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. **APRIL 11, 2017**

Presently before the Court is Defendant Pfizer Inc.'s Second Motion to Dismiss. (ECF No. 103.) For the following reasons, Defendant's Motion will be denied.

I. BACKGROUND

A. Procedural History

On March 1, 2016, we ruled on Defendant's First Motion to Dismiss Plaintiffs' First Amended Complaint. *United States v. Pfizer, Inc.*, No. 05-6795, 2016 WL 807363 (E.D. Pa. Mar. 1, 2016); (ECF Nos. 93, 94.) The factual background surrounding this matter is set forth in that Memorandum.

On March 15, 2016, Relators filed a Second Amended Complaint. (SAC, ECF No. 98.) On May 6, 2016, Defendant filed the instant Motion to Dismiss. (Def.'s Mot., ECF No. 103.) Relators filed a Memorandum in Opposition to Defendant's Motion to Dismiss on June 24, 2016. (Rels.' Mem. Opp., ECF No. 107.) On July 13, 2016, Defendant filed a Reply Memorandum in Support of its Motion. (Def.'s Reply, ECF No. 109.) On July 27, 2016, Relators filed a Reply Memorandum in Opposition to Defendant's Memorandum. (Rels.' Reply, ECF No. 111.) Since that time, Defendant has submitted three separate "notices of supplemental authority," and

Relators have submitted one "notice of supplemental authority." On October 31, 2016, Defendant filed the first Notice of Supplemental Authority (ECF No. 115), and on December 22, 2015, Relators filed a response (ECF No. 116). On January 30, 2017, Defendant filed a second Notice of Authority (ECF No. 117), and on March 6, 2017, Relators filed a response (ECF No. 118). On March 15, 2017, Defendant filed a third Notice of Authority (ECF No. 119), and on March 25, 2017, Relators filed a response (ECF No. 120). On April 7, 2017, Relators filed a Notice of Supplemental Authority. (ECF No. 121.) The Second Motion to Dismiss is now ready for disposition.

B. Parties' Contentions

Defendant advances four arguments in support of its Second Motion to Dismiss. First, Defendant contends that the Court lacks subject matter jurisdiction over portions of Relators' SAC. In the prior Memorandum, we concluded that Relators' claims were barred by the first-to-file rule. However, we permitted Relators to file an amended complaint. *Pfizer*, 2016 WL 807363, at *8. Defendant now argues that Relators lack subject matter jurisdiction because Relators are required to file a separate action in order to cure the jurisdictional defect. Defendant further argues that even if Relators were to file a new action, it would be time-barred under the False Claim Act's ("FCA") six-year statute of limitations. Second, Defendant maintains that its off-label use of Vfend on neutropenic patients and for empiric therapy is covered by Medicare and other healthcare programs. Third, Defendant alleges that Relators have failed to state a claim that Defendant paid kickbacks to physicians and pharmacists. Defendant argues that its actions do not qualify as illegal kickbacks because they are protected by a safe harbor regulation. Fourth, Defendant argues that Relators have not stated a claim under the FCA because Relators did not allege that Defendant submitted reimbursement claims to the FDA that contained

expressly false statements. Defendant argues that Relators must rely on the implied false certification theory, and that Relators have failed to properly state a claim under that theory. Defendant further argues that Relators have failed to satisfy the materiality requirement of the FCA because the government continued to pay for Vfend after Relators' allegations in 2005.

Relators reject each of Defendant's arguments, citing our previous Memorandum, which Relators claim addressed many of the same arguments that Defendant raises in the instant Motion. With regard to Defendant's jurisdictional argument, Relators argue that this Court specifically permitted Relators to file the SAC to reassert their claims. Relators argue that because they added no additional factual allegations in their SAC, and filed the SAC pursuant to the Court's Order, Defendant's argument is invalid. Further, Relators argue that they have pled facts sufficient to state a claim of fraudulent inducement under the FCA. Relators argue that they have satisfied the FCA's materiality requirement because they alleged that Defendant presented false and misleading statements to the FDA, which in turn caused the FDA to approve Vfend to treat Candida infections. With regard to Defendant's other allegations, Relators maintain that these allegations merely restate the arguments that Defendant made in its First Motion to Dismiss, and should accordingly be dismissed.

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*, 129 S. Ct. 1937, 1949 (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*, 129 S. Ct. at 1949 (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), "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*, 129 S. Ct. at 1949). "A complaint may not be dismissed 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). 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*, 129 S. Ct. at 1949).

