UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

UNITED STATES OF AMERICA *ex rel.* JOSEPH IBANEZ AND JENNIFER DERRICK, *et al.*,	:	Civil Action No. 1:11-CV-029
	:	
	:	Judge William O. Bertelsman
Plaintiffs and Relators,	:	
v.	:	
BRISTOL-MYERS SQUIBB COMPANY And OTSUKA AMERICA PHARMACEUTICAL, INC.	:	
Defendants.	:	

DEFENDANT BRISTOL-MYERS SQUIBB COMPANY'S MOTION
TO DISMISS THE SECOND AMENDED COMPLAINT

Pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6) and the Local Rules of this Court, Defendant Bristol-Myers Squibb Company ("BMS") hereby moves to dismiss all claims against BMS set forth in the Second Amended Complaint filed by Relators Joseph Ibanez and Jennifer Edwards (formerly known as Jennifer Derrick) ("Relators"). BMS relies on its Memorandum of Law in Support of its Motion to Dismiss filed herewith and incorporated herein by reference. As grounds for its motion, BMS states the following:

Relators' federal law causes of action are subject to dismissal. Relators fail to plead the claims in Count I under the federal False Claims Act ("FCA") with the particularity required by Fed. R. Civ. P. 9(b) and Sixth Circuit precedent. Relators likewise fail to state a claim in Count XXXI for retaliation in violation of the FCA. Neither Relator alleges facts sufficient to demonstrate any of the three elements of an FCA retaliation claim, each of which is an independent reason to dismiss these claims under Rule 12(b)(6).

Once Relators' federal claims are dismissed, the Court should decline to exercise supplemental jurisdiction over the state law counts. Alternatively, Relators fail to plead the state-law FCA claims in Counts II through XXX with the particularity required by Rule 9(b) for the same reasons that the federal FCA claims fail in this regard. And their state-law employment claims in Counts XXXII and XXXIII fail to state a claim under Rule 12(b)(6).

WHEREFORE, BMS respectfully requests that the Court dismiss the Second Amended Complaint in its entirety with prejudice to Relators.

Dated: October 8, 2014

Respectfully submitted,

/s/ Glenn V. Whitaker

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CERTIFICATE OF SERVICE

I hereby certify that a true and exact copy of the foregoing was filed with the Clerk of Courts using the CM/ECF System, which will send notification electronically to all counsel of record this 8th day of October, 2014.

/s/ Glenn V. Whitaker

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DEFENDANT BRISTOL-MYERS SQUIBB COMPANY'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS THE SECOND AMENDED COMPLAINT

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INTRODUCTION

The Sixth Circuit has held—over and over—that when a relator files a False Claims Act complaint that alleges a fraud scheme without alleging details about any false claims, the complaint should be dismissed for failure to plead fraud with particularity. Despite amending their complaint for a second time, Relators Joseph Ibanez and Jennifer Edwards (formerly known as Jennifer Derrick) do not—and in fact, admit they cannot—meet this standard, which the Sixth Circuit has termed a "strict requirement" to survive dismissal. *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 472 (6th Cir. 2011) ("In *Bledsoe*, *Sanderson*, and *Marlar*, we imposed a strict requirement that relators identify actual false claims."). Relators' pleading deficiency is thus a fatal flaw under binding Sixth Circuit precedent.

Relators' Second Amended Complaint ("SAC") generally alleges that Bristol-Myers Squibb ("BMS") and Otsuka America Pharmaceutical, Inc. ("Otsuka") promoted the prescription drug Abilify to certain physicians for off-label uses and violated the Anti-Kickback Statute beginning in 2005.[1] The SAC contains no information about any false claims submitted to the government and provides no details of any falsity or misrepresentation in any claim. It is equally silent as to specifics about any allegedly unlawful kickbacks and describes only a handful of instances involving statements that arguably approach off-label marketing. Instead, Relators repeatedly make the unsubstantiated leap that BMS must have knowingly caused false claims to be submitted because it provided "call lists" to sales representatives that included doctors who treated pediatric or geriatric patients. Relators' broad "call list" assertions are based on the faulty premise that doctors with a pediatric specialty never treat adults, and doctors with a geriatric

[1] Relators filed suit making these allegations at a time that BMS was under a Corporate Integrity Agreement ("CIA") with the United States, which subjected BMS to heighten oversight by the government. The government nevertheless closed the CIA on time, did not criticize BMS's efforts to comply with the CIA, and did not intervene in this case.

specialty never treat adults or geriatric patients who suffer from schizophrenia, bipolar disorder, or major depressive disorder. Abilify is approved by the Food and Drug Administration ("FDA") for all of these uses and certain pediatric uses too. Even more problematic for Relators, the SAC comes nowhere close to providing the detail necessary to sustain their claim in Count I that BMS caused false claims to be submitted from 2005 to the present through nationwide kickback and off-label promotion schemes, or that BMS entered into a conspiracy to defraud the government through the submission of false claims. Count I should be dismissed.

The only other federal cause of action, Count XXXI, is equally deficient. This count asserts FCA retaliation claims, but fails to allege facts demonstrating that the Relators engaged in FCA-protected activity or that BMS knew about and terminated them because of that conduct. As for the state-law causes of action, the Court can either dismiss them for pleading deficiencies or decline to exercise supplemental jurisdiction over them. The state FCA counts (Counts II-XXX) fail under Rule 9(b), and their state employment counts (Counts XXXII-XXXIII) are for causes of action that no longer exist or require prerequisites that Relators failed to meet. For all of the above reasons, the SAC should be dismissed in its entirety with prejudice.

