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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

UNITED STATES OF AMERICA ex rel. JOSEPH IBANEZ and JENNIFER EDWARDS, *Relators-Appellants*, *v.* BRISTOL-MYERS SQUIBB COMPANY; OTSUKA AMERICA PHARMACEUTICAL, INC., *Defendants-Appellees*.	No. 16-3154

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.

Argued: December 6, 2016

Decided and Filed: October 27, 2017

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

COUNSEL

ARGUED: William C. Meyers, GOLDBERG KOHN LTD., Chicago, Illinois, for Relators. Jessica L. Ellsworth, HOGAN LOVELLS US LLP, Washington, D.C., for Appellee Bristol-Myers Squibb. Jennifer L. Spaziano, SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP, Washington, D.C., for Appellee Otsuka. **ON BRIEF:** William C. Meyers, David J. Chizewer, Emily D. Gilman, GOLDBERG KOHN LTD., Chicago, Illinois, Jennifer M. Verkamp, Frederick M. Morgan, Jr., Chandra Napora, MORGAN VERKAMP LLC, Cincinnati, Ohio, for Relators. Jessica L. Ellsworth, Mitchell J. Lazris, Eugene A. Sokoloff, HOGAN LOVELLS US LLP, Washington, D.C., for Appellee Bristol-Myers Squibb. Jennifer L. Spaziano, Mitchell S. Ettinger, Caroline Van Zile, SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP, Washington, D.C., Daniel E. Izenson, Thomas F. Hankinson, KEATING MUETHING & KLEKAMP, PLL, Cincinnati, Ohio, for Appellee Otsuka.

McKEAGUE, J., delivered the opinion of the court in which KETHLEDGE, J., joined, and STRANCH, J., joined in part. STRANCH, J. (pp. 19–23), delivered a separate opinion concurring in part and dissenting in part.

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. § 1320-7b(b); caused the use or creation of false records material to false claims, 31 U.S.C. § 4729(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 28 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 *Bledose 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.

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 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 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

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[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 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).

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 3719(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 (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 3719(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 (2007).

Section 3719(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.
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> 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, 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

[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).

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 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

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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 a 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, 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.

alleged fraudulent transactions, meaning the public disclosure bar does not implicate fraud connected to post-agreement improper promotion of Abilify.

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 (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.

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 (2003) (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (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 (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 (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.