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 with regard to the "particularity" requirement of Rule 9(b). The Third Circuit has adopted the approach of 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). 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 quotation marks omitted).

III. DISCUSSION

A. Subject Matter Jurisdiction

1. Amended Complaint

In its First Motion to Dismiss, Defendant argued that Relators' claims were barred by the FCA's first-to-file rule. We noted that a relator is only entitled to relief under the FCA if the relator is the first person to file the complaint. *Pfizer*, 2016 WL 807363, at * 6; *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."). We cited the Supreme Court's decision in *Kellogg Brown & Root Servs. v. United States ex rel. Carter*, 135 S. Ct. 1970, 1979 (2015), which held that a *qui tam* suit under the FCA is no longer deemed "pending" once it is dismissed. *Pfizer*, 2016 WL 807363, at *8. Since the first action, the *Worsfold* action had been dismissed, we granted Relators leave to file an amended complaint to assert claims that had previously been barred by the first-to-file rule. *Id.* Defendant argues, however, that an amended complaint does not cure the first-to-file jurisdictional bar. Defendant argues that if a case was barred by the FCA's first-to-file rule, a relator must file a new action.

The First Circuit Court of Appeals is the only circuit court to have addressed this issue. *See U.S. ex rel. Gadbois v. PharMerica Corp.*, 809 F.3d 1 (1st Cir. 2015). In *Gadbois*, the relators filed a complaint in the District of Rhode Island; however, the district court dismissed the relator's claim for lack of subject matter jurisdiction. 809 F.3d at 3. The district court

dismissed the claim pursuant to the FCA's first-to-file rule because there was already a similar case pending in the Eastern District of Wisconsin. *Id*. However, while the case was pending on appeal in the First Circuit, the case in the Eastern District of Wisconsin was dismissed. *Id*. at 4. Citing *Kellogg*, the First Circuit permitted the relators to supplement their complaint pursuant to Rule 15(d) in order to cure the jurisdictional defect. (*Id*. at 4-5.) The court justified its decision by stating that Rule 15 helps "courts and litigants to avoid pointless formality." *Id.* at 4. The First Circuit also noted that courts are encouraged to allow parties to supplement their pleadings "when doing so will promote the economic and speedy disposition of the entire controversy between the parties, will not cause undue delay or trial inconvenience, and will not prejudice the rights of any of the other parties to the action." *Id*. (internal quotation marks and citation omitted).[1] We agree with the reasoning of the First Circuit.

Like the facts in *Gadbios*, the pending *Worsfold* case was dismissed, and therefore was no longer "pending" for purposes of the first-to-file rule under the FCA. We are satisfied that

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[1] Defendant cites the district court case of *United States v. Medco Health Sols., Inc.*, No. 11-684, 2017 WL 63006, at *12 (D. Del. Jan. 5, 2017) as authority for the proposition that filing an amended complaint does not correct a first-to-file jurisdictional defect. The case notes that there is a split in authority among various district courts, and held that the reasoning in *Gadbois* and in our previous denial of Defendant's First Motion to Dismiss "does not hold up under scrutiny." *Id*. at 12.

We note that several district courts have held that relators are not required to re-file a case to cure a jurisdictional defect, and are instead permitted to file an amended complaint with the court. *See, e.g., United States ex rel. Wood v. Allergan, Inc.*, No. 10-5645, 2017 WL 1233991, at *15 (S.D.N.Y. Mar. 31, 2017) (concluding "that a violation of the rule is curable through the filing of an amended or supplemental complaint after the earlier-filed action was dismissed"); *United States v. Cephalon, Inc.*, 159 F. Supp. 3d 550, 558 (E.D. Pa. 2016) (finding that "it would be unjust to require relators to refile their claims even though their only procedural roadblock was dismissed over two years ago and they have amended their complaint since then"); *U.S. ex rel. Kurnik v. PharMerica Corp.*, No. 11-01464, 2015 WL 1524402, at *6 (D.S.C. Apr. 2, 2015) (holding that the relator was permitted to file an amended complaint after the first-filed case was dismissed, and that doing so "does not run afoul of the policy behind the FCA because it does not threaten [the defendants] with double recovery").

Relators were permitted to file the SAC as a cure for the jurisdictional defect present with the FAC. Accordingly, the SAC is not jurisdictionally barred under the FCA's first-to-file rule.

