IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

THE UNITED STATES OF AMERICA, *et al.*, *ex rel*. CATHERINE A. BROWN and BERNARD G. VEZEAU,	:	
	:	CIVIL ACTION
v.	:	
	:	NO. 05-6795
PFIZER, INC.	:	

MEMORANDUM

SURRICK, J. **FEBRUARY 29, 2016**

Presently before the Court is Defendant Pfizer Inc.'s Motion to Dismiss. (ECF No. 42.) For the following reasons, Defendant's Motion will be granted in part and denied in part.

I. BACKGROUND

A. Procedural History

Defendant Pfizer Inc. ("Pfizer") is a developer and marketer of pharmaceutical products headquartered in New York, New York. (Am. Compl. ¶ 16, ECF No. 19.) Among the pharmaceutical drugs developed by Pfizer was Voriconazole, an anti-fungal medication, which was marketed under the trade name "Vfend." (*Id.* at ¶ 2.) Pfizer sought and obtained approval from the United States Food and Drug Administration ("FDA") to market Vfend as a first-line treatment for invasive aspergillosis and for candidemia in non-neuotropenic (non-immuno-suppressed) patients. (*Id.* at ¶ 40.)[1]

Relator Catherine A. Brown is a native of South Africa who was employed by Pfizer. (Am. Compl. ¶ 14.) Brown was initially employed by Pfizer in January of 1995 in Pfizer's

[1] "Neutropenic" or immuno-suppressed patients have serious illnesses and include transplant recipients, chemotherapy patients, and those with Acquired Immuno-deficiency Syndrome ("AIDS"). (Am. Compl. ¶ 2.)

Johannesburg, South Africa branch. (*Id.*) In March of 1997, Brown was promoted to South African Product Manager for the antifungal Diflucan. (*Id.*) In January of 2000, Brown accepted a position as Marketing Manager with Pfizer Global Pharmaceuticals in New York and was promoted to Senior Marketing Manager in January of 2002. (*Id.*) Brown was a Senior Marketing Manager until she resigned, effective November 4, 2005. (*Id.*)

Relator Bernard G. Vezeau is a Major in the United States Army Reserve who has twice been employed by Pfizer. (*Id.* at ¶ 15.) From 1989 through 1992, Vezeau was a sales representative for Pfizer with one of the highest-producing sales territories in the United States. (*Id.*) In November of 2003, Vezeau rejoined Pfizer and served as Senior Product Manager on Pfizer's Worldwide Vfend Marketing Team until December 21, 2005. (*Id.*)

Relators filed a *qui tam* Complaint, under seal, on December 29, 2005, pursuant to the Federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729, *et seq*. on behalf of the United States. Relators alleged one count of an FCA violation, specifically that Defendant made fraudulent representations and statements to the FDA in Vfend's New Drug Application ("NDA") and through the off-label promotion of Vfend for empiric use and in neutropenic patients. (Compl. ¶¶ 155-157, 170, ECF No. 1.) Nearly four years later, on December 1, 2009, Relators filed an Amended Complaint on behalf of the United States, twenty-one states,[2]

[2] These states and their corresponding false claims act statutes include: California (California False Claims Act, Cal. Gov. Code §§ 12650, *et seq.*); Delaware (Delaware False Claims & Reporting Act, 6 Del. C. §§ 1201, *et seq.*); Florida (Florida False Claims Act, Fla. Stat. Ann. §§ 68.081, *et seq.*); Georgia (Georgia False Medicaid Claims Act, O.C.G.A. §§ 49-4-168, *et seq.*); Hawaii (Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(3)); Illinois (the Illinois Whistleblower Reward & Protection Act, 74 Ill. Comp. Stat. §§ 175, *et seq.*); Indiana (Indiana False Claims and Whistleblowers Protection Act, Ind. Code Ann. § 5-11-5.5); Louisiana (Louisiana Medical Assistance Program Integrity Law, La. Rev. Stat. Ann. §§ 46:437, *et seq.*); Massachusetts (Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §§ 5, *et seq.*); Michigan (Michigan Medicaid False Claims Act, Mich. Comp. Laws §§ 400.601, *et seq.*, and Michigan Public Acts, 1977 PA 72); Montana (Montana False Claims Act, Mont. Code Ann. §§

two cities,[3] and the District of Columbia,[4] which added twenty-six claims, including one alleging conspiracy, and others related to violations of state and city law false claims acts. (Am. Compl. ¶¶ 221-540.) In its Amended Complaint, Relators allege conduct from the original complaint along with the additional unlawful off-label promotion of Vfend for use by pediatric patients and for prophylactic therapy. (*Id.* at ¶¶ 140-44.) Specifically, the Amended Complaint contains claims that Defendant: (1) knowingly caused to be presented false or fraudulent claims for payment, in violation of 31 U.S.C. § 3729(a)(1); (2) knowingly caused to be made or used false records or statements to get false or fraudulent claims for payment, in violation of 31 U.S.C. § 3729(a)(2); and (3) entered into conspiracies with paid "speakers," medical marketing firms, "experts," and other third parties for the purpose of defrauding the United States Government, in violation of 31 U.S.C. § 3729(a)(3). (*Id.* at ¶¶ 202-220.)

17-8-403, *et seq.*); Nevada (Nevada False Claims Act, Nev. Rev. Stat. Ann. §§ 357.0 10, *et seq.*); New Hampshire (New Hampshire False Claims Act, New Hamp. Stat. Ann. § 167:61-b); New Jersey (New Jersey False Claims Act, N.J. Stat. § 2A:32C-1); New Mexico (New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-F-4(A)-(C), and New Mexico Fraud Against Taxpayers Act, N.M. Stat. §§ 44-9-1, *et seq.*); Oklahoma (Oklahoma Medicaid False Claims Act, 63 Okl. Stat. §§ 5053, et se*q.*); Rhode Island (Rhode Island False Claims Act, R.I. Gen. Laws §§ 9-1.1-1, *et seq.*); Tennessee (Tennessee False Claims Act, Tenn Code Ann. §§ 4-18-103, *et seq.*, Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-182, *et seq.*); Texas (Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code, Ch. 36 §§ 36.002, *et seq.*); Virginia (Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.3, *et seq.*); and Wisconsin (Wisconsin False Claims for Medical Assistance, Wis. Stat. §§ 20.931, *et seq.*) (Am. Compl. ¶¶ 212-540.)

Each of these states notified the Court of their decision not to intervene in this action pursuant to their respective statutes. (*See* July 24 Order, ECF No. 55.)

[3] Even though Relators allege that they brought suit on behalf of the City of Chicago and the City of New York, there are no specific Counts related to such claims.

Both the City of Chicago and City of New York notified the Court of their decision not to intervene in this action pursuant to their respective statutes. (*See* July 24 Order, ECF No. 55.)

[4] Relators filed claims on behalf of the District of Columbia, pursuant to the District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(1).

The District of Columbia notified the Court of its decision not to intervene in this action. (*See* July 24 Order, ECF No. 55.)

