court’s view, all Relator needs to do at this stage (with respect to the level of physicians’ knowledge of the locator) is to allege, with particularity, that the surgeons who appeared on the locator were aware that they were listed and that, therefore, they were aware they were receiving the unlawful remuneration that allegedly violated the AKS (*i.e.* free marketing). Relator does that in the FAC through the allegations recounted above. And if true, those allegations at least arguably place the surgeons’ LAP-BAND referrals in the “causal chain” between the free marketing and the allegedly false claims, irrespective of whether the surgeons were also aware of the quota. *Teva Pharmaceuticals*, 2019 WL 1245656, at \*24.

