IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI WESTERN DIVISION

CAROL HINTON,	)	
	)	
Relator/Plaintiff,	)	
	)	
v.	)	Case No. 18-cv-00244-SRB
	)	
INTEGRA LIFESCIENCES HOLDINGS CORPORATION, et al.,	)	
	)	
Defendants.	)	

ORDER

Before the Court is Defendant Integra LifeSciences Holdings Corporation and Integra LifeSciences Corporation's Motion to Dismiss Relator's Amended Complaint With Prejudice. (Doc. #55.) Plaintiff/Relator Carol Hinton ("Plaintiff") consents to the dismissal of Defendant Integra LifeSciences Holdings Corporation but otherwise opposes the motion.[1] Upon review, the motion is GRANTED insofar as Plaintiff's claims against Integra LifeSciences Holdings Corporation are DISMISSED WITHOUT PREJUDICE. The motion is DENIED in all other respects.

I. FACTUAL BACKGROUND

This is a *qui tam* case filed by Plaintiff under the False Claims Act ("FCA") on behalf of herself and the United States of America.[2] Plaintiff generally alleges that Defendant Integra

[1] The United States of America filed a notice stating that it consents to the dismissal without prejudice of Integra LifeSciences Holdings Corporation. (Doc. #67); *see* 31 U.S.C. § 3730(b)(1) (stating that an action under the False Claims Act "may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting").

[2] The FCA "permits an individual, or relator, to file a *qui tam* action on behalf of the United States against persons or entities who knowingly submit or cause to be submitted false claims to the government or who knowingly make, use, or cause to be made false records or statements to get a false claim paid by the government." *Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 315 (D. Mass. 2011) (citing 31 U.S.C. § 3729 *et seq.*). The United States may intervene in a *qui tam* action, but has declined to do so in this case.

LifeSciences Corporation ("Defendant") unlawfully promoted medical devices for off-label use which then caused doctors and hospitals to submit false claims for reimbursement to the government. Plaintiff also alleges Defendant unlawfully terminated her employment after she reported unlawful off-label marketing. Plaintiff asserts a claim under the FCA, 31 U.S.C. §§ 3729-3733, and under the anti-retaliation provision of the FCA, 31 U.S.C. § 3730(h).

The following allegations are taken from Plaintiff's Amended Complaint (Doc. #46) without further quotation or attribution unless otherwise noted. For the purpose of resolving the pending motion, the allegations are assumed true and simplified to the extent possible. Additional allegations relevant to the pending motion are discussed in Section III.

Defendant develops, manufactures, and markets medical devices and surgical instruments. Defendant sells its products directly through sales forces and distribution channels. Defendant employed Plaintiff from 1995 until 2015. At the time of her termination, Plaintiff held the position of Senior Regional Business Manager.

Auragen is a medical device marketed and sold by Defendant. Auragen consists of epileptic grid and strip devices, and is used by physicians for brain mapping. The grid or strip is connected to an electrode that measures electrical activity in a patient's brain. The Food and Drug Administration ("FDA") approved Auragen for intraoperative use to monitor electrical activity during surgery. However, the FDA has not approved Auragen for post-operative monitoring.

Despite the lack of FDA approval, Defendant marketed Auragen for post-operative use. Defendant subsequently learned that post-operative use could harm patients. Nonetheless, Defendant "never retrained the sales force or terminated the off-label marketing of" Auragen.

(Doc. #46, p. 19.)[3] Plaintiff alleges that Defendant made "false and misleading statements and omissions . . . in training materials, device training to doctors and promotional materials stating that [Auragen] w[as] indicated for post-operative use, even though they are only approved for intra-operative use." (Doc. #46, p. 20.)

Plaintiff's FCA claim arises from Defendant's off-label marketing of Auragen. Plaintiff alleges that Defendant's false statements and marketing: "(a) caused physicians to submit false claims to Medicare, Medicaid and other federal and state health care programs seeking reimbursement for uses of [Auragen] that [Defendant] knew were not approved by the FDA and were off-label and, therefore, ineligible for reimbursement from federal or state health care programs;" and "(b) used false or fraudulent statements to get federal health care programs to reimburse millions of dollars in false and fraudulent claims submitted by these physicians." (Doc. #46, p. 24.)