After the United States Government declined to intervene in this action pursuant to Section 3730(b)(2)(A) of the FCA,[5] we entered an order on November 28, 2011 unsealing the original Complaint. (Nov. 28 Order, ECF No. 32.) On May 7, 2012, we entered an order amending our order of November 28, 2011 and unsealed all complaints filed in this matter. (May 7 Order, ECF No. 46.)

On April 9, 2012, Defendant filed a Motion to Dismiss seeking dismissal of Relators' Amended Complaint in its entirety. (Def.'s Mot., ECF No. 42.) Relators filed a Response to Defendant's Motion to Dismiss on August 2, 2012. (Rels.' Resp., ECF No. 56.) On November 30, 2012, Defendant filed a Reply memorandum. (Def.'s Reply, ECF No. 69.)

After the briefing on this Motion to Dismiss closed, the parties continued to file "notices of supplemental authority." On January 8, 2014, Defendants submitted a letter to the Court (ECF No. 72), to which Relators submitted a reply letter dated January 17, 2014 (ECF No. 73.) On February 21, 2014, June 19, 2014, September 29, 2014, March 3, 2015, June 4, 2015, and October 21, 2015, Relators filed Notices of Supplemental Authority. (ECF Nos. 74, 83, 85, 87, 90, 92.) Defendant filed responses to each of Relators' Notices of Supplemental Authority. (ECF Nos. 77, 84, 86, 88, 91, 93.)

[5] Even if the Government declines to intervene, as it has here, Relators may still pursue claims pursuant to the FCA. 31 U.S.C. § 3730(b)(4)(B); *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 182 (3d Cir. 2001). Although it was entitled to do so, the Government did not file a motion to dismiss the action. 31 U.S.C. § 3730(c)(2)(A).

B. Factual History

The allegations in Relators' Amended Complaint involve the prescription drug Vfend.[6] Relators allege that Defendant developed Vfend in the mid-1990s with the intention of having the drug approved for use in treating aspergillosis, a fungal infection that results from fungi of the genus aspergillus. (Am. Compl. ¶ 40.) Vfend was to treat fungal infections caused by the Candida genus of yeast, which can result in either a localized and topical infection or a blood-borne infection. (*Id.*)

On November 17, 2000, Defendant submitted its first two NDAs for Vfend, seeking to obtain FDA indications, or approval for use, for Prophylaxis Therapy,[7] Empiric Therapy,[8] and Documented Therapy.[9] (Am. Compl. ¶¶ 44-45.) Of paramount importance was obtaining FDA approval for use in Empiric Therapy, which constituted half of all prescriptions written for antifungal drugs, and serious Candida infections, which accounted for approximately 80% of prescriptions written for treatment of documented fungal infections. (*Id.* at ¶¶ 47-48.) Defendant sought to have Vfend approved for "first-line" indications, that is, as the primary drug to treat fungal infections. (*Id.* at ¶ 49.)

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[6] In consideration of Defendant's Motion to Dismiss under Federal Rule of Civil Procedure 12(b)(6), "we accept all factual allegations as true [and] construe the complaint in the light most favorable to the Plaintiff." *DelRio-Mocci v. Connolly Props., Inc.*, 672 F.3d 241, 245 (3d Cir. 2012) (quoting *Warren Gen. Hosp. v. Amgen, Inc.*, 643 F.3d 77, 84 (3d Cir. 2011)). We rely on the operative facts as presented in Relators' Amended Complaint.

[7] Prophylaxis Therapy is the prescribing of antifungal medications to "at-risk" patients who are not yet symptomatic. (Am. Compl. ¶ 45.)

[8] Empiric Therapy involves the pre-diagnosis use of antifungal drugs when a physician suspects a patient suffers from a fungal infection. (Am. Compl. ¶ 45.) In the United States, half of antifungal drug sales relate to Empiric Therapy. (*Id.* at ¶ 61.)

[9] Documented Therapy refers to cases where test results have confirmed the specific pathogen causing the fungal infection. (Am. Compl. ¶ 45.)

Vfend was approved by the FDA on May 24, 2002. (*Id.* at ¶ 53.) The FDA approved Vfend for treatment of invasive aspergillosis and second line or "salvage" therapy for fungal infections caused by specific pathogens. (*Id.* at ¶ 53; *see also* Am. Compl. Ex. A. ("Vfend is indicated for use in the treatment of the following fungal infections: Invasive aspergillosis . . . Candidemia in non-neutropenic patients . . . Esophageal candidiasis . . . Serious fungal infections . . . .").) The FDA did not approve Vfend for Candidiasis (blood-borne fungal infections) or Empiric Therapy indication. (Am. Compl. ¶¶ 58-64.) On two separate occasions, in February of 2004 and December of 2004, the FDA expanded indications for Vfend. (*Id.* at ¶¶ 66-67.)

Relators allege that Defendant submitted false and misleading NDAs to the FDA for approval of Vfend and illegally marketed Vfend for off-label uses. (*Id.* at ¶¶ 3, 69.)[10] Despite the lack of an FDA indication for Empiric Therapy, Relators allege that Defendant concealed critical information from the FDA and the medical community[11] and misrepresented the results of a Candida 608 Study (the "608 Study"), including misleading statements about Vfend's efficacy and the scope of FDA approval. (Am. Compl. ¶ 70). With regard to the 608 Study, Relators allege that "[a]t all time material, Pfizer knew that the 608 Study was seriously flawed and its results grossly misleading because Pfizer had mistakenly switched the primary and secondary endpoints for that study." (*Id*. at ¶ 71.) Defendant ultimately disclosed the fact that the endpoints had been switched and requested that the endpoints be switched to what was originally intended; however, the FDA refused. (*Id*. at ¶ 77.) Relators allege that despite being aware of the invalid

[10] "Off-label" use connotes indications that were not approved by the FDA, but which are prescribed by medical doctors. (Am. Compl. ¶ 3.)

[11] Specifically, Relators allege that Defendant masked clinical test results that reflected that Vfend was ineffective in treating C. glabrata, the fungal infection with the highest mortality rate, and concealed or obscured the renal toxicity and attendant dangers of using Vfend to combat fungal eye infections. (Am. Compl. ¶ 3.)

results of the 608 Study, Defendant nevertheless exploited the study and used the results to market Vfend for uses for which it had not been approved or medically determined to be safe. In addition, Relators allege that Defendant prevented distribution of harmful internal documentation, including a white paper on Vfend (Am. Compl. ¶ 121),[12] embarked on an aggressive campaign to promote off-label use of the drug (Am. Compl. ¶ 124),[13] and provided illicit compensation to "community professionals"[14] in exchange for promoting the off-label use of Vfend (Am. Compl. ¶¶ 167-68).

Since Defendant launched Vfend in 2002, sales of the drug have totaled approximately $1.9 billion. (*Id.* at ¶ 198.) Off-label sales were approximately $950 million through the end of 2009. (*Id.*) Relators allege that in conjunction, the misrepresentations to the FDA and medical community, the promotion of improper off-label use of Vfend, and the payment of kickbacks to various individuals to encourage the distribution of Vfend has resulted in false claims being submitted to federal and state Governments in excess of $250 million. (*Id.* at ¶ 8.)

