

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

CIVIL ACTION NO. 1:11-cv-029 (WOB)

UNITED STATES OF AMERICA EX REL.
JOSEPH IBANEZ, ET AL.

RELATORS

VS.

BRISTOL-MYERS SQUIBB CO., ET AL.

DEFENDANTS

MEMORANDUM OPINION AND ORDER

This is a *qui tam* action brought pursuant to the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3730, as well as various state-analog laws. On behalf of the United States and several State governments, Joseph Ibanez and Jennifer Edwards ("Relators") -- former sales representatives for Bristol-Myers Squibb Co. ("BMS") -- allege that BMS and Otsuka America Pharmaceutical, Inc. ("Otsuka") engaged in nationwide, fraudulent schemes to market the atypical-antipsychotic drug ABILIFY® for off-label uses, causing the submission of fraudulent claims for payment on ABILIFY® prescriptions to the United States in violation of 31 U.S.C. § 3729(a)(1)(A). Relators further allege that, as a part of the fraudulent schemes, BMS and Otsuka violated the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), caused the use or creation of false records material to false claims, 31 U.S.C. § 3729(a)(1)(B), failed to reimburse the United States for overpayments, *id.* § 3729(a)(1)(G), conspired to violate the FCA, *id.* § 3729(a)(1)(C), and that BMS retaliated against Relators for their efforts to curtail the fraudulent schemes, *id.* § 3730(h). Finally, Relator Edwards alleges that BMS improperly terminated her employment in violation of Arizona law, Ariz. Rev. Stat. § 23-1501.

This matter is before the Court on Defendants' separate motions to dismiss Relators' second amended complaint ("SAC"), filed pursuant to Federal Rule of Civil Procedure 12(b)(6). Docs. 60, 61. Relators filed a combined response to Defendants' motions, and Defendants subsequently filed separate replies. Docs. 65, 66, 67.

The Court held oral argument on these motions on March 9, 2015, after which it took them under advisement.¹ The Court now issues the following Memorandum Opinion and Order. For the reasons stated herein, the Court grants Otsuka's motion to dismiss and grants in part and denies in part BMS's motion.

I. FACTS²

ABILIFY® is an atypical antipsychotic drug that BMS and Otsuka marketed jointly from at least 2005 to 2012. Doc. 52, ¶ 2. During the same period, Relators worked for BMS as pharmaceutical-sales representatives responsible for promoting ABILIFY® to prescribing psychiatrists. *Id.* ¶¶ 17-18.

Relators plead in detail allegations concerning three nationwide, fraudulent schemes in which BMS and Otsuka jointly engaged. *See id.* ¶¶ 137(2)-227, 249-58.³ The first alleged scheme involved promotion

¹ Court reporter Luke Lavin recorded the proceedings. Jennifer Verkamp, Frederick Morgan, Jr., William Myers, and Chandra Napora represented Relators. Jessica Ellsworth, Mitchell Lazris, Christopher Wassen, and Glenn Whitaker represented BMS, and Jennifer Spaziano, Daniel Izenon, and Ava Trower represented Otsuka.

² Because many of Relators' factual allegations are analyzed in detail later in the Court's Opinion, this section provides only a brief overview of Relators' allegations and theories of liability.

³ Relators' SAC contains two sets of paragraphs numbered 137 through 153. Doc. 52, at 36-41 (containing the first set), 41-49 (containing the second). The Court will cite the first set as paragraphs 137-53 and the second as paragraphs 137(2)-53(2).

of ABILIFY® to pediatric psychiatrists for uses not approved by the Food and Drug Administration ("FDA") -- known as off-label promotion. *Id.* ¶¶ 137(2)-201. The second alleged scheme involved the off-label promotion of ABILIFY® to psychiatrists who treat geriatric patients. *Id.* ¶¶ 202-27. The final alleged scheme involved paying illegal kickbacks to prescribing psychiatrists in order to increase the number of prescriptions written for ABILIFY®. *Id.* ¶¶ 249-58.

Relators' allegations largely parallel those from previous FCA cases that the United States filed against BMS and Otsuka. *See id.* ¶¶ 101-02, 119. In 2007, in order to settle a FCA suit based on its alleged off-label promotion of ABILIFY®, BMS entered into a five-year Corporate Integrity Agreement ("CIA") with the Office of the Inspector General of the Department of Health and Human Services. *Id.* ¶¶ 89, 101-02. As part of its CIA, BMS agreed to modify its business practices in various ways to bring the company into compliance with the FCA, AKS, and other federal laws. *Id.* ¶ 90. Similarly, in 2008, Otsuka entered into a five-year CIA with the government to settle a FCA suit based on its alleged off-label promotion of ABILIFY®. *Id.* ¶¶ 106-07. Otsuka also agreed to modify its business practices in various ways to bring the company into compliance with the FCA, AKS, and other federal laws. *Id.* ¶ 108. Many of Relators' allegations against BMS and Otsuka relate to alleged violations of the CIAs that the companies entered into with the United States. *Id.* ¶¶ 88-121.

Relators allege that they reported issues of BMS's failure to comply with its CIA, as well as its failure to comply with federal and state laws, to their superiors at BMS. *Id.* ¶¶ 292-311. Relators

further allege that BMS unlawfully retaliated against them and terminated their employment for reporting those compliance issues. *Id.* ¶¶ 303-04, 310-11.

II. ANALYSIS

In order to survive Defendants' Rule 12(b)(6) motions to dismiss, Relators' SAC must contain "enough facts to state [claims] to relief that [are] plausible on [their] face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). The Court must construe the SAC in the light most favorable to Relators and accept all factual allegations as true. *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 467 (6th Cir. 2011).

Because the FCA is a statute that prohibits fraud on the government, "[c]omplaints alleging FCA violations must comply with [Federal] Rule [of Civil Procedure] 9(b)'s requirement that fraud be pled with particularity." *Id.* at 466. In order to meet the particularity requirement, Relators, "must allege (1) the time, place, and content of the alleged misrepresentation, (2) the fraudulent scheme, (3) the defendant's fraudulent intent, and (4) the resulting injury." *Id.* (quoting *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.* ("*Bledsoe II*"), 501 F.3d 493, 504 (6th Cir. 2007)) (internal quotation marks omitted).