Plaintiff's anti-retaliation claim arises from Defendant's alleged off-label marketing of CUSA, a different medical device.[4] The FDA approved CUSA for the removal of soft and hard tissue. However, Defendants allegedly "marketed the CUSA for . . . 'off-label' uses, including hepatic (liver) tumors and then gynecological tumors[.]" (Doc. #46, p. 26.) Defendants allegedly "made false and misleading statements to treating doctors and others to the effect that CUSAs were medically accepted for the off-label uses being promoted and, therefore, were eligible for Medicare, Medicaid and other federal and state health care program

[3] All citations to a page number refer to the pagination automatically generated by CM/ECF.

[4] According to Defendant, the "CUSA product line . . . consists of a series of tissue ablation and surgical aspirator device systems that assist in removing fibrous tissue during surgical procedures." (Doc. #56, p. 11.)

reimbursement[.]" (Doc. #46, pp. 25-26.)[5] Plaintiff made internal complaints about the off-label marketing of CUSA and alleges she was harassed and terminated because of those complaints.

On March 29, 2018, Plaintiff filed this lawsuit against Defendant. Plaintiff filed the operative Amended Complaint on December 13, 2021. Count I is brought under the FCA, 31 U.S.C. § 3729(a)(1). Plaintiff alleges that "Defendant[] knowingly presented or caused to be presented false or fraudulent claims to be submitted to Medicare, Medicaid and other government healthcare budgets for [Auragen] and associated products that were not FDA-approved for the purposes for which Defendants marketed, promoted and sold them." (Doc. #46, p. 39.) Among other forms of relief, Plaintiff requests damages on behalf of the United States and that she be awarded a portion of those damages as provided by the FCA.

Count II asserts a claim for unlawful retaliation under 31 U.S.C. § 3730(h). This claim is based on Plaintiff's complaints of the off-label promotion of CUSA. Plaintiff alleges that Defendant wrongfully harassed her and terminated her employment in retaliation for her lawful reporting of "potential violations of the False Claims Act[.]" (Doc. #46, p. 40.) Among other forms of relief, Plaintiff requests an award of back pay, front pay, and retirement plan benefits.

Defendant now moves to dismiss both counts under Federal Rule of Civil Procedure 9(b) and 12(b)(6). Defendant argues Count I is barred by the applicable statute of limitations and

[5] The Amended Complaint summarily alleges that Defendant violated the Federal Anti-Kickback Act, 42 U.S.C. § 1320a-7b, by "offering and providing illegal remuneration to physicians, in the form of endowed hospital chairs, as an inducement to use CUSAs for off-label purposes." (Doc. #46, p. 25.) Defendant argues that Plaintiff "fails to allege any facts to support [this] boilerplate allegation." (Doc. #56, p. 26 n. 5.) Plaintiff's opposition brief does not expressly discuss any claim under the Anti-Kickback Act. As a result, the Court agrees with Defendant. To the extent Plaintiff attempts to state an Anti-Kickback claim, that claim is dismissed for Plaintiff's failure to allege any facts that would plausibly support such a claim.

fails to state a claim upon which relief may be granted. Defendant argues Count II also fails to state a claim. Plaintiff opposes the motion, and the parties' arguments are addressed below.[6]

II. LEGAL STANDARD

Rule 12(b)(6) provides that a defendant may move to dismiss for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). "To survive a motion to dismiss [for failure to state a claim], a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citations and quotation marks omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ash v. Anderson Merchs., LLC*, 799 F.3d 957, 960 (8th Cir. 2015) (quoting *Iqbal*, 556 U.S. at 678). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678.

Rule 9(b) provides that when "alleging fraud . . . a party must state with particularity the circumstances constituting fraud[.]" Fed. R. Civ. P. 9(b). "Because the FCA is an anti-fraud statute, complaints alleging violations of the FCA must comply with Rule 9(b)." *Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir. 2006). "This particularity requirement demands a higher degree of notice than that required for other claims, and is intended to enable the defendant to respond specifically and quickly to the potentially damaging allegations." *Benaissa v. Trinity Health*, 963 F.3d 733, 739 (8th Cir. 2020) (citations and quotation marks omitted). To

[6] The parties' briefs raise a number of arguments. Both parties also attached a chart that discusses whether various allegations adequately state a claim, and whether Plaintiff could cure any deficiencies. (Doc. #56-1, "Relator's Allegations—Deficiencies Under Fed. R. Civ. P. 9(b)"); (Doc. #65-5, "Relator's Rebuttal to Alleged Rule 9(b) Deficiencies"). Defendant's chart is 10 pages long and Plaintiff's rebuttal chart is 60 pages long. The Court has considered all of the parties' arguments and exhibits, but this Order does not address each and every argument asserted by the parties. The Court generally agrees with Defendant that the Amended Complaint is not a model of clarity and contains allegations that are arguably contradictory. However, for the reasons discussed herein, the Court finds that Count I and Count II should not be dismissed.

state a claim under Rule 9(b), "the complaint must plead such facts as the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result." *Id.* (citations and quotation marks omitted).

III. DISCUSSION

A. Count I—False Claims Act

Count I alleges that Defendant unlawfully promoted Auragen for off-label use which "caused the submission of false claims by doctors and hospitals who billed federal and state health care programs for these non-approved devices and/or non-approved indications." (Doc. #46, p. 24.) To provide context to this claim, the following generally explains how medical devices are approved for use and how manufacturers may market such devices for off-label use.

"The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.,* regulates the approval and marketing of medical devices." *Nowak*, 806 F. Supp. 2d at 316. "No medical device may be marketed in the United States without prior approval [or clearance] by the [FDA] for its intended use." *Id.* A Class II device, such as Auragen, may be cleared through a 510(k) process "based upon [the] prior approval of a substantially equivalent device." *Id.* at 317.[7]

"To obtain 510(k) clearance to market a device, the manufacturer must submit a premarket notification, including . . . the intended uses of the device[.]" *Id.* A device cleared "through the 510(k) process does not constitute FDA 'approval' of the device; it limits the cleared use of the device to those indications listed in the application as the intended uses." *Id.*

[7] Defendant states that Auragen is a Class II device (Doc. #56, p. 11), and the Court assumes that is accurate for purposes of resolving the pending motion. The pending motion does not turn on the specific 510(k) process and that process is not further discussed herein.

(citations omitted). A manufacturer that promotes or markets "a device for any indication not approved or cleared by the FDA and indicated on the label is considered an 'off-label' promotion and is unlawful" under the FDCA. *Id.* (citing 21 U.S.C. § 331(d)).

However, a plaintiff does not state an FCA claim by merely alleging improper off-label marketing. *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1051 n. 6 (N.D. Cal. 2009); *see also Benaissa*, 963 F.3d at 739. "The FCA generally attaches liability, not to the underlying fraudulent activity, but to the claim for payment" from the government. *Benaissa*, 963 F.3d at 739 (citations and quotation marks omitted). The defendant's conduct must have had the "purpose and effect of causing the United States to pay out money it is not obligated to pay[.]" *Costner v. URS Consultants, Inc.*, 153 F.3d 667, 677 (8th Cir. 1998).

1. Count I is Not Barred by the Statute of Limitations

Defendant argues Count I should be dismissed because it is barred by the applicable statute of limitations. An FCA claim may not be brought:

> (1) more than 6 years after the date on which the violation of section 3729 is committed, or
>
> (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed, whichever occurs last.

31 U.S.C. § 3731(b)(1)-(2).

Defendant contends the six-year limitation period is applicable and that "the underlying fraudulent conduct occurred, at the latest, in January 2011 . . . but [Plaintiff] failed to commence this action until March 29, 2018[.]." (Doc. #56, p. 14) (internal citations omitted). Plaintiff argues the ten-year limitation period is applicable under *Cochise Consultancy, Inc. v. Hunt*, 139 S. Ct. 1507 (2019). As set forth below, the Court agrees with Plaintiff.