[12] Relator Vezeau was asked to write a C. Glabrata "white paper" for Pfizer employees involved in the promotion of Vfend to physicians. (Am. Compl. ¶ 111.)

[13] Examples of the campaign to engage in off-label promotion included the preparation and distribution of misleading marketing materials to hospitals and sales representatives and the publication of an inaccurate article in a medical journal. (Am. Compl. ¶¶ 124, 126, 129.)

[14] These individuals include physicians, pharmacists, industry officials, and "crusaders" who were compensated in the form of honoraria, preceptorships, travel expenses, speaking and "training fees," and appearance fees. (Am. Compl. ¶¶ 4-5.) Without disclosing their identities, Relators allege that Defendant paid at least nine physicians and pharmacists with "in kind" kickbacks for promoting the off-label use of Vfend. (*Id.* at ¶ 172.) In addition, Relators allege that Defendant employed a network of 350 to 400 paid Vfend speakers who conducted programs on behalf of Vfend and who hand-delivered checks to physicians who assisted in promoting Vfend. (*Id.* at ¶ 180.)

C. Parties' Contentions

Defendant advances six independent arguments in support of dismissal of Relators' Amended Complaint. First, Defendant contends that the Court lacks subject matter jurisdiction over portions of Relators' Amended Complaint as Relators were not the first-to-file a *qui tam* complaint regarding certain aspects of Defendant's off-label promotion of Vfend and that such a failure bars those claims. (Def.'s Mot. 5.) Second, Defendant maintains that Relators' Amended Complaint represents an impermissible attempt to bootstrap an FCA action to an alleged violation of the Food, Drug and Cosmetic Act. (*Id.* at 8.) Third, Defendant argues that Relators' theory of fraud is contradicted by their pleadings and that the Supreme Court has confirmed the FDCA's ban on private enforcement suits on such claims. (*Id.* at 13.) Fourth, Defendant contends that Relators' allegations regarding off-label promotion of Vfend are insufficiently pleaded and did not result in any false claims being filed with the Government. (*Id.* at 14, 19.) Fifth, Defendant maintains that Relators' claims pertaining to kickbacks to physicians and pharmacists do not relate to any false claims being filed with the Government. (*Id.* at 25.) Finally, Defendant argues that Relators have failed to properly bring false claims act suits pursuant to the various state, city, and the District of Columbia false claims acts and therefore such claims must be dismissed. (*Id.* at 27.)

Relators argue that they were the first to file claims related to Defendant's violation of the FCA, that their Amended Complaint is well-pleaded and provides detailed allegations, and that Rule 9(b) does not require Relators to provide evidence of actual false claims at the pleading stage. (Rels.' Resp. 3-4.)

II. LEGAL STANDARD

Under Federal Rule of Civil Procedure 8(a)(2), "a pleading that states a claim for relief must contain a short and plain statement of the claim showing that the pleader is entitled to relief." Failure to state a claim upon which relief can be granted is basis for dismissal of the complaint. Fed. R. Civ. P. 12(b)(6). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, 'to state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556). While a court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading, the plaintiff may be entitled to relief," *Phillips v. Cnty of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008) (citations and internal quotation marks omitted), "a court need not accept as true 'legal conclusions' or '[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements . . . ." *Wilson v. City of Philadelphia*, 415 F. App'x 434, 436 (3d Cir. 2011) (quoting *Iqbal*, 556 U.S. at 678). "A complaint may not be dismissed merely because it appears unlikely that the plaintiff can prove those facts or will ultimately prevail on the merits." *McTernan v. City of York, Pa.*, 564 F.3d 636, 646 (3d Cir. 2009) (citation omitted). However, a plaintiff's claims "must contain 'more than an unadorned, the-defendant-unlawfully-harmed-me accusation.'" *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (quoting *Iqbal*, 556 U.S. at 678).

An FCA complaint must meet the heightened pleading standard set forth by Federal Rule of Civil Procedure 9(b), which demands that a plaintiff "state with particularity the circumstances constituting the fraud or mistake." Fed. R. Civ. P. 9(b). Therefore, a plaintiff must allege "the who, what, when, where and how of the events at issue." *In re Rockefeller Ctr. Props., Inc. Secs. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (citation and internal quotation marks omitted). There is a split among the circuit courts as to what the pleading requirement is to satisfy the "particularity" requirement of Rule 9(b). The Third Circuit has adopted the approach taken by the First, Fifth, and Ninth Circuits, which "have taken a more nuanced reading of the heightened pleading requirements of 9(b)." *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156 (3d Cir. 2014) (citation omitted). Under *Foglia*, "it is sufficient for a plaintiff to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.* (citations and internal quotation marks omitted).

III. DISCUSSION

A. Federal False Claims Act

The FCA imposes liability on anyone 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." *See* 31 U.S.C. § 3729(a)-(b). The statute defines the term claim as "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property . . . ." *Id.* at § 3729(b)(2). While "recovery under the FCA is not dependent upon the government's sustaining monetary damages," *Varljen v. Cleveland Gear Co., Inc.*, 250 F.3d 426, 429 (6th Cir. 2001), the purpose of the act is to protect

against fraud "'that might result in financial loss to the Government.'" *Hutchens v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 183 (3d Cir. 2001) (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 233 (1968)); *see also United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc*., 149 F.3d 227, 230 (3d Cir. 1998) ("The False Claims Act prescribes civil penalties for knowingly submitting fraudulent claims to the federal government. Under the Act, the United States may bring a civil suit to recover funds lost through such transactions."); *United States ex rel. Wilkins v. United Health Group*, Inc., 659 F.3d 295, 304 (3d Cir. 2011) ("The primary purpose of the FCA 'is to indemnify the government-through its restitutionary penalty provisions-against losses caused by a defendant's fraud.'") (quoting *Mikes v. Straus*, 274 F.3d 687, 696 (2d Cir. 2001)); *Rodriguez v. Our Lady of Lourdes Med. Ctr*., 552 F.3d 297, 304 (3d Cir. 2008) (dismissing suit for failure to state a claim after finding that FCA claims must pertain to pecuniary losses by the federal Government or risk converting the statute into "a blunt instrument to enforce compliance with all . . . regulations rather than only those regulations that are a precondition to a payment") (citation and internal quotation marks omitted), *abrogated on other grounds* by *United States ex rel. Eisenstein v. N.Y.C, N.Y*, 556 U.S. 928 (2009).

