

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.

ALLERGAN, INC., *et al.*

Defendants.

Civil Case No. 1:17-cv-00668-SAG

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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. 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. Both Defendants opposed Relator’s motion, ECF 95, 96, and Relator filed a reply. ECF 97. The Court has reviewed the motion, both oppositions, and Relator’s reply, along with the accompanying exhibits. No hearing is necessary. *See* Loc. R. 105.6 (D. Md. 2021). For the reasons set forth below, Relator’s motion will be granted.

I. BACKGROUND FROM THE SAC

Defendants are two medical device companies that have, at different times, owned the LAP-BAND brand. ECF 77 ¶¶ 47, 51. The LAP-BAND is a surgically implanted device used for the treatment of obesity. *Id.* ¶ 97. 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.* ¶ 98.

At different times, both Defendants used the website www.lapband.com to advertise and market the LAP-BAND product. *Id.* ¶ 111. Among other features, the website included a physician locator 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.* ¶ 114. 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.* ¶¶ 114-15, 117-18.

Relator alleges that the website became a powerful tool for patients to find surgeons who could perform LAP-BAND surgery and, in turn, “provided a constant flow of business to the included surgeons.” *Id.* ¶ 121, 123. However, Relator also alleges 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.* ¶¶ 7-8.

Relator is a bariatric surgeon qualified to perform all three of the major bariatric operations: gastric bypass, sleeve gastrectomy, and gastric band surgery. *Id.* ¶ 31. He learned about the LAP-

BAND website and its physician locator at a practice development seminar in February, 2012. *Id.* ¶ 129-30. 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.* ¶ 130. 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.* ¶ 133-34. 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.* ¶¶ 135-36. The Account Manager told Relator he would be “granted access to the website” and “added to the physician locator.” *Id.* ¶ 137.

Relator was added to the physician locator in June, 2012. *Id.* ¶ 142. 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.* ¶ 143, that he believes “resulted from Allergan’s dissatisfaction with his LAP-BAND productivity.” *Id.* ¶ 144. A few months later, he was temporarily “locked out” of his www.lapband.com account. *Id.* ¶ 146-47. 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.* ¶ 148-49.

In March, 2013, Relator was removed from the physician locator and was denied access to the website. *Id.* ¶ 153. Relator contacted his Allergan Account Manager who promised to investigate the matter. *Id.* ¶ 155-56. 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.* ¶ 161. 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.* ¶ 167. Relator later spoke on the phone with the Vice President of Sales who confirmed that only surgeons who performed 40 LAP-BAND surgeries per year were included on the website's physician locator and that the requirement was "related to 'quality.'" *Id.* ¶¶ 171-72, 176. Relator has never been reinstated on the physician locator. *Id.* ¶ 158.

Apollo purchased the LAP-BAND brand in or around December, 2013. *Id.* ¶ 51. Apollo maintained a quota for inclusion on the physician locator through at least 2018. *Id.* ¶ 193.

On those facts, the Court granted Defendants' motions to dismiss the SAC primarily because the SAC failed to allege any facts to support Relator's conclusions that Defendants acted "knowingly and willfully" or with "the intent to induce the referral of business or purchases[.]" ECF 91 at 13-17.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 15 provides that a party seeking to amend its pleading after twenty-one days following service may do so "only with the opposing party's written consent or the court's leave." Fed. R. Civ. P. 15(a)(2). However, the Rule requires courts to "freely give leave when justice so requires." *Id.* The Fourth Circuit's policy is "to liberally allow amendment." *Galustian v. Peter*, 591 F.3d 724, 729 (4th Cir. 2010). Accordingly, leave to amend should be denied only if "prejudice, bad faith, or futility" is present. *See Johnson v. Oroweat Foods Co.*, 785 F.2d 503, 509-10 (4th Cir. 1986) (interpreting *Foman v. Davis*, 371 U.S. 178 (1962)); *Hart v. Hanover Cnty. Sch. Bd.*, 495 F. App'x 314, 315 (4th Cir. 2012). This Court retains authority to grant Plaintiff leave to amend its complaint, even after previously dismissing the complaint pursuant to a Rule 12(b)(6) motion to dismiss. *See e.g., Abdul-Mumit v. Alexandria Hyundai, LLC*, 896 F.3d 278, 293 (4th Cir. 2018), *cert. denied sub nom* 139 S. Ct. 607 (2018). Ultimately, the

decision to grant leave to amend rests in this Court's discretion. *Foman*, 371 U.S. at 182; *Laber v. Harvey*, 438 F.3d 404, 428 (4th Cir. 2006) (en banc).