In *Cochise*, the Supreme Court construed § 3731(b) and stated that "if a relator instead discovers the fraud on the day it occurred and the Government does not discover it, the relator could have as many as 10 years to bring suit." *Cochise*, 139 S. Ct. at 1513. Applying this language, one court explained that:

> The Supreme Court recently held that the limitations period in § 3731(b)(2) is available in a relator-initiated suit in which the Government has declined to intervene. The Complaint was filed on June 1, 2012, which is presumably 'the date when facts material to the right of action [we]re known or reasonably should have been known by the official of the United States charged with responsibility to act.' Because Relator was not an 'official of the United States,' he was entitled to bring suit under the FCA for any conduct occurring after June 1, 2002.

United States v. Andover Subacute & Rehab Ctr. Servs. One, Inc., No: 12-03319-SDW-SCM, 2019 WL 4686963, at * 6 n.19 (D.N.J. Sept. 26, 2019) (citations omitted); *Sperandeo v. Neurological Institute & Specialty Ctr. PC*, No. 2:14-CV-158-JVB-JEM, 2021 WL 1177071, at * 4 (N.D. Ind. Mar. 29, 2021) (denying motion to dismiss under § 3731(b) because "[al]though the complaint was filed more than six years after some of the alleged violations, it was not filed more than ten years after an alleged violation").[8]

Here, Plaintiff argues—and Defendant does not dispute—that the Government had no knowledge of the alleged FCA violations before this case was filed on March 29, 2018. Under *Cochise*, the applicable statute of limitations under § 3731(b)(2) is therefore ten years prior to March 29, 2018. Because "the Complaint alleges that the underlying fraudulent conduct occurred . . . in January 2011," Count I is not time-barred. (Doc. #56, p. 14.)

The Court further finds Count I would not be barred even if a six-year limitations period applied. The Amended Complaint alleges in part that Defendant "sought approval for post-

[8] Defendant's reply brief does not mention *Cochise* and summarily states that it disputes the applicability of the 10-year statute of limitations. (Doc. #70, p. 5 n.1.)

operative use in 2013, but the FDA rejected the application. And so [Defendant] continued unlawfully marketing the grids off-label." (Doc. #46, p. 24.) The Amended Complaint further alleges that "even at the present time of this filing [Defendant is] advertising the grids and the durability of the grids for 'various phases of monitoring,' even though they are still approved only for intraoperative monitoring, and they have no approval for any other 'various phases of monitoring.'" (Doc. #46, p. 24.) These allegations plausibly allege fraudulent conduct within six years prior to the filing of this lawsuit.

Defendant argues these allegations "do not satisfy Rule 9(b)'s particularity requirements" or "tie these allegations into a continuous pattern of conduct not barred by the statute of limitations." (Doc. #56, p. 14.) For the reasons discussed throughout this Order, the Court rejects this argument. Consequently, the Court finds that Count I is not barred under the six or ten-year statute of limitations.

2. Count I Adequately States a Claim Under Rule 9(b) and 12(b)(6)

Defendant argues the Amended Complaint fails to adequately state a claim for relief under the FCA. The FCA recognizes two types of claims: a "presentment" claim and a "false statement" claim. 31 U.S.C. § 3729(a)(1)(A), (B). To state a presentment claim under § 3729(a)(1)(A), a plaintiff must allege with particularity the following elements: "(1) the defendant presented, or caused to be presented, a claim for payment or approval" to the government; (2) "the claim was false or fraudulent;" and (3) "the defendant knew the claim was false or fraudulent." *Benaissa*, 963 F.3d at 739; *Olson v. Fairview Health Servs. of Minn.*, 831 F.3d 1063, 1070 (8th Cir. 2016).

A false statement claim under § 3729(a)(1)(B) has the following elements: "(1) the defendant made a false record or statement; (2) the defendant knew the statement was false;

(3) the statement was material; and (4) the statement made a claim for the government to pay money or forfeit money due." *Benaissa*, 963 F.3d at 741.[9] In contrast to § 3729(a)(1)(A), "[t]here is no 'presentment' requirement for a § 3729(a)(1)(B) claim. However, the plaintiff must plead a connection between the alleged fraud and an actual claim made payable to the government." *Id.* (citation and quotation marks omitted).[10]

First, Defendant argues Count I should be dismissed because Plaintiff "broadly generalizes that all Auragen devices are defective and dangerous to patients when used off-label, and thus no off-label use is 'medically necessary' or 'reasonable and necessary' and all reimbursement claims for off-label use are false." (Doc. #56, pp. 17-18; Doc. #70, pp. 8-9.) Because "[r]eimbursement is indeed appropriate, even for off-label use, where a physician determines the product to be 'reasonable and necessary' for the actual use," Defendant argues Plaintiff failed to plead that any claim to the government was false. (Doc. #56, p. 17; Doc. #70, p. 8.)

As discussed above, the off-label use of a medical device does not automatically mean that a subsequent claim for payment was false or fraudulent. *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d at 1051 n.6. "For medical devices, eligibility for reimbursement depends on whether the procedure performed is 'medically necessary' or 'reasonable and necessary.'" *Bennett v. Boston Scientific Corp.*, 2011 WL 1231577, at * 5 (S.D. Tex. Mar. 31, 2011). To adequately

[9] Defendant briefly addresses the materiality element. The Court finds that Plaintiff has adequately pled materiality. (Doc. #46, pp. 12-13) (alleging in part that "whether or not a medical device is promoted for off-label uses the government is billed for is material to the government's decision to pay").

[10] Plaintiff argues "[t]he false statements made to the hospital about the grid's post-operative approval and safety was the violation of 31 U.S.C. § 3729(a)(1)(B), and the submission of the invoice that followed by [Defendant] was the violation of 31 U.S.C. § 3729(a)(1)(A)[.]" (Doc. #65, pp. 18-19.) However, the parties' briefs generally combine their false statement and presentment arguments and do not contain separate discussions of each type of claim. (Doc. #56, p. 9) (arguing that "[i]n any event . . . the [Amended] Complaint fails under both § 3729(a)(1)(A) and (B)). This Order focuses on the primary arguments raised by the parties and refers to the FCA claim in general.

state an FCA claim, a "relator must allege sufficient facts to support an inference that the use of the device is not 'medically necessary' or 'reasonable and necessary.'" *Id.*

Upon review, the Court finds that Plaintiff has plausibly alleged such facts. The Amended Complaint alleges that Auragen devices "were not reasonable and medically necessary, and were medically unsafe for non-approved uses," including post-operative use. (Doc. #46, pp. 24-25.) Plaintiff alleges that Defendant's off-label promotion of Auragen "was dangerous for patient care because [Auragen] was not designed for implantation or post-operative monitoring." (Doc. #46, p. 22.)

As required by Rule 9(b), these assertions are supported with particular examples. Plaintiff alleges that Defendant encouraged Dr. Eddie Chang at the University of California—San Francisco ("UCSF") to use Auragen for post-operative use. In 2010, Dr. Chang implanted Auragen in a patient for post-operative use. However, "part of the grid fell apart." (Doc. #46, p. 14.) Dr. Chang "could not find one or two of the contacts upon removal" and "was concerned if the grids could do long term harm if left in the patient's brain." (Doc. #46, p. 14.) Dr. Chang also allegedly reported to Defendant that "blood seeped through the cables," which meant the grid was not completely sealed. (Doc. #46, p. 19.) The failure of a seal could lead to "infection" and "air trapped inside the skull . . . can put pressure on the brain and require surgery[.]" (Doc. #46, p. 19.)

Additionally, Plaintiff alleges she "knows of between 6 and 8 patients who were harmed at the University of Kansas Medical Center alone when [Defendant's] depth electrodes sheared off leaving part of the electrode imbedded in the patient's head." (Doc. #46, p. 22.) Plaintiff alleges "the malfunctioning of these products while being used for purposes for which they had not been approved by the FDA, and the resulting injuries, were not limited to [UCSF or the

University of Kansas Medical Center], nor to just the events of which [Plaintiff] has knowledge." (Doc. #46, p. 22.) Finally, Plaintiff alleges the FDA denied Defendant's application for post-operative use of Auragen in 2013.

At the motion to dismiss stage, these allegations plausibly allege that Defendant marketed Auragen for off-label use and that such use is not medically necessary or reasonable and necessary. Defendant's arguments to the contrary are rejected. To the extent Defendant argues that off-label use of Auragen "may be" reimbursable, that argument is better resolved after the benefit of discovery. (Doc. #56, p. 17.)

Second, Defendant argues that Plaintiff "does not plausibly allege that [Defendant] falsely represented that Auragen is safe and effective for post-operative monitoring or implantation . . . [and] therefore fails to allege that any reimbursement claims were false." (Doc. #56, p. 18; Doc. #70, pp. 9-10.) The Court disagrees. The Amended Complaint alleges Defendant "routinely" and falsely represented that Auragen "was indicated for post operative monitoring." (Doc. #46, p. 23.) The Amended Complaint alleges Defendant "misled medical providers to believe that the grid was designed in such a way and with such materials that the grid could not fail or erode or break off in the brain tissue if used in these off label ways." (Doc. #46, p. 23.)

In addition, Plaintiff alleges she logged on Defendant's internal training site which "directed the representatives to sell the value of the welded contacts to improve *post-operative monitoring* signals from the grids." (Doc. #46, pp. 15-16) (emphasis in original). Plaintiff further alleges that Defendant's "Vice President of Marketing, Chris Von Jako, and Epilepsy specialist, Bill Chiklakis, were directly involved in encouraging post-operative use of epilepsy grids." (Doc. #46, pp. 13-14.) Plaintiff alleges "[a]fter the incident with Dr. Chang, [Defendant]

had knowledge that the grids could come apart during post operative use. Yet, despite knowing that, and that the epilepsy grids were continuing to be marketed off label . . . [Defendant] never retrained the sales force or terminated the off-label marketing of the grids." (Doc. #46, p. 19.)

Based on these and additional allegations, the Court finds the Amended Complaint plausibly alleges that Defendant falsely represented that Auragen is safe and effective for post-operative monitoring and/or implantation. Defendant's arguments to the contrary are rejected.

Third, Defendant argues the Amended Complaint fails to plead with particularity that it presented, or caused to be presented, a false claim or false certification to the United States. (Doc. #56, pp. 19-25; Doc. #70, pp. 5-11.) "A plaintiff can satisfy this requirement by pleading (1) representative examples of the false claims, or (2) the particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Benaissa*, 963 F.3d at 739 (citations and quotation marks omitted). According to Defendant, Plaintiff "does not allege a single example of the submission of a false claim" or allegations that would support an inference of a false claim. (Doc. #56, pp. 19-23.)

Upon review, the Court finds the Amended Complaint adequately alleges that a false claim was submitted to the government. Plaintiff alleges in part that Defendant "submitted or caused the submission of false claims for payment to taxpayer funded government healthcare programs, and made false records or statements material to false claims for payment[.]" (Doc. #46, p. 2.) Plaintiff also alleges Defendant's conduct "caused the submission of false claims by doctors and hospitals who billed federal and state health care programs for . . . non-approved devices and/or non-approved indications." (Doc. #46, p. 24.)

These assertions are supported by particularized facts. Plaintiff alleges that "Defendant is not allowed to provide specific CPT (reimbursement codes) without a specific approved

indication, yet Tim McCarthy, Vice President of Neurosurgery Sales, repeatedly sent out or discussed CPT codes for post-operative use of [Defendant's] epilepsy grids." (Doc. #46, p. 21.)[11] In addition, Plaintiff alleges that "[n]inety percent or more of [Defendant's] epilepsy product line was used for implantation and post operative monitoring. These were each unlawful off-label uses, including uses for which the government could not lawfully be billed." (Doc. #46, p. 23.) As discussed above, Defendant allegedly trained its sales force to market Auragen for off-label use, and that its sales force followed that directive.

Under these circumstances, Plaintiff has adequately alleged an off-label marketing "scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Benaissa*, 963 F.3d at 739. Therefore, the Court rejects Defendant's argument that Plaintiff failed to adequately allege a false claim was submitted to the government. For all these reasons, and for the additional reasons stated by Plaintiff, the Court finds the Amended Complaint adequately states a presentment and a false statement claim under the FCA. Defendant's motion to dismiss Count I is denied.

B. Count II—Retaliation

Count II asserts a retaliation claim against Defendant. The FCA provides that "[a]ny employee . . . shall be entitled to all relief necessary to make that employee . . . whole, if that employee . . . is discharged . . . threatened, harassed, or in any other manner discriminated against . . . because of lawful acts done by the employee . . . in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter." 31 U.S.C. § 3730(h)(1). To state a claim under this statute, a plaintiff must adequately allege the following elements: "(1) the plaintiff was engaged in conduct protected by the FCA; (2) the plaintiff's

[11] Defendant's reply brief argues that reimbursement codes and/or reimbursement amounts cannot plausibly support the submission of a false claim, but this argument is rejected at the motion to dismiss stage.

employer knew that the plaintiff engaged in the protected activity; (3) the employer retaliated against the plaintiff; and (4) the retaliation was motivated solely by the plaintiff's protected activity." *Strubbe v. Crawford Cnty. Mem. Hosp.*, 915 F.3d 1158, 1166-67 (8th Cir. 2019) (citation and quotation marks omitted).

In this case, Plaintiff alleges she was harassed and terminated after making internal complaints about Defendant's off-label promotion of CUSA. Defendant argues this claim should be dismissed for two primary reasons: (1) Plaintiff has not adequately alleged she engaged in protected activity; and (2) Plaintiff has not adequately alleged Defendant had knowledge of any protected activity. Both arguments are addressed below.

1. Whether Plaintiff Engaged in Protected Activity

To adequately state the protected activity element, a plaintiff must allege that: (1) her conduct was "in furtherance of an FCA action or an effort to stop one or more FCA violations;" and (2) her conduct was "aimed at matters which are calculated, or reasonably could lead, to a viable FCA action," meaning the employee "in good faith believes, and a reasonable employee in the same or similar circumstances might believe, that the employer is possibly committing fraud against the government." *Strubbe*, 915 F.3d at 1167 (cleaned up).

Defendant contends that Plaintiff's "purported whistleblowing was aimed not at exposing false claims for payment, but at [Defendant's] promotion of CUSA for liver applications." (Doc. #56, p. 26.) According to Defendant, Plaintiff "alleges that the off-label promotion of CUSA violated the FDCA, not the FCA, and her alleged whistleblowing activity did not connect any regulatory violation to fraud or the submission of false claims." (Doc. #56, p. 27.) As explained below, the Court rejects this argument.

In part, Plaintiff alleges that CUSA had not been approved by the FDA for gynecological oncology or liver uses. Nonetheless, Plaintiff and other employees were directed and/or pressured by their supervisors to market CUSA to liver surgeons and for gynecological oncology. On July 21, 2014, Plaintiff's supervisor, John Golden ("Golden") sent a memo to Plaintiff and other regional business managers "requiring their sales teams to contact all gynecology, liver, and neurosurgeons in their territory at every account in the next 75 days." (Doc. #46, p. 30.)

After reviewing the memo, Plaintiff reminded Golden that Defendant could not promote CUSA to liver surgeons because it had not been approved by the FDA. Golden allegedly told Plaintiff she did not "have the balls to do the job" and that "she was too concerned about . . . following the rules." (Doc. #46, p. 30-31.) Among other things, Golden also stated that Defendant needed to hit certain sales numbers and therefore decided to expand CUSA to the liver and gynecology markets.

This conversation concerned Plaintiff and she decided to report Golden for "pushing CUSA for liver applications and gynecological oncology[.]" (Doc. #46, p. 33.) Plaintiff alleges that:

> [W]ith a good faith belief that what she was being directed to do was not legal, could endanger patient safety, and even result in fraud against patients, insurance plans, and the government, she called [Defendant's] Compliance Hotline and reported Mr. Golden's July 2014 memo, her name, and the conversation that she had with Mr. Golden[.]