In order to establish a *prima facie* violation of Section 3729(a)(1) of the FCA, a relator must prove that: "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004). Section 3729(a)(1) thus contains a "presentment clause." In order to properly plead a violation of Section 3729(a)(2), a relator must aver that "the defendant made or used (or caused someone else to make or use) a false record in order to cause the false claim to be actually paid or approved." *Id.* at 242. Section 3729(a)(3) imposes liability on a person or entity

who "conspires to defraud the Government by getting a false or fraudulent claim allowed or paid." 30 U.S.C. § 3729(a)(3). To state a claim under Section 3729(a)(3), a relator must properly plead that: "(1) the defendant conspired with one or more persons to get a false or fraudulent claim allowed or paid by the Government; and (2) that one or more conspirators performed any act to get a false or fraudulent claim allowed or paid." *United States ex rel. Atkinson v. Penn. Shipbuilding Co.*, No. 94-7316, 2000 WL 1207162, at *7 (E.D. Pa. Aug. 24, 2000) (quoting *United States v. Hill*, 676 F. Supp. 1158, 1173 (N.D. Fla. 1987)).

B. FCA's First-to-File Rule

Addressing first Defendant's argument that certain of Relators' claims are barred by the FCA's first-to-file rule, under the FCA, a relator is only entitled to relief if he or she is the first to file the complaint. *See* 31 U.S.C. § 3730(b)(5) ("When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action."); *see also United States ex rel. Merena v. SmithKline Beecham Corp.*, 205 F.3d 97, 102 (3d Cir. 2000). If a relator files a complaint under the FCA based on the facts underlying the outstanding claims in a pending action, the court must complete a claim-by-claim analysis to determine if Section 3730(b)(5) precludes any portion of the suit. *Merena*, 205 F.3d at 102. In part, the first-to-file rule exists because "a relator who merely adds details to a previously exposed fraud does not help 'reduce fraud or return funds to the federal fisc,' because 'once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds.'" *United States ex rel. Branch Consultants v. AllState Ins. Co.*, 560 F.3d 371, 378 (5th Cir. 2009) (quoting *LaCorte*, 149 F.3d at 234). In construing the first-to-file rule, courts should be "mindful of the need to preserve a balance between the amendment's two competing goals" of providing "adequate incentives for whistle-

blowing insiders" and the "discouragement of opportunistic plaintiffs" in *qui tam* actions. *LaCorte*, 149 F.3d at 234.

1. The Worsfold Action

Defendant contends that the Court lacks subject matter jurisdiction under Rule 12(b)(1) over allegations of off-label promotion of Vfend that were already the basis of a prior-filed *qui tam* suit. The parties' dispute involves the case of *United States of America ex rel. Paul Worsfold v. Pfizer, Inc.*, No. 09-11522 (D. Mass), a collateral lawsuit against Defendant, which addresses issues similar to those raised in Relators' Amended Complaint. Relators' original complaint was filed on December 29, 2005. (*See* Compl., ECF No. 1.)

In conjunction with the original complaint, Relators filed a disclosure memorandum with the Government pursuant to 31 U.S.C. § 3730(a)(2). (Rels.' Resp. 14 & Ex. A.) The original complaint and disclosure memorandum alleged that Defendant was denied an indication for empiric treatment in certain patients and that Defendant marketed Vfend to such patients despite having been denied such an indication. (Compl. ¶¶ 47-54; Rels.' Resp. Ex. A.) In addition, Relators alleged that Defendant engaged in off-label marketing to promote Vfend for both empiric use and to patients with neutropenia. (*Id.* at ¶¶ 24, 53-54, 88, 91, 105, 152.) Relators served the Government with supplemental disclosure statements on October 10, 2006, December 31, 2007, and February 20, 2008. (Rels.' Resp. 14-19 & Exs. B, C, D.)

On September 14, 2009, the *Worsfold* action was filed in the District of Massachusetts. (Rels.' Resp. 19 & Ex. E.) In *Worsfold*, the relator alleged that Pfizer promoted Vfend and Eraxis for off-label purposes. (Rels.' Resp. 19 & Ex. E ¶¶ 32-38.) On December 1, 2009, the relator filed an amended complaint in *Worsfold*, this time alleging off-label promotion of Vfend for Empiric Therapy and for use in pediatric patients, highlighting the FDA's rejection of

Defendant's requested indication for Empiric Therapy, and Pfizer's use of marketing materials to sell Vfend for use in neutropenic patients. (Rels.' Resp. 20 & Ex. F ¶¶ 20, 26, 45-61, 99.) That same day, Relators filed their Amended Complaint with this Court. (*See* Am. Compl.) Relators contend that the operative date in *Worsfold* stems from that relator's filing of a fourth amended complaint on November 12, 2010. (Rels.' Resp. 3.)

There is no dispute that Relators here were the first in time to file a *qui tam* action related to Defendant's illegal marketing of Vfend. Relators' initial complaint was filed on December 29, 2005. Even taking the filing of *Worsfold*'s initial complaint on September 14, 2009 as the operative date in that matter, Relators' action precedes *Worsfold*'s by nearly four years. However, Defendant contends that Relators' allegations pertaining to Pfizer's promotion of Vfend for off-label prophylactic and pediatric use are preempted by the *Worsfold* action because Relators did not assert these claims until their Amended Complaint, which was filed after the amended complaint in the *Worsfold* action was filed. (*Id.* at 7 (*comparing* Ex. 2, D. Mass. Am. Compl. ¶¶ 56-61, *with* Am. Compl. ¶¶ 124(e), 140(a), 141-43 and Ex. 2, D. Mass. Am. Compl. ¶ 60, *with* Am. Compl. ¶ 144, and Ex. 2, D. Mass Am. Compl. ¶¶ 20, 35, 55, 140 *with* Am. Compl. ¶¶ 45(a), 68(a), 124(a), 140(c), 147)).

The Third Circuit has provided useful guidance on reviewing two complaints for determining whether the later complaint is barred by the first-to-file rule:

> Section 3730(b)(5) provides that when a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action. Giving each word its ordinary meaning, the phrase 'related action based on the facts underlying the pending action,' clearly bars claims arising from events that are already the subject of existing suits. A later case need not rest on precisely the same facts as a previous claim to run afoul of this statutory bar. Rather, if a later allegation states all the essential facts of a previously-filed claim, the two are related and section 3730(b)(5) bars the later claim, even if that claim incorporates somewhat different details.

LaCorte, 149 F.3d at 232-233 (internal citations and quotation marks omitted). "Stated differently, the first-to-file rule applies when an earlier complaint 'subsumes all the material elements' of a later claim or where a later claim merely 'echo[e]s . . . the broader allegation' of the earlier complaint." *United States ex rel. Cestra v. Cephalon, Inc.*, No. 14-1842, 2014 WL 5038393, at *4 (E.D. Pa. Oct. 9, 2014) (quoting *LaCorte*, 149 F.3d at 238, 236). Application of § 3730(b)(5) requires a claim-by-claim comparison of the original and later-filed complaints. *See LaCorte*, 149 F.3d at 235-36. Only those claims that arise from events that are already subject to the earlier complaint are barred. *Id.*

A claim-by-claim comparison of Relators' Amended Complaint with the amended complaint in the *Worsfold* action reveals that the allegations concerning the off-label promotion of Vfend for pediatric and prophylactic use in both complaints are strikingly similar. Both complaints allege that Defendant promoted Vfend off-label for use in pediatrics by directing its sales force to market directly to children's hospitals. Both complaints allege that Defendant engaged in a marketing campaign to promote Vfend off-label for prophylactic purposes, despite that fact that Vfend was not approved for prophylactic use. In fact, Relators' original Complaint makes no mention of off-label promotion of Vfend for pediatric use or prophylactic use. The allegations contained in Relators' Amended Complaint are based on the same facts and merely 'echo[] . . . the broader allegations" of the *Worsfold* action. As a result, Relators' FCA claims based upon allegations that Defendant promoted Vfend off-label for pediatric and prophylactic use are barred by § 3730(b)(5).