2. Statute of Limitations

Defendant argues that even if this Court determines that the SAC cures jurisdictional defects in light of the *Worsfold* dismissal, the Relators' claims are nonetheless time-barred. Defendant argues that the FCA has a six-year statute of limitations, and therefore Relators' pediatric and prophylactic claims are time-barred. Defendant states that Relators seek recovery for pediatric and prophylactic reimbursement claims submitted between 2002 and 2009. Relators filed the SAC on March 15, 2016. The original complaint was filed on December 29, 2005. Defendant contends that the operative complaint that courts should use when determining if a claim is time-barred under the FCA is the complaint filed following dismissal of the first-filed action. Here, that would be the SAC, which would result in Relators' pediatric and prophylactic claims being time-barred. Relators respond that for statute of limitations purposes, the SAC should relate back to the date of the original complaint. Defendant argues that the SAC cannot relate back to the original complaint because (1) the original complaint does not allege claims of off-label pediatric or prophylactic use of Vfend and (2) this Court lacked subject-matter jurisdiction over the original complaint.

Rule 15(c) provides that "[a]n amendment to a pleading relates back to the date of the original pleading when . . . the amendment asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out—or attempted to be set out—in the original pleading." *See also ASARCO, LLC v. Union Pac. R. Co.*, 765 F.3d 999, 1004 (9th Cir. 2014) ("An otherwise time-barred claim in an amended pleading is deemed timely if it relates back to the date of a timely original pleading."). The Supreme Court has held that "relation back

depends on the existence of a common core of operative facts uniting the original and newly asserted claims." *Mayle v. Felix*, 545 U.S. 644, 646 (2005). The Third Circuit has held that an amended complaint relates back "only where the opposing party is given fair notice of the general fact situation and the legal theory upon which the amending party proceeds . . . ." *Glover v. F.D.I.C.*, 698 F.3d 139, 146 (3d Cir. 2012) (internal quotation marks and citation omitted). "If the amendment relates back to the date of the filing of the original complaint, the amended complaint is treated, for statute of limitations purposes, as if it had been filed at that time." *Garvin v. City of Phila*., 354 F.3d 215, 220 (3d Cir. 2003) (citation omitted). The relation back provision "aims to ameliorate the harsh result of the strict application of the statute of limitations." *Id.*

Relators argue that the pediatric and prophylactic off-label claims alleged in the SAC arise out of the conduct alleged in the original complaint. Relators cite to their allegations in the original complaint, which state that Defendant engaged in illegal off-label promotion of Vfend. Relators argue that this behavior arises out of a common set of operative facts—namely off-label promotion of Vfend (original complaint) and, more specifically, off-label promotion of Vfend for pediatric and prophylactic use (SAC). Defendant argues that Relators' SAC does not relate back to their original complaint because the original complaint does not specifically mention off-label promotion of Vfend for pediatric or prophylactic use.

As noted above, Relators filed the original complaint on December 29, 2005. (Compl., ECF No. 1.) Relators' original complaint alleged Defendant's violations under the FCA, pointing to Defendant's off-label promotion of Vfend. (*Id.* ¶¶ 12, 14-15.) Relators stated that Vfend was not approved to treat patients with Candida infections, and that physicians were only permitted to prescribe Vfend to non-neutropenic patients. (*Id.* ¶ 24.) Relators pled that

Defendant promoted Vfend illegally, specifically that Defendant alleged that "Vfend is equally efficacious against all species of Candida, despite having irrefutable evidence that it is not." (*Id.* ¶ 152.) These pleadings support allegations that Defendant engaged in illegal off-label promotion of Vfend, in violation of the FCA. While Relators did not allege that Defendant promoted Vfend off-label for pediatric and prophylactic purposes specifically, they did plead that Defendant "marketed Vfend off-label for empiric therapy . . . ." (*Id.* ¶ 171.) Relators' original complaint also contained allegations that Defendant provided misleading information to the FDA. Relators' allegations in the SAC state more specifically that Defendant promoted Vfend off-label for pediatric and prophylactic use. We find that Relators' allegations in the SAC arise out of the conduct that Relators alleged in their original complaint, namely that Pfizer promoted Vfend for impermissible off-label uses. We also find that Relators' original complaint gave Defendant fair notice of the general fact situation that Relators allege in the SAC.