A. FCA Claims against BMS and Otsuka

The FCA provides in pertinent part:

(a) Liability for certain acts.--

(1) **In general.**--Subject to paragraph (2), any person who--

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), . . . or (G);

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, . . . plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a). Relators assert claims against BMS and Otsuka for violations of § 3729(a)(1)(A), 3729(a)(1)(B), and 3729(a)(1)(G), as well as conspiracy claims pursuant to § 3729(a)(1)(C).

1. Section 3729(a)(1)(A) Claims

a. Arguments

BMS first argues that Relators' § 3729(a)(1)(A) claims based on violations of the AKS are not pled with particularity. It contends that the SAC fails to allege with particularity any specific false claims that resulted from kickbacks. Doc. 60-1, at 8-10. BMS next argues that Relators have failed to state § 3729(a)(1)(A) claims based on alleged off-label marketing of ABILIFY®. It contends that the SAC fails to allege with particularity the fraudulent schemes and whether any false claims resulted. *Id.* at 10-14.

Otsuka also argues that Relators' § 3729(a)(1)(A) claims fail because the SAC does not identify a false claim submitted to the government for payment. Doc. 61, at 7-10. It next argues that

Relators have not pled sufficient facts to implicate Otsuka in the alleged off-label marketing and kickback schemes. *Id.* at 10-15. Finally, Otsuka argues that Relators failed to plead that Otsuka knowingly participated in the alleged fraud. *Id.* at 15-16.

As to their § 3729(a)(1)(A) claims based on violations of the AKS, Relators respond that they adequately pled those claims by identifying the illegal inducements that BMS and Otsuka offered to increase ABILIFY® prescriptions, including paid speaking engagements and free meals, and alleging that the purpose of the inducements was to increase the number of claims for ABILIFY® submitted to federal-health-care programs. Doc. 65, at 33-35.

With respect to their § 3729(a)(1)(A) claims alleging off-label promotion, Relators respond that the SAC pleads the allegedly fraudulent schemes with such particularity that it shows with "virtual certainty" that Defendants' off-label-promotion resulted in the submission of false claims to the government. *Id.* at 25-28.

Relators respond to Otsuka's arguments by contending that the SAC contains sufficient facts to allege Otsuka's participation in the fraudulent schemes. Relators also contend that the SAC's allegations of Otsuka's knowledge are sufficient because those allegations are not subject to Rule 9(b)'s particularity requirement. *Id.* at 28-31.

b. Analysis

Relators allege that BMS and Otsuka participated jointly in three separate fraudulent schemes: an off-label-promotion scheme to market ABILIFY® to psychiatrists that treat pediatric patients, Doc. 52, ¶¶ 137(2)-201, an off-label-promotion scheme to market ABILIFY® to

psychiatrists that treat geriatric patients, *id.* ¶¶ 202-27, and a scheme to violate the AKS by providing inducements to those psychiatrists, *id.* ¶¶ 249-58.

Like in *Chesbrough*, the main issue the Court must resolve with respect to Relators' § 3729(a)(1)(A) claims relates to Rule 9(b)'s "misrepresentation" aspect -- "the actual presentment of a false claim to the government." 655 F.3d at 467, 470-72. For the following reasons, the Court holds that Relators have not pled any of their § 3729(a)(1)(A) claims with the particularity required by Rule 9(b).

i. Appropriate Pleading Standard

The parties vigorously dispute the pleading standard that the Court should apply to test the allegations in Relators' SAC against Rule 9(b)'s requirements. Doc. 60-1, at 6-15; Doc. 61, at 6-10; Doc. 65, at 18-25; Doc. 66, at 3-7; Doc. 67, at 3-6. Defendants rely on reasoning from prior Sixth Circuit cases stating that a relator must plead the specifics of a false claim in order to survive a defendant's motion to dismiss based on Rule 9(b).⁴ Relators, however, rely on two of the same cases -- *Bledsoe II* and *Chesbrough* -- for the proposition that the Sixth Circuit might apply a "relaxed" pleading

⁴ *Chesbrough*, 655 F.3d at 472 ("In *Bledsoe*, *Sanderson*, and *Marlar*, we imposed a strict requirement that relators identify actual false claims."); *United States ex rel. Marlar v. BWXT Y-12, LLC*, 525 F.3d 439, 446 (6th Cir. 2008) (stating that a relator must "identify [the] specific claims that were submitted to the United States" (quoting *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006))); *Bledsoe II*, 501 F.3d at 509 ("[W]e hold that a relator bringing an action under the FCA must allege specific false claims with particularity in order to comply with Rule 9(b)."); *Sanderson*, 447 F.3d at 877 ("[T]he fraudulent claim is 'the sine qua non of a [FCA] violation.'" (quoting *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002))).

standard to these facts.⁵ But this dispute is immaterial. Even if the Court applies the “relaxed” standard that Relators favor, the SAC does not allege with particularity facts “which support a strong inference” that BMS and Otsuka caused the submission of fraudulent claims to the government. See *Chesbrough*, 655 F.3d at 471.

ii. Off-Label Promotion to Pediatric Providers

Relators’ allegations of illegal, off-label promotion of ABILIFY® by BMS and Otsuka to pediatric targets boil down to the following:

- Prior to October 2007, ABILIFY® was not FDA-approved for treating pediatric patients. But between 2005 and October 2007, BMS and Otsuka sales representatives regularly called on psychiatrists who treated primarily, or only, pediatric patients. Relators allege that any promotion to those psychiatrists was illegal promotion for an off-label use. Doc. 52, ¶¶ 137(2)-151(2).
- In October 2007, ABILIFY® received FDA approval for a single use in pediatric patients: treatment of schizophrenia in patients aged thirteen to seventeen. In February 2008, ABILIFY® received FDA approval for another pediatric use: treatment of manic and mixed episodes for Bipolar I Disorder in patients aged ten to seventeen. *Id.* ¶ 144(2). However, despite the fact that the CIAs BMS and Otsuka entered into with the federal government in 2007 and 2008 required the companies to augment their call targets so that their sales representatives would not promote ABILIFY® to psychiatrists who treated only patients for whom there was no FDA-approved indication for ABILIFY®, each company

⁵ *Chesbrough*, 655 F.3d at 471 (“Although we do not foreclose the possibility that this court may apply a ‘relaxed’ version of Rule 9(b) in certain situations, we do not find it appropriate to do so here. The case law just discussed suggests that the requirement that a relator identify an actual false claim may be relaxed when, even though the relator is unable to produce an actual billing or invoice, he or she has pled facts which support a strong inference that a claim was submitted. Such an inference may arise when the relator has ‘personal knowledge that the claims were submitted by Defendants . . . for payment.’” (quoting *United States ex rel. Lane v. Murfreesboro Dermatology Clinic, PLC*, No. 4:07-cv-4, 2010 WL 1926131, at *5 (E.D. Tenn. May 12, 2010))); *Bledsoe II*, 501 F.3d at 504 n.12 (“We do not intend to foreclose the possibility of a court relaxing this rule in circumstances where a relator demonstrates that he cannot allege the specifics of actual false claims that in all likelihood exist, and the reason that the relator cannot produce such allegations is not attributable to the conduct of the relator.”).

continued to promote ABILIFY® for off-label uses to pediatric psychiatrists. *Id.* ¶¶ 147(2)-151(2).

- From October 2007 to October 2009, BMS and Otsuka sales representatives continued to market ABILIFY® to child psychiatrists for off-label uses by (1) focusing on symptoms rather than on medical conditions and (2) advocating ABILIFY® to treat conditions for which the FDA had not approved its use. *Id.* ¶¶ 153(2)-155.
- After October 2009, BMS and Otsuka sales representatives began promoting ABILIFY® to child psychiatrists for the treatment of depression in pediatric patients, despite the fact that the FDA has never approved the drug for such a use. *Id.* ¶¶ 165-68.

But no matter how particularly Relators have pled the off-label-promotion scheme that BMS and Otsuka engaged in -- and they have pled the alleged scheme with sufficient particularity -- the SAC also must contain particular allegations that *at minimum* "support a strong inference that a claim was submitted." *Chesbrough*, 655 F.3d at 471.

Relators cannot meet this standard because the SAC does not identify a single pediatric psychiatrist who wrote an off-label prescription that was filled by a patient and on which some entity submitted a fraudulent claim for reimbursement to a federal-health-care program. Even Relators' SAC recognizes the degrees of separation between Defendants' off-label promotion and the actual submission of a false claim:

279. *If [ABILIFY®] is prescribed for a government healthcare beneficiary, it results in a claim for payment for the drug which is submitted by a pharmacy, often through a pharmacy benefits manager or through a government healthcare program contractor. Defendants knew that such claims were submitted to government healthcare programs for every government-insured patient who was prescribed [ABILIFY®]. And Defendants specifically sought out for inclusion on their call lists providers who prescribed high volumes of drugs to government healthcare beneficiaries.*

Doc. 52, ¶ 279 (emphasis added).

Relators' pleading does not raise a "strong inference" that BMS and Otsuka caused the submission of a false claim for payment because such a conclusion requires no fewer than *five* sequential inferences drawn in Relators' favor: (1) that Defendants' off-label promotion caused pediatric psychiatrists to write prescriptions for ABILIFY®, (2) that those prescriptions were for off-label uses of ABILIFY®, (3) that the patients who received those prescriptions participate in federal-health-care programs, (4) that the patients actually filled the off-label prescriptions, and (5) that some entity submitted claims for reimbursement to the government on the off-label prescriptions. Accepting all factual allegations as true and drawing all inferences in Relators' favor, the SAC arguably covers inferences (1) and (2) above, but the SAC certainly does not reach inferences (3) through (5). Relators' SAC therefore does not support a "strong inference" that the off-label promotion of ABILIFY® to pediatric psychiatrists by BMS and Otsuka caused the submission of false claims to the government.

At the hearing, Relators' counsel raised several more specific arguments meriting discussion: (1) that if the Court requires Relators to plead the specifics of a false claim, then they must present more evidence to survive a motion to dismiss based on the particularity rule than is required at trial; (2) that the general allegations in the SAC that BMS and Otsuka "caused false claims to be submitted" are enough to meet the "relaxed" *Chesbrough* pleading standard; and

(3) that the SAC's specific allegations regarding Dr. Elliott Friedeman are sufficient to satisfy the particularity rule.

The Court understands Relators' argument that the FCA pleading standards requiring a relator to identify a specific false claim -- or at minimum a strong inference that such claims were submitted -- in order to survive a motion to dismiss may seem at odds with the fact that a relator may rely on circumstantial evidence to prove the submission of false claims at trial. But this argument is unavailing for two reasons. First, this Court cannot alter the pleading standards set out in the Sixth Circuit's case law. Second, the case law does not require Relators to plead the specifics of every false claim they allege -- or even the specifics of one if their pleading raises a strong enough inference -- but only "*representative samples* of the broader class of claims." *Bledsoe II*, 501 F.3d at 510.

The pleading standards established by the Sixth Circuit therefore allow a relator to "support more generalized allegations of fraud . . . to the extent that the relator's examples are" representative samples. *Id.* Accordingly, if a relator can show one particular example of an allegedly broader class of claims at the pleading stage, then she may use circumstantial evidence to prove the existence of that broader class of claims at trial. In the Court's opinion, this standard strikes the appropriate balance between Rule 9(b)'s requirements and a relator's ability to prove the existence of a broader scheme at trial through the use of circumstantial evidence.

Next, the SAC contains many variations on the following allegation: "Defendants caused to be submitted, and, on information

and belief, continue to cause submission of, false claims to government healthcare programs for payment of [ABILIFY®] for noncovered [sic] and nonpayable [sic] uses." Doc. 52, ¶ 25; see also, e.g., *id.* ¶¶ 8, 88, 106, 121, 153, 290, 314, 322-24. Relators contended at oral argument that these allegations are sufficient to meet the "relaxed" *Chesbrough* pleading standard. But Relators freely admit in the SAC that "while [they] have significant evidence of the fraud alleged . . . , much of the documentary evidence necessary to prove the allegations in [the SAC] is in the exclusive possession of either the Defendants or the United States." *Id.* ¶ 23. And Relators also admit in the very next paragraph that they are not privy to "the information regarding the claims for payment caused to be submitted by Defendants. This information is in the exclusive possession and control of the Defendants, the United States, the Plaintiff States, the physicians who prescribed [ABILIFY®] off-label, and the pharmacies that filled the prescriptions for [ABILIFY®]." *Id.* ¶ 24.

This latter admission alone could bring Relators' claims outside the ambit of *Chesbrough*, wherein the Sixth Circuit stated that a strong inference of false claims would arise when the Relators have "personal knowledge" of the fraudulent claims. 655 F.3d at 471. As pharmaceutical-sales representatives at BMS, Relators have no personal knowledge of any claims submitted and freely admit as much. Although Relators' situation arguably falls within the *Bledsoe II* court's statement that the Sixth Circuit could relax Rule 9(b)'s requirements "where a relator demonstrates that he cannot allege the specifics of actual false claims that in all likelihood exist, and the reason that

the relator cannot produce such allegations is not attributable to the conduct of the relator," 501 F.3d at 504 n.12, that dictum is so broadly worded that the Court could undermine the purpose of the particularity rule by allowing Relators' claims to move forward as pled.

The Court already has given Relators the benefit of a relaxed pleading standard that the Sixth Circuit *might apply in future cases*. But the Court will not apply that exception in such a way that it swallows the existing and well-settled rules for FCA pleading.

Finally, Relators hone in on the SAC's allegations related to Dr. Elliot Friedeman to argue that they have pleaded their § 3729(a)(1)(A) claims relating to the off-label promotion of ABILIFY® to pediatric psychiatrists with sufficient particularity. Doc. 52, ¶¶ 188, 190, 195, 283. In paragraphs 188 and 190 of the SAC, Relators identify Dr. Freideman as an Ohio physician who treats primarily pediatric patients and should have been removed from sales representatives' target lists prior to 2009 in light of the CIAs but remained a target in 2009 and 2010.

In paragraph 195, drawing all reasonable inferences in Relators' favor, the SAC alleges that a BMS sales representative, Marty Hensley, made calls on Dr. Friedeman only with materials devoted to a mental-health condition, major depressive disorder, for which ABILIFY® does not have an FDA-approved use for Dr. Friedeman's pediatric patients. Relators accordingly allege that "any promotional efforts [Hensley]

made to Dr. Friedeman would necessarily entail off-label marketing.”⁶ Paragraph 283 of the SAC then explains BMS and Otsuka’s practice of “track[ing] the prescribing levels of all their target physicians” and “track[ing of] government health reimbursement breakdown[s] of their target audiences,” including pediatric providers. The SAC cites Dr. Friedeman as an example of this practice, noting that he “issued a total of 149 [ABILIFY®] prescriptions” during the three months prior to February 2010. *Id.* ¶ 283.

Allowing Relators the reasonable inference -- arguably two inferences -- that BMS’s off-label marketing caused Dr. Friedeman to write off-label prescriptions for ABILIFY®, the SAC does not contain allegations that fill the inferential gaps the Court previously identified. Those inferential gaps include: (1) whether Dr. Friedeman wrote even one off-label prescription to a participant in a federal-health-care program; (2) whether even one federal-health-care program participant actually filled a prescription from Dr. Friedeman; and (3) whether any entity actually submitted a claim for reimbursement to the government for even one off-label prescription written by Dr. Friedeman.

Because none of the arguments Relators raised at the hearing undercuts the Court’s conclusion that Relators’ SAC does not create a strong inference that BMS and Otsuka caused the submission of false claims to the government, the Court accordingly dismisses Relators’

⁶ The Court notes that this paragraph of the SAC also contains allegations related to BMS and Otsuka’s alleged violations of the AKS that led to the submission of false claims to the United States. The Court will specifically address those allegations in the portion of this Opinion devoted to Relators’ claims premised on the AKS.

§ 3729(a)(1)(A) claims relating to the off-label promotion of ABILIFY® to pediatric psychiatrists.

iii. Off-Label Promotion to Geriatric Providers

Relators' allegations of illegal, off-label promotion of ABILIFY® by BMS and Otsuka to geriatric targets boil down to the following:

- Since April 2005, the FDA has warned that prescribing drugs like ABILIFY® to geriatric patients suffering from dementia creates an increased risk of death. Doc. 52, ¶¶ 132-35.
- Prior to 2007, the only FDA-approved indications for ABILIFY® in adult patients were the treatment of Schizophrenia and Bipolar I Disorder. In November 2007, the FDA approved ABILIFY® for the treatment of depression in adults. *Id.* ¶¶ 122-24.
- Between June 2005 and October 2007, BMS and Otsuka sales representatives targeted nursing home psychiatrists in an effort to get those doctors to prescribe ABILIFY® to geriatric patients for off-label uses despite the risks involved. BMS and Otsuka engaged in this off-label promotion despite the fact that the number of nursing home patients suffering from Schizophrenia and Bipolar I Disorder is so low that such a group is considered a "ghost population." *Id.* ¶¶ 202-03.
- BMS and Otsuka allegedly took advantage of the fact that many nursing home patients suffer from some symptoms similar to depression that ABILIFY® can alleviate and promoted the drug for treatment of those symptoms, which constitutes off-label promotion of the drug. *Id.* ¶ 204.

Relators' SAC does not support a "strong inference" that BMS and Otsuka's alleged off-label promotion of ABILIFY® to nursing home psychiatrists that treat geriatric patients caused the submission of false claims to the government for the same reasons discussed above with respect to pediatric psychiatrists.

The Court accordingly also dismisses Relators' § 3729(a)(1)(A) claims relating to the off-label promotion of ABILIFY® to nursing home psychiatrists.

iv. Violations of the Anti-Kickback Statute

The AKS provides, in pertinent part, that

(2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b)(2). A claim submitted in violation of the AKS is a false claim for purposes of the FCA. *Id.* § 1320a-7b(g). Relators allege that BMS and Otsuka violated the AKS by offering illegal inducements to ABILIFY® prescribers, including paid speaking engagements and free meals, for the purpose of increasing claims to federal-health-care programs. Doc. 52, ¶¶ 249-58.

According to Relators, in order to state an FCA claim based on violations of the AKS, they must allege that BMS and Otsuka knowingly and willfully (1) offered or paid any remuneration of any kind, directly or indirectly, (2) which was intended to induce the utilization of federal-health-care services. Doc. 65, at 34 (citing *United States v. Bay State Ambulance & Hosp. Rental Serv.*, 874 F.2d 20, 30 (1st Cir. 1989)). Relators cannot meet this standard because they have not pled with particularity facts alleging that the

illegal remuneration BMS and Otsuka paid "was intended to induce the utilization of federal-health-care services." *Id.*

Relators pled some conduct that arguably violates the AKS in paragraphs 249 to 258 of the SAC, but there are no facts showing with particularity that BMS and Otsuka intended the psychiatrists prescribing ABILIFY® as a result of illegal kickbacks to utilize federal-health-care services. The SAC alleges that "Relators observed [ABILIFY®] sales representatives creating and/or inviting providers to paid programs, including speaking engagements and lunches, *to induce high quintile prescribers and their 'key influencers' to continue to write [ABILIFY®] prescriptions.*" Doc. 52, ¶ 249 (emphasis added). Another paragraph similarly alleges that BMS and Otsuka "offered physicians and 'key influencers' incentives, including paid speaking engagements, paid lunches, expensive dinners, free samples, and other incentives, as an inducement to prescribe [ABILIFY®]." *Id.* ¶ 257. The SAC then concludes its AKS allegations by stating in a conclusory manner that "Defendants' conduct violated the Anti-Kickback Statute and known conditions of payment in government healthcare programs. Claims resulting from these violations are false claims." *Id.* ¶ 258.

But the SAC nowhere alleges that any of the physicians it claims received improper kickbacks, or the elimination of improper kickbacks, due to ABILIFY® prescribing levels -- Dr. Friedeman, Dr. Amita Patel, Dr. Mahmood Rahman, Dr. Geraldine Wu, Dr. Randy Sansone, and Dr. Michael Chan -- actually wrote even one prescription to a federal-health-care program participant on which an entity submitted a claim for reimbursement to the government. See *id.* at ¶¶ 195, 249-58, 283.

The SAC thus at most alleges that BMS and Otsuka violated the AKS in order to increase the total number of ABILIFY® prescriptions. The same facts that are missing from Relators' other § 3729(a)(1)(A) claims -- those demonstrating with particularity that BMS and Otsuka's conduct led to the submission of false claims -- are likewise missing from their AKS claims.

The Court accordingly dismisses Relators' § 3729(a)(1)(A) claims based on violations of the AKS.

2. Section 3729(a)(1)(B) Claims

a. Arguments

BMS does not make a specific argument for dismissal of Relators' § 3729(a)(1)(B) claims; it instead relies on its arguments directed at Relators' § 3729(a)(1)(A) claims. See Doc. 60-1, at 8-15 & n.14.

Otsuka argues that the Court should dismiss Relators' § 3729(a)(1)(B) claims because the SAC alleges that Otsuka violated this provision only in conclusory terms and fails to allege how any promotional documents were material to the underlying false claims. Doc. 61, at 16-17.

Relators do not respond directly to Otsuka's arguments in favor of dismissal of their claims under § 3729(a)(1)(B); they instead rely on their arguments opposing dismissal of their § 3729(a)(1)(A) claims. See Doc. 65, at 18-31.

b. Analysis

Section 3729(a)(1)(B) imposes liability on one who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." The Supreme Court has held

that this species of FCA claim does not require "proof that the defendant caused a false record or statement to be presented or submitted to the Government," *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 671 (2008) (emphasis added), but that "does not relieve [Relators] of the need to plead a connection between the alleged fraud and an actual claim made to the government," *Chesbrough*, 655 F.3d at 473 (emphasis added).

Relators pled many allegedly fraudulent statements that BMS and Otsuka representatives made to psychiatrists in order to increase the number of ABILIFY® prescriptions. Doc. 52, at ¶¶ 228-48. But Relators do not plead with particularity facts that connect those allegedly false statements to a specific false claim for ABILIFY® or that show how the alleged falsehoods were material to a specific false claim. Relators' pleading of their § 3729(a)(1)(B) claims thus suffers from the same deficiency as their § 3729(a)(1)(A) claims: they cannot tie BMS and Otsuka's allegedly illegal conduct to even one specific false claim.

The Court accordingly dismisses Relators' § 3729(a)(1)(B) claims.

3. Section 3729(a)(1)(G) Claims

a. Arguments

BMS argues that the SAC fails to plead with particularity "details about any overpayment that BMS received. Without at least alleging the details" of an overpayment by the government, BMS contends, Relators' § 3729(a)(1)(G) claims should be dismissed. Doc. 60-1, at 14 n.11.

Otsuka raises the same argument as BMS in favor of dismissal of Relators' § 3729(a)(1)(G) claims. Doc. 61, at 17-18.

Relators respond that the CIAs BMS and Otsuka entered into with the government contained stipulated-penalties provisions. They allege that, because BMS and Otsuka falsely certified that they were in compliance with the CIAs, BMS and Otsuka avoided paying penalties that they owed to the government. Relators also contend that BMS and Otsuka violated § 3729(a)(1)(G) when they failed to refund the government for overpayments received as a result of their alleged off-label promotion and kickback schemes. Doc. 65, at 37-40.

b. Analysis

In order to state a § 3729(a)(1)(G) claim -- known as a "reverse false claim" -- Relators must allege sufficient facts to show with particularity that both BMS and Otsuka received overpayments from the government and failed to refund those overpayments. 31 U.S.C. § 3729(a)(1)(G). The SAC does not contain the required allegations.

In their opposition, Relators tellingly do not cite a single paragraph of the SAC that supports their § 3729(a)(1)(G) claims. And the SAC mentions "overpayments" in only two relevant places. Paragraphs 291 and 325 state:

291. Moreover, these continued schemes have resulted in overpayments by government healthcare programs. Notwithstanding the terms of their CIAs or their obligations to report overpayments, Defendants have illegally retained these overpayments and continued their illegal conduct.

325. As a result of their violations, Defendants received overpayments from government healthcare programs and failed to return the money to the Government in a

timely manner. Defendants' ongoing and knowing failure to report these overpayments violates the False Claims Act, 31 U.S.C. § 3729(a)(1)(G).

Doc. 52, ¶¶ 291, 325. These allegations are devoid of factual development and barely amount to "a formulaic recitation of the elements of a cause of action." *Twombly*, 550 U.S. at 555.

Relators argue that the stipulated-penalties provisions from the CIAs that BMS and Otsuka entered into with the government also suffice to show that BMS and Otsuka retained monies they should have paid to the government. Because Relators did not plead any reference to the stipulated-penalties provisions of the CIAs in the SAC, however, the Court rejects this argument. See Doc. 52, ¶¶ 88-121. Defendants' Rule 12 motions test the sufficiency of the allegations in the SAC, not the sufficiency of Relators' arguments in opposition.

The Court accordingly dismisses Relators' § 3720(a)(1)(G) claims.

4. Section 3729(a)(1)(C) Claims

a. Arguments

BMS argues that Relators' SAC fails to state a claim for conspiracy to violate the FCA. BMS contends that the SAC does not meet the relevant pleading standards because it "does not detail a single plan, general conspiratorial objective, or unlawful agreement that BMS and Otsuka formed to defraud the government into paying false claims, and it does not allege any act in furtherance of an agreement." Doc. 60-1, at 14-15.

Otsuka first argues that the deficiencies in Relators' other FCA claims should lead to the dismissal of their § 3729(a)(1)(C) conspiracy claims. Otsuka next argues that the SAC does not allege

any facts plausibly suggesting that Otsuka entered into a conspiracy to violate the FCA. Doc. 61, at 18.

Relators respond that the SAC contains sufficient allegations for the Court to infer that Defendants had a plan to promote ABILIFY® off label, that they shared in the objective of that plan, and that they took steps in furtherance thereof. Doc. 65, at 35-38.

b. Analysis

The Southern District of Ohio has explicated the elements of a FCA-conspiracy claim:

To plead an FCA conspiracy, [Relators] must allege: "(1) that there was a single plan to get a false claim paid, (2) that the alleged coconspirators shared in the general conspiratorial objective to get a false claim paid, and (3) that one or more conspirators performed an overt act in furtherance of the conspiracy"

United States ex rel. Antoon v. Cleveland Clinic Found., 978 F. Supp. 2d 880, 897-98 (S.D. Ohio 2013) (quoting *United States ex rel. Judd v. Maloy*, No. 3:03-CV-241, 2006 WL 2583318, at *9 (S.D. Ohio Sept. 6, 2006)). For the reasons stated above related to Relators' § 3729(a)(1)(A) claims, the SAC does not allege with particularity a "single plan to get a false claim paid" between Otsuka and BMS.

Even accepting all factual allegations as true and drawing all reasonable inferences in their favor, Relators have alleged, at most, a single plan to get doctors to prescribe ABILIFY® for off-label uses. As discussed in detail above, the Court must make several assumptions in Relators' favor in order to construe the alleged fraudulent schemes as ones designed to induce the government to pay false claims.

The Court accordingly dismisses Relators' § 3720(a)(1)(C) claims.

B. FCA-Retaliation Claims against BMS

Relators each allege that BMS terminated their employment in violation of the anti-retaliation provision of the FCA, 31 U.S.C. § 3730(h). Doc. 52, ¶¶ 772-75. Importantly, the particularity rule does not apply to claims asserting violations of § 3730(h). See *Marlar*, 525 F.3d 439, 448-49 (applying only Rule 8).

1. Arguments

BMS argues that each Relator has failed to plead sufficient facts to state a FCA-retaliation claim, attacking Relators' pleading on all three elements of the cause of action. Doc. 60-1, at 15-18.

Relators respond that they have pled sufficient facts to survive a motion to dismiss on all three elements of their FCA-retaliation claims. Doc. 65, at 45-48.

2. Analysis

In order to state a claim for improper retaliation in violation of the FCA, a plaintiff must allege that (1) she was "engaged in a protected activity," (2) that her "employer knew that [she] engaged in the protected activity," and (3) that her "employer discharged . . . [her] as a result of the protected activity." *Marlar*, 525 F.3d at 449 (quoting *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 566 (6th Cir. 2003)) (internal quotation marks omitted). FCA-protected activity includes "lawful acts done by the employee . . . in furtherance of an action under this section or other efforts to stop

[one] or more violations of this subchapter.” 31 U.S.C. § 3730(h) (1) (emphasis added).⁷

Relators pled their FCA-retaliation claims in paragraphs 772 through 775 of the SAC. Those paragraphs state:

772. As alleged in above, Relators engaged in lawful acts in furtherance of efforts to stop one of more violations of 31 U.S.C. § 3729.

773. Because of Relators’ lawful acts, Relators were subjected to discrimination in the terms and conditions of their employment by BMS, including but not limited to their wrongful termination.

774. The Defendant’s discrimination against Relators was a violation of 31 U.S.C. § 3730(h).

775. As a consequence of Defendant’s violation of 31 U.S.C. § 3730(h), Relators suffered damages.

Doc. 52, ¶¶ 772-75. These allegations are nothing more than “a formulaic recitation of the elements of a cause of action,” *Twombly*, 550 U.S. at 555, and insufficient to satisfy Rule 8. In order for Relators’ FCA-retaliation claims to survive, then, other areas of the SAC must contain “enough facts to state [claims] to relief that [are] plausible on [their] face.” *Id.* at 570.

a. Relator Edwards

Paragraphs 305 through 311 of the SAC contain the allegations pertinent to Relator Edwards’s claim for retaliatory termination:

305. Relator Edwards experienced similar retaliatory conduct in Arizona. She began reporting her concerns about

⁷ The Court notes that the Fraud Enforcement Recovery Act of 2009 (“FERA”), Pub L. No. 111-21, 123 Stat. 1624, amended § 3730(h) to broaden the FCA’s definition of protected activity. See *Jones-McNamara v. Holzer Health Sys.*, No. 2:13-cv-616, 2014 WL 1671495, at *2-5 (S.D. Ohio Apr. 28, 2014) (stating that protected activity can “take the form of trying to stop the misconduct by external means (e.g., an FCA action) or by internal means (e.g., reporting violations up a company’s chain of command in an effort to effectuate institutional course correction)”); see also *Halasa v. ITT Educ. Servs.*, 690 F.3d 844, 847-48 (7th Cir. 2012).

potential compliance issues relating to inappropriate call targets for [ABILIFY®] on or about November 2, 2009.

306. In response, Ms. Edwards experienced negative attention and criticism of her performance, and her concerns were unaddressed.

307. Ms. Edwards and Mr. Ibanez had conferred over work email and work phones regarding their mutual concerns about inappropriate call targets and illegal promotion activities.

308. On or about April or May 2010, Mr. Ibanez also communicated to Ms. Edwards that he contacted the U.S. Attorney's Office in Boston, Massachusetts regarding Defendants' illegal practices.

309. Within days, on May 12, 2010, Ms. Edwards was informed she was being terminated. Like Mr. Ibanez, she was advised that they were investigating and had reached the conclusion that she had falsified sales calls.

310. These allegations are unsupported. However, Ms. Edwards was not given an opportunity to evaluate the allegations against her or rebut them. Rather, she was terminated.

311. Ms. Edwards's termination was in retaliation for her actions to stop violations of governing laws and regulations which resulted in false claims to government healthcare programs.

Doc. 52, ¶¶ 305-11.

BMS first contends that Relator Edwards has not alleged that she engaged in FCA-protected activity. This argument, however, is unavailing in light of the new protected-activity standard quoted above and discussed in footnote 6. Following the enactment of FERA, Relator Edwards needed only to report alleged misconduct up the chain of command in order to engage in FCA-protected activity. And the SAC plausibly alleges that Relator Edwards did just that.

BMS next contends that Relator Edwards has not alleged that BMS knew of the FCA-protected activity in which she engaged. But at the motion-to-dismiss stage, where the Court must accept as true all

factual allegations and draw all reasonable inferences in Relator Edwards's favor, the SAC sufficiently pleads that BMS knew of her FCA-protected activity. By reporting compliance issues up the chain of command, Relator Edwards put her superiors on notice. The fact that she subsequently experienced unjustified criticism of her performance further supports the reasonable inference that BMS knew that Relator Edwards had engaged in FCA-protected activity.

BMS finally contends that Relator Edwards has not alleged that BMS terminated her because she engaged in FCA-protected activity. But the fact that Relator Edwards was not given an opportunity to respond to the allegations of misconduct against her prior to her termination supports the reasonable inference that her termination was because of the FCA-protected activity in which she engaged.

The Court accordingly holds that Relator Edwards sufficiently pled her FCA-retaliation claim.

b. Relator Ibanez

Paragraphs 292 through 304 of the SAC contain the allegations pertinent to Relator Ibanez's claim for retaliatory termination:

292. On or about 2008, Relator Ibanez began raising compliance issues with his employer, objecting to inappropriate detailing and inappropriate call targets for the promotion of [ABILIFY®].

293. On or around December of 2009, for example, Relator Ibanez emailed the BMS legal department regarding a compliance concern from a paid BMS speaker, Dr. Neil Richtand at the University of Cincinnati Department of Psychiatry, regarding the promotion of [ABILIFY®] in the geriatric population.

294. Thereafter, in January 2010, Relator was contacted by the Gary Delvecchio, Director of Compliance for U.S. Pharmaceuticals, and participated in a conference call with Mr. Delvecchio and a lawyer for the Neuroscience

Division in which he discussed Dr. Richtand's concerns and his own concerns about patterns and practices of off-label promotions occurring with [ABILIFY®]. In follow-up to that conference call, Relator Ibanez participated in numerous phone calls and emails with Mr. Delvecchio regarding his concerns about false and misleading advertising/data presentations for both pediatric and geriatric use and unlawful/unsafe use of an antipsychotic such as [ABILIFY®] in the geriatric patient population. In one of these emails, Relator Ibanez reported that, in a meeting discussing how to increase sales to a high quintile office where only patients 18 and under are seen, an OBS rep stated: "The [ABILIFY®] message is not important . . . it's selling [] [ABILIFY®] in the physician's office not [sic] matter their specialty."

295. After raising his concerns, Mr. Ibanez began to receive negative performance reviews and experience negative attention and other retaliatory conduct in the terms and conditions of his employment.

296. By way of example, on April 12, 2010, Relator Ibanez was counseled by his superior for failing to "embrace teamwork" by objecting to inappropriate call targets. In that memorandum, Relator Ibanez's manager Keith Watters stated:

Embraces Teamwork: (Not Meeting)

Joe, since our 2009 restructuring, you have been very hesitant to embrace the new PFS targets. Since December 1, you have called me on a daily basis discussing your concern between PFS and OBS, and who should be calling on which targets. It seems as though you are very hesitant to work among your OBS colleagues with shared targets.

297. Mr. Watters also criticized that "Some of the emails you have sent to [BMS representative] Marty & [Otsuka representative] Alec are very direct and state that they should not be calling on these targets."

298. Mr. Watters' memorandum delivered other illegitimate criticisms of Relator Ibanez's performance.

299. After Relator Ibanez's concerns about illegal promotion activities went unaddressed, Relator contacted representatives of the United States to report this information.

300. The retaliatory conduct by BMS created a hostile work environment for Relator. The stress of this

environment forced Relator to go on a health leave on or about May 2010.

301. While on leave, Relator continued to discuss compliance issues with the BMS Human Resources ("HR") representatives.

302. In response, HR informed him that they had begun investigating him for fraudulent sales calls.

303. The information regarding these supposed fraudulent calls were fabricated. Instead of permitting Mr. Ibanez to evaluate or rebut this information, BMS notified him that he was being terminated on or about July 16, 2010. Mr. Ibanez received his last paycheck from BMS through July 23, 2010.

304. Mr. Ibanez was terminated in retaliation for his actions to stop violations of governing laws and regulations which resulted in false claims to government healthcare programs.

Doc. 52, ¶¶ 292-304.

Relator Ibanez has adequately pled FCA-protected activity. His allegations are more developed than Relator Edwards's and demonstrate that he had multiple conversations with executives at BMS concerning compliance issues related to improper call targets.

For the same reasons that Relator Edwards adequately pled BMS's knowledge and causation, Relator Ibanez has also so pled. His conversations with Watters show that Relator Ibanez's superiors were aware of his FCA-protected activity. Watters' subsequent negative performance reviews of Relator Ibanez support the reasonable inference that BMS was displeased with his conduct. And the fact that Relator Ibanez was terminated while on medical leave without an opportunity to respond to the allegations against him supports the reasonable inference that his termination was because of the FCA-protected activity in which he engaged.

The Court accordingly holds that Relator Ibanez also sufficiently pled his FCA-retaliation claim.

C. Relator Edwards' Arizona-Employment Claim against BMS

Relator Edwards alleges that BMS terminated her employment in violation of the Arizona Employment Protection Act ("AEPA"), Ariz. Rev. Stat. § 23-1501. Doc. 52, at ¶¶ 785-90.

1. Arguments

BMS argues that, before an employee may invoke the AEPA, the employee must have informed her employer of a reasonable belief that it was violating Arizona, rather than federal, law. It contends that the Court should dismiss this claim because Edwards has not so pled. Doc. 60-1, at 20.

Relator Edwards responds that she has adequately pled that BMS violated the AEPA in paragraphs 786 and 787 of the SAC. Doc. 65, at 45 n.27.

2. Analysis

The AEPA prohibits retaliation against an employee for

disclosure by the employee in a reasonable manner that the employee has information or a reasonable belief that the employer, or an employee of the employer, has violated, is violating or will violate the Constitution of Arizona or the statutes of this state to either the employer or a representative of the employer who the employee reasonably believes is in a managerial or supervisory position and has the authority to investigate the information provided by the employee and to take action to prevent further violations

Ariz. Rev. Stat. § 23-1501(c)(ii). Based on the statute's plain meaning, BMS is correct that Relator Edwards must have pled facts showing that she reasonably informed a superior at BMS that the company was in violation of Arizona law. See *Galati v. Am. W.*

Airlines, Inc., 69 P.3d 1011, 1015 (Ariz. Ct. App. 2003) (stating that no "statutory public policy exception exists for whistleblowing associated with federal regulations").

Relator Edwards cites to paragraphs 786 and 787 of the SAC in opposition to BMS's motion to dismiss. Those paragraphs state:

786. Relator Edwards, during the course of her employment, became aware that [BMS] was in violation of federal and comparable state laws in regard to its illegal promotion of the drug [ABILIFY®]. Such laws would include, without limitation, laws governing Medicaid coverage and Arizona statutes, A.R.S. § 36-2918 and § 36-2957.

787. Relator Edwards took steps to disclose to BMS management and other personnel of her concerns that its promotional campaigns were not compliant with healthcare laws, and to stop violations of the federal and state FCAs.

Doc. 52, ¶¶ 786-87.⁸

Although whether the SAC sufficiently states a claim that BMS violated the AEPA is a close question, Rule 8 does not demand "detailed factual allegations." *Twombly*, 550 U.S. at 570. Relator Edwards's allegations in the SAC amount to more than "labels and conclusions," "a formulaic recitation of the elements of a cause of action," *id.* at 555, or "an unadorned, the defendant-unlawfully-harmed-me accusation," *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The SAC identifies the Arizona laws at issue and then states that Relator Edwards informed BMS management of her belief that BMS was violating those Arizona laws. These allegations are enough to survive a motion to dismiss.

⁸ Although Relator Edwards does not cite to them in the footnote of her opposition to the motion to dismiss that discusses this claim, the Court notes that paragraphs 305 through 311 of the SAC -- quoted above -- also contain factual allegations that relate to her claim under the AEPA.

The Court accordingly holds that Relator Edwards sufficiently pled her Arizona-employment claim.

D. State-Law Claims under FCA Analogs against BMS and Otsuka

Relators also bring claims under several state statutes analogous to the FCA. California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Hawaii, Indiana, Iowa, Louisiana, Michigan, Minnesota, Montana, Nevada, New Jersey, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Washington, Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia enacted these statutes.⁹ Doc. 52 at ¶ 1.

Because the Court has dismissed Relators' FCA claims -- save for their retaliation claims -- it accordingly declines to exercise supplemental jurisdiction over these analogous state-law claims.

III. CONCLUSION

For the foregoing reasons, the Court grants Otsuka's motion to dismiss and grants in part and denies in part BMS's motion.

⁹ Relators also initially pled claims under the Maryland and New Mexico FCA analogs, but Relators abandoned those claims in response to arguments made in Otsuka's motion to dismiss. Doc. 65, at 43 n.26.

Therefore, having heard the parties and the Court being sufficiently advised,

IT IS ORDERED that:

(1) Otsuka's motion to dismiss, Doc. 61, be, and is hereby, **GRANTED**. As indicated above, Defendant Otsuka is hereby **DISMISSED**;

(2) Bristol-Myers Squibb's motion to dismiss, Doc. 60, be, and is hereby, **GRANTED IN PART AND DENIED IN PART**.

This 27th day of March, 2015.



Signed By:

William O. Bertelsman *WOB*

United States District Judge