(Doc. #46, p. 33.)

Upon review, the Court finds these allegations adequately plead protected activity. Specifically, Plaintiff adequately alleges that her conversation with Golden and her subsequent report to the Compliance Hotline were good faith "effort[s] to stop one or more FCA violations."

Strubbe, 915 F.3d at 1167. The Court also rejects Defendant's argument that Plaintiff failed to "allege facts supporting both an objective and subjective good-faith belief that the government was being defrauded by the submission of false claims." (Doc. #70, p. 13); *see also Strubbe*, 915 F.3d at 1167.[12]

Defendant next argues that Plaintiff's "alleged whistleblowing activity did not connect any regulatory violation to fraud or the submission of false claims." (Doc. #56, p. 27.) The Court disagrees. As discussed above, Plaintiff alleges that Golden directed her and others to market CUSA for off-label uses. Plaintiff alleges this off-label marketing was specifically tied to hitting certain sales numbers. Plaintiff alleges her belief that the off-label marketing would "result in fraud against patients, insurance plans, and the government[.]" (Doc. #46, p. 33.) These allegations are sufficient to avoid dismissal.

For these reasons, the Court rejects Defendant's argument that Plaintiff failed to adequately allege she engaged in protected activity.

2. Whether Defendant Had Knowledge of the Protected Activity

Defendant argues the Amended Complaint fails to adequately allege that it knew of any protected activity. (Doc. #56, pp. 28-29; Doc. #70, p. 13.) Specifically, Defendant argues the Amended Complaint "fails to allege knowledge on behalf of [Defendant] because it was [Plaintiff's] job as a Senior Regional Business Manager to, among other things, ensure her sales team promoted [Defendant's] products consistent with [Defendant's] training, including prohibiting off-label promotion." (Doc. #56, p. 28.) Defendant contends that "[a]bsent some

[12] Defendant appears to argue Plaintiff lacked the good faith necessary to engage in protected activity because "the use of CUSA for liver applications has been on-label since 1998." (Doc. #56, p. 27.) However, Jacquie Lipton, Defendant's marketing manager, allegedly told Plaintiff in 2014 that Defendant "was at least one year away from obtaining [FDA] . . . approval to market CUSA to liver surgeons." (Doc. #46, p. 30.) Plaintiff further alleges that at the relevant times, CUSA had not been approved for gynecological oncology. These allegations support a good faith belief of illegality and thus the protected activity element.

connection to false claims or fraud, [Plaintiff] merely alleges she did her job, and that is insufficient to put [Defendant] on notice that [Plaintiff] engaged in activity protected by the FCA." (Doc. #56, p. 28.)

However, as discussed above, Plaintiff has plausibly alleged fraud and false claims. Plaintiff further alleges she confronted Golden and called Defendant's Compliance Hotline to stop illegal off-label marketing and the submission of fraudulent claims to the government. At the pleading stage, these actions were sufficient to notify Defendant of potential fraud and false claims. For these reasons, the Court rejects Defendant's argument that Plaintiff failed to adequately plead notice or knowledge of protected activity.[13]

For these reasons, and for the additional reasons stated by Plaintiff, the Court finds that Plaintiff has adequately stated a retaliation claim under the FCA.

IV. CONCLUSION

Accordingly, Defendants' Motion to Dismiss Relator's Amended Complaint With Prejudice (Doc. #55) is GRANTED IN PART and DENIED IN PART. The motion is GRANTED insofar as Plaintiff's claims against Defendant Integra LifeSciences Holdings Corporation are DISMISSED WITHOUT PREJUDICE. The motion is DENIED in all other respects. Plaintiff's alternative request to amend her complaint is denied as moot.

IT IS SO ORDERED.

/s/ Stephen R. Bough
STEPHEN R. BOUGH
UNITED STATES DISTRICT JUDGE

Dated: April 6, 2022

[13] To the extent Defendant argues Plaintiff cannot state a retaliation claim based solely on her job title and duties, that argument is also rejected. Section 3730(h) protects "any employee" from retaliation. 31 U.S.C. § 3730(h).