Defendants also argue that this Court did not have subject-matter jurisdiction over the original complaint because of the first-to-file rule. We reject this argument because "a district court does not lack subject matter jurisdiction over an action that may be barred on the merits by the first-to-file rule." *United States ex rel. Hayes v. Allstate Ins. Co.*, No. 16-705, 2017 WL 1228551, at *3 (2d Cir. Apr. 4, 2017). Interpreting the FCA, the Second Circuit in *Hayes* noted that "[b]ecause the FCA 'clearly state[s]' that *other* limitations on *qui tam* actions are jurisdictional, but does not 'clearly state[]' that the first-to-file rule is jurisdictional, we must treat the first-to-file rule 'as nonjurisdictional in character.'" *Id.* (quoting *Sebelius v. Auburn Reg'l Med. Ctr.*, 133 S. Ct. 817, 824 (2013)). The D.C. Circuit also held that the first-to-file bar "does not speak in jurisdictional terms or refer in any way to the jurisdiction of the district courts." *U.S. ex rel. Heath v. AT & T, Inc.*, 791 F.3d 112, 120 (D.C. Cir. 2015), *cert. denied sub*

nom. AT&T, Inc. v. U.S. ex rel. Heath, 136 S. Ct. 2505 (2016) (quoting *Arbaugh v. Y & H Corp.*, 546 U.S. 500, 515 (2006)); *see also Allergan*, 2017 WL 1233991, at *11 ("[T]he first-to-file rule bears only on whether a *qui tam* plaintiff has properly stated a claim, rather than on the scope of courts' jurisdiction." (citation and internal quotation marks omitted)). *But see, U.S. ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 376-77 (5th Cir. 2009); *Walburn v. Lockheed Martin Corp.*, 431 F.3d 966, 970 (6th Cir. 2005). Since we did not lack subject-matter jurisdiction over Relators' original complaint, we reject Defendant's argument that the SAC cannot relate back to the original complaint for lack of jurisdiction.

Accordingly, we conclude that the SAC relates back to the date of the original complaint—December 29, 2005—and therefore Relators' clams are not time-barred by the FCA's six-year statute of limitations.

B. Off-Label Promotion

1. Medicare

In our previous Memorandum, we determined that "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." *Pfizer*, 2016 WL 807363, at *12 (emphasis in original). However, we did not similarly dismiss Relators' Medicare claims. *Id.* Rather, we found that in order for Vfend's off-label use for empiric therapy to be reimbursable by Medicare, it must (1) be supported by a recognized compendium, and (2) must not be identified as "not indicated for 'Empiric Therapy in Febrile Neutropenic Patients'" in one or more statutorily-recognized compendia. *Id.* (citing 42 U.S.C. § 1395x(t)(2)(B)). We therefore granted Relators the opportunity to explore through discovery whether such statutorily-recognized compendium existed. *Id.*

Defendant argues that we should have dismissed Relators' Medicare claims. Defendant argues that "[c]ontrary to the Court's suggestion" the statutory provision that we cited—42 U.S.C. § 1395x(t)(2)(B)—does not apply to Vfend. (Def.'s Mot. 14.) Defendant contends that the statute we cited to relates "solely to" anticancer drugs. (*Id*.) Defendant argues that, like Medicaid, Medicare covers Vfend when used for empiric therapy. We rejected that argument in our previous Memorandum, and we reject it here.

The statutory provision does not state that it applies "solely to" drugs or biologicals used in an anticancer regimen, as Defendant suggests. Rather, the text states the following: "the term 'drugs' *also includes* any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication." 42 U.S.C. § 1395x(t)(2)(A) (emphasis added). Defendant's contention that this statutory provision is limited to anticancer drugs is misguided. "Courts must presume that a legislature says in a statute what it means and means in a statute what it says there. When the words of a statute are unambiguous, then this first canon is also the last: judicial inquiry is complete." *In re Phila. Newspapers, LLC*, 599 F.3d 298, 304 (3d Cir. 2010) (quoting *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992)). The statute does not state that it only applies to anticancer drugs. The statute makes clear that it *also* applies to anticancer drugs, and we therefore interpret the statute to encompass drugs such as Vfend.

Accordingly, we continue to hold that Relators should be given the opportunity to engage in discovery to identify any statutorily-recognized compendium which states that Vfend is "not medically appropriate" for empiric therapy in Neutropenic Patients.