With respect to the futility analysis, it “does not involve an evaluation of the underlying merits of the case.” *Kolb v. ACRA Control, Ltd.*, 21 F. Supp. 3d 515, 522 (D. Md. 2014) (quoting *MTB Serv., Inc. v. Tuckman-Barbee Constr. Co.*, No. RDB-12-2109, 2013 WL 1819944, at *3 (D. Md. App. 30, 2013)). “To the contrary, ‘[u]nless a proposed amendment *may clearly be seen to be futile* because of substantive or procedural considerations, . . . conjecture about the merits of the litigation should not enter into the decision whether to allow amendment.’” *Next Generation Grp., LLC v. Sylvan Learning Ctrs., LLC*, No. CCB-11-0986, 2012 WL 37397, at *3 (D. Md. Jan. 5, 2012) (emphasis added) (quoting *Davis v. Piper Aircraft Corp.*, 615 F.2d 606, 613 (4th Cir.), *cert. dismissed*, 448 U.S. 911 (1980)). This Court has discussed the overlap between a court's review for futility under Rule 15 and for failure to state a claim under Rule 12(b)(6):

There is no question, to be sure, that leave to amend would be futile when an amended complaint could not survive a Rule 12(b)(6) motion. *See U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008). Yet the Court need not apply the Rule 12(b)(6) standard when determining whether leave to amend would be futile. The Court applies a much less demanding standard: whether “the proposed amendment is clearly insufficient or frivolous on its face.” *Johnson*, 785 F.2d at 510.

Aura Light US Inc. v. LTF Int'l LLC, Nos. GLR-15-3198 & GLR-15-3200, 2017 WL 2506127, at *5 (D. Md. June 8, 2017).

III. ANALYSIS

Both Defendants argue that Relator's proposed amendments are futile because they fail to address the deficiencies this Court identified when it dismissed the SAC. They argue that Relator merely recast, and expanded on, the SAC's deficient allegations without adding any new factual

allegations that could plausibly state a claim for a violation of the AKS and, correspondingly, the FCA. This Court disagrees.

To establish that the Defendants acted “knowingly and willfully,” the SAC primarily relied on a barebones description of a series of phone calls between Relator and Allergan officials during which Relator communicated his belief that the quota-based criteria for inclusion on the physician locator violated the AKS. *See* ECF 91 at 14. Relator also argued in his briefing on Defendants’ motions to dismiss the SAC that Allergan officials’ decisions to speak with him over the phone (instead of in writing) was indicative of their intent to avoid any written communication with Relator regarding the physician locator and his concerns about it. *See id.* at 14. As the Court recognized, that argument was not supported by any factual allegations in the SAC. *Id.* at 14 n.3.

While the TAC hardly reveals bombshell allegations of Defendants’ purported fraud, it alleges facts that, taken as true, may allow a plausible inference of willfulness. The TAC alleges that in Dr. Fitzer’s March 28, 2013 phone call with Mr. Didio, he “explain[ed] to Mr. Didio how Allergan’s conduct violated the [AKS],” and that the two “debate[d]” the validity of that accusation. ECF 94-2 ¶ 211-12. Relator also now 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 the new allegations, “Mr. Didio did not deny it. His response to that accusation was silence.” *Id.* ¶ 216. Moreover, the TAC now 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, the TAC alleges that Mr. Didio specifically refused to provide Dr. Fitzer with “documentation of the

quota system in writing.” *Id.* ¶ 219. If true, these allegations could support an inference that senior Allergan officials knew exactly how the quota scheme violated the AKS, that they pursued it anyway, and that they intentionally avoided documenting it in writing. Those inferences could, in turn, support a conclusion that Allergan was acting “with a bad purpose,” as the willfulness prong of an AKS violation requires. *Bryan v. United States*, 524 U.S. 184, 192-93 (1998).

Allergan argues that these additions do not change “the sum and substance of the allegations” in the SAC. ECF 96 at 9-10. That may be true, but Relator’s new factual allegations provide a plausible factual basis for the previously unsupported and conclusory allegations in the SAC. It remains true that, as the Court previously held, “neither the fact that Relator told Allergan that he believed the physician locator violated the AKS, nor the fact that Allergan decided to speak with Relator on the phone rather than in writing about that concern, indicates that Allergan was acting with malintent.” ECF 91 at 15. But the fact that Relator apparently explained *how* the scheme violated the AKS; that Relator and Mr. Didio “debate[d]” that claim; that Relator confronted Mr. Didio about the purported marketing-related reasons for the scheme and disputed his contention that the quota was meant to ensure quality care; that Mr. Didio indicated he would speak with Allergan’s CEO about the matter; and that Mr. Didio specifically refused to provide Relator with written documentation of the policy are all facts that could plausibly support what were otherwise bare conclusions in the SAC.