Relators argue that the Court should take notice of supplemental disclosures that they submitted to the Department of Justice ("DOJ") after their original complaint was filed but before the amended complaint was filed in the *Worsfold* action. Relators contend that the

supplemental disclosures provided to the DOJ—but not given to Pfizer until after it filed its motion to dismiss—put the DOJ on notice of Defendant's off-label promotion of Vfend for pediatric and prophylactic use. (Rels.' Opp. 31.) Defendant contends that Relators are foreclosed from relying on disclosures to the DOJ as part of the record for a first-to-file determination, arguing that courts limit their analyses to a comparison of the complaints. (Def.'s Reply 4.) Relators respond that the statutory language of the first-to-file rule in the FCA depends on "the facts underlying the pending action," which encompasses more than the four corners of the complaint and permits this Court to consider its numerous disclosures to the DOJ. (Rels.' Opp. 2 (citing 31 U.S.C. § 3730(b)(5)).) We disagree.

The framework for considering arguments under § 3730(b)(5) is based upon a comparison of the claims asserted in the earlier-filed and later-filed complaints. *LaCorte*, 149 F.3d at 235-36 (stating that the court "may decide whether the later complaints allege the same material elements as claims in the original lawsuit simply by comparing the original and later complaints"); *see also In re Natural Gas Royalties Qui Tam Litig. (CO2 Appeals)*, 566 F.3d 956, 964 (10th Cir. 2009) ("The first-to-file bar is designed to be quickly and easily determinable, simply requiring a side-by-side comparison of the complaints."); *United States ex rel. Ortega v. Columbia Healthcare*, 240 F. Supp. 2d 8, 15 (D.D.C. 2003) ("The only evidence needed to determine if a complaint is barred by § 3730(b)(5)'s first-to-file rule is the complaints themselves."). Relators have provided no authority, and we are aware of none, that would permit the Court to look at extra-judicial filings made to the DOJ in determining whether the court has jurisdiction under the first-to-file rule. In fact, the case relied on by Relators actually contradicts their position. In *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 33 (1st Cir. 2009), the relators argued that information that they provided to the DOJ "in response to

its inquiries concerning the allegations contained in the Original Complaint" should be considered in considering whether claims were barred by the first-to-file rule. The First Circuit rejected Relators' argument, noting that "[t]he first-to-file rule is exception free . . . and does not permit us to consider the Information." *Id*. (internal citations and quotation marks omitted). The court also stated that "[h]ad [the relator] wanted to include the allegations contained in the Information, he had his opportunity to do so when he filed the Original Complaint seven months earlier." *Id*. at 33-34. The supplemental disclosures that Relators provided to the DOJ will not be considered in our analysis.

2. Leave to Amend the Amended Complaint

Relators request that they be granted leave to file an amended complaint in the event that the Court determines that the claims for off-label promotion of Vfend for pediatric and prophylactic use are barred by the first-to-file rule. (*See* Rels.' Jan. 17, 2014 Letter, ECF No. 73.) On November 22, 2013, the Massachusetts District Court dismissed the *Worsfold* action on grounds that the allegations failed to state a cause of action under Rule 9(b). (Def.'s Jan 8, 2014 Ltr. Ex. A, ECF No. 72.)[15] Relators here contend that as a result of the dismissal of the *Worsfold* action, that action is no longer "pending" for purposes of the first-to-file rule in § 3730(b)(5).

The United States Supreme Court recently held that "a *qui tam* suit under the FCA ceases to be 'pending' once it is dismissed." *Kellogg Brown & Root Servs. v. United States ex rel. Carter*, 135 S. Ct. 1970, 1979 (2015). In *Kellogg Brown*, the relator's *qui tam* complaint was dismissed under the first-to-file rule as a result of a similar actions pending in Maryland and Texas. *Id*. at 1974-75. After the actions in Maryland and Texas were dismissed, the relator sought to file an amended complaint. The Supreme Court considered the language of

[15] The *Worsfold* Court noted that because the case was dismissed under the heightened pleading standard of Rule 9(b), it did not address Pfizer's argument that the allegations were barred by the first-to-file rule.

§ 3730(b)(5), and concluded that the term 'pending' as used in the statute should be given its ordinary meaning—"remaining undecided" or "awaiting decision." *Id*. at 1978. In interpreting the term 'pending' this way, the Court concluded that "an earlier suit bars a later suit while the earlier suit remains undecided but ceases to bar that suit once it is dismissed." *Id*. Under *Kellogg Brown*, the *Worsfold* action is no longer pending as a result of its dismissal. Relators may file an amended complaint to assert the claims that were barred by the first-to-file rule. *See id.* at 1978-79. Accordingly, Relators' request for leave to file an amended complaint will be granted.

C. The FCA and the FDCA

Next, Defendant argues that Relators' "fraud-on-the-FDA-theory" fails as a matter of law because it constitutes an impermissible attempt by a private party to enforce the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq*. ("FDCA"). Relatedly, Defendant argues that Relators failed to allege that it misled the FDA in the first place because Relators concede that the allegedly switched endpoints in Study 608—which formed the bases of the FDA's approval for Vfend—was an inadvertent mistake that was ultimately disclosed to the FDA.

The FDCA does not regulate the practice of medicine. Therefore, physicians may lawfully prescribe prescription drugs for off-label uses. *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012). There is an "asymmetry" in the FDCA, however, in that off-label prescriptions are permitted, but manufacturers are prohibited from marketing off-label uses to physicians. *Id.* Section 337(a) of the FDCA states that "proceedings for the enforcement, or to restrain violation of [the FDCA] . . . *shall be by and in the name of* the United States. 21 U.S.C. § 337(a) (emphasis added).

Defendant contends that Relators' claims fall under the purview of the FDCA and not the FCA because Relators do not identify any false claims that were actually submitted to the Government for reimbursement. Defendant states that "'[t]he *sine qua non* of a False Claims Act violation' is the filing of 'an actual false claim' for payment against a government.'" (Def.'s Mot. 1 (quoting *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004).) Defendant argues that because Relators fail to provide specific details about how any reimbursement claims involving Vfend were ineligible for payment, they fail to make out an FCA claim. Moreover, Defendant claims that Relators' allegations are more appropriately characterized as violations of the FDCA, which forbids the marketing of drugs for off-label uses, and that any claims relating to Defendant's alleged misrepresentations to the FDA would be an end-run around the FDCA's ban on private enforcement actions. (*Id.* at 10.)

Defendant relies on *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), where the Court held that the "plaintiffs' state-law fraud-on-the-FDA claims" were pre-empted by the FDCA and the FDA's regulatory scheme. *Id.* at 350 ("State law-fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives."). *Buckman* is inapposite, and Defendant's reliance on it is misguided. The claims in *Buckman* were state law tort claims, not claims brought under the FCA. Defendant has provided no authority, and we are aware of none, that has extended the holding in *Buckman* to FCA claims. Indeed, courts faced with similar arguments raised by Defendant have rejected them. *See, e.g.*, *U.S. ex rel. Krahling v. Merck & Co.*, 44 F. Supp. 3d 581, 593 (E.D. Pa. 2014) (rejecting argument that *Buckman* precludes FCA claims, and endorsing position by the United States Government that "[h]olding that only the Government, and not a relator, can litigate a False Claims Act suit arising from . . . conduct in violation of the

FDA regulations would be inconsistent with the purposes of the [FCA]"); *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 51 (D. Mass. 2001) (noting that "the failure of Congress to provide a cause [of] action for money damages against a pharmaceutical manufacturer for marketing off-label drugs [in the FDCA] does not preclude an FCA claim where the manufacturer has knowingly caused a false statement to be made to get a false claim paid or approved by the government in violation of 31 U.S.C. § 3729(a)").

Rather than make generalized allegations with respect to violations of FDA regulations, Relators allege that Defendant caused the presentment of false claims and the use of false records in having claims paid by the Government. (Am. Compl. ¶ 8.)[16] Accordingly, Relators properly assert claims under the FCA rather than the FDCA and we consider those claims at this stage based on the applicable pleading requirements. *See Krahling*, 44 F. Supp. 3d at 593 ("Relators allege that Defendant consistently and deliberately withheld pertinent information as to the safety and efficacy of a medication from the government. It is this alleged omission that is the grounds for FCA liability.").

Defendant's argument that Relators' claims should be dismissed because the switched endpoints in the 608 Study was merely a mistake that was ultimately disclosed to the FDA is rejected. While it may be true that Defendant disclosed the switched endpoints to the FDA, the Complaint alleges a fraud much larger in scope than Defendant invites us to believe. Relators allege that Defendant's submission of the 608 Study with the mistaken endpoints caused the FDA to grant Defendant approval to treat Candida infections and that such approval would not

[16] Defendant assails Relators for promoting a "fraud-on-the-FDA" theory of the case. (Def.'s Mot. 8-10; Def.'s Reply 8-10.) As Relators consistently argue, and as the Court understands their Amended Complaint, allegations about Defendant's misrepresentations to the FDA are relevant insofar as they relate to the indications granted by the FDA, the subsequent off-label promotion of Vfend by Defendant, and the resulting false claims submitted to the Government. Relators cannot and do not assert a general "fraud-on-the-FDA" cause of action.

have been given if the proper endpoint had been submitted to the FDA. (Am. Compl. ¶¶ 75, 83-100, 105.) More importantly, however, Relators allege that "Pfizer knew that the 608 Study was seriously flawed and its results grossly misleading," (*id*. at ¶ 71), and despite this, "hid from view the lower efficacy and higher mortality rates among the patients in the 608 Study who had C. glabrata infections" (*id*. at ¶ 87), and concealed the adverse test results from the FDA and the medical community. According to Relators, despite knowledge of the dangers of Vfend revealed by the 608 study, Defendant embarked on a marketing campaign that "cynically exploited the switched endpoints of the 608 Study by repeatedly, and falsely, claiming that Vfend was a superior antifungal treatment." (*Id*.) These allegations are sufficient.

D. Off-Label Promotion of Vfend

Defendant also argues that Relators' allegations regarding off-label promotion of Vfend are insufficiently pleaded under Rule 9(b), and that Defendant's promotion of the drug did not result in any false claims being filed with the Government. Specifically, Defendant contends that Relators have failed to allege with sufficient particularity that any false claims for reimbursement were submitted to federal health care providers and that as a result, Relators failed to state FCA claims. Defendant also argues that many of the off-label uses cited by Relators are in-fact, reimbursable by federal health care providers because they are deemed "medically accepted" or "medically necessary" by statutorily-approved drug compendia.

1. Particularity Requirement Under Rule 9(b)

To state an FCA claim, Relators must satisfy the particularity standard of Rule 9(b). The Third Circuit has confirmed that a plaintiff bringing an FCA claim need not allege the actual submission of a false claim, but must provide "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually

submitted." *Foglia*, 754 F.3d at 157-58 (citation and internal quotation marks omitted). "Describing a mere opportunity for fraud will not suffice. Sufficient facts to establish a plausible ground for relief must be alleged." *Id*. at 158 (citations and internal quotation marks omitted). The inquiry is "two-fold: to satisfy Rule 9(b) first relator must allege particular details of a scheme to submit false claims and second he must provide reliable indicia that lead to a strong inference the scheme caused claims to be actually submitted for reimbursement by government health programs." *United States ex rel. Cestra v. Cephalon*, No. 14-1842, 2015 WL 3498761, at *4 (E.D. Pa. June 3, 2015).

Relators have alleged sufficient facts with particularity to support their FCA claims under Rule 9(b) and *Foglia*. First, Relators have provided sufficient detail on "the who, what, when, where and how of the events at issue." *In re Rockefeller*, 311 F.3d at 217 (internal quotation marks omitted). Relators allege with particularity an elaborate scheme by Pfizer to promote Vfend off-label for empiric therapy, prophylactic therapy, the treatment of Candida infections in immuno-suppressed (neutropenic) patients, and for pediatric use. Promoting Vfend for use in these areas involved Defendant making knowing misrepresentations of the 608 Study and concealing data that would reveal risks associated with prescribing Vfend to particular patients. Relators allege that Defendant misrepresented the 608 Study through various means, including training its sales force to use the 608 Study despite its flawed results, employing respected doctors known as "key opinion leaders," creating speaker programs where doctors and pharmacists were paid to convince others to prescribe Vfend, compensating physician "Crusaders" who were targeted high-prescribers of Vfend, hiring third-party "ghost-writers" to write critical medical studies on behalf of highly compensated "key opinion leaders" to promote the off-label scheme, paying pharmacists to promote Vfend to hospital formulary decision-

makers, and making payments to physicians through "preceptorships." (Am. Compl. ¶¶ 167, 171-72, 173-83, 186-88, 189, 194, 194-95, 197-98.) Relators also identify with particularity the individuals involved in the fraudulent scheme, including Pfizer employees and sales representatives, physicians, and pharmacists. At times, Relators identified these individuals by their initials, for purposes of maintaining privacy.

Relators have also provided reliable indicia that lead to a strong inference that Defendant's fraudulent scheme caused claims to be submitted for reimbursement by government health care programs. Defendant contends that Relators' FCA claims fail because they did not identify a single off-label prescription that was reimbursed by a federal health care provider. However, the Third Circuit has "never held that a [*qui tam*] plaintiff must identify a specific claim for payment *at the pleading stage* of the case to state a claim for relief." *Foglia*, 754 F.3d at 156 (emphasis in original) (citation and internal quotation marks omitted); *see also Cephalon*, 2015 WL 3498761, at *5 ("Rule 9(b) does not as a matter of law, require that relator allege specific examples of false claims." (citation and internal quotation marks omitted)); *U.S. ex rel. Underwood v. Genentech, Inc.*, 720 F. Supp. 2d 671, 679 (E.D. Pa. 2010) (denying the defendant's motion to dismiss and reasoning that relator could not reasonably "be required to identify at the pleading stage a specific false claim submitted to the Government by a third party"). The fact that Relators did not identify a single reimbursement is not fatal to their claims at this stage of the proceedings.

In lieu of identifying a specific false claim, Rule 9(b) requires some other reliable indicia of actual submission. In this regard, Relators allege the incredible success of Defendant's marketing efforts in increasing the sale of Vfend and gaining an edge over competitors in the antifungal drug market. Since Vfend launched in 2002, its sales totaled approximately $1.9

billion. Forty percent of those sales were for Empiric Therapy, which was not an FDA-approved indication. Relators allege that, as of 2009, Pfizer received approximately $950 million in off-label sales of Vfend. This success, coupled with the marketing efforts targeted at hospitals, physicians, and pharmacists, to prescribe Vfend for off-label use, gives rise to a strong inference that Defendant's off-label marketing scheme caused the submission of false claims to government health care providers. *See Cephalon*, 2015 WL 3498761, at *5 (finding success of defendant's off-label promotion scheme and defendant's efforts "to ensure that off-label prescriptions were actually reimbursed by government programs" reliable indicia under Rule 9(b)). Relators' allegations are sufficient under Rule 9(b).

2. Off-Label Use Recognized by Medical Compendia

Defendant also contends that Relators' claims should be dismissed because the off-label uses cited in the Amended Complaint are actually reimbursable by federal health care programs. As a result, they are not "false or fraudulent" for purposes of the FCA. According to Defendant, even if the use of a drug is not listed on the FDA-approved label, a claim based on that use may still be reimbursed by federal health care programs if the use is recognized by a medical compendium.

"Whether a use is covered under federal programs generally depends on whether medical items or services are reasonable and necessary." *U.S. ex rel. Simpson v. Bayer Corp.*, No. 05-3895, 2013 WL 4710587, at *11 (D.N.J. Aug. 30, 2013). Drugs that are prescribed for "medically accepted indications" are generally considered reasonable and necessary, and therefore reimbursable under Medicare and Medicaid, even if they are prescribed off-label. *U.S. ex rel. Gohil v. Sanofi-Aventis U.S. Inc.*, 96 F. Supp. 3d 504, 518-19 (E.D. Pa. 2015). Under the Medicaid statute, a "medically accepted indication" is defined as a "use for a covered outpatient

drug which is approved under the [FDCA] or use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section." 42 U.S.C. § 1396r-8(k)(6). Under the Medicare statute, a "medically accepted indication" is "any use which has been approved by the [FDA] for the drug" or use that is "supported by one or more citations which are included . . . in one or more of the following [drug] compendia . . . unless . . . the use is identified as not indicated in one or more such compendia" 42 U.S.C. § 1395x(t)(2)(B). "In other words, under the Medicare statute, an adverse recommendation in one compendium overrides a positive recommendation in another." *Cephalon*, 2015 WL 3498761, at *9.

Defendant contends that Vfend is listed as a "use" for "Empiric Therapy in Febrile Neutropenic Patients" and for pediatric patients age 12 and older in the American Hospital Formulary Service Drug Information ("AHFS-DI"). (Def.'s Resp. to Rel's 4th Notice of Supp. Auth., ECF No. 88.) The AHFS-DI is a recognized drug compendium in both the Medicare and Medicaid statutes. *See* 42 U.S.C. § 1396r-8(g)(1)(B)(i) (Medicaid); 42 U.S.C. § 1395x(t)(2)(B) (Medicare). Defendant provided the Court with sections of the AHFS-DI on Vfend for the years 2002 through 2009.

A review of the AHFS-DI on Vfend shows that "Empiric Therapy in Febrile Neutropenic Patients" is an approved "use" for Vfend. (*See* Def's Resp. to Rel's 4th Notice of Supp. Auth. at Ex. A.) Accordingly, it would appear that although the FDA has not approved Vfend for Empiric Therapy, a statutorily-recognized drug compendium has approved Vfend for use in Empiric Therapy in Febrile Neutropenic Patients. Therefore, any of Relators' claims that are based on prescriptions reimbursed *by Medicaid* for "Empiric Therapy in Febrile Neutropenic Patients" cannot form the basis of an FCA claim, and will be dismissed. *See Gohil*, 96 F. Supp.

3d at 519 (dismissing FCA claims based on promotion of off-label use when use was listed in statutorily-recognized drug compendium). However, the same cannot be said for claims that are based on prescriptions reimbursed *by Medicare* for "Empiric Therapy in Febrile Neutropenic Patients." As noted above, to be reimbursable by Medicare, off-label use must be supported by a recognized compendium—and here it is recognized by the AHFS-DI—but must also not "be identified as not indicated in one or more" other statutorily recognized compendia. The Medicare statute recognizes at least two other statutory compendia in addition to the AHFS-DI in its definition of medically accepted indication. *See* 42 U.S.C. § 1395x(t)(2)(B). Defendant has provided the Court with only the AHFS-DI. Relators will be permitted to explore through discovery whether Vfend is not indicated for "Empiric Therapy in Febrile Neutropenic Patients" in those other statutorily-recognized drug compendia. Accordingly, we will not dismiss at this juncture Relators' claims that are based on prescriptions reimbursed by Medicare for "Empiric Therapy in Febrile Neutropenic Patients."[17]

Relators' claims based on off-label promotion for pediatric use will also not be dismissed. The AHFS-DI does not clearly indicate a use for pediatric patients ages 12 and older. Under the "Warnings/Cautions" section of the listing, the AHFS-DI indicates that "[s]afety and efficacy [is] not established in children younger than 12 years of age." (Def's Resp. to Rel's 4th Notice of Supp. Auth. at Ex. A.) The parties dispute the meaning of the language contained in the AHFS-DI as it pertains to use for pediatric patients. Therefore, discovery would assist in reconciling its

[17] Relators also assert that false claims were submitted to other federal health care providers, such as TRICARE, The Railroad Retirement Medicare ("RRM") program, the Federal Employees Health Benefits Program ("FEHBP"), and the Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPUS"). Defendant has not alleged that the statutory and regulatory authority governing payments of claims by these federal health care providers refer to drug compendia like the AHFS-DI for determining whether the use of a drug is medically necessary. Therefore, any of Relators' claims based on reimbursements made by these federal health care providers will not be dismissed.

meaning. In addition, Relators allege that Pfizer promoted Vfend off-label in pediatric hospitals and for pediatric use. This use may include patients under age 12 in addition to those over the age of 12. It would be inappropriate to resolve these factual disputes at this stage of the proceedings.

E. The "Kickback Scheme"

Defendant also claims that Relators failed to articulate particularized facts that pertain to the "kickback scheme" and have not properly pleaded a violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(3)(A)-(F). (Def.'s Mot. 25.)[18] Defendant also contends that Relators' kickback allegations are fatally flawed because the physicians submitting a claim are neither identified nor part of the alleged kickback. (Def.'s Mot. 26.) Notwithstanding Defendant's arguments to the contrary, Relators have satisfied Rule 9(b)'s burden. Relators have set out Defendant's alleged actions from as far back as 2002. (Am. Compl. ¶¶ 40, 126.) Specifically, Relators allege, *inter alia*, that Defendant "misrepresented and concealed the true import of the 608 Study which was used to obtain approval in 2004 for use of Vfend in treating invasive Candida fungal infections" (*id.* at ¶ 70), paid physicians to submit an article to the New England Journal of Medicine advocating for off-label use of Vfend in 2002 (*id.* at ¶ 126), distributed misleading marketing materials to sales representatives and doctors starting in May of 2002 (*id.* at ¶ 127), and provided illegal kickbacks to physicians and pharmacists for the purpose of influencing their behavior (*id.* at ¶ 168). Relators allege that as a result of these unlawful acts, Defendant contributed to the filing of over $250 million in false claims. (*Id.* at ¶ 8.) With the benefit of discovery, Relators may establish these claims. Relators' Amended Complaint contains thorough allegations of a complex scheme to defraud the federal Government with false

[18] Relators' Amended Complaint does not allege a violation of the Anti-Kickback Statute.

claims. At this stage of the proceedings, Relators have satisfied Rule 9(b)'s pleading requirements.

F. Specific Intent and Conspiracy

Defendant also argues that Relators fail to plead specific intent as required by Section 3729(a)(2). (Def.'s Mot. 30.) "To make its *prima facie* case, a FCA plaintiff must allege that the defendant, at the time it submitted its false or fraudulent claims, (1) [had] actual knowledge of the information; or (2) act[ed] in reckless disregard of the truth or falsity of the information alleged to be false." *United States v. Merck-Medco Managed Care, LLC*, 336 F. Supp. 2d 430, 440 (E.D. Pa. 2004) (internal quotation and citation omitted). Here, Relator alleges that Defendant's marketing activities created the market for the off-label use of Vfend and that Defendant purposefully encouraged such a use even though it had no credible evidence that Vfend would be effective in that context. Relators have properly pleaded a violation of Section 3729(a)(2).

Defendant also maintains that Relators fail to plead a conspiracy claim under Section 3729(a)(3). (Def.'s Mot. 31.) The conduct that Relators highlight in their Amended Complaint establishes that Defendant conspired with physicians, pharmacists, sales representatives, and speakers to promote Vfend for the purpose of filing false claims and that they performed acts to ensure such claims were filed. Specifically, Relators allege that Defendant's illicit compensation of physicians and pharmacists was intended to unduly influence prescribers and decision-makers with respect to the off-label use of Vfend. (Am. Compl. ¶ 168.) Indeed, Relators identify a number of speakers (*id.* at ¶ 181), sales representatives (*id.* at ¶ 189), pharmacists (*id.* at ¶¶ 172, 192), and physicians (*id.* at ¶¶ 172, 197), who were compensated in this manner. Relators have properly pleaded a violation of Section 3729(a)(3).

G. State and Local False Claims Act Claims

Finally, Defendant argues that Relators fail to comply with relevant filing and disclosure requirements in the various state and city claims asserted pursuant to local false claims acts.[19] (Def.'s Mot. 32.) Principally, Defendant maintains that Relators' state-law claims must be dismissed because they have not pled specific violations of state fraud statutes. (*Id.*); *see Foglia v. Renal Ventures Mgmt.*, No. 09-1552, 2011 WL 5882020, at *8 (D.N.J. Nov. 23, 2011); *United States ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709, 723 (N.D. Tex. 2011) ("[Relator] provides no details of the alleged fraud in the other states, but to plead properly, even where the allegations are stated on information and belief, a plaintiff must set forth in the complaint the facts supporting the belief."). Relators submit that no such specificity is necessary at the pleading stage. (Rels.' Resp. 54.)

In light of our finding that Relators need not provide evidence of actual false claims at the pleading stage, *see infra* at Section III.A.3, we will not require Relators to provide specific details particularized for each state allegedly defrauded by Defendant's illegal acts.

1. Michigan Claim

Defendant maintains that Relators' claims under the Michigan Medicaid False Claims Act, §§ 400.601, *et seq.* are statutorily barred by Michigan's Comp. Laws § 600.2946. (Def.'s Mot. 34.) In doing so, Defendant relies on the decision in *Attorney General v. Merck Sharp & Dohme Corp.*, 807 N.W.2d 343 (2011). In *Merck*, the court of appeals ruled that the State of Michigan could not assert a state false claims act suit against Merck for misrepresentations related to the safety and efficacy of the prescription drug Vioxx. *Id.* at 344. In doing so, the

[19] Relators respond that they did, in fact, provide each relevant state with notice of the Amended Complaint under seal. (Rels.' Resp. 54.) Considering Defendant's threadbare argument and the fact that each state notified the Court of their intention not to intervene, *see* July 24 Order, ECF No. 55, we find that the record suggests Relators complied with relevant filing and disclosure requirements.

court reasoned that the "safety and efficacy of Vioxx is central to plaintiffs' claims" and that the case was a products liability action such that Merck was immune from suit under Michigan law. *Id.* at 349 (citing MCL § 600.2946(5)). Unlike *Merck*, here we confront allegations of off-label promotion of a prescription drug for uses beyond the FDA's approval. Accordingly, at this stage, Relators' claims under the Michigan Medicaid False Claims Act may proceed.

2. New Mexico Claims

Defendant contends that Relators are not "affected persons" under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-F-4(A)-(C), and have failed to obtain a "substantial evidence" determination necessary for a *qui tam* action. (Def.'s Mot. 33-34.) Having failed to obtain authorization from the New Mexico Attorney General, Relators agree to dismiss their New Mexico claims, Counts 18 and 19, under the New Mexico Medicaid False Claims Act, and New Mexico Fraud Against Taxpayers Act, N.M. Stat. §§ 44-9-1, *et seq*. (Rels.' Resp. 55.) Accordingly, Counts 18 and 19 are dismissed without prejudice.

3. New York City and City of Chicago Claims

Defendant contends that Relators claim to have brought this action on behalf of the City of New York and the City of Chicago, but have failed to include any such counts in their Amended Complaint, and that Relators have effectively abandoned such claims. (Def.'s Mot. 32.) Rather than abandoning such claims, Relators have simply not properly pleaded violations of the false claims acts in those cities. Moreover, as noted above, the City of Chicago and the City of New York notified the Court of their decision not to intervene. *See infra* at Section I.A n.3.

IV. CONCLUSION

Based upon the foregoing, Defendant's Motion to Dismiss the Amended Complaint will be granted in part and denied in part.

An appropriate Order follows.

BY THE COURT:

R. BARCLAY SURRICK, J.