2. Other Federal Programs

Defendant also alleges that four other federal healthcare programs cover Defendant's use of Vfend for empiric therapy. These federal programs are: TRICARE, the Federal Employees

Health Benefits Program ("FEHBP"), the Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA"), and the Railroad Retirement Medicare Program ("RRM"). We addressed Defendant's arguments in our previous Memorandum and stated that "Defendant ha[d] not alleged that the statutory and regulatory authority governing payments of claims by [the four] federal health care providers refer to drug compendia like the AHFS-DI for determining whether the use of a drug is medically necessary." *Pfizer*, 2016 WL 807363, at *12 n.17. Accordingly, we held that Relators' claims should not be dismissed. *Id*. Similarly, we maintain that if Defendant does not cite to any relevant statutory authority that is instructive in this case, we will not dismiss Relators' claims.

TRICARE – Defendant argues that TRICARE will reimburse off-label drugs when it is "medically necessary." Defendant cites to the TRICARE Policy Manual, stating that TRICARE considers "nationally accepted standards of practice in the medical community." (Def.'s Mot. 17.) However, Defendant fails to cite to any statutory authority which states that support from AHFS-DI and DRUGDEX—the compendia Defendant cites to in support of its off-label use—deems Vfend medically necessary for empiric use. Consistent with our previous ruling, we will not dismiss Relators' claim.

FEHBP – Defendant argues that FEHBP covers use of Vfend for empiric therapy because multiple compendia support such use. However, Defendant acknowledges that "[t]here is no law or regulation mandating when a prescription drug is insurable and reimbursable under FEHBP." (*Id*. at 18 (citation omitted).) Defendant attempts to argue that because AHFS-DI and DRUGDEX support empiric use of Vfend, this Court should deem it medically necessary. Consistent with our previous ruling, we will not dismiss Relators' claim.

CHAMPVA – Defendant argues that CHAMPVA covers empiric use of Vfend for the same reasons that TRICARE does so. Since Defendant has failed to identify any statutory authority dictating coverage for CHAMPVA in this circumstance, we reject Defendant's argument and will not dismiss Relators' claim.

RRM – Defendant argues that the RRM applies the same coverage standards as Medicare. Since we will permit Relators to engage in discovery to identify other compendium for their Medicare claim, we similarly permit Relators to engage in discovery for their RRM claim.

C. Kickbacks

1. Rule 9(b) Requirements

Defendant argues that Relators have failed to state a claim under the Anti-Kickback Statute. Defendant argues that Relators' allegations simply contain conclusory statements and do not provide factual allegations that raise Relators' claims above a speculative level. In our prior Memorandum, we ruled that Relators' FAC contained "thorough allegations of a complex scheme to defraud the federal Government with false claims." *Pfizer*, 2016 WL 807363, at *13. As support that Relators satisfied Rule 9(b)'s pleading requirements, we cited Relators' allegations, which included the following:

> 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, paid physicians to submit an article to the New England Journal of Medicine advocating for off-label use of Vfend in 2002, distributed misleading marketing materials to sales representatives and doctors starting in May of 2002, and provided illegal kickbacks to physicians and pharmacists for the purpose of influencing their behavior. Relators allege that as a result of these unlawful acts, Defendant contributed to the filing of over $250 million in false claims.

Id. (internal citations and quotation marks omitted).

Relators have pled similar facts in the SAC. Relators' SAC states the following: 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" (SAC ¶ 69); Defendant paid physicians to write and submit an article to the New England Journal of Medicine advocating for the off-label use of Vfend for empiric therapy when they "well knew that the 603 Study results showed that Vfend was not suitable for [such a] use" (*id*. ¶ 125); Defendant distributed "misleading materials . . . urging physicians to prescribe Vfend" and similarly "encouraged its sales representatives to promote Vfend for 'early and aggressive therapy'" (*id*. ¶¶ 126, 128); and Defendant "participated in, encouraged, and authorized the unlawful payment of illegal kickbacks to physicians and pharmacists in order to increase sales of Vfend, a substantial percentage of which were for 'off-label' uses" (*id*. ¶ 166). Relators claim that the federal Government paid "in excess of $250 million in false claims for the purchase of Vfend" since 2002. (*Id*. ¶ 8.)

Defendant argues that these allegations fail to state a claim because Relators have not alleged that any of Pfizer's speakers or sales representatives paid physicians to specifically market Vfend. Defendant cites *United States v. Celgene Corp.*, No. 10-3165, 2016 WL 7626222 (C.D. Cal. Dec. 28, