No. 17-

IN THE

Supreme Court of the United States

UNITED STATES OF AMERICA EX REL. JOSEPH IBANEZ AND JENNIFER EDWARDS,

Petitioners,

v.

BRISTOL-MYERS SQUIBB COMPANY; OTSUKA AMERICA PHARMACEUTICAL, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

JENNIFER M. VERKAMP
FREDERICK M. MORGAN
CHANDRA NAPORA
MORGAN VERKAMP LLC
35 East 7th Street,
Suite 600
Cincinnati, OH 45202

DAVID J. CHIZEWER
Counsel of Record
WILLIAM C. MEYERS
EMILY D. GILMAN
GOLDBERG KOHN LTD.
55 East Monroe, Suite 3300
Chicago, IL 60603
(312) 201-4000
david.chizewer@goldbergkohn.com

Counsel for Petitioners

April 3, 2018

279867

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

QUESTION PRESENTED

The False Claims Act was carefully crafted by Congress to allow private whistleblowers, or relators, to assist the United States government in recovering monies fraudulently billed to the government. The Act allows for recovery of treble damages from any person who presents, or causes a third party to present, a false or fraudulent claim to the United States government, or who has created a false statement material to the submission of a false or fraudulent claim. Like other actions sounding in fraud, parties pleading FCA cases must "state with particularity the circumstances constituting fraud" under Federal Rule of Civil Procedure 9(b). The question presented, currently unanswered by the patchwork of conflicting and confusing standards in the circuit courts, is:

Can a False Claims Act relator satisfy the pleading requirements of Federal Rule of Civil Procedure 9(b) by alleging facts from which a reasonable person would deem the inference that a false claim was submitted at least as compelling as any opposing inference?

PARTIES TO THE PROCEEDING

Petitioners, and Plaintiffs-Appellants below, are Joseph Ibanez and Jennifer Edwards.

Respondents, and Defendants-Appellees below, are the Bristol-Myers Squibb Company and Otsuka America Pharmaceutical, Inc.

TABLE OF CONTENTS

Table of Contents

TABLE OF APPENDICES

TABLE OF CITED AUTHORITIES

Page

CASES

Page

Page

Page

Page

STATUTES AND OTHER AUTHORITIES

Cited Authorities

PETITION FOR WRIT OF CERTIORARI

The False Claims Act ("FCA") is the most important tool for combating fraud against the federal government, which has grown rampantly. The scale of federal contracting, and healthcare and defense contracting in particular, has provided ample opportunities for individuals and companies to take advantage of the public trust. Private whistleblowers, or relators, are expressly empowered by the FCA's *qui tam* provisions to step into the shoes of the government and bring actions for recovery where they have personal knowledge of fraudulent activity that has caused the submission of false or fraudulent claims to government payors.

The FCA was initially enacted in 1863 to combat Civil War procurement, and Congress has long reaffirmed its commitment to this important tool. FCA amendments have consistently garnered bipartisan support, and Congress expressly expanded the reach of the FCA in 2009 after the scope of FCA liability was cabined by several court decisions. S. Rep. No. 111-10, at 4 (2009). In the past three decades, FCA actions have recovered over $48 billion on behalf of the government for the submission of false or fraudulent claims. A significant portion of this recovery has been for false claims submitted to the government pursuant to illegal off-label marketing schemes, where pharmaceutical companies market their drugs for uses unapproved by the Food and Drug Administration. The Department of Justice settled off-label marketing claims against GlaxoSmithKline for $2 billion in 2012, Johnson & Johnson for $1.72 billion in 2013, Pfizer for $1 billion in 2009, Abbott for $800 million in 2012, Eli Lilly for $800 million in 2009, and Amgen for $612 million in 2012.

Of course, the FCA is "not an all-purpose antifraud statute." *Universal Health Servs. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003 (2016). Neither the statute, nor federal rules of pleading and procedure, contemplate or permit "fishing expeditions" whereby anyone hoping to take advantage of the Act's *qui tam* provision may bring baseless claims in hopes of using the court system to uncover fraud. Under Federal Rule of Civil Procedure 9(b), a successful complaint under the Act must allege with sufficient particularity both information about the fraudulent scheme itself and facts indicating that false or fraudulent claims were, in fact, submitted to the government as a result of that scheme.

But Rule 9(b) provides a standard of pleading, not of proof. It governs not what relators must show in order to win a judgment in their favor, but what relators must allege to survive a motion to dismiss. In the FCA context, it is critical that a relator allege with particularity "circumstances constituting fraud." But there is no consensus among the courts of appeal regarding what it means to allege the *submission* of a false or fraudulent claim. Certain courts of appeals have decided that if a relator's particularized allegations create an *inference* that a false claim was submitted to the government, but do not entirely foreclose the possibility that such a claim was not submitted, then only conclusive, direct evidence (i.e., plaintiff's personal knowledge of the claim submission) will satisfy the pleadings standard.

Requiring an FCA complaint to foreclose all negative inferences from the facts alleged contradicts both the pleading standard and precedent set by this Court, and it fails to accomplish the goal used to justify it. There

are many hurdles over which FCA relators must jump. Relators must adequately allege, and eventually prove, that defendants violated a standard of conduct and that the violation was so meaningful that it affected whether the defendant was entitled to be paid by the Government. Relators must also adequately allege that a defendant knew not only that its conduct was wrong, but that the conduct affected how much the Government should pay, if at all. There are also additional procedural hurdles of an FCA claim, such as whether the allegations were publicly disclosed or filed earlier by someone else.

No doubt this Court should test these issues up front. In the mine run of FCA cases, the pleading and proving of these issues—rather than the issue of whether a claim was actually submitted—determines the fate of virtually all cases. Unsurprisingly, Petitioners are unable to locate a single case, even in circuits that apply a more lenient Rule 9(b) standard, where an FCA relator was able to plead a detailed fraudulent scheme, but there turned out to be no false claim submitted to the government. Imposing a strict standard for alleging the *submission* aspect of a false claim does not stop baseless FCA cases from going forward; it just creates a detrimental hurdle for cases where a detailed fraudulent scheme is alleged but the relator does not have visibility into the billing process. Yet some circuits continue to insist that relators submit direct evidence that claims were submitted in order to survive a motion to dismiss.

Qui tam relators and Petitioners in this case, Joseph Ibanez and Jennifer Edwards, are the consummate corporate insiders whom the FCA contemplates as whistleblowers. As former Bristol-Myers Squibb sales

representatives, Petitioners alleged a rich set of facts concerning Respondents' multibillion-dollar scheme to defraud the government by encouraging physicians to prescribe the atypical antipsychotic drug Abilify to their Medicare and Medicaid patients for off-label—and often dangerous—uses. Despite Petitioners' detailed allegations, the district court dismissed their complaint because it did not include or describe representative false claims submitted to the government, and the district court did not believe the allegations led to the "strong inference" that false claims were submitted.

Petitioners then moved to amend their complaint to add specific data linking Respondents' marketing efforts to particular Abilify prescriptions filled by particular federally-insured patients and paid for by the government. The 193-page Third Amended Complaint identified, *inter alia*, specific doctors targeted by Respondents' scheme, specific data about the doctors' prescribing patterns and patient populations, specific dates on which sales representatives visited those doctors, specific patients for whom those doctors prescribed Abilify off-label, and specific prescriptions for off-label prescriptions submitted to government healthcare payors for reimbursement.

However, the district court dismissed again, and a divided Sixth Circuit panel held that amending the complaint would be futile because Petitioners' allegations did not foreclose the possibility that Respondents' scheme did not cause the representative claims to be submitted. The Sixth Circuit demanded that Petitioners include direct, rather than circumstantial, proof of the causal connection between Respondents' scheme and the specific off-label prescriptions reimbursed by the government—

essentially requiring that the representative claims pled give rise to a *necessary* inference, rather than a reasonable or even strong inference, that Respondents' scheme caused the representative claims to be submitted to and paid for by the government. *See* App. 21a–24a.

In other words, the Sixth Circuit required that relators' allegations eliminate any competing inference that the claim was submitted for some other reason. Such a requirement violates this Court's articulation of what it means to plead "with particularity." An irrefutable inference is *not* required—rather, a complaint alleges a fact with sufficient particularity where the allegations create an inference "at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs v. Makor Issuer Rights*, 551 U.S. 308, 324 (2007).

Indeed, it is well-established that, unless a statute demands otherwise, any element of a civil case—including causation—can be established by circumstantial evidence. *See e.g.*, *Desert Palace, Inc. v. Costa*, 539 U.S. 90, 100 (2003) (quoting *Rogers v. Mo. Pac. R.R.*, 352 U.S. 500, 508, n.17 (1957)) ("The reason for treating circumstantial and direct evidence alike is both clear and deep rooted: 'Circumstantial evidence is not only sufficient, but may also be more certain, satisfying and persuasive than direct evidence.'"). Circuits that require direct evidence of every "link" of an FCA scheme, like the Sixth Circuit, hold relators to a higher causation standard at the pleading stage than that to which they are held after a fully developed record. *See e.g.*, *Wyatt v. Cole*, 504 U.S. 158, 174 (1992) (Kennedy, J., concurring) (stating that, at summary judgment, "a plaintiff may rely on circumstantial rather than direct evidence to make his case").

Allegations establishing an inference that a false claim was submitted "at least as compelling" as the inference that no claim was submitted more than satisfy the particularity requirement of Rule 9(b). Notably, none of the circuits articulate the standard of particularity or the definition of a "strong inference" in the manner announced by this Court in *Tellabs*. In fact, among the circuit courts, there is little consensus regarding what Rule 9(b) requires an FCA relator to plead regarding the submission of false or fraudulent claims. The First, Second, Third, Fifth, Seventh, Eighth, Ninth, Tenth, Eleventh, and D.C. Circuits, hold that, in cases like this one, Rule 9(b)'s mandate is fulfilled when the complaint alleges facts that outline the fraudulent scheme with particularity and provide "reliable indicia" leading to a "reasonable inference," or in some cases a "strong inference," that false claims were indeed submitted to government payors.

By contrast, the Fourth and Sixth Circuits require relators without personal knowledge of the defendant's billing or claim submission processes to allege details about specific, identifiable false claims that were submitted to the government. In the instant case, the Sixth Circuit not only required details about specific false claims, but required relators both to produce a representative false claim and to show that this claim gave rise to a necessary inference of fraud.

This split among the circuits means that, in wide swaths of the country, relators are held to an impermissibly high pleading standard, one where they must prove certain aspects of their claims in order to survive a motion to dismiss. The very relators contemplated by Congress in

enacting the *qui tam* provisions of the FCA—corporate-insider relators like Petitioners—are unlikely to be privy both to the material details of the fraudulent scheme and the details of the resultant bills. In large and complex corporations such as drug companies, defense contractors, or healthcare providers, billing functions are likely to be separated from those employees who are aware of material violations or asked to implement fraudulent schemes. Requiring plaintiffs to plead details of specific false claims, or even to produce representative false claims, distorts the purposes of both the FCA and the federal pleading regimen. Rule 9(b) is designed to test whether the case has merit, not to inquire into the merits themselves—particularly not the aspect of the case's merits least likely to render the case implausible. The Court should grant this petition to resolve the split among the circuits and clarify that FCA relators, like other fraud plaintiffs, can satisfy Rule 9(b) by alleging facts from which a reasonable person would deem the inference that a false claim was submitted at least as compelling as any opposing inference.

OPINIONS BELOW

The Sixth Circuit's opinion is reported at 874 F.3d 905 and reproduced at App. 1a–33a. The Sixth Circuit's order denying Petitioners' Motion for Rehearing is reproduced at App. 34a–35a. The district court's opinion dismissing Petitioners' Second Amended Complaint is available at 2015 WL 1439054 (S.D. Ohio, Mar. 27, 2015) and reproduced at App. 53a–93a. The district court's opinion dismissing Petitioners' Third Amended Complaint is available at 2015 WL 12991207 (S.D. Ohio, Sept. 24, 2015) and reproduced at App. 36a–52a.

JURISDICTION

The Sixth Circuit issued its opinion on October 27, 2017, and denied rehearing on January 3, 2018. *See* App. 1a–35a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTES AND RULES INVOLVED

31 U.S.C. § 3729(a) provides, in relevant part:

> (1) [A]ny person who—
>
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> * * *
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act… plus 3 times the amount of damages which the Government sustains because of the act of that person.

Rule 8 of the Federal Rules of Civil Procedure provides, in relevant part:

> (a) CLAIM FOR RELIEF. A pleading that states a claim for relief must contain:
>
> * * *
>
> (2) a short and plain statement of the claim showing that the pleader is entitled to relief[.]

Rule 9 of the Federal Rules of Civil Procedure provides, in relevant part:

> (b) FRAUD OR MISTAKE; CONDITIONS OF MIND. In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.

STATEMENT OF THE CASE

A. Statutory Background

Congress has always intended that the False Claims Act serve as an effective tool against fraud on the government. The FCA, sometimes known as "Lincoln's Law," was originally enacted in 1863 "in order to combat rampant fraud in Civil War defense contracts." *Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*, 135 S. Ct. 1970, 1973 (2015). Congress amended the FCA in 1986 in response to several notable abuses by defense contractors. As a result of these amendments, the federal government recovered over $56 billion via the FCA between 1986 and 2017. *See* UNITED STATES DEP'T OF JUSTICE, *Justice Department Recovers Over $3.7*

Billion from False Claims Act Cases in Fiscal Year 2017 (Dec. 21, 2017), https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017. In large part to counteract the effects of caselaw that had constrained the efficacy of the FCA, Congress again amended the Act in 2009, expanding both substantive liability and procedural tools available to the government. *See, e.g.*, *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488 (D.C. Cir. 2004); *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123 (2008).

Since 2009, the FCA has provided for liability against any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)–(B). Defendants found to be liable must pay treble damages and a statutory penalty of up to $21,916 per false claim submitted. *Id.* § 3729(a)(1); 28 C.F.R. § 85.5.

The FCA provides that private citizens, known as relators, may bring an action on the government's behalf. 31 U.S.C. § 3730(b)(1). The government may elect to intervene in an action brought by a relator. *Id.* § 3730(c)(1). If it does not, the relator may continue with the action on her own. *Id.* § 3730(b)(4).

FCA complaints must comply with Federal Rules of Civil Procedures 8(a) and 9(b); Rule 8(a) requires simplicity, and Rule 9(b) requires particularity. These "two rules must be read in conjunction with each other"; "[o]f primary importance in understanding the requirement of Federal Rule 9(b) . . . is the recognition that it does not render the

general principles of simplicity set forth in Rule 8 entirely inapplicable to pleadings alleging fraud." 5A Wright & Miller, *Federal Practice and Procedure* § 1298 (3d ed.). Rule 8, of course, contemplates "simplicity and flexibility" in pleadings, and even the heightened Rule 8(a) pleading standard defined in *Twombly* and *Iqbal* requires only that allegations be plausible, not conclusive. *Id.*; *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556–57 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009). Rule 9(b)'s particularity requirement serves to define this plausibility in the context of pleading fraud. It "does not require absolute particularity or a recital of the evidence, especially when some matters are beyond the knowledge of the pleader and can only be developed through discovery." 5A Wright & Miller, *Federal Practice and Procedure* § 1298 (3d ed.).

The purpose of Rule 9(b)'s particularity requirement is to ensure that a defendant has sufficient notice of the allegations against it. *Id.*, § 1297. In FCA cases, Rule 9(b) best effectuates Congress' intent by ensuring that credible allegations that provide sufficient notice to the defendant can proceed, and recognizing that whistleblowers' individual knowledge may not encompass the full scope of the fraudulent scheme. As a rule of pleading, Rule 9(b) must serve only as a gatekeeper to the merits of a case, requiring that the allegations be sufficiently substantive to proceed rather than requiring probative evidence at the time of the complaint.

B. Relators and Proceedings Below

Petitioner, and Relator below, Joseph Ibanez served as a sales representative for Respondent Bristol-Myers Squibb (BMS) from 2002 through his retaliatory termination in July 2010. Petitioner, and Relator below,

Jennifer Edwards served as a sales representative for BMS from 1988 through 1996, and again from 2005 through her retaliatory termination in May 2010.[1] Both Ibanez and Edwards were assigned to the sale of Abilify from 2005 through their wrongful terminations in 2010. Respondents BMS and Otsuka improperly induced sales of Abilify through illegal marketing of off-label uses, and provided illegal incentives to prescribing physicians in violation of the Anti-Kickback Statute.

As sales representatives, Ibanez and Edwards did not have access to actual false claims submitted during the course of their employment, as these claims would have been submitted by pharmacies filling improper prescriptions. But Ibanez and Edwards knew that government healthcare programs paid specific false claims as a result of Respondents' improper marketing of Abilify. During their employment with BMS, Ibanez and Edwards routinely discussed issues like government healthcare program formularies with the physicians they targeted, and they assisted these physicians in navigating obstacles the physicians encountered when prescribing Abilify to patients insured by federal government payors—both generally, and with regard to particular government healthcare beneficiaries. Petitioners' supervisors specifically instructed them to target physicians with high volumes of government-insured patients, and before they marketed to a particular physician, Respondents provided Petitioners data demonstrating how many Abilify prescriptions that physician had written in the previous months that had been paid for by government healthcare

1. Petitioners' claims for wrongful termination have been stayed pending the outcome of this petition.

programs. In conversation with particular physicians, they discussed off-label Abilify prescriptions for particular patients, and they personally observed that many of these patients were beneficiaries of government healthcare programs. BMS data confirmed that physicians targeted by Petitioners were paid by government healthcare programs for the Abilify prescriptions they wrote.

Relators Ibanez and Edwards filed their initial complaint in this action under seal in January 2011, and filed their First Amended Complaint, also under seal, in November 2012. On December 17, 2013, the government declined to intervene. Relators moved to amend the complaint in August 2014, and filed a Second Amended Complaint in September 2014. The Second Amended Complaint, some 187 pages, alleged that BMS and Otsuka conspired to market the atypical antipsychotic drug Abilify for off-label uses, in direct contravention of Corporate Integrity Agreements with the United States government, in which BMS and Otsuka had specifically agreed not to engage in off-label marketing of Abilify. Relators alleged that BMS and Otsuka conspired to market Abilify to children and adolescents at a time when the drug was not approved for children and adolescents. And once the drug received limited approvals in this population, the drug companies "marketed it for the treatment of depression and associated symptoms in children and adolescents, even though Abilify was never approved, and in fact contained a Black Box warning"—the strongest warning possible—"for treatment of depression in children and adolescents."

Further, BMS and Otsuka conspired to market Abilify "for the treatment of elderly patients with dementia,"

many of whom were Medicare beneficiaries residing in nursing homes, "despite the fact that Abilify carried a Black Box warning for treatment of patients with dementia." These allegations were supported by extensive detail regarding specific physicians to whom Relators and their colleagues marketed Abilify, and information about their patient populations; detailed information regarding the drug companies' marketing strategies, including, for example, specific dates and locations of high-end dinner events for physicians held by BMS, specific instructions given by supervisors to sell to physicians serving pediatric populations, and specific call lists and prescribing data.

In October 2014, Respondents moved to dismiss pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6), arguing that Petitioners failed to meet Rule 9(b)'s particularity standard because they did not allege details of specific false claims submitted to the government. In their reply to the motion to dismiss, Petitioners emphasized that Respondents misstated the significance of the fact that no specific false claims were attached to the complaint "by misconstruing the applicable pleading standard and ignoring the allegations which create a 'strong inference' that false claims were in fact submitted."

In March 2015, the district court granted in part and denied in part Respondents' motions to dismiss, allowing only Petitioners' FCA counts pertaining to improper retaliation to survive. App. 53a–93a. The district court found that "no matter how particularly [Petitioners] have pled the off-label promotion scheme that BMS and Otsuka engaged in—and they have pled the alleged scheme with sufficient particularity", Petitioners did not plead the *submission* of a false claim with sufficient particularity

because they did 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." App. 64a.

In particular, the district court found that the conclusion that Respondents caused the submission of a false claim for payment required "no fewer than *five* sequential inferences drawn in [Petitioners'] favor: (1) that Respondents' 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." App. 65a.

The district court found that the Second Amended Complaint supported the first and second, but not the third, fourth, and fifth, inferences. App. 65a. But Petitioners alleged personal knowledge of patients of target physicians who were beneficiaries of government healthcare programs (inference three), and it is no leap to infer that government healthcare beneficiaries receiving prescriptions for antipsychotic drugs are more likely than not to fill them, and that pharmacies would seek reimbursement for those filled prescriptions.

On July 24, 2015, Petitioners filed a motion for leave to file a Third Amended Complaint. The proposed Third Amended Complaint included, in relevant part, data supporting Petitioners' allegations that Medicare

and Medicaid had actually paid for claims for Abilify prescriptions, including specific prescriptions: (1) written by providers targeted by Respondents' off-label marketing scheme; and (2) prescribed for off-label uses. In September 2015, the district court declined to allow Petitioners to file the Third Amended Complaint on grounds that the information Petitioners added to the complaint were public disclosures such that the complaint would be dismissed under the FCA's public disclosure bar. App. 36a–52a.

Relators appealed. The Sixth Circuit reversed the district court's ruling that the complaint was based on public disclosures, but a divided panel nevertheless held that amendment would be futile because the Third Amended Complaint failed to satisfy Rule 9(b). The court held "relators must identify a representative claim with *specificity* as to each necessary component of the alleged scheme; identifying a claim that merely infers one or more of these elements is inadequate." App. 21a. The court found that the representative claims Petitioners added to the complaint were "not adequately connected to [Respondents'] improper promotion," because competing inferences could be drawn. App. 24a. Essentially, the court required that the complaint eliminate those competing inferences with direct evidence in order to adequately plead their claims.

Judge Stranch dissented. She emphasized that Rule 9(b) is a rule of pleading which should be interpreted in context. "[P]articularity is not necessarily synonymous with representative samples. . . . Relators, unlike the government, do not have many legal tools available to discern details of claims during the pleading stage. Making those legal tools available is precisely the purpose

of discovery." App. 30a. Emphasizing the intent of Congress in enacting the FCA, Judge Stranch noted that "the majority erred by failing to read the third amended complaint in the light most favorable to the plaintiff and to accept all factual allegations as true . . . . The facts in the third amended complaint—detailed examples of the alleged scheme backed by personal knowledge and statistical evidence—are sufficient to satisfy Rule 9(b)'s requirement that the 'circumstances constituting fraud' are stated with particularity." App. 31a–33a.

Petitioners sought rehearing en banc in November 2017. The petition was denied on January 3, 2018. App. 34a–35a.

REASONS FOR GRANTING THE PETITION

This Court should grant certiorari to clarify whether False Claims Act relators may satisfy Rule 9(b) by alleging facts from which a reasonable person would deem the inference that a false claim was submitted at least as compelling as any other. *Tellabs*, 551 U.S. at 324. The Sixth Circuit's decision in this case, and standards for pleading FCA claims generally, squarely contradicts *Tellabs*. Moreover, the various Rule 9(b) standards applied by the lower courts of appeals both conflict with each other and create confusion regarding the pleading standard. Any FCA complaint that meets the *Tellabs* standard satisfies Rule 9(b).

A. The Sixth Circuit's Rule 9(b) Standard in FCA Cases Contradicts the Supreme Court's Holding in *Tellabs*

The Court examined the meaning of pleading with "particularity" in *Tellabs v. Makor Issuer Rights*, a case brought under the Private Securities Litigation Reform Act ("PSLRA") (15 U.S.C. 78u-4 (2010)). The PSLRA requires a plaintiff to plead "with particularity facts giving rise to a strong inference that defendant acted with the requisite state of mind." *Tellabs*, 551 U.S. at 326.

The Court held that to plead a strong inference, plaintiffs must allege facts from which "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 324 (emphasis added). The Court explained:

> The strength of an inference cannot be decided in a vacuum. The inquiry is inherently comparative: How likely is it that one conclusion, as compared to others, follows from the underlying facts? To determine whether the plaintiff has alleged facts that give rise to the requisite "strong inference" of scienter, a court must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff. *The inference that the defendant acted with scienter need not be irrefutable*, i.e., of the "smoking-gun" genre, or even the "most plausible of competing inferences," *Fidel*, 392 F.3d, at 227 (quoting *Helwig v. Vencor, Inc.*, 251 F.3d

> 540, 553 (C.A.6 2001) (en banc)). Recall in this regard that § 21D(b)'s pleading requirements are but one constraint among many the PSLRA installed to screen out frivolous suits, while allowing meritorious actions to move forward. See *supra*, at 2508, and n. 4. Yet the inference of scienter must be more than merely "reasonable" or "permissible"—it must be cogent and compelling, thus strong in light of other explanations.

Tellabs, 551 U.S. at 324 (emphasis added).

The PSLRA's requirement that a complaint create a "strong inference" of scienter is a hurdle even higher than Rule 9(b)'s particularity requirement. But, as Judge Stranch's dissent implies, the allegations in this case more than satisfy the standard set by the Court in *Tellabs*. Petitioners are corporate insiders who were directed by Respondents to engage in an extensive off-label marketing scheme for the atypical antipsychotic Abilify. That marketing plan was contrary not only to applicable law, but also to the Corporate Integrity Agreements that Respondents had signed with the government. Petitioners were instructed as to the unlawful marketing strategy by their supervisors. They called on physicians who exclusively treated populations for whom Abilify was contraindicated and who were beneficiaries of government healthcare programs. They discussed off-label treatment plans for specific patients who were insured by the government.

Petitioners were not only aware of, but relied on in the course of their employment, extensive data about

target physicians' prescribing patterns, including specific information about off-label prescriptions filled by government-insured patients. And in their proposed Third Amended Complaint, Petitioners even provided extensive statistical data tracking off-label prescriptions, including to federally insured patients, written by physicians whom Respondents' targeted with off-label messaging, as well as 66 specific examples of claims paid by Massachusetts Medicaid for off-label prescriptions written by doctors specifically targeted by Respondents with off-label messaging.

Petitioners also included information regarding one specific Medicaid beneficiary, referenced in the complaint as D.M., who was prescribed Abilify for off-label purposes by doctors targeted by Respondents. The Third Amended Complaint alleges that from 2007 to 2010, Respondents, through Petitioner Ibanez and other sales representatives, illegally promoted Abilify for off-label uses to physicians at Cincinnati Children's Hospital Medical Center ("CCHMC"). In 2010, one such physician prescribed Abilify to D.M., at the time a four-year-old Medicaid beneficiary, to treat his recently-diagnosed ODD and ADHD. In 2010, Abilify was not approved to treat either ODD or ADHD, and it was not approved to treat children under the age of six. D.M. continued to be seen by providers at CCHMC and continued to be prescribed Abilify for off-label uses. For example, on July 16, 2013, another physician at CCHMC, Dr. Jennifer Bowden, to whom Respondents marketed Abilify off-label until at least 2012, prescribed D.M. Abilify for his "mood"—an off-label use. D.M. had that prescription filled, and it was paid for by Ohio Medicaid.

It is possible, though not probable, that Respondents' off-label marketing scheme did not cause a false claim to be submitted. For example, perhaps the doctor who prescribed D.M. the off-label prescriptions in 2010, despite working for the very hospital group where Respondents illegally marketed Abilify, was absent each time Respondents targeted CCHMC physicians with that off-label message. Perhaps Dr. Bowden will testify that she somehow forgot all about the illegal promotion she had received from Respondents over the years, notwithstanding that Petitioners allege D.M. had been treated at CCHMC where Dr. Bowden worked since 2010, and Dr. Bowden had received the off-label promotion at least through 2012.

But on the facts alleged here, it is far more plausible that Medicaid paid for D.M.'s (and government healthcare programs paid for others') off-label prescriptions because the doctors who wrote them had been illegally marketed to by Respondents. While the inference of an actual false claim is not irrefutable, causation under the FCA requires not proof that no other result was possible, but that the result was foreseeable. *See e.g., United States v. Luce*, 873 F.3d 999, 1013–14 (7th Cir. 2017). Rule 9(b) similarly does not require a plaintiff's allegations to eliminate all innocent explanations for a defendant's conduct. *See Tellabs*, 531 U.S. at 319–20. And yet in this case, the existence of these competing inferences, remote as they may be, is exactly why the Sixth Circuit affirmed the district court's denial of Petitioners' motion for leave to amend.

The standard applied here not only contraducts Rule 9(b) and the standard set by this Court in *Tellabs*, it is

nonsensical in the FCA context. In the pharmaceutical industry, as in many other industries, the mechanical process of billing the government is far-removed from the process of selling and providing the relevant products, and those actually engaged in billing may not be aware of any fraud underlying the claims they are processing. Requiring "personal billing-related knowledge" effectively removes countless individuals in a position to blow the whistle on fraud against the government—such as sales representatives, doctors, and nurses—from the pool of potential relators, a result clearly contrary to Congress's purpose in enacting and continuing to refine the FCA. Requiring *proof* of a causal link in the pleadings, rather than allegations that meet the FCA's causation standard, creates further conflict among the courts of appeal.

As the Second Circuit recently recognized, "It is not the purpose of Rule 9(b), as applied to FCA qui tam actions, to render the FCA toothless as to particularly clever fraudulent schemes." *United States ex rel. Chorches for Bankr. Estate of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 86 (2d Cir. 2017). Indeed, a rule that requires relators to plead substantive details of the fraud while also having personal billing-related knowledge would only incentivize a government contractor to circumvent its legal obligations under the Act by "insulating its accounting department from personnel with operational knowledge." *Id.*

Heath care is one of the largest industries in the United States economy, and health care fraud alone is estimated to cost Medicare and Medicaid from $30 to $98 billion annually, as Judge Stranch noted in dissent. App. 27a (quoting *United States ex rel. Doghramji v. Cmty.*

Health Sys., Inc., 666 F. App'x 410, 419 (6th Cir. 2016) (Stranch, J., concurring)). And the structure of health care organizations can be analogized to that of other companies that submit claims to the government (for example, defense contractors) in that billing personnel are likely to be separated from personnel who have knowledge of underlying fraud or noncompliance, as discussed above.

As Judge Stranch advocates in her dissent, it is critical that the FCA pleading standard support—not prevent—individuals who are aware of noncompliance or fraudulent schemes and have the courage to bring a lawsuit based on them. This is not hyperbole: It is precisely the intent of Congress. Congress amended the FCA in 1986 "to strengthen the Government's hand in fighting false claims, and to encourage more private enforcement suits," *Graham Cty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 298 (2010) (citations and internal quotation marks omitted), and again in 2009, expanding protections for relators and expressly seeking to restore the "effectiveness of the False Claims Act," which had "recently been undermined by court decisions which limit the scope of the law." S. Rep. No. 111-10, at 4 (2009). As the Seventh Circuit, recognizing the importance of appropriate inferences when applying Rule 9(b) to *qui tam* complaints, observed, requiring an FCA plaintiff to allege either an actual, specific false claim, or personal billing-related knowledge, would "take[] a big bite out of qui tam litigation." *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 954 (7th Cir. 2009).

B. The Circuit Courts, Ignoring This Court's Holding in *Tellabs*, Are Sharply Divided on the Application of Rule 9(b) in False Claims Act Cases

The Courts of Appeals have not come to a consensus on how *qui tam* relators without direct knowledge of billing practices may satisfy Rule 9(b)'s particularity standard. *See* 5A Wright & Miller, *Federal Practice and Procedure* § 1298 (3d ed.). Indeed, no court of appeals has explicitly recognized the *Tellabs* standard in the context of an FCA case, even though weighing the competing inferences drawn from detailed facts alleged about a fraudulent scheme is a straightforward and practical way to apply Rule 9(b) to allegations regarding the submission of false claims.

Instead, as the Solicitor General has acknowledged in submissions to this Court, the circuits have "reached inconsistent conclusions" about what a relator must allege regarding the submission of a false claim in order to survive Rule 9(b). Br. for United States as Amicus Curiae at 10, *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, No. 12-1349 (U.S. Feb. 25, 2014). The Fourth and Sixth Circuits require that relators plead a specific, representative false claim in nearly all cases. Even circuits that permit the inference of claim submission disagree about whether that inference must be a "strong inference" or simply a "reasonable inference," and some circuits will permit the inference of claim submission only in specific cases. For instance, the Eighth and Eleventh Circuits allow only a strong inference for relators who are corporate insiders, and the First Circuit permits an inference where third parties submitted the actual false claims to the government. The Second, Third, Fifth,

Seventh, Ninth, Tenth, and D.C. Circuits draw inferences regardless of the billing process or the status of the relator.

The inconsistency between the circuit courts is not only confusing and unpredictable, it is often outcome-dispositive: Defendants can escape liability without substantive proceedings on the merits in circuits that apply a "stringent" Rule 9(b) standard to FCA cases. As a result, the government cannot recover millions, if not billions, of dollars, which properly belong to the public. The "stringent" standard of 9(b) particularity is out of sync with the foundational requirements of Rule 8(a) and our system's simple, flexible approach to notice pleading. It is also contrary to the intent of Congress, which has consistently reaffirmed its intent to allow anyone with genuine knowledge of fraud against the government to serve as an FCA relator.

In the Fourth and Sixth Circuits, relators, at the pleading stage, must produce or provide details of an actual, representative false claim submitted to the government. The Sixth Circuit holds that where the alleged fraudulent scheme is "complex and far-reaching," relators must plead details not only of the scheme itself, but "must also identify a representative false claim that was actually submitted to the government." *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 470 (6th Cir. 2011) (quoting *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493 (6th Cir. 2007)). In *United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, the Sixth Circuit acknowledges a narrow exception where the relator has "specific personal knowledge" of a defendant's billing practices that supports the "strong inference that a [false]

claim was submitted." 838 F.3d 750, 769 (6th Cir. 2016). The Sixth Circuit has emphasized that for corporate-outsider relators in particular, "[t]he identification of at least one false claim with specificity is an indispensable element of a complaint that alleges a [False Claims Act] violation." *United States ex rel. Hirt v. Walgreen Co.*, 846 F.3d 879, 881 (6th Cir. 2017).

The Fourth Circuit requires that relators allege details of specific false claims submitted to the government with particularity, including "the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." *United States v. Triple Canopy, Inc.*, 775 F.3d 628, 634 (4th Cir. 2015); *see also United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 457 (4th Cir. 2013). Thus, though plaintiff-relators in the Fourth Circuit need not necessarily append a copy of a false claim actually submitted to the government to their complaint, functionally they must have access to such information in order to survive a motion to dismiss.

The Eighth and Eleventh Circuits hold that corporate outsiders—that is, relators who would not have gathered information about the fraudulent scheme in the course of their employment with the defendant—meet Rule 9(b)'s particularity standard only when they plead details both of the scheme itself and of the false claims submitted. The Eighth Circuit requires relators to "plead such facts as the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result." *United States ex rel. Thayer v. Planned Parenthood of*

the Heartland, 765 F.3d 914, 916–17 (8th Cir. 2014); *see also United States ex rel. Dunn v. N. Mem'l Health Care*, 739 F.3d 417, 420 (8th Cir. 2014). The Eleventh Circuit requires that relators provide allegations, "stated with particularity, of a false claim actually being submitted to the Government," *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1312 (11th Cir. 2002), "identify[ing] the particular document and statement alleged to be false, who made or used it, when the statement was made, how the statement was false, and what the defendants obtained as a result." *United States ex rel. Matheny v. Medco Health Sols., Inc.*, 671 F.3d 1217, 1225 (11th Cir. 2012).

The Eighth Circuit similarly relies on a "strong inference" test for corporate insiders, holding that they satisfy Rule 9(b) by "alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Thayer*, 765 F.3d at 917. And the Eleventh Circuit allows "a relator with direct, first-hand knowledge of the defendants' submission of false claims gained through her employment with the defendants" to satisfy 9(b) without any details about particular claims at all. *United States ex rel. Mastej v. Health Mgmt. Assocs., Inc.*, 591 F. App'x 693, 704 (11th Cir. 2014).

The Second Circuit, the most stringent of the "inferential" circuits, holds that "a complaint can satisfy Rule 9(b)'s particularity requirement by making plausible allegations creating a strong inference that specific false claims were submitted to the government and that the information that would permit further identification of those claims is peculiarly within the opposing party's

knowledge." *Chorches*, 865 F.3d at 86. In so holding, the Second Circuit noted explicitly its view that this interpretation accords with the purposes of both Rule 9(b) and the False Claims Act itself, emphasizing that the "strong inference" standard affords defendants fair and sufficient notice while not "discourag[ing] the filing of meritorious *qui tam* suits that can expose fraud against the government" and allowing corporate fraudsters to escape liability simply by clever insulation of one department from another. *Id.*

The Third Circuit requires relators to plead "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted" and has even allowed statistical evidence establishing a strong probability that false claims were submitted for a portion of the imported goods in question. *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 157–58 (3d Cir. 2014); *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 839 F.3d 242 (3d Cir. 2016).

The Fifth Circuit uses nearly the same test, allowing relators who cannot rely upon specific false claims submitted to survive a motion to dismiss "by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009); *accord United States v. Bollinger Shipyards, Inc.*, 775 F.3d 255, 260 (5th Cir. 2014).

The Ninth Circuit has joined the Fifth, explicitly declining, "as a matter of course, [to] require a relator to identify representative examples of false claims." *Ebeid ex*

rel. United States v. Lungwitz, 616 F.3d 993, 998 (9th Cir. 2010) and even holding that "a complaint need not allege a precise time frame, describe in detail a single specific transaction, or identify the precise method used to carry out the fraud." *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1180 (9th Cir. 2016).

In circumstances of "indirect" fraud (where the false claims were submitted by third parties rather than the defendant), the First, Seventh, Tenth, and D.C. Circuits agree that "the precise details of individual claims are not, as a categorical rule, an indispensable requirement of a viable False Claims Act complaint." *United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 126 (D.C. Cir. 2015). In the Seventh Circuit, a relator's "pleading [need not] exclude all possibility of honesty in order to give the particulars of fraud. It is enough to show, in detail, the nature of the charge, so that vague and unsubstantiated accusations of fraud do not lead to costly discovery and public obloquy." *Lusby*, 570 F.3d at 854–55 (citing *Ashcroft v. Iqbal,* 556 U.S. 662 (2009) and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007)). The *Lusby* court was also careful to acknowledge that the pleading stage is distinct from evaluation of the merits of the case: "[t]o say that fraud has been *pleaded* with particularity is not to say that it has been *proved* (nor is proof part of the pleading requirement)." *Id.* at 855. The Tenth Circuit further holds that "claims under the FCA need only show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as a part of that scheme." *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010).

Finally, where third parties other than the defendant would have submitted the actual false claims to the government, the First Circuit holds that a relator need only plead "'factual or statistical evidence to strengthen the inference of fraud beyond possibility' without necessarily providing details as to each false claim." *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 39 (1st Cir. 2017) (quoting *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29 (1st Cir. 2009)).

Petitioners' Third Amended Complaint satisfies even the most stringent interpretation of Rule 9(b). But even Petitioners' Second Amended Complaint—which did not provide representative false claims, but did plead detailed facts about Respondents' underlying fraudulent scheme to market Abilify off-label specifically to providers with high populations of government healthcare beneficiaries—would have satisfied the First, Second, Third, Fifth, Seventh, Eighth, Ninth, Tenth, Eleventh, and D.C. Circuits.

But none of these courts have explicitly recognized the *Tellabs* standard in the context of an FCA case, which would simplify the analysis in the circuits applying an inferential Rule 9(b) standard to the submission of false claims and negate the impermissibly stringent requirement in other circuits that certain FCA relators must include details regarding a specific false claim in their complaints. Relators should not be held to a higher pleading standard in FCA cases than plaintiffs in PSLRA cases, and the standard imposed in several circuits directly contradicts the holding in *Tellabs*. Applying the *Tellabs* standard in FCA cases would resolve the conflict between

this Court's articulation of the meaning of pleading with particularity and the various confusing and incompatible standards the courts of appeal apply.

This Court should grant certiorari to affirm this as the nationwide standard, assuring that corporate fraudsters cannot escape liability simply by being sued in the Fourth or Sixth Circuits.

C. The Decision Below Is Incorrect and Creates a Standard that Deviates from the Federal Pleading Regime and this Court's Precedent, Invalidating Congress' Intent with Regard to the False Claims Act

Petitioners urge the Court to provide a clear rule of decision for these cases, as it did in *Tellabs* for PSLRA cases. But if that is a bridge too far, it is nonetheless inescapable that the Sixth Circuit's decision in this case—and its pleading requirements in general—conflict with this Court's articulation of what it means to allege a fact with particularity.

The Sixth Circuit's decision below follows a pleading standard that requires relators to have access to all documentation supporting or resulting from a credibly alleged fraudulent scheme. Such a standard precludes a substantial amount of *qui tam* litigation: How many employees of large corporations conducting business with the government are privy to the details of a plan to defraud the government *and* have personal involvement with the billing process sufficient to intercept a representative false claim or qualify for the narrow *Prather* exception? Relators Ibanez and Edwards were sales representatives and thus placed on the front lines of Respondents' fraudulent

scheme. The false claims resulting from this scheme were submitted by pharmacies; sales representatives like Ibanez and Edwards are unlikely to have had any contact with the individual patients filling the prescriptions, let alone the pharmacist or the pharmacy's billing staff. The Sixth Circuit's standard renders the FCA toothless against almost all such "indirect" fraud, and incentivizes corporate fraudsters, as the Second Circuit warned in *Chorches*, to escape FCA liability simply by insulating billing from other corporate functions.

D. The Issue Is Legally and Economically Important

The question presented here is of critical importance not only to FCA litigants, but to the ability of the government to recover funds on behalf of the public fisc.

As evidenced by the fact that every circuit has recently construed Rule 9(b)'s particularity pleading standard with regard to the False Claims Act, this question has recurred and will continue to recur frequently. The Fourth Circuit and Sixth Circuit have set a standard that is nearly impossible for most whistleblowers to meet.

False Claims Act suits brought by *qui tam* relators are responsible for the majority of the federal government's recoveries. Relators, then, have been responsible for as much as $35 billion of the $56 billion the government has recovered via the FCA since its 1986 amendment. A constrained Rule 9(b) standard would preclude many if not most of these suits. By contrast, an affirmation of the majority "inferential" standard would effectuate the intent of Congress in ensuring that plausible FCA claims are judged on the merits, rather than on whether relator worked in the billing department.

CONCLUSION

For the foregoing reasons, this Court should grant this petition.

Respectfully Submitted,

Jennifer M. Verkamp
Frederick M. Morgan
Chandra Napora
Morgan Verkamp LLC
35 East 7th Street,
Suite 600
Cincinnati, OH 45202

David J. Chizewer
Counsel of Record
William C. Meyers
Emily D. Gilman
Goldberg Kohn Ltd.
55 East Monroe, Suite 3300
Chicago, IL 60603
(312) 201-4000
david.chizewer@goldbergkohn.com

Counsel for Petitioners

April 3, 2018

APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT, FILED OCTOBER 27, 2017

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

No. 16-3154

UNITED STATES OF AMERICA *ex rel.* JOSEPH IBANEZ AND JENNIFER EDWARDS,

Relators-Appellants,

v.

BRISTOL-MYERS SQUIBB COMPANY; OTSUKA AMERICA PHARMACEUTICAL, INC.,

Defendants-Appellees.

Appeal from the United States District Court
for the Southern District of Ohio at Cincinnati.
No. 1:11-cv-00029—William O. Bertelsman,
District Judge.

December 6, 2016, Argued;
October 27, 2017, Decided;
October 27, 2017, Filed

Before: McKEAGUE, KETHLEDGE,
and STRANCH, Circuit Judges.

Appendix A

OPINION

McKEAGUE, Circuit Judge. Relators Joseph Ibanez and Jennifer Edwards, former employees of Bristol-Myers Squibb Co. (BMS), bring this *qui tam* action alleging that BMS, together with Otsuka America Pharmaceutical, Inc. (Otsuka), engaged in a complex, nationwide scheme to improperly promote the antipsychotic drug Abilify. Relators assert that this scheme caused claims for reimbursement for the drug to be submitted to the government, in violation of the False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, and several state-law analogues. The district court dismissed the complaint in part and subsequently denied relators' motion to amend. Because neither the second amended complaint nor the proposed third amended complaint satisfies Rule 9(b)'s pleading requirements, we affirm the district court's orders.

I

A. Factual Background

Since 1999, BMS and Otsuka have sold and marketed the drug Abilify. Both relators Joseph Ibanez and Jennifer Edwards worked as BMS sales representatives marketing Abilify from 2005 to 2010.

Abilify is an antipsychotic drug approved for various prescriptive uses by the FDA. It has three approved adult uses. It was approved to treat schizophrenia in 2002; to treat symptoms related to Bipolar I Disorder in 2004; and as a supplemental treatment for major depressive

disorder in 2007. Abilify also has three approved uses for pediatrics. It was approved to treat schizophrenia in 13 to 17 year-olds in 2007; to treat symptoms associated with Bipolar I Disorder in patients 10 to 17 years old in 2008; and to treat irritability associated with autistic disorder for patients 6 to 17 years old in 2009. There are no expressly disapproved treatments for elderly patients, but the FDA has included a warning since 2007 that Abilify is associated with increased mortality rate in elderly patients with dementia-related psychosis.

Relators' FCA complaint boils down to two separate theories. First, relators allege that defendant pharmaceutical companies engaged in a scheme to encourage providers to prescribe Abilify for unapproved ("off-label") uses and that some of those off-label prescriptions were paid for by government programs. Second, relators assert that defendants improperly induced providers to prescribe Abilify through remunerations and benefits in violation of the Anti-Kickback Statute. Relators assert that requests for government reimbursement for off-label prescriptions and prescriptions induced by kickbacks constitute false claims under the FCA.

These allegations come on the heels of a set of nearly identical allegations leveled against BMS and Otsuka some nine years earlier. In 2007, BMS entered into a five-year Corporate Integrity Agreement as part of a settlement of a *qui tam* action which also involved improper promotion of Abilify. In 2008, Otsuka entered into its own five-year Corporate Integrity Agreement as a result of yet another *qui tam* action alleging the same misconduct. The two

agreements used similar language to require Otsuka and BMS to adopt procedures and programs designed to ensure compliance with the FCA, the Anti-Kickback Statute, and cease off-label promotion of Abilify. The relators allege that, despite those agreements, the two companies continued to promote Abilify off-label and offer kickbacks to physicians who prescribed it.

B. Procedural Background

Relators brought this action under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and twenty-eight state-law analogues after disclosure to the government, which declined to intervene. Specifically, the complaint alleges that defendants' illegal promotion of Abilify caused the government to pay off-label prescriptions in violation of 31 U.S.C. § 3729(a)(1)(A). The complaint further alleges that, as part of these fraudulent schemes, defendants violated the Anti-Kickback Statute, 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 Ibanez and Edwards for internally reporting the company's alleged failure to comply with federal and state laws and the Corporate Integrity Agreements, *id.* § 3730(h).

In response to relators' second amended complaint, defendants filed motions to dismiss pursuant to Fed. R. Civ. P. 12(b)(6). The district court granted Otsuka's motion to dismiss, and granted in part and denied in

part BMS's motion, dismissing all of the *qui tam* claims. As a result, the only claims that survived were the retaliation claims brought against BMS and Edwards' Arizona-employment claim analogue. The court declined to exercise supplemental jurisdiction over the remaining state law claims. Proceedings continued in the district court on the retaliation claims.

However, relators moved to file a third amended complaint under Fed. R. Civ. P. 15(a)(2), and attached the proposed complaint. The district court directed the parties to address changes made in the complaint that it saw as potentially implicating the FCA's public-disclosure bar. Following responsive filings, the court found the public-disclosure bar precluded many of the amendments and that the amended complaint otherwise failed to plead presentment with adequate particularity to survive a Rule 12(b)(6) motion. Accordingly, the court denied relators' motion to file a third amended complaint on the basis of futility. The court subsequently granted a Rule 54(b) motion staying litigation on the retaliation claims and granting final judgment certification on both the order resolving the partial motion to dismiss and the order denying the motion to amend. Relators now timely appeal those certified orders.

II

A. Jurisdiction

The district court had jurisdiction over claims arising under the False Claims Act claims pursuant to 31 U.S.C.

§ 3732(a). The district court certified its order partially granting defendants' Rule 12(b)(6) motion and its order denying relators' Rule 15(a)(2) motion under Fed. R. Civ. P. 54(b). "Although Rule 54(b) relaxes the traditional finality requirement for appellate review, it does not tolerate immediate appeal of every action taken by a district court." *Gen. Acquisition, Inc. v. GenCorp, Inc.*, 23 F.3d 1022, 1026 (6th Cir. 1994). Neither party challenges this court's jurisdiction to hear the certified orders on appeal. Nonetheless, we must still satisfy ourselves that the certification was proper. Otherwise, appellate jurisdiction is lacking. *Lowery v. Fed. Express Corp.*, 426 F.3d 817, 820 (6th Cir. 2005).

The district court's determination that certification was proper has two components. First, entry of final judgment as to one or more but fewer than all of the claims or parties; and second, that there is no just reason for delay. The first component is reviewed de novo and the second for abuse of discretion. *Id.* at 821.

The district court's orders collectively ended the litigation of relators' *qui tam* claims against Otsuka and BMS, leaving only relators' personal, employment-based retaliation claims against BMS. *See* R. 73, Dist. Ct. Op. I, PID 1228; R. 97, Dist. Ct. Op. II, PID 2168. There was no error in deeming these orders final. That is, no matter how the record might develop in further proceedings on the unresolved retaliation claims against BMS, there are no grounds on which the dismissed claims would be subject to reopening. Second, the district court did not abuse its discretion in finding there was "no reason to

delay" appeal of the orders. As noted by the district court in its certification order, "the *qui tam* and employment-based retaliation claims are sufficiently distinct, such that permitting immediate appeal will not cause piecemeal appeals" and so allowing this appeal to go forward would "create judicial and economic efficiencies." *See* R. 102, Order, PID 2195-96. Thus, the court weighed relevant considerations and did not abuse its discretion in determining that there was no reason for delay. *See Lowery*, 426 F.3d at 821-22. We now consider the orders certified for appeal.

B. Standard of Review

"This Court reviews *de novo* a district court's dismissal of a complaint for failure to state a claim, including dismissal for failure to plead with particularity under [Rule] 9(b)." *United States ex rel. Eberhard v. Physicians Choice Lab. Servs., LLC*, 642 F. App'x 547, 550 (6th Cir. 2016) (quoting *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.* ("*Bledsoe II*"), 501 F.3d 493, 502 (6th Cir. 2007)). "Complaints alleging FCA violations must comply with Rule 9(b)'s requirement that fraud be pled with particularity because 'defendants accused of defrauding the federal government have the same protections as defendants sued for fraud in other contexts.'" *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 466 (6th Cir. 2011) (quoting *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 563 (6th Cir. 2003)). Thus, "[w]here a relator pleads a complex and far-reaching fraudulent scheme," she also must provide "examples of specific false claims submitted to the government pursuant to that scheme"

in order to proceed to discovery on the scheme. *United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 838 F.3d 750, 768 (6th Cir. 2016) (quoting *Bledsoe II*, 501 F.3d at 510). "In the *qui tam* context, 'the Court must construe the complaint in the light most favorable to the plaintiff, accept all factual allegations as true, and determine whether the complaint contains enough facts to state a claim to relief that is plausible on its face.'" *United States ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 502 (6th Cir. 2008) (quoting *Bledsoe II*, 501 F.3d at 502).

C. Second Amended Complaint

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

Section 3729(a)(1)(A) of the FCA prohibits "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). A claim under § 3729(a)(1)(A) "requires proof that the alleged false or fraudulent claim was 'presented' to the government." *United States ex rel. Marlar v. BWXT Y-12, LLC*, 525 F.3d 439, 445 (6th Cir. 2008). At the pleading stage, this requirement is stringent: "where a relator alleges a 'complex and far-reaching fraudulent scheme,' in violation of § 3729(a)(1), it is insufficient to simply plead the scheme; [s]he must also identify a representative false claim that was actually submitted to the government." *Chesbrough*, 655 F.3d at 470 (quoting *Bledosoe II*, 501 F.3d at 510). Alternatively, a claim may survive a Rule 12(b)(6) motion if it includes allegations showing "specific personal knowledge" supporting a "strong inference that a [false] claim was submitted." *Prather*, 838 F.3d at 769.

Appendix A

Relators allege defendants participated in a complex, nationwide scheme to improperly promote Abilify which caused false claims to be submitted to the government. These allegations include a long chain of causal links from defendants' conduct to the eventual submission of claims. Rule 9(b) requires relators to adequately allege the entire chain—from start to finish—to fairly show defendants caused false claims to be filed.

To cover the ground from one end of this scheme—defendants' improper promotion—to the other—claims for reimbursement—the complaint must allege specific intervening conduct. First, a physician to whom BMS and Otsuka improperly promoted Abilify must have prescribed the medication for an off-label use or because of an improper inducement. Next, that patient must fill the prescription. Finally, the filling pharmacy must submit a claim to the government for reimbursement on the prescription. While this chain reveals just what an awkward vehicle the FCA is for punishing off-label promotion schemes,[1] a single adequately pled claim of

1. A recent opinion from the Second Circuit described the FCA's awkward application to off-label promotion schemes well:

> [I]t is unclear just whom Pfizer could have caused to submit a "false or fraudulent" claim: The physician is permitted to issue off-label prescriptions; the patient follows the physician's advice, and likely does not know whether the use is off-label; and the script does not inform the pharmacy at which the prescription will be filled whether the use is on-label or off. We do not decide the case on this ground, but we are dubious of [relator]'s assumption that any one of these

this nature would allow relators to satisfy Rule 9(b)'s pleading requirement and proceed to discovery on the entire scheme.

In order to survive defendants' motion, relators must provide a representative claim that describes each step with particularity: a prescription reimbursement submitted to the government for a tainted prescription of Abilify. *See Prather*, 838 F.3d at 768. Relators do not adequately identify a representative false claim. Relators allege knowledge of a complex scheme related to the promotion of Abilify, but they do not provide any representative claim that was actually submitted to the government for payment. Lacking a specific claim, relators encourage the court to apply a "relaxed" Rule 9(b) pleading standard that, despite having been suggested by prior opinions, had not been applied by this court until very recently. *See id.* The *Prather* standard is an exception to our usual rule, and applies only if "a relator alleges specific personal knowledge that relates directly to billing practices," supporting a "strong inference that a [false] claim was submitted." *Id.* (citing *Chesbrough*, 655 F.3d at 471).

Prather's personal knowledge exception applies in limited circumstances. *See United States ex rel. Hirt*

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participants in the relevant transactions would have knowingly, impliedly certified that any prescription for Lipitor was for an on-label use.

United States ex rel. Polansky v. Pfizer, Inc., 822 F.3d 613, 619-20 (2d Cir. 2016).

v. Walgreen Co., 846 F.3d 879, 881 (6th Cir. 2017). In *Chesbrough*, an independent radiology consultant—alleging the radiology billings he reviewed were fraudulent—had insufficient personal knowledge to support the necessary inference that false claims were submitted because he had no involvement with billing procedures. *Chesbrough*, 655 F.3d at 471. Likewise, in *Eberhard*, relators failed to adequately plead knowledge because they could not show they had "personal knowledge of billing practices or contracts with the government." *Eberhard*, 642 F. App'x at 552 (6th Cir. 2016) (citing *Chesbrough*, 655 F.3d at 471-72). In fact, the only time this court has ever applied a personal knowledge exception to FCA pleading requirements was in *Prather* itself. *See Prather*, 838 F.3d at 770. There, the exception applied under circumstances where the relator was specifically employed to review medical treatment documentation allegedly submitted to Medicare—i.e., she reviewed allegedly false claims themselves. *Id.* at 768. It was only this "detailed knowledge of the billing and treatment documentation related to the submission of requests for final payment, combined with her specific allegations regarding requests for anticipated payments" that satisfied a relaxed 9(b) standard. *Id.* at 770.

Here, relators do not allege this type of personal knowledge. Relators were sales representatives of BMS and, unlike the relator in *Prather*, did not directly engage with claims whatsoever. In order for the *Prather* exception to apply, it is not enough to allege personal knowledge of an allegedly fraudulent scheme; a relator must allege adequate personal knowledge of billing practices

themselves. *Id.* at 768. Relators fail to do so. Thus, absent a representative false claim derived from the alleged promotional scheme, the second amended complaint fails to adequately plead a violation of 31 U.S.C. § 3729(a)(1)(A).

Accordingly, relators have failed to adequately allege a violation of 31 U.S.C. § 3729(a)(1)(A) in their second amended complaint.

2. Section 3729(a)(1)(B), (C) and (G) Claims

In addition to their claims under 31 U.S.C. § 3729(a)(1)(A), relators allege violations of three other sections of the FCA. 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." Section 3729(a)(1)(G) imposes liability on one who accepts overpayment from the government and fails to refund that overpayment—a so-called "reverse false claim." Section 3729(a)(1)(C) imposes liability on anyone who "conspires to commit a violation" of the FCA's other prohibitions. The district court dismissed relators' claims relating to all three.

Section 3729(a)(1)(B) requires a relator to "plead a connection between the alleged fraud and an actual claim made to the government." *Chesbrough*, 655 F.3d at 473. The alleged connection must be evident. *See Allison Engine Co. v. U.S. ex rel. Sanders*, 553 U.S. 662, 671-72, 128 S. Ct. 2123, 170 L. Ed. 2d 1030 (2008)). Otherwise, "a cause of action under the FCA for fraud directed at private entities would threaten to transform

the FCA into an all-purpose antifraud statute." *Id.* at 672. Thus, although relators allege defendants made false or fraudulent statements in order to increase the number of Abilify prescriptions, there are no allegations connecting these statements to any claim made to the government. Such statements, even if false, rely on a "link between the false statement and the Government's decision to pay or approve a false claim [that] is too attenuated to establish liability." *Id.* Thus, relators fail to adequately plead a 31 U.S.C. § 3729(a)(1)(B) claim because they rely on a too-attenuated chain connecting alleged false statements to the submission of claims. *See Chesbrough*, 655 F.3d at 473.

Section 3729(a)(1)(G) requires a relator to allege facts that show defendants received overpayments from the government and failed to refund those payments. *See* 31 U.S.C. § 3729(a)(1)(G); *Prather*, 838 F.3d at 774. Alternatively, a section 3729(a)(1)(G) violation is made out if the relator pleads adequate "'proof that the defendant made a false record or statement at a time that the defendant owed to the government an obligation'—a duty to pay money or property." *Chesbrough*, 655 F.3d at 473 (quoting *Am. Textile Mfrs. Inst., Inc. v. The Ltd., Inc.*, 190 F.3d 729, 736 (6th Cir. 1999)); 31 U.S.C. § 3729(a)(3). The district court held relators failed to adequately plead a reverse false claim.

We agree. Relators do not plead facts that show defendants received overpayment, much less that they retained it. Moreover, relators provide no facts showing defendants were under an affirmative obligation to the government at the time the alleged false statements

were made. 31 U.S.C. § 3729(a)(3); *see Am. Textile Mfrs. Inst.*, 190 F.3d at 741. Thus, these allegations amount to nothing more than an impermissible "formulaic recitation of the elements of a cause of action" and were properly dismissed. *Bell Atlantic Corp., et al. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007).

Section 3729(a)(1)(C), prohibiting FCA conspiracies, requires a relator to plead facts showing that there was a plan or agreement "to commit a violation of" one or more of the FCA subsections. *See* 31 U.S.C. § 3729(a)(1)(C). The district court determined relators failed to adequately plead an FCA conspiracy. In the court's words,

> [e]ven 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 . . . . [T]he Court must make several assumptions in Relators' favor in order to construe the alleged fraudulent schemes as one *designed to* induce the government to pay false claims.
>
> R. 73, Dist. Ct. Op. I, PID 1218 (emphasis added).

We agree. There are insufficient allegations to show there was a plan to get false claims paid. The alleged plan was to increase Abilify prescriptions through improper promotion. While this may be condemnable, it does not amount to a conspiracy to violate the FCA. Even

if it was foreseeable that somewhere down the line off-label prescriptions of Abilify would be submitted to the government for payment, that foreseeable consequence does not subsume the aim of the agreement. In other words, to adequately allege an FCA conspiracy, it is not enough for relators to show there was an agreement that made it *likely* there would be a violation of the FCA; they must show an agreement was made *in order to* violate the FCA. *See United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 27 (2d Cir. 2016) (affirming the holding that a "claim of conspiracy to violate the FCA was deficient because the [complaint] 'fails to identify a specific statement where [defendants] agreed to defraud the government'").

The chain that connects defendants' alleged misconduct to the eventual submission of false claims to the government is an unusually attenuated one and relators provide no specific statement showing the plan was made in order to defraud the government. *Id.* at 27. The absence of such a conspiratorial statement, in conjunction with relators' failure to adequately plead a violation of any other section of the FCA, renders insufficient the otherwise bare allegation that there was an FCA conspiracy. *Twombly*, 550 U.S. at 556. Accordingly, we uphold the dismissal of the conspiracy claim.

We therefore affirm the district court's order dismissing in part relators' second amended complaint.

D. Third Amended Complaint

Relators also appeal the district court's denial of their motion to file a third amended complaint. Although a court should freely give leave to amend a complaint when justice so requires, it does not need to give leave if doing so would be futile, such as when the amended complaint cannot survive a motion to dismiss. *SFS Check, LLC v. First Bank of Del.*, 774 F.3d 351, 355 (6th Cir. 2014). After partially dismissing the second amended complaint, the district court granted relators leave to file a Rule 15 motion to amend and provided a deadline by which to do so.[2] Relators timely filed the motion, attaching the third amended complaint. The district court denied relators' motion for futility because it could not survive a Rule 12(b)(6) motion to dismiss. A district court's order denying a Rule 15(a) motion to amend is typically reviewed for abuse of discretion. *Rose v. Hartford Underwriters Ins. Co.*, 203 F.3d 417, 420 (6th Cir. 2000). However, where the district court denies leave to amend because the complaint,

2. The parties do not challenge this particular order, but we note that, in these circumstances, the district court was under no obligation to grant relators leave to file a Rule 15 motion to amend. Where parties have fully argued the merits of a 12(b)(6) motion to dismiss and the district court has duly considered those arguments and issued an opinion resolving the motion, it is a stretch to say justice requires granting leave to cure the complaint's deficiencies as identified in adversarial pleadings and the district court's order—even where the initial order turned on a failure to meet Rule 9(b)'s particularity requirements. *See SNAPP, Inc.*, 532 F.3d at 510-11 (noting that "*Bledsoe II* should not be taken to imply that the district court must grant Relator leave to file an amended complaint") (Suhrheinrich, J., concurring).

as amended, would not withstand a motion to dismiss, that denial is reviewed de novo. *Seaton v. TripAdvisor LLC*, 728 F.3d 592, 596 (6th Cir. 2013). Thus, we review the district court's order de novo.

1. Public-Disclosure Bar

Generally, unless the relator was an "original source" within the meaning of the statute, the FCA bars a claim based on publicly disclosed information. *U.S. ex rel. Antoon v. Cleveland Clinic Found.*, 788 F.3d 605, 614 (6th Cir. 2015); 31 U.S.C. § 3730(e)(4)(A)-(B) (2012). The district court determined that several of the new facts and allegations included in the third amended complaint ran afoul of the public-disclosure bar, undermining the viability of the claims. Relators challenge that conclusion on appeal.

On March 23, 2010, the public-disclosure bar was amended by the Patient Protection and Affordable Care Act. Pub. L. 111-148, 124 Stat. 119 (2010). What constitutes "public disclosure" and an "original source" changed with the FCA amendment, but a common principle remains; public disclosure occurs "when enough information exists in the public domain to expose the fraudulent transaction." *See Antoon*, 788 F.3d at 614-15. Because relators' complaint alleges fraud spanning from 2005 to 2015, the amended complaint is subject to both versions of the public-disclosure bar. *See id.* at 614-15 (holding that the FCA public disclosure bar in effect at the time of the alleged fraud, not the time of filing, applies). But, as conceded by both parties, any difference in statutory

language is irrelevant if the outcome would be the same under either version. *See U.S. ex rel. Lockey v. City of Dallas*, 576 F. App'x 431, 437-38 (5th Cir. 2014) ("While the language in the current version of the [FCA] differs from [that] in the prior version of the statute . . . on the facts of this case, the outcome is the same."). Here, the outcome is the same under both versions of the statute.

To decide whether a claim has been publicly disclosed, courts look at the essential elements of alleged fraud to determine if enough information exists in the public domain to expose the fraudulent transaction. *See Dingle v. Bioport Corp.*, 388 F.3d 209, 212 (6th Cir. 2004); *Antoon*, 788 F.3d at 614-15. Thus, the public disclosure bar is not implicated—even if one or more of a claim's essential elements are in the public domain—unless the exposed elements, taken together, provide adequate notice that there has been a fraudulent transaction. *See Dingle*, 388 F.3d at 212; *U.S. ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 512-13 (6th Cir. 2009) (holding public disclosure barred a federal claim that alleged substantially the same conduct as a previously filed state civil action).

Exposing a fraudulent transaction under an off-label promotion scheme requires a relator to string together several necessary elements. Here, relators must connect defendants' promotion of Abilify to the eventual submission of a related claim to the government. But it is this first link in the chain—the improper promotion of the drug—that is crucial. This is because, even if the scheme's other elements were publicly disclosed—e.g., it was publicly disclosed that the government had paid claims for off-label

prescriptions of Abilify—the FCA is implicated only if that conduct is somehow tied back to improper promotion.[3] Thus, no fraud was publicly disclosed without disclosure of this key element.

Here, defendants assert that the government's previous FCA actions and resultant Corporate Integrity Agreements constitute disclosure of defendants' improper promotion of Abilify. The district court agreed, finding that relators' alleged scheme "closely track[s]" the pre-agreement promotion scheme. R. 97, Dist. Ct. Order, PID 2160. However, it was error for the court to hold that this resemblance alone called for dismissal under the public disclosure bar.

If a fraudulent off-label promotion scheme was publicly disclosed and then resolved, allegations of improper promotion that took place before the agreements putatively ended the scheme would necessarily implicate the public disclosure bar. But allegations that the scheme either continued despite the agreements or was restarted after the agreements are different. It cannot be assumed that the government is aware a fraudulent scheme continues (or was restarted) simply because it had uncovered, and then resolved, a similar scheme before.[4] Indeed, the most

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3. Highlighting, once again, just how awkward it is to use the FCA to punish pharmaceutical companies for improper promotion of prescription medication. *See Polansky*, 822 F.3d at 615.

4. This may be true only to the extent that the new allegations are temporally distant from the previously resolved conduct. *See U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 43 F. Supp. 3d 332,

logical inference to draw from defendants' agreements to cease improper promotion of Abilify is that they had done so. Thus, to the extent that relators are able to describe with particularity post-agreement, improper promotion of Abilify, the mere resemblance of those allegations to a scheme resolved years earlier is not by itself enough to trigger the public disclosure bar.[5]

Here, other than the fact that the alleged scheme resembled that described in the prior enforcement action, defendants do not otherwise show the alleged improper promotion was publicly disclosed. Thus, there was not enough information in the public domain to expose the alleged fraudulent transactions, meaning the public disclosure bar does not implicate fraud connected to post-agreement improper promotion of Abilify.

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353 (S.D.N.Y. 2014) ("Allegations that an extensive fraudulent scheme occurred [and was resolved] on February 14 strongly indicate that the scheme is still taking place on February 15 and February 16"). Here, instantaneous compliance with the Corporate Integrity Agreements was unlikely, but relators' allegations that the fraud continued intentionally for years after the agreements were entered into goes well beyond any reasonable period the government may have expected it to.

5. We note that Rule 9(b)'s particularity requirements prevent a relator from proceeding to discovery on bare allegations that generally describe the same or similar conduct as a prior FCA action. The particularity requirement is stringent. *See Chesbrough*, 655 F.3d at 470.

2. Representative False Claims Under Section 3729(a)(1)(A)

As previously discussed, outside the narrow circumstances described in *Prather*, Rule 9(b) requires relators to provide facts identifying a representative claim that was presented to the government, i.e., "[t]he actual *submission* of a *specific* request for anticipated payment to the government." *Prather*, 838 F.3d at 768-69. Because relators do not allege personal knowledge supporting the strong inference that claims were submitted such that the *Prather* exception could apply, they must provide the court with a specific representative claim submitted to the government pursuant to the alleged scheme. *See id.* at 768.

In this context, a representative claim consists of a request for a prescription reimbursement submitted to the government for either an off-label prescription of Abilify or one induced and written by a specific provider to whom either or both defendants improperly promoted the drug. To that end, relators must identify a representative claim with *specificity* as to each necessary component of the alleged scheme; identifying a claim that merely infers one or more of these elements is inadequate. *See Yuhasz*, 341 F.3d at 564 ("[A] plaintiff should not be able to avoid the specificity requirements of Rule 9(b) by relying upon the complexity of the edifice which he created") (internal quotation marks); *SNAPP, Inc.*, 532 F.3d at 506 ("Rule 9(b) 'does not permit an [FCA] plaintiff merely to describe a private scheme in detail but then to allege simply . . . that claims requesting illegal payments must have been submitted, were likely submitted or should have been

submitted to the Government.'") (quoting *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006)). The third amended complaint identifies many inference-based claims. All are inadequate under our FCA pleading standard.

Relators' failure to identify a representative claim with adequate specificity warrants a few examples. For one, relators attach an exhibit identifying reimbursement for prescriptions of Abilify paid to various pharmacies by Massachusetts Medicaid for prescriptions of Abilify filled for pediatric patients before the drug had any pediatric indication. However, nothing connects any of the prescribing physicians, not identified by name or care facility, to defendants' improper promotion. Similarly, relators attach an exhibit identifying Abilify prescriptions paid by California Medi-Cal as prescribed by two physicians with whom the defendants allegedly had a relationship. All the same, the patient diagnoses by these doctors are not identified; meaning it is not a necessary inference that any one of the Abilify prescriptions they wrote was for an off-label use. Moreover, there is nothing about the alleged relationship between these physicians and the defendants that can be characterized as a violation of the Anti-Kickback Statute or that any particular Abilify prescription they wrote was improperly induced. The same failures undercut Abilify prescriptions paid by Kentucky Medicaid.

Relators also attempt to identify a representative claim by describing a patient identified as "D.M." and two Abilify prescriptions written for him. First, relators

attach a receipt for an Abilify prescription written to treat D.M. and filled by a Kroger Pharmacy in 2015. Second, relators attach a 2013 diagnostic assessment of D.M., reporting that he was taking Abilify as prescribed by another doctor in July of that year. Both prescriptions were for off-label uses, but neither is an adequately pled representative claim.

First, the complaint fails to adequately allege that the 2013 prescription was presented to the government for payment. The complaint does not identify a pharmacy or any other entity that may have submitted a claim for reimbursement to a government program for the 2013 prescription. However, relators allege that, because D.M. had been a Medicaid beneficiary "for nearly all of his life," the prescription was reimbursed by Ohio Medicaid. R. 82-1, Third Amd. Complt., ¶ 341. But absent any factual support for this allegation and lacking any identifying information on who may have submitted a claim to the government for the 2013 prescription, we are not to simply assume a claim was presented to the government because relators say so. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678-79, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009); *Prather*, 838 F.3d at 768. In this regard, the 2013 prescription lacks the specificity of the 2015 prescription—which at least identifies the relevant pharmacy and notes that D.M. paid nothing to fill that prescription—though even that additional detail neither confirms nor denies that Ohio Medicaid (or any other government program) was presented with a prescription for reimbursement. In sum, absent any support for the allegation that the 2013 prescription was submitted to a government program or any more specificity as to that claim, it is not representative of the alleged scheme.

Second, the 2015 prescription fails at an earlier link in the scheme's chain because it is not adequately connected to defendants' improper promotion. Relators allege that the prescription was written by a physician who was working as a provider at a facility to which defendants allegedly promoted Abilify from 2005 to 2007. Thus, the complaint relies on inference to bridge a gap of approximately eight years between the alleged promotion in 2007 and D.M.'s 2015 prescription. This hardly satisfies the *Twombly* standard. *See Twombly*, 550 U.S. at 556. In short, the D.M. prescriptions are not adequately pled representative claims.

There are many other claims identified in the complaint which are similarly inadequate to provide the single, specific claim for reimbursement required to survive a motion to dismiss. We will not belabor the point by individually discussing the inadequacies of each claim (there are many), but suffice it to say that relators have not identified a single request for prescription reimbursement submitted to the government for a prescription of Abilify written by a provider to whom either or both defendants improperly promoted the drug. Relators have therefore failed to adequately plead a violation of 31 U.S.C. § 3729(a)(1)(A). Accordingly, the district court correctly held that those claims would not survive a motion to dismiss.

3. Claims Under Section 3729(a)(1)(B), (C), and (G)

Relators' three related claims, under 31 U.S.C. § 3729(a)(1)(B), (C), and (G), would likewise not survive a motion to dismiss.

Relators nowhere cure the inadequacy of their pleadings as to the section 3729(a)(1)(C) conspiracy claim. As in the second amendment complaint, there is no alleged plan to get a false claim paid and the allegations remain no more than threadbare recitations of the elements of the cause of action. *See Twombly*, 550 U.S. at 555. Accordingly, as amended, that claim would not survive a Rule 12(b)(6) motion to dismiss.

Relators do beef up allegations relating to their section 3729(a)(1)(B) claim, but the claim continues to fall short. Despite amending the complaint to include a plethora of data showing Abilify claims submitted to government reimbursement programs, those claims, as before, are not adequately tied to any allegedly false statements made by defendants. Thus, the connection between false statements and claims submitted to the government remains "too attenuated to establish liability." *See Allison Engine Co.*, 553 U.S. at 671-72.

The amended reverse false claims allegations rely on the Corporate Integrity Agreements, attached to the third amended complaint. Relators assert these documents created an obligation to pay the government under the FCA. However, section 3729(a)(1)(G)'s "obligation" does not include "those contingent obligations that arise only because the government has prohibited an act, or arising after the exercise of government discretion." *Am. Textile Mfrs. Inst.*, 190 F.3d at 741. The district court found the Corporate Integrity Agreements to be "contingent obligations" and failed to trigger a reverse false claim.

We agree. Both defendants were subject to nearly identical Corporate Integrity Agreements, the breach of which "may" have led to obligations to pay stipulated penalties. R. 82-2, BMS CIA, PID 1758; R. 82-3, Otsuka CIA, PID 1825. Yet even an alleged breach of these agreements did not, by itself, constitute an obligation to pay the government. This is because the penalties for a breach of the agreements were subject to discretionary enforcement by the Office of the Inspector General, who was to determine whether the penalties were "appropriate" before triggering an administrative review process to collect those penalties. R. 82-2, BMS CIA, PID 1760-61; R. 82-3, Otsuka CIA, PID 1827. This is the type of non-obligation that fails to satisfy 31 U.S.C. § 3729(a)(1)(G). *See Am. Textile Mfrs. Inst.*, 190 F.3d at 738 ("[e]xamples of contingent obligations include those arising from civil and criminal penalties that impose monetary fines after a finding of wrongdoing . . . [and] attach only after the exercise of administrative or prosecutorial discretion"). Accordingly, relators fail to adequately plead a reverse false claim in their third amended complaint.

In sum, even considering the newly pled facts, amending the complaint would be futile as it would not survive a motion to dismiss. Accordingly, we affirm the district court's denial of relators' motion to amend.

III.

Because relators have failed to plead a violation of the FCA with adequate particularity, we **AFFIRM** the orders certified for appeal by the district court and **REMAND** for further proceedings consistent with this opinion.

Appendix A

CONCURRING IN PART AND DISSENTING IN PART

JANE B. STRANCH, Circuit Judge, concurring in part and dissenting in part. The American health care system, the context for this case, is not only a life and death industry, but also the source of one in every eight jobs in the United States and one dollar of every six in our gross domestic product. *See* Employment by Major Industry Sector, Bureau of Labor Statistics (Dec. 8, 2015), https://www.bls.gov/emp/ep_table_201.htm; National Health Expenditure Projections 2016-2025, Ctrs. for Medicare & Medicaid Servs. at 1, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2016.pdf (last visited Oct. 20, 2017). The scale of health care fraud is comparably huge. As I have previously discussed, rampant health care fraud in the United States likely costs Medicare and Medicaid between $30 and $98 billion each year. *United States ex rel. Doghramji v. Cmty. Health Sys., Inc.*, 666 F. App'x 410, 419 (6th Cir. 2016) (Stranch, J., concurring). That cost is transferred to us all in the forms of higher health care bills, premiums, co-pays, and taxes. The False Claims Act (FCA), the legal vehicle that relators use to bring claims identifying and combatting that fraud, operates on the same massive scale, having allowed the United States to recover over $31 billion between 2009 and 2016. *See* Justice Department Recovers Over $4.7 Billion From False Claims Act Cases in Fiscal Year 2016, U.S. Dep't of Justice (Dec. 14, 2016), https://www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016 .

Qui tam relators are critical to the FCA's operation. Their suits are responsible for over sixty-three percent of FCA recoveries between 1986 and 2008. *Doghramji*, 666 F. App'x at 419 (Stranch, J., concurring). When drafting the FCA, "Congress wrote expansively, meaning 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.'" *Cook County v. United States ex rel. Chandler*, 538 U.S. 119, 129, 123 S. Ct. 1239, 155 L. Ed. 2d 247 (2003) (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 232, 88 S. Ct. 959, 19 L. Ed. 2d 1061 (1968)). Congress has not backed down from this expansive position. To the contrary, Congress amended the Act in 1986 "to strengthen the Government's hand in fighting false claims, and to encourage more private enforcement suits," *Graham Cty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 298, 130 S. Ct. 1396, 176 L. Ed. 2d 225 (2010) (citations and internal quotation marks omitted), and then expanded its scope again in 2009, *Boegh v. EnergySolutions, Inc.*, 772 F.3d 1056, 1062 (6th Cir. 2014). In the 2009 amendments, Congress recognized the important role of *qui tam* relators, explained that the "effectiveness of the False Claims Act ha[d] recently been undermined by court decisions which limit the scope of the law," and expanded FCA protections for relators. S. Rep. No. 111-10, at 4 (2009). This case arises in the context of that Congressional concern and is reviewed under the post-2009 provisions of the FCA.

I respectfully dissent from the majority opinion except for its public-disclosure bar analysis in Part II(D)(1). I concur in the holding that the public-disclosure bar does not apply to fraudulent schemes that continue

or are restarted following a defendant's entry into an agreement with the government. Maj. Op. at 11-14. A contrary rule would allow a company to use publicly disclosed agreements to avoid liability for future bad acts that mirror previous misdeeds. The rule announced today, on the other hand, ensures that the public-disclosure bar does not prohibit a challenge to improper post-agreement behavior. I turn to the reasons for my dissent.

The relators allege that the defendants violated the FCA by once again submitting hundreds of millions of dollars of claims for prescriptions of an illegally promoted drug. The complaint alleges facts based on the relators' personal knowledge, collaboration with others, and extensive research. At this stage in the proceedings, "the Court must construe the complaint in the light most favorable to the plaintiff, accept all factual allegations as true, and determine whether the complaint contains enough facts to state a claim to relief that is plausible on its face." *United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 838 F.3d 750, 761 (6th Cir. 2016) (quoting *United States ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 502 (6th Cir. 2008)).

When sounding in fraud, claims brought under the FCA must satisfy Rule 9(b)'s requirement that the relevant fraudulent circumstances be stated "with particularity." Fed. R. Civ. P. 9(b); *see also United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007). Particularized pleading in this context typically requires a showing of a false claim that was actually submitted to the government. *Bledsoe*, 501 F.3d at 505 ("A relator cannot meet this [pleading] standard

without alleging which specific false claims constitute a violation of the FCA."). But, as our sister circuits have concluded, particularity is not necessarily synonymous with representative samples. Particularity may also be satisfied where a relator "alleg[es] particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009); *see also United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 86 (2d Cir. 2017); *United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 126, 416 U.S. App. D.C. 289 (D.C. Cir. 2015); *United States ex rel. Thayer v. Planned Parenthood of the Heartland*, 765 F.3d 914, 917-18 (8th Cir. 2014); *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156-57 (3d Cir. 2014); *Ebeid v. Lungwitz*, 616 F.3d 993, 998-99 (9th Cir. 2010); *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010); *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 30 (1st Cir. 2009); *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009).

When applying a strict pleading standard in cases prior to *Prather*, we left open the possibility that a relator can survive a motion to dismiss when the relator "has pled facts which support a strong inference that a claim was submitted." *Prather*, 838 F.3d at 769 (quoting *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 471 (6th Cir. 2011)); *see also United States ex rel. Sheldon v. Kettering Health Network*, 816 F.3d 399, 414 (6th Cir. 2016). In *Prather*, we noted that every circuit that has applied a heightened pleading standard "has retreated from such a requirement in cases in which other detailed factual

allegations support a strong inference that claims were submitted." *Prather*, 838 F.3d at 772 (citing *Thayer*, 765 F.3d at 917-18; *Lemmon*, 614 F.3d at 1172; *United States ex rel. Walker v. R&F Props. of Lake Cty., Inc.*, 433 F.3d 1349, 1360 (11th Cir. 2005)). We then "confirm[ed] our adoption of that exception," holding that a plaintiff can "survive a motion to dismiss by pleading specific facts based on her personal billing-related knowledge that support a strong inference that specific false claims were submitted for payment." 838 F.3d at 773.

As was the case in *Prather*, we are confronted in this case with "detailed factual allegations [that] support a strong inference that claims were submitted." *Id.* at 772. In light of our governing precedent, I think that the majority erred by failing to read the third amended complaint in the light most favorable to the plaintiff and to accept all factual allegations as true. That complaint points to off-label prescriptions that were written by physicians targeted in the alleged scheme and paid for by state Medicaid programs—and so, ultimately, submitted to the United States government. For example, "Dr. 3" was targeted by defendants in their marketing scheme to increase off-label sales of Abilify starting in May 2007. Dr. 3 wrote a prescription for a twelve-year-old patient that was filled on January 29, 2008 at a specific CVS pharmacy; the $370.59 bill was paid by Massachusetts Medicaid. The use was off-label because, at the time, Abilify had not been medically indicated for patients under the age of thirteen. As another example, in April 2010, relator Ibanez personally sat in on a meeting discussing how to promote off-label use of Abilify to a specific child and adolescent psychiatrist in Cincinnati. That doctor had

just written 124 prescriptions for Abilify that had been filled between November 2009 and January 2010 and paid for by Kentucky Medicaid. As discussed in the majority opinion, prescriptions for off-label use of Abilify were written for juvenile D.M. and paid for by Ohio Medicaid. Maj. Op. at 15-16. The majority is concerned with the lack of information about D.M.'s receipt of Medicaid reimbursements and the gap between promotion and filling the prescription. *Id.* But the complaint explains that relator Ibanez himself targeted the facility where D.M. was first prescribed Abilify during the year when he was first prescribed it. The complaint alleges that D.M. "routinely filled his Abilify prescriptions at Kroger pharmacies" and was reimbursed by Ohio Medicaid; the 2015 prescription the majority finds insufficiently linked to the initial promotion is offered as "but one example" of that continuous trend from the initial prescription in 2010. These examples, and the many others with which the complaint abounds, provide adequate and fair notice to defendants of the claims brought against them.

The First Circuit correctly recognized that a relator alleging that the defendant induced third parties to file false claims can "satisfy Rule 9(b) by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility' without necessarily providing details as to each false claim." *Duxbury*, 579 F.3d at 29 (quoting *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007)). These relators employed this method to support the examples of false claims described above. First and foremost, the relators have personal knowledge of the corporate strategies employed to promote off-label uses of Abilify. They also provide extensive statistical

evidence that creates the strong inference both that this scheme occurred and that it resulted in substantial claims paid by the government.

The majority opinion points out that the facts in this complaint are not identical to those in *Prather*, where the relator alleged "specific personal knowledge that relates directly to billing practices." Maj. Op. at 7 (quoting *Prather*, 838 F.3d at 769). I agree that the relators in this case were not personally involved in billing. However, the relators here have nonetheless "pled facts which support a strong inference that a claim was submitted." *Prather*, 838 F.3d at 769 (quoting *Chesbrough*, 655 F.3d at 471). Relators, unlike the government, do not have many legal tools available to discern details of claims during the pleading stage. Making those legal tools available is precisely the purpose of discovery. The facts in the third amended complaint—detailed examples of the alleged scheme backed by personal knowledge and statistical evidence—are sufficient to satisfy Rule 9(b)'s requirement that the "circumstances constituting fraud" are stated with particularity. Fed. R. Civ. P. 9(b).

In summary, I concur in the majority opinion's holding that the public-disclosure bar does not apply here. I cannot agree with the remainder of the majority opinion because the relators have pled facts sufficient to satisfy Rule 9(b) by identifying specific claims and supplementing those identifications with personal knowledge and statistical evidence. Thus, under our precedent and in accordance with the purposes of the FCA specified by Congress, this case should not be dismissed. I therefore respectfully dissent.

APPENDIX B — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT, FILED JANUARY 3, 2018

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

No. 16-3154

UNITED STATES OF AMERICA EX REL. JOSEPH IBANEZ AND JENNIFER EDWARDS,

Relators-Appellants,

v.

BRISTOL-MYERS SQUIBB COMPANY; OTSUKA AMERICA PHARMACEUTICAL, INC.,

Defendants-Appellees.

BEFORE: McKEAGUE, KETHLEDGE, and STRANCH, Circuit Judges.

ORDER

The court received a petition for rehearing *en banc*. The original panel has reviewed the petition for rehearing and concludes that the issues raised in the petition were fully considered upon the original submission and decision of the case. The petition then was circulated to the full

court.* No judge has requested a vote on the suggestion for rehearing *en banc*.

Therefore, the petition is denied.

ENTERED BY ORDER OF THE COURT

/s/
Deborah S. Hunt, Clerk

* Judge White recused herself from participation in this ruling.

APPENDIX C — MEMORANDUM OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT, SOUTHERN DISTRICT OF OHIO, WESTERN DIVISION, FILED SEPTEMBER 24, 2015

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 COMPANY

Defendant.

MEMORANDUM OPINION AND ORDER

Introduction

This is a *qui tam* action brought pursuant to the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3730. On behalf of the United States and various State governments, Joseph Ibanez and Jennifer Edwards ("Relators"), former sales representatives for Bristol-Myers Squibb ("BMS"), allege that BMS and Otsuka America Pharmaceutical ("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 § 3729(a)(1)(A).

This matter is before the Court on Relators' Motion for Leave to File Third Amended Complaint Instanter ("Motion"). Doc. 82. Defendants BMS and Otsuka filed separate Responses to Relators' Motion, Docs. 83 & 84. After Defendant Otsuka pointed out in its Response that some of Relators' new factual allegations in the proposed Third Amended Complaint ("TAC")[1] might implicate the FCA's public-disclosure bar, Doc. 84, at 18 n.8,[2] the Court directed Relators to address issues related to the public-disclosure bar in their Reply by separate Order, Doc. 86. Relators subsequently filed a Reply, Doc. 92, and Defendants BMS and Otsuka filed separate Surreplies with the Court's leave, Docs. 93 & 94.

The Court has reviewed this matter and concludes that oral argument is unnecessary.

Analysis

A. Legal Standards

1. Motion for Leave to Amend Complaint

Federal Rule of Civil Procedure 15(a)(2) states that "[t]he court should freely give leave [to amend] when justice so requires." But a federal trial court does not

1. The proposed TAC is in the record at Doc. 82-1.

2. All page numbers cited to in the parties' filings are to the PAGEID # at the top of the page, rather than to the page number included by the parties at the bottoms of the pages.

have to give a party leave to amend her complaint if doing so would be futile, such as when the amended complaint cannot survive a motion to dismiss. *SFS Check, LLC v. First Bank of Del.*, 774 F.3d 351, 355 (6th Cir. 2014).

2. False Claims Act Pleading

Claims brought under the FCA are subject to the heightened pleading standard of Rule 9(b)'s particularity requirement. *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 466 (6th Cir. 2011). In order to meet the particularity requirement, Relators, at minimum, "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)).

In its prior order dismissing Relators' FCA claims as insufficiently pled, the Court gave Relators the benefit of a "relaxed" pleading standard that the Sixth Circuit discussed in Chesbrough but has not applied subsequently -- the "strong inference" standard. Doc. 73, at 7-8. But Relators state in their current Motion that they have provided the Court with representative samples of a broader class of false claims "that satisfies the *Bledsoe II* pleading standard." Doc. 82, at 7. Because Relators state that the proposed TAC can meet the normal rules for FCA pleading and not just the strong-inference standard from *Chesbrough*, the Court will apply the *Bledsoe II* standard to the proposed TAC.

Appendix C

B. Public-Disclosure Bar

Defendants argue that Relators' reliance on materials in the proposed TAC that fall within the FCA's public-disclosure bar renders the filing of Relators' proposed TAC futile. There are two versions of the public-disclosure bar that apply to Relators' proposed TAC. *United States ex rel. Antoon v. Cleveland Clinic Found.*, 788 F.3d 605, 614-15 (6th Cir. 2015).

Prior to March 23, 2010, the FCA provided the following with respect to public disclosures and the original-source requirement:

> (4)(A) *No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media*, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who has *direct and independent knowledge of the information on which the allegations are based* and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(2)(A)-(B) (2006) (emphasis added).

Appendix C

Effective March 23, 2010, as part of the Affordable Care Act ("ACA"), Congress amended the public-disclosure bar and original source-requirement to read as follows:

> (4)(A) *The court shall dismiss an action or claim under this section*, unless opposed by the Government, *if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed--*
>
> (i) *in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party*;
>
> (ii) *in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or*
>
> (iii) *from the news media*,
>
> unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means a*n individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions* in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or

> transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

31 U.S.C. § 3730(e)(4)(A)-(B) (2012) (emphasis added).

In *Antoon*, the Sixth Circuit relied on two recent Supreme Court decisions Court stating that this amendment is not retroactive, *Schindler Elevator Corp. v. United States ex rel. Kirk, 131 S. Ct. 1885, 1889 n.1 (2011), and Graham County Soil & Water Conservation District v. United States ex rel. Wilson*, 559 U.S. 280, 283 n.1 (2010), to hold that the pre-ACA version of the public-disclosure bar applies to allegations of fraud on the government that predate the 2010 amendment. *Antoon*, 788 F.3d at 614-15. Because Relators' allegations of fraud against Defendants BMS and Otsuka in the proposed TAC extend from 2005 to 2015, *see* Doc. 82-1, ¶¶ 112, 342, the Court must apply the jurisdictional pre-ACA version of the public-disclosure bar to their allegations of fraud that pre-date March 23, 2010. For Relators' allegations that post-date March 23, 2010, the Court must apply the non-jurisdictional public-disclosure bar.[3]

Importantly, for purposes of the pre-ACA public-disclosure bar, "a person who bases *any part* of a FCA claim on publicly disclosed information is effectively precluded from asserting that claim in a *qui tam* suit."

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3. Although the post-ACA version of the public-disclosure bar is not jurisdictional in nature, it expressly authorizes dismissal of an action or claim. 31 U.S.C. § 3730(e)(4)(A).

United States ex rel. Bledsoe v. Cmty. Health Sys. ("Bledsoe I"), 342 F.3d 634, 646 (6th Cir. 2003) (emphasis added). Further, "the general case law pertaining to the [public-disclosure] bar is still applicable . . . , regardless of whether the cases were decided before or after" the enactment of the ACA. U*nited States v. Chattanooga-Hamilton Cnty. Hosp. Auth.*, No. 1:10-cv-322, 2014 WL 7912981, at *4 (E.D. Tenn. Mar. 28, 2014). This is so because

> the primary difference between the pre-[ACA] and post-[ACA] language is that the pre-[ACA] language emphasizes that the allegations must be "based upon the public disclosure" whereas the post-[ACA] language emphasizes that the disclosure must involve "substantially the same allegations or transactions." Even prior to the [ACA], however, the United States Court of Appeals for the Sixth Circuit explained that "[i]n making this determination of whether an action is 'based upon' a public disclosure, a court should look to whether substantial identity exists between the publicly disclosed allegations or transactions and the *qui tam* complaint."

Id. (final alteration in original) (quoting *United States ex rel. Jones v. Horizon Healthcare Corp.*, 160 F.3d 326, 332 (6th Cir. 1998)).

In its August 13 Order, the Court directed Relators to inform it as to "where and how" they obtained the

following information relied on in the proposed TAC: (1) information concerning the minor, D.M.; (2) information concerning state court lawsuits filed by two women in New York; (3) information related to claims paid by Medicaid in New York, Massachusetts, and California; (4) information concerning remuneration Otsuka paid to Dr. Jason Kellogg in 2015; (5) Medicare Provider Utilization and Payment Data from CMS; (6) a June 16, 2013 article in the *Orange County (CA) Register*; (7) a 2015 GAO report concerning use of antipsychotics in elderly patients; and (8) an April 18, 2015 letter from the FDA to Otsuka. Doc. 86, at 1-2.

According to the Sixth Circuit in *Antoon*:

> A public disclosure occurs "when enough information exists in the public domain to expose the fraudulent transaction.'" *United States ex rel. Jones v. Horizon Healthcare Corp.*, 160 F.3d 326, 331 (6th Cir. 1998) (quoting *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994)). There is enough information in the public domain if "'the information is sufficient to put the government on notice of the likelihood of related fraudulent activity.'" [*United States ex rel. Poteet v. Medtronic, Inc.*], 552 F.3d [503,] 512 (quoting *United States ex rel. Gilligan v. Medtronic, Inc.*, 403 F.3d 386, 389 (6th Cir. 2005)). Public disclosure "includes documents that have been filed with a court, such as discovery documents and a plaintiff's complaint," *ibid.*, even if the plaintiffs filed the

> documents themselves, U*nited States ex rel. Jones v. Horizon Healthcare Corp.*, 160 F.3d 326, 333 (6th Cir. 1998). Public disclosure also includes responses to FOIA requests. *Schindler Elevator*, 131 S. Ct. at 1893.

788 F.3d at 615-16.

The information in categories (3) through (5) above implicates at least one version of the public-disclosure bar. It is unnecessary to analyze the remaining sources, because Relators use the Medicaid and CMS data pervasively throughout their proposed TAC. It is also unnecessary to analyze whether the government was on notice of the fraud alleged by Relators, because it is indisputable that Relators' allegations closely track previous FCA actions that the United States filed against BMS and Otsuka, those that resulted in Defendants' CIAs. Doc. 82-1, ¶¶ 110-11.

As to the information concerning Medicaid claims paid by New York, Massachusetts, and California, they are public disclosures for purposes of the pre-ACA version of the public-disclosure bar, but they are not public disclosures for purposes of the post-ACA version of the public-disclosure bar. Relators explain in their Reply that they "provided the [S]tates with names of a sampling of physicians including those who were targeted by Defendants with off-label messaging and/or who were speakers for Defendants, and the [S]tates provided data confirming that those physicians wrote off-label prescriptions for [ABILIFY®], which were submitted to and paid for by Medicaid." Doc. 92, at 10.

Whether Relators utilized the States' FOIA analogs or some other mechanism to obtain this information from the States, these sources qualify as public disclosures because they are the functional equivalent of a FOIA request. And State FOIA requests are public disclosures for purposes of the pre-ACA, jurisdictional public-disclosure bar. *See United States ex rel. Fried v. West Indep. Sch. Dist.*, 527 F.3d 439, 442 (5th Cir. 2008). To the extent that Relators rely on this information in support of allegations of fraud that predate March 23, 2010, the Court lacks jurisdiction over those claims because there can be no colorable argument that Relators are the original sources of claims data obtained from State Medicaid programs. Relators use the information to buttress their pediatric off-label promotion allegations, Doc. 82-1, ¶ 344, so the Court lacks jurisdiction over that claim for fraud alleged to have occurred prior to March 23, 2010. Amendment of that portion of the pediatric off-label promotion claim would therefore be futile.

As to the information about Dr. Kellogg and the Medicare provider data that Relators obtained from CMS, those sources qualify as public disclosures under either version of the public-disclosure bar. In *Schindler Elevator*, the Supreme Court defined "report" in the public-disclosure bar to mean "something that gives information," a "notification," or "[a]n official or formal statement of facts or proceedings." 131 S. Ct. at 1891. There is no question that information posted on the CMS website falls within the latter definition; the aggregate data are an official statement of facts. To the extent that Relators rely on this information in support of allegations

of fraud that predate March 23, 2010, the Court lacks jurisdiction over those claims because there likewise can be no colorable argument that Relators are the original sources of claims and remuneration data obtained from CMS. Relators use this information to buttress their pediatric and geriatric off-label promotion claims, Doc. 82-1, ¶¶ 259, 345, as well as their alleged AKS claims, *id.* ¶ 259, so the Court lacks jurisdiction over those claims for fraud alleged to have occurred prior to March 23, 2010, and the claims that post-date March 23, 2010, are subject to dismissal. Amendment of these claims would thus be futile.

B. Remaining Claim[4]

The only remaining claim is Relators' FCA claim premised on Defendants' CIAs with the federal government. Amendment of this claim would also be futile because the CIAs do not create a concrete obligation to pay the government money absent intervening discretionary action by the government. Alternatively, even if the CIAs could support a reverse false claim, Relators' pleading of these claims cannot satisfy Rule 9(b)'s particularity requirement.

In *Chesbrough*, the Sixth Circuit affirmed the dismissal of a relators' reverse false claim because they

4. In their Motion, Relators mention only their FCA claims for off-label promotion to pediatric and geriatric providers, their FCA claims premised on the AKS, and their FCA claims premised on Defendants' CIAs with the federal government. Doc. 82, at 6-14. The Court thus does not address Relators' other claims that the Court ruled on in its prior Memorandum Opinion and Order.

did not "identify in their complaint any concrete obligation owed to the government by [Defendant] at the time an allegedly false statement was made." 655 F.3d at 473. The *Chesbrough* court so reasoned because a prior Sixth Circuit case, *American Textile Manufacturers Institute, Inc. v. The Limited, Inc.*, 190 F.3d 729 (6th Cir. 1999), stated: "Contingent obligations -- those that will arise only after the exercise of discretion by government actors--are not contemplated by the [FCA]." *Id.* at 738. Defendants argue persuasively that the stipulated-penalties provisions of their CIAs with the government do not give rise to any concrete obligation to pay the government money.

As Relators plead in their proposed TAC:

> 372. Pursuant to the CIAs, the OIG *may* "exercise its contractual right to demand payment" of the penalties by "demand letter" after finding that Defendants "failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate. . . ." 2007 CIA, p. 44, Section X.C.1; 2008 CIA, p. 31, Section X.C.1.

Doc. 82-1, ¶ 372 (emphasis added). Relators' pleading thus shows that, before BMS or Otsuka owed any money to the government pursuant to the stipulated-penalties provisions of the CIAs, the government had the option (hence the word "may") to send a demand letter to Defendants after determining that collecting on the stipulated penalties was appropriate. BMS also points to other sections of the CIAs stating that Defendants have a

right to cure any alleged defect or seek a hearing before an administrative law judge ("ALJ") to contest that a defect occurred. Doc. 83, at 23 (citing BMS CIA § X.C.2); *see also* Doc. 82-3, § X.C.2.

In short, the government's discretion with respect to whether to levy a stipulated penalty against Defendants under the explicit terms of the CIAs, combined with Defendants' rights to cure any alleged defect or to seek a hearing in front of an ALJ to contest an alleged defect, leads the Court to conclude that the stipulated-penalty provisions are contingent obligations, rather than concrete obligations of the sort envisioned by the *American Textile* and *Chesbrough* courts.[5]

Even if the Court concludes that Defendants' CIAs create concrete obligations that could give rise to a

5. The Court notes that there is a split of authority among other United States District Courts on this issue. One district court has agreed with Defendants' argument and the above reasoning. *United States ex rel. Booker v. Pfizer, Inc.*, 9 F. Supp. 3d 34, 49 (D. Mass. 2014) ("The mere fact that Pfizer's failure to report '*might* result in a fine or penalty is insufficient' to establish an 'obligation' to pay the government under § 3729(a)(1)(G)." (quoting *United States ex rel. Bahrani v. Conagra, Inc.*, 465 F.3d 1189, 1195 (10th Cir. 2006)). Two other district courts have reached the opposite conclusion. *United States ex rel. Boise v. Cephalon, Inc.*, No. 08-cv-287, 2015 WL 4461793, at *3-7 (E.D. Pa. July 21, 2015) (reasoning that a reverse false claim premised on a CIA can proceed because a contractual duty to pay is not contingent on the aggrieved party filing a lawsuit); *Ruscher v. Omnicare, Inc.*, No. 4:08-cv-3396, 2014 WL 4388726, at *5-6 (S.D. Tex. Sept. 5, 2014) (similar).

reverse false claim, Relators still have not pled their reverse false claims with the particularity required by Rule 9(b). Relators fail to plead the "time, place, and content" of any alleged misrepresentations by BMS and Otsuka. *Chesbrough*, 655 F.3d at 466 (quoting *Bledsoe II*, 501 F.3d at 504).

Relators argue that paragraphs 362 to 379 of the proposed TAC plead their reverse false claims with particularity. The relevant paragraphs from that section of the proposed TAC state:

> 366. Accordingly, Defendants engaged in a deliberate plan to knowingly submit false reports to the OIG -- as required per the terms of the CIA -- that either materially misrepresented the facts concerning their illegal conduct or concealed such conduct altogether. As such, Defendants knowingly made, used, or caused to be made or used, false records or statements material to an obligation to pay or transmit money or property to the government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the government.
>
> * * *
>
> 373. Defendants, through their compliance departments, falsely certified to the government that they had fully complied with its CIA

obligations, and they concealed from the government reportable events, about which Defendants were aware both because they directed those events and because they were brought such violations to the attention of at least BMS by employees like Relators who were fulfilling their obligation to report violations of federal and state laws.

374. Rather than comply with the CIAs, Defendants have ignored both the letter and the spirit of the agreements, prioritizing the maximization of profits over compliance with federal and state laws.

375. Defendants' promotion of Abilify for off label uses constituted a violation of their obligations under their respective CIAs, and they failed to report the same, in violation of their respective CIAs.

376. Similarly, each time they failed to properly report to OIG the kickbacks they paid to induce physicians to prescribe more Abilify, Defendants violated the terms of their respective CIAs.

* * *

379. Defendants made reverse false claims in violation of 31 U.S.C. § 3729(a)(1)(G) by falsely certifying compliance with their respective CIAs' reporting requirements in order to avoid

> their obligations to pay stipulated penalties under the CIAs.

Doc. 82-1, ¶¶ 366, 373-76, 379.

The Court notes initially that throughout this section of the proposed TAC -- and for that matter throughout all of both the SAC and the proposed TAC -- Relators refer generically to "Defendants," rather than alleging any specific conduct that either BMS or Otsuka engaged in that would violate the FCA. This deficiency alone is sufficient for the Court to find these allegations insufficiently pled under Rule 9(b). *Bledsoe I*, 342 F.3d at 643 ("A complaint 'may not rely upon blanket references to acts or omissions by all of the "defendants," for each defendant named in the complaint is entitled to be apprised of the circumstances surrounding the fraudulent conduct with which he individually stands charged.'" (quoting *Benoay v. Decker*, 517 F. Supp. 490, 493 (E.D. Mich. 1981), *aff'd*, 735 F.2d 1363 (6th Cir. 1984))).

Additionally, Relators have not pled with particularly who at either BMS or Otsuka was responsible for preparing the certifications to the government, what the certifications said, when the certifications were filed, what the reportable events were that Defendants allegedly concealed from the government, or what action the government took in response (such as demanding stipulated penalties or allowing Defendants to cure defects in their certifications). Without more than unsupported statements that Defendants concealed some relevant information from the government and then filed false

certifications stating their compliance with the CIAs, Relators fail to state a claim. Amendment of this claim, like all of Relators' other claims, would be futile.

Therefore, having reviewed this matter, and being sufficiently advised,

IT IS ORDERED that Relators' Motion for Leave to File Third Amended Complaint Instanter (Doc. 82) be, and is hereby, **DENIED**.

This 24th day of September, 2015.

Signed By:

/s/: William O. Bertelsman
United States District Judge

APPENDIX D — MEMORANDUM OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO, WESTERN DIVISION, FILED MARCH 27, 2015

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.

March 27, 2015, Decided
March 27, 2015, Filed

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]

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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 Izenson, and Ava Trower represented Otsuka.

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. FACTS[2]

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 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

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).

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.

Appendix D

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, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (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 standard to these facts.[5] But this

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))).

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

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

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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 U.S. Dist. LEXIS 46847, 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.").

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 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.

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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.

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' § 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, 128 S. Ct. 2123, 170 L. Ed. 2d 1030 (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 U.S. Dist. LEXIS 63465, 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.

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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).

> 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 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.

Appendix D

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(A)(3)(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.*, 205 Ariz. 290, 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, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009). The SAC identifies the Arizona laws at issue and then states that Relator Edwards informed BMS management of her belief that

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.

BMS was violating those Arizona laws. These allegations are enough to survive a motion to dismiss.

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.

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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:

/s/ William O. Bertelsman

United States District Judge