For example, alleging that several phone calls occurred (as the SAC did) is not a fact-based allegation that Allergan was avoiding written communication with Dr. Fitzer about the quota system. But alleging (as the TAC does) that Allergan officials specifically refused to provide written documentation of that system upon request is a fact that, if true, could plausibly support an inference of willfulness. Similarly, the allegation (in the SAC) that Relator told Allergan it was

violating the AKS provides no facts that relate to Allergan's state of mind. But the TAC's allegations that Mr. Didio debated the legality of the quota scheme and indicated that he would discuss it with Allergan's CEO could support an inference that Allergan was acting willfully.

The TAC also alleges enough facts to address the SAC's deficiencies with respect to the "intent to induce" referrals or purchases prong of an AKS violation. Whereas the SAC alleged no facts that could lead to an inference of Defendants' intent to induce referrals or purchases, the TAC alleges several. In addition to the conversation between Dr. Fitzer and Mr. Didio, described above, 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." ECF 94-2 ¶ 143. Relator also provides factual allegations that support the SAC's conclusory assertions that Defendants' quality justification for the physician locator was a "pretext." As Relator now alleges in the TAC, "[i]f Allergan had a concern that low-referring LAP-BAND® surgeons produce inadequate outcomes, there are established channels to address that problem, including providing additional training and petitioning the FDA to change the credentialing procedures for surgeons." *Id.* ¶ 225. Finally, the TAC, unlike the SAC, alleges that several surgeons, in fact, increased the number of LAP-BAND surgeries they performed immediately after the quota was implemented. *Id.* ¶ 324. While ultimately Relator need not show that a kickback scheme was successful in order to prove a violation of the AKS, these new fact-based allegations lend support to his previously conclusory allegations.

For its part, Apollo argues that Relator should not be permitted to amend its complaint as against Apollo because none of the new facts relate to Apollo. ECF 95 at 7. But Relator has consistently alleged that senior Allergan officials who knew about, and implemented, the quota scheme left Allergan and began working at Apollo once it acquired the LAP-BAND brand in

December, 2013. ECF 94-2 ¶¶ 71-73. Relator alleges that those individuals perpetuated the fraudulent scheme on Apollo's behalf for several years. *Id.* ¶ 291. Accordingly, the new allegations in the TAC are no more futile with respect to Apollo than they are with respect to Allergan.

Apollo also argues that it would be unduly prejudicial to allow Relator to amend his complaint because it will “result in lengthy, expensive Rule 12(b)(6) briefing[] . . . on the same claims that these parties already briefed and this Court already decided.” ECF 95 at 8. To analyze whether amendment would unduly prejudice a defendant, courts analyze factors like whether amendment will require the defendant to “engage in significant new preparation[,]” *Smith v. Angelone*, 111 F.3d 1126, 1134 (4th Cir. 1997), whether it will cause “added expense and the burden of a more complicated and lengthy trial[,]” *id.*, or whether the proposed amendment “raises a new legal theory that would require the gathering and analysis of facts not already considered by the opposing party.” *Johnson*, 785 F.2d at 510.

Apollo has not come close to making an adequate showing of undue prejudice. If anything, its argument that the TAC is very similar to the SAC cuts *against*, rather than in favor, of a finding of prejudice, because little new preparation or analysis will be required. This case will likely proceed to another round of Rule 12(b)(6) motions to dismiss. When it does, Defendants are free to, and indeed are encouraged to, cross-reference and incorporate their prior briefing to the extent that briefing overlaps with Defendants' current arguments.¹

¹ Lastly, Apollo argues that Relator's failure to comply with Local Rule 103.6(d), which required Relator to seek Defendants' consent to amend, is evidence of his bad faith. While the parties are expected to abide by the Local Rules in all contexts, Relator's failure to seek consent clearly does not mean he filed the proposed amendment in bad faith. It is more likely that Relator either was unaware of the requirement that he seek consent or came to the understandable conclusion that, after several years of contested investigation and litigation, and after Defendants' successful motions to dismiss, Defendants were exceedingly unlikely to consent to a third amended

With the new factual allegations in the proposed TAC, this Court cannot conclude that “the proposed amendment is clearly insufficient or frivolous on its face.” *Johnson*, 785 F.2d at 510. Accordingly, Relator’s motion to amend will be granted.

IV. CONCLUSION

For the reasons set forth above, Relator’s Motion to Amend, ECF 93, will be GRANTED. A separate order follows.

Dated: December 9, 2021

/s/
Stephanie A. Gallagher
United States District Judge

complaint. Both parties are counseled, however, that the Local Rules should be strictly followed as this litigation proceeds.