STATUTORY AND REGULATORY BACKGROUND

A. The False Claims Act.

The FCA prohibits submitting, or causing to be submitted, false or fraudulent claims to the federal government. 31 U.S.C. § 3729.[2] It permits private citizens, called "qui tam plaintiffs" or "relators" to file suit in the name of the government and themselves and to retain a portion of any money recovered from the law suit. *See id.* § 3730. FCA complaints are filed

[2] The FCA was amended multiple times during the time period covered by Relators' allegations (2005-2011). The SAC cites the current statutory provisions, including 31 U.S.C. § 3729(a)(1)(A), (B), (C), and (G), and because none of the amendments substantively affect the analysis in this motion, this motion does too unless otherwise noted.

under seal and served on the government so that the government can investigate and decide whether to intervene in the matter. 31 U.S.C. § 3730(b).

The focus of the statute is on false claims, not underlying unlawful conduct. It "does not create liability merely for a [claimant's] disregard of Government regulations or improper internal policies unless, as a result of such acts, the [claimant] makes a false claim." *U.S. ex rel. Marlar v. BWXT Y-12, LLC*, 525 F.3d 439, 448 (6th Cir. 2008) (citation and quotation marks omitted; alternations in original); *see also Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877-78 (6th Cir. 2006) ("[T]he statute attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment."). As a result, merely asserting that a defendant engaged in "illegal practices," like off-label marketing of a drug, does not state a claim unless the relator sufficiently establishes it caused false claims for federal payment to be submitted. *U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720 (1st Cir. 2007). If a complaint fails to allege with particularity the existence of false claims, it fails to state an FCA cause of action as a matter of law.

B. FDA Approval of Abilify.

FDA has approved Abilify to treat numerous conditions, as Relators acknowledge. For adults, it has been FDA approved since 2002 to treat schizophrenia, since 2004 to treat acute manic or mixed episodes associated with Bipolar I Disorder ("bipolar disorder"), and since 2007 as an adjunctive treatment for major depressive disorder ("MDD"). SAC ¶¶ 122-24. For children, it has been FDA approved since 2007 to treat schizophrenia in 13-to-17 year olds, since 2008 to treat bipolar disorder in 10-to-17 year olds, and since 2009 to treat irritability associated with autistic disorder in 6-to-17 year olds. *Id.* ¶¶ 125, 127-28.

When FDA concludes that there are important limitations of use for the drug, for example, differences in drug effectiveness in a subgroup like the elderly, these limitations are

noted in the "Indications and Usage" section of the FDA-approved product labeling. *See* 71 Fed. Reg. 3922, 3938 (Jan. 24, 2006) ("This information [Indications and Usage Highlights Section] would include major limitations of use (e.g., particular subsets of the populations, second line therapy status)"), 3944 ("FDA agrees that the 'Indications and Usage' section must discuss differences in drug effectiveness in subgroups for which there is substantial evidence for such differences"). There is not currently, and there never has been, a limitation concerning elderly patients in the "Indication and Usage" section of Abilify's product labeling.[3]

FDA regulates product labeling, not the practice of medicine. Once a drug is approved, doctors "may lawfully use or prescribe that product for uses or treatment regimens that are not included in the product's approved labeling." FDA, Office of Policy, *Guidance for Industry—Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Jan. 2009), *available at* http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm; *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (off-label use is "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine"); SAC ¶¶ 29, 38.

FACTUAL BACKGROUND

In September 2007, BMS entered into a CIA with the government stemming from

[3] All of the iterations of Abilify's product label since its initial approval in 2002 are publicly available on FDA's website by entering "Abilify" into the Drugs@FDA database, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. All atypical antipsychotics, including Abilify, warn health care professionals about the risk of increased mortality associated with treating elderly patients with dementia-related psychosis. *See* FDA, *Public Health Advisory* (Apr. 2005), *available at* http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm053171.htm. FDA recommends that "[p]hysicians who prescribe antipsychotics to elderly patients with dementia-related psychosis should discuss this risk of increased mortality with their patients, patients' families, and caregivers." FDA, *Information for Health Care Professionals* (June 2008), *available at* http://www.fda.gov/drugs/drugsafety/post marketdrugsafetyinformationforpatientsandproviders/ucm124830.htm#.

allegations that BMS had improperly promoted Abilify for pediatric use and to treat dementia-related psychosis in geriatric patients when neither was an FDA-approved use. SAC ¶¶ 89, 101.[4] Midway through the agreement's five-year term, Relators filed this action in the name of the government alleging that BMS had not complied with the agreement's obligations, particularly those relating to physician call lists, and had been continuously engaging in unlawful conduct since signing the agreement. D.E. 1-1, Compl. ¶¶ 2, 85 (Jan. 12, 2011). After Relators made these extensive allegations of non-compliance, the government closed BMS's CIA on time in December 2012. And it declined to intervene in this action in December 2013. D.E. 23, Government's Declination of Intervention (Dec. 17, 2013).

Relators were Abilify sales representatives at the time BMS entered into the CIA. They allege that BMS and Otsuka caused the submission of false claims to the federal health care programs from 2005-2011 by including physicians on Abilify call lists who treat children, adolescents, and geriatric patients and promoting Abilify off-label to those physicians. *E.g.*, SAC ¶¶ 2, 139, 140. They acknowledge, however, that Abilify was FDA-approved for various pediatric uses beginning in 2007 and for MDD in adults also in 2007. *Id.* ¶¶ 124-28. They also allege that BMS provided illegal inducements to induce doctors to prescribe Abilify. *Id.* ¶ 249.

The SAC does not contain any allegations about any Abilify claim that was submitted to a federal health care program for either an off-label, non-reimbursable use of the drug[5] or as a result of any unlawful remuneration. Nor does it contain any allegations about any claims for

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[4] BMS denied these allegations in the course of the settlement.

[5] Medicaid, Medicare Part D, and other federal health care programs generally cover a drug when it is used for a "medically accepted indication," which includes both uses that are FDA approved and uses that are supported by a listing in one of the drug compendia identified in the Medicaid statute. 42 U.S.C. §§ 1396r-8(d)(1)(B)(i), (k)(6), (g)(1)(B)(i); 42 U.S.C. § 1395w-102(e); *see also* SAC ¶¶ 53-54, 68, 77. Claims that are for reimbursable uses of a drug are not false claims. *E.g.*, *U.S. ex rel. Nathan v. Takeda*, 2011 WL 2182422, at *3 (E.D. Va. May 4, 2011); *U.S. ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 45 (D. Mass. 2001).

payment that were submitted to the government for either an off-label, non-reimbursable use of Abilify or as a result of any unlawful remuneration. The SAC acknowledges that Relators lack this information. *Id.* ¶¶ 23-24. Relators nevertheless assert, in general terms, that BMS and Otsuka knew that the "natural and probable consequence" of their conduct was the submission of claims to government payors for non-payable uses of Abilify nationwide. *Id.* ¶¶ 259, 269, 278.

Ibanez and Edwards allege that BMS terminated them, wrongly, for falsifying sales calls. Specifically, Ibanez alleges that after he reported compliance issues to BMS and objected to inappropriate call targets in 2008 through January 2010, he was wrongly terminated for fraudulent sales calls on July 16, 2010. *Id.* ¶¶ 292-304. Edwards alleges that she reported a concern about inappropriate call targets in November 2009 and was wrongly terminated in May 2010 for having falsified sales calls. *Id.* ¶¶ 305, 309.

Relators assert 33 causes of action: Count I alleges a violation of the FCA, 31 U.S.C. §§ 3729(a)(1)(A)-(C), (G); Counts II-XXX allege violations of state FCA statutes; Count XXXI alleges violations of the FCA's retaliation provision, 31 U.S.C. §3730(h); and Counts XXXII-XXXIII allege violations of Ohio and Arizona state employment law. After this action was filed under seal, the United States, and all of the States and the District of Columbia, declined to intervene. *See* D.E. 3. The First Amended Complaint was unsealed and served on Defendants in May 2014. Shortly after that, Relators filed the SAC. This motion to dismiss followed.

ARGUMENT

I. COUNT I SHOULD BE DISMISSED FOR FAILURE TO PLEAD FRAUD WITH PARTICULARITY AS REQUIRED BY RULE 9(b).

A. To satisfy Rule 9(b), a relator must allege details of false claims—not just details of a "fraud scheme."

Rule 9(b)'s heightened pleading standard applies to FCA causes of action. *Chesbrough*, 655 F.3d at 466. "At a minimum, Rule 9(b) requires that the plaintiff specify the 'who, what,

when, where, and how' of the alleged fraud." *Sanderson*, 447 F.3d at 877 (citation omitted). And because the alleged fraud that the FCA makes actionable is the submission of *false claims* to the government, the Sixth Circuit has repeatedly held that a relator alleging a violation of the "false claims" provisions—§ 3729(a)(1)(A) and (B)—cannot simply describe a course of conduct and then assert that false claims likely exist. To comply with Rule 9(b) and avoid dismissal, relators must satisfy the "strict requirement" that they allege details of actual false claims. *Chesbrough*, 655 F.3d at 472.

For example, in *Sanderson*, the Sixth Circuit held that a hospital-employee relator did not satisfy Rule 9(b) in alleging an FCA violation based on false hospital cost reports; even though he detailed a fraudulent accounting methodology that his employer allegedly used, he did not plead details about any false claims. 447 F.3d at 877 (holding that a complaint that "sets out at some length a description of the accounting methodology" alleged to be prohibited and "even identif[ies] some of the specific loans" was subject to dismissal because "[u]nfortunately for the plaintiff, there is no specific information about the filing of the claims themselves").

Similarly, in *U.S. ex rel. Bledsoe v. Community Health Systems, Inc.*, 501 F.3d 493, 505 (6th Cir. 2007), the Sixth Circuit held that an employee-relator who alleged that he encountered upcoding and other billing irregularities while working for the defendant did not plead an FCA cause of action with particularity because he did not detail any false claims that were submitted to the government as a result of that irregularity. As the appeals court explained, "pleading an actual false claim with particularity is an indispensable element of a complaint that alleges an FCA violation in compliance with Rule 9(b)." *Id.* at 505. The Sixth Circuit specifically rejected the relator's argument that he only needed to allege a "false scheme, rather than specific false claims," concluding that such a standard would be irreconcilable with the language of Rule 9(b)

and inconsistent with the FCA and Sixth Circuit precedent. *Id.* at 504, 505 n.13.

Finally, in *Chesbrough*, the Sixth Circuit affirmed the dismissal of an FCA action alleging that a medical services company was submitting claims to the government for worthless services. The court again held the relators did not meet the Rule 9(b) standard because they had not identified any actual false claims that allegedly resulted from the scheme. Although they had detailed a fraud scheme and provided patient, physician, and technician names and dates of service, they could not connect that scheme to any specific claims submitted to the government. 655 F.3d at 464, 468-69. *Accord Marlar*, 525 F.3d at 446 (holding that an employee-relator failed to plead with particularity that her employer had violated the FCA by submitting false reports of workplace-related injuries to the government because she had no personal knowledge of any false claim being submitted and failed to allege any "concrete facts" showing that such claims were submitted).

B. Relators' FCA cause of action does not meet the Sixth Circuit standard for Rule 9(b) because Relators do not allege details of false claims.

Like the relators in *Chesbrough*, *Sanderson*, *Bledsoe*, and *Marlar*, Relators' Count I does not plead an FCA violation with the particularity required under Sixth Circuit precedent. It is deficiently pled for the same reasons the complaints were in those cases: it broadly alleges a fraudulent scheme—that BMS marketed Abilify off-label by retaining doctors who treat pediatric and geriatric patients on call lists and by paying kickbacks to encourage doctors to prescribe Abilify—but does not allege any details about any purportedly false claims submitted to the federal health care programs resulting from that scheme.

1. Count I is deficiently pled to the extent it is premised on false claims resulting from unlawful remuneration.

Despite broadly asserting that BMS engaged in a fraudulent scheme of paying kickbacks to doctors, in violation of the Anti-Kickback Statute, Relators make no allegations about any

false claims that resulted from those kickbacks. SAC ¶¶ 258, 269, 277.[6] In fact, only ten paragraphs in the SAC purport to describe this scheme. *Id.* ¶¶ 249-258. At best, those paragraphs identify three doctors in Ohio as being on a company speaker list—only one of whom BMS is alleged to have actually engaged for a speaker program—and make some generic assertions that physicians were offered "paid lunches" and "expensive dinners." *Id.* They also mention two doctors in Ohio who were removed from a company speaker list; *being removed* from a speaker list, however, cannot possibly be payment of an unlawful kickback. *Id.* Based on those sparse allegations, Relators contend that there was a nationwide, multi-year scheme of paying unlawful kickbacks to doctors to induce them to prescribe Abilify for federal health care program patients and that it caused (entirely unidentified) false claims to be submitted for Abilify.

That is a far cry from pleading the " 'who, what, when, where, and how' " of an FCA violation based on unlawful remuneration. *Sanderson*, 447 F.3d at 877. Count I does not plead a *scheme* with particularity because it fails to provide details of any "paid lunch," or "expensive dinner," or any other allegedly unlawful remuneration, and it certainly does not plead any *false claims* that supposedly resulted from that scheme. In fact, even for the three doctors that the SAC identifies as on a speaker list, it does not allege that any of them treated federal health care program patients in their practice, prescribed Abilify for a federal program patient, were paid for speaking presentations they did not deliver, were paid more than fair market value for their services, or were paid for an inappropriate number of engagements—despite the fact that these

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[6] The Anti-Kickback Statute makes it illegal to pay a kickback to induce someone to furnish or arrange "any item or service for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7(b)(2). The statute was amended in 2010 to state that "a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the FCA]." Pub. L. No. 111-148, § 6402(f), 124 Stat. 119 (2010).

are the kinds of details that would lend some substance to what are otherwise wholly conclusory and speculative assertions.

As in *Sanderson*, "what is alleged in the complaint before [the Court] is limited to speculation and unsupported conclusion:" that BMS provided some form of unlawful remuneration on some unidentified dates in some unidentified way to unidentified physicians all over the country, and those unidentified physicians then wrote prescriptions for unidentified federal health care program participants on unidentified dates, and those unidentified individuals then filled the prescriptions at unidentified pharmacies that submitted unidentified claims for reimbursement to the federal government. 447 F.3d at 878. Rule 9(b) requires more. *See Bledsoe*, 501 F.3d at 514 ("Relator does not identify any specific instance where Medicare or Medicaid was wrongfully billed. Relator's failure to allege false claims with particularity is fatal to these allegations in his [complaint]."). Count I should be dismissed to the extent it is premised on an unlawful kickback scheme and resulting false claims.

2. Count I is deficiently pled to the extent it is premised on false claims resulting from off-label marketing.

Relators' allegations of false claims stemming from off-label marketing are spread across many more pages of the SAC, but they are just as substantively lacking. In this aspect of their FCA claim, too, Relators fail to plead both a fraud scheme and whether any false claims resulted with specificity. First, the shortcoming as to the scheme: The SAC relies on broad, generic statements about off-label marketing, but ultimately details only a small handful of instances in which a BMS representative made a statement that might arguably even approach off-label promotion. These few instances fail to plead with particularity the specific details of a corporate wide scheme of inappropriately promoting Abilify off-label. To be sure, Relators allege that BMS call lists included doctors at nursing homes and who treat children and adolescents. But

that does not amount to a "fraud scheme."[7]

Promotion of Abilify for geriatric use was never per se improper (contrary to Relators' suggestion, SAC ¶ 142) because there has never been a limitation concerning elderly patients in the "Indications and Usage" section of its product label. *Supra* 3-4. In addition, patients at nursing homes frequently struggle with depression, including MDD, and may also have schizophrenia and bipolar disorder. *E.g.*, SAC ¶ 202 (noting that a "small" percentage of nursing home patients have schizophrenia or bipolar disorder); Geriatric Mental Health Foundation, *Late Life Depression: A Fact Sheet* (noting that depression affects over 6 million Americans over age 65).[8] Similarly, doctors who treat juvenile patients frequently treat adults too. *See, e.g.*, Lisa Faille, Ph.D. et. al., *Child and Adolescent Psychiatry, The Next 10 Years*, Psychiatric Times (July 1, 2007) ("[M]any . . . child and adolescent specialists also treat adult patients . . . ."). On-label messages are not transformed into fraud just because of a doctor's specialty or who a doctor might be treating at a particular point in time.

The shortcomings as to the lack of detail about false claims are even more problematic for Relators. The Sixth Circuit law is clear that "pleading an actual false claim with particularity is an indispensable element of a complaint that alleges an FCA violation in compliance with Rule 9(b)." *Bledsoe*, 501 F.3d at 505. And courts all around the country agree that "[m]erely alleging off-label marketing . . . is not sufficient, without more, to plead a false claims act violation." *U.S. ex rel. Rost v. Pfizer*, 253 F.R.D. 11, 16-17 (D. Mass. 2008). In *Rost*, for instance, the First Circuit held that a complaint was deficiently pled even though it "amply

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[7] Nothing in the CIA precluded BMS from promoting Abilify to pediatric or geriatric specialists; and even if it had, a violation of the CIA would be a contractual violation not actionable through the FCA. *E.g., U.S. ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co.*, 612 F.3d 724, 734 (4th Cir. 2010) ("garden-variety issues of contractual performance" are not actionable under FCA).

[8] *Available at* http://www.gmhfonline.org/gmhf/consumer/factsheets/depression_factsheet.html.

describe[d] illegal practices in which [the defendant] allegedly engaged" because it did not plead facts showing that false claims were submitted. *U.S. ex rel. Rost v. Pfizer, Inc.* 507 F.3d 720, 733 (1st Cir. 2007). Thus, even though the defendant had entered into a deferred prosecution agreement with the government as to a criminal information charging the company with off-label promotion of its drug, *id.* at 725, by failing to plead details of any false claims, the relator failed to plead an FCA cause of action with particularity. *Id.* at 733. As the court explained, "[i]t may well be that doctors who prescribed [the drug] for off-label uses as a result of [the company's] illegal marketing of the drug withstood the temptation and did not seek federal reimbursement, and neither did their patients," or that the drug was prescribed "for off-label uses only where the patients paid for it themselves or when the patients' private insurers paid for it." *Id.*[9]

The *Rost* analysis is particularly applicable given the Sixth Circuit's holding that pleading specific false claims is an indispensable element of an FCA action. *See Chesbrough*, 655 F.3d at 472; *Marlar*, 525 F.3d at 446; *Bledsoe*, 501 F.3d at 505; *Sanderson*, 447 F.3d at 878. These cases make clear, again and again, that the Sixth Circuit's "strict requirement" that relators identify actual false claims is just that: a strict requirement. *Chesbrough*, 655 F.3d at 472.

Even if Relators take the position that they could not include all of the false claims at issue, given that they are alleging a nationwide scheme covering multiple years, the Sixth Circuit has defined how the strict requirement applies under those circumstances. The complaint must "provide[] examples of specific false claims submitted to the government pursuant to that scheme." *Bledsoe*, 501 F.3d at 505. The SAC does not do this, or even attempt to do this. It

[9] *Accord U.S. ex rel. Worsfold v. Pfizer Inc.*, 2013 WL 6195790, at *7 (D. Mass. Nov. 22, 2013) (dismissing FCA claim generally alleging that the defendant promoted certain drugs off-label because the relator did not plead details about any false claims resulting from off-label promotion); *U.S. ex rel. Polansky v. Pfizer, Inc.*, 2009 WL 1456582, at *6 (E.D.N.Y. 2009) (dismissing FCA complaint premised on alleged off-label-marketing that did not sufficiently allege resulting false claims); *U.S. ex rel. West v. Ortho-McNeil Pharm., Inc.*, 2007 WL 2091185, at *4-5 (N.D. Ill. July 20, 2007) (same).

does not identify any physician who wrote a prescription for a federal health care program participant to use Abilify off-label as a result of BMS's promotion for that off-label use.[10] Along with not identifying any doctors or patients, or off-label statements made to the unnamed doctors, it does not identify any details of any claim, such as *who* submitted it, *what* the contents were, *what* federal healthcare program received the claim, or *when* or *where* or *how* any such claim was submitted to the government.

Instead, Relators only make general assertions "on information and belief" that BMS caused false claims to be submitted, SAC ¶ 25; that "the natural, probable, and foreseeable consequence" of BMS's off-label promotion was claims to government health care programs for non-covered uses, SAC ¶¶ 259; and that false claims to these programs were the "direct, proximate, and intended result" of BMS's actions, SAC ¶ 290. But false claims are " 'the *sine qua non* of a False Claims Act violation,' " *Sanderson*, 447 F3d at 878 (citation omitted), and accordingly, particularized details about such claims are "an indispensable element of a complaint that alleges an FCA violation in compliance with Rule 9(b)." *Bledsoe*, 501 F.3d at 505. Relators cannot satisfy Rule 9(b)'s standards based only on a contention " 'that claims requesting illegal payments *must have been* submitted, *were likely* submitted or *should have been* submitted to the Government.' " *Sanderson*, 447 F.3d at 877 (citation omitted; emphases added). *Accord Polansky*, 2009 WL 1456582, at *5 ("[A] relator cannot circumscribe the Rule 9(b) pleading requirements by alleging a fraudulent scheme in detail and concluding, that as a result of the fraudulent scheme, false claims must have been submitted.").

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[10] Offering an allegation about the total amount of Medicaid claims for Abilify from 2005-2013 (SAC ¶ 285) is unavailing given the lack of allegations about any specific or representative non-reimbursable claim that is included in that total. *See U.S. ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 506 (6th Cir. 2008) (affirming dismissal of FCA action that "d[id] not identify any individual representative claim for payment made" to the government and just estimated "the approximate value" of the defendants' contracts with the government).

The SAC admits that this is what Relators seek here. In a section titled "Evidentiary Basis For Rule 9(B), Fed. R. Civ. P. Allegations," Relators state that they "lack complete details" about their allegations, "do not have access to all of the information regarding the claims for payment," and are offering their assertions about false claims "on information and belief." SAC ¶¶ 22, 24, 25. Although the Sixth Circuit has not ruled out the possibility of relaxing the 9(b) requirements in certain circumstances, it has repeatedly rejected requests to do so where, as is the case here, relators lack any personal knowledge about false claims. *Chesbrough*, 655 F.3d at 472; *Bledsoe*, 501 F.3d at 504 n.12; *see also Hendricks v. Bronson Methodist Hosp., Inc.*, 2014 WL 3752917, at *6 (W.D. Mich. July 30, 2014); *U.S. ex rel. McMullen v. Ascension Health*, 2013 WL 6073549, at *4 (M.D. Tenn. Nov. 18, 2013); *U.S. ex rel. Antoon v. Cleveland Clinic Found.*, 978 F. Supp. 2d 880, 897 (S.D. Ohio 2013); *U.S. ex rel. Dennis v. Health Mgmt. Assoc., Inc.*, 2013 WL 146048, at *16 (M.D. Tenn. Jan. 14, 2013). To the extent Relators intend to make a similar request, it should be rejected here for the same reasons it was in those cases.[11]

C. Relators do not plead a FCA conspiracy with particularity either.

Relators' FCA-conspiracy allegations are deficiently pled under Rule 9(b). *See Dennis*, 2013 WL 146048, at *17 (Rule 9(b) applies to FCA-conspiracy claims). As this Court has held, "[t]o plead an FCA conspiracy, a relator 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

[11] Besides making allegations about false claims under 31 U.S.C. § 3729(a)(1)(A) and (B), Count I asserts that BMS received "overpayments" from federal health care programs and failed to return the money in violation of § 3729(a)(1)(G). SAC ¶¶ 291, 325. If Relators intended to raise "overpayment" as a separate issue, it too is deficiently pled under Rule 9(b). The SAC does not provide any details about any overpayment that BMS received. Without at least alleging the details of a specific allegation, this claim is also subject to dismissal. *U.S. ex rel. Winkler v. BAE Sys., Inc.*, 957 F. Supp. 2d 856, 876-77 (E. D. Mich. 2013) ("No effort to develop the factual basis for this claim, which requires at least an allegation that the defendant owed the government a debt at the time of the alleged false statement, appears in the Complaint.").

furtherance of the conspiracy to get a false claim paid." *Antoon*, 978 F. Supp. 2d at 898; *see also U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 193 (5th Cir. 2009) (relator must plead with particularity both the existence of an unlawful agreement to get a false or fraudulent claim paid by the government and "at least one act performed in furtherance of that agreement"). Relators' pleading falls well short. The SAC 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. Further, to the extent that the FCA claims in Count I are not actionable for the reasons identified above, neither is the FCA conspiracy claim. *E.g., U.S. ex rel. Vigil v. Nelnet, Inc.*, 639 F.3d 791, 801 (8th Cir. 2011) (complaint that fails to state claims under § 3729(a)(1)(A) and (B) "likewise fails to state an actionable conspiracy claim under [§ 3729(a)(1)(C)]"); *U.S. ex rel. Winkler*, 957 F. Supp. 2d at 876. Because Relators fail to plead facts supporting each element of an FCA-conspiracy claim with particularity, that aspect of Count I should be dismissed.

II. COUNT XXXI SHOULD BE DISMISSED BECAUSE EDWARDS AND IBANEZ FAIL TO STATE A CLAIM FOR FCA RETALIATION UNDER § 3730(h).

The SAC's only other federal cause of action is Count XXXI, which alleges that BMS violated the FCA's retaliation provision. That provision prohibits terminating an employee "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). To plausibly plead a retaliation claim, Edwards and Ibanez must allege that: (1) they engaged in protected activity; (2) BMS knew that they had engaged in protected activity; and (3) BMS terminated them "because of" that protected activity.[12] *Marlar*, 525 F.3d at 449; *see also Univ.*

[12] Although this provision was amended in 2009, the elements of a § 3730(h) claim remain the same before and after this amendment. *See U.S. ex rel. Nowak v. Medtronic, Inc.*, 2011 WL

of Texas SW Med. Ctr. v. Nassar, -- U.S. --, 133 S. Ct. 2517 (2013) (where federal employment statute uses the phrase "because of," it requires a showing of "but-for" causation); *U.S. ex rel. Schweizer v. Oce N. Am.*, 956 F. Supp. 2d 1, 13-14 (D.D.C. 2013) (applying *Nassar* to FCA retaliation claim). None of these three prongs are satisfied here, for either Ibanez or Edwards.

A. Edwards fails to plead facts supporting each element of the claim.

Edwards fails to satisfy each of the three prongs of an FCA retaliation claim. Her only allegations are that she "began reporting her concerns about potential compliance issues relating to inappropriate call targets for Abilify" in November 2009, SAC ¶ 305, and that she conferred with Ibanez via phone and email about their "mutual concerns about inappropriate call targets and illegal promotion activities." *Id.* ¶ 307. These statements do not allege protected activity. "For the first prong, the protected activity must relate to 'exposing fraud' or 'involvement with a false claims disclosure.' If the protected activity is internal reporting, the reports 'must allege fraud on the government.' It is not enough to assert mere regulatory violations." *U.S. ex rel. Howard v. Lockheed Martin Corp.*, -- F. Supp. 2d --, 2014 WL 1612165, at *29 (S.D. Ohio Mar. 25, 2014) (internal citations to *McKenzie v. BellSouth Tel., Inc.*, 219 F.3d 508 (6th Cir. 2000) omitted)); *accord Marlar*, 525 F.3d at 449. In other words, to be protected activity, "the internal reporting of wrongdoing must establish some nexus to the FCA." *McKenzie*, 219 F.3d at 517.

Edwards does not allege that she made any internal reports expressing concern about fraud on the government or false claims; her reports, by her own allegation, were about what doctors were listed on call lists. That alleges, at most, concerns about regulatory compliance, which is not FCA protected activity. *See, e.g.*, *Watts v. Lyon Cty. Ambulance Serv.*, 2013 WL 557274, at *8 (W.D. Ky. Feb. 12, 2013) ("Merely urging compliance is similarly not enough.");

3208007, at *23 (D. Mass. July 27, 2011) (which version of the statute applies makes "no substantive difference" because the two elements of the claim are "essentially the same").

U.S. ex rel. New Mexico v. Deming Hosp. Corp., 992 F. Supp. 2d 1137, 1165 (D.N.M. 2013) (dismissing FCA retaliation claim where employees "were concerned exclusively with regulatory violations and patient care concerns"); *Frett v. Howard Univ.*, 2014 WL 939499, at *7 (D.D.C. Mar. 10, 2014) (employee failed to allege protected activity through allegation that he notified the defendant about a compliance issue with ERISA requirements).

Edwards's FCA retaliation claim also fails because she does not allege that BMS knew of any protected conduct or terminated her as a result. "While the notice need not explicitly characterize a plaintiff's concerns as involving false claims against the government, there must be some reason for the employer to suspect that the plaintiff was contemplating a *qui tam* action or was assisting the government in an FCA investigation." *Kachaylo v. Brookfield Tp. Bd. of Tr.*, 778 F. Supp. 2d 814, 820 (N.D. Ohio 2011). Nothing Edwards alleges would have given BMS reason to suspect she was contemplating or assisting in a *qui tam* action. She does not allege to whom she reported any concerns about call targets, and she does not allege that BMS knew she was "confer[ing]" with Ibanez about "mutual concerns." SAC ¶ 307. And even if she had complained to BMS about call lists, "[m]erely grumbling to the employer about . . . regulatory violations does not satisfy the [scienter] requirement." *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 567-68 (6th Cir. 2003) (citation omitted); *see also U.S. ex rel. New Mexico*, 992 F. Supp. 2d at 1165 (finding employer lacked knowledge of protected activity where nothing in employee's allegations "suggests that she raised any concerns with Defendants regarding fraudulent billing, false claims, or any other activity that might be covered under the FCA"). The SAC does not plausibly allege sufficient notice to BMS for an FCA retaliation claim.

As for the third requirement, there can be no plausible allegation that BMS acted with retaliatory intent when Edwards lacks an allegation of protected activity or BMS's knowledge of

such activity. *E.g., U.S. ex rel. Karvelas v. Melrose Wakefield Hosp.*, 360 F.3d 220, 237 n.22 (1st Cir. 2004) (when relator cannot show he engaged in protected conduct, he "cannot meet the second and third elements of an FCA retaliation claim, as those depend upon the first").

B. Ibanez also fails to plead facts supporting each element of the claim.

Ibanez's retaliation claim faces the same pleading deficiencies. Although he alleges a wider variety of complaints about regulatory compliance than Edwards does, all of those complaints express concern with regulatory compliance—not fraud on the government. SAC ¶¶ 292-294, 299 (alleging that Ibanez raised "compliance issues" about "inappropriate detailing and inappropriate call targets," "the promotion of Abilify in the geriatric population," "off-label promotions," "false and misleading advertising/data presentations," "unlawful/unsafe use of an antipsychotic such as Abilify in the geriatric patient population," and "illegal promotion activities"). Even his alleged contact with the United States was to report information regarding his "concerns about illegal promotion activities"—not to report fraud on the government. SAC ¶ 299. None of these (or any other allegations in the SAC) are sufficient to plead protected FCA activity—i.e., activity to further an FCA action or stop fraud on the government.

Ibanez likewise does not plead that BMS knew he had contacted the government or was contemplating or assisting in a *qui tam* action. SAC ¶ 299; *Kachaylo*, 778 F. Supp. 2d at 820. He does not contend that he told BMS about it or that BMS learned about it in some other way. His own allegation is that he was terminated "for his actions to stop violations of governing laws and regulations" that he now says "resulted in false claims." SAC ¶ 304. To state an FCA retaliation claim, he must allege that he was terminated *because of* protected activity, not for complaining about something that he now asserts "resulted in false claims."

III. RELATORS' STATE LAW CLAIMS SHOULD BE DISMISSED.

Relators also assert various state FCA and employment claims that can be disposed of in various ways. Most simply, if the Court dismisses the federal claims, it can decline to exercise supplemental jurisdiction over the state claims. *Pinney Dock & Transp. Co. v. Penn Cent. Corp.*, 196 F.3d 617, 621 (6th Cir. 1999) (discussing "strong presumption" that state claims should be dismissed if federal claims are dismissed). The state-law claims are also deficiently pled.

State FCA claims. Counts II through XXX contend that various state FCA statutes were violated. Because these claims must be pled with particularity under Rule 9(b) like federal FCA claims, these state claims are likewise deficiently pled. *See, e.g.*, *Dennis*, 2013 WL 146048, at *6 (because federal FCA claims were dismissed under Rule 9(b), "the analogous claims under Tennessee law are likewise subject to dismissal").[13] BMS incorporates by reference the additional deficiencies that warrant dismissal identified by Otsuka in its memorandum of law.

Ibanez's Ohio-law employment claims. Count XXXII alleges that Ibanez was terminated in violation of an Ohio whistleblower statute and Ohio's common law public policy. It states a claim for neither. The whistleblower Statute, Ohio Rev. Code § 4113.52, "require[s] strict compliance" with its prerequisites, including informing the employer orally and through a written report of the details of a violation of state or federal law. *Ross v. Teleperformance USA, Inc.*, 2013 WL 6158021, at *16 (S.D. Ohio Nov. 25, 2013). Ibanez's generic allegation about expressing "concerns" relating to the promotion of Abilify does not meet this standard. SAC ¶ 294; *Dobrski v. Ford Motor Co.*, 2013 WL 1303786, at *4 (N.D. Ohio Mar. 28, 2013) (written report must "convey sufficient detail to identify or describe a violation rising to the level of a criminal offense, as required by the plain language of the whistleblower statute"). And his

[13] In fact, they are even more deficiently pled under Rule 9(b) because the SAC asserts essentially no allegations *at all* about any of the state claims. *E.g.*, SAC ¶¶ 1, 10, 16 (only mentions of Colorado in the SAC).

common law claim fails because it requires "identify[ing] a source of public policy separate from the public policy embodied in R.C. 4113.52," the Whistleblower Statute. *Celeste v. Wiseco Piston*, 2005 WL 3528877, at *3 (Ohio App. Dec. 23, 2005) (citations omitted). Ibanez, however, relies on the public policy protecting whistleblowers "manifested in Ohio Rev. Code Ann. § 4113.52." SAC ¶ 782. He does not identify any "clear public policy" manifested in some other statute that was jeopardized by his termination. As a result, his claim fails. *Lesko v. Riverside Methodist Hosp.*, 2005 WL 1482549, at *9 (Ohio App. June 23, 2005).

Edwards' Arizona-law employment claims. Edwards's employment claims in Count XXXIII also fail to state a claim. To state a claim under the Arizona Employment Protection Act ("AEPA"), A.R.S. §23-1501, an employee must have informed her employer of a reasonable belief that it was violating *Arizona* law. *Gorney v. Ariz. Bd. of Regents*, 2013 WL 5348304, at *7 (D. Ariz. Sept. 24, 2013) ("there is no statutory public policy exception for whistleblowing associated with federal regulations," and so "A.R.S. § 23-1501 does not support Plaintiff's claim for wrongful termination based on his disclosures related to a violation of federal law"); *Galati v. Am. West Airlines, Inc.*, 205 Ariz. 290, 294 (App. Div. 2003) (same). Edwards does not allege that she did so. As for her "common law" claim, the Arizona Court of Appeals has held that no common law public policy cause of action survived the enactment of AEPA. *Larson v. United Natural Foods West Inc.*, 2014 WL 575950, at *3 (Ariz. App. Feb. 13, 2014) (AEPA "displac[es] the common law" and governs employment claims " 'exclusively' ") (citation omitted).

CONCLUSION

For the foregoing reasons, the Court should grant BMS's motion and dismiss the SAC in its entirety with prejudice to Relators.

Dated: October 8, 2014

Respectfully submitted,

/s/ Glenn V. Whitaker

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CERTIFICATE OF SERVICE

I hereby certify that a true and exact copy of the foregoing was filed with the Clerk of Courts using the CM/ECF System, which will send notification electronically to all counsel of record this 8th day of October, 2014.

/s/ Glenn V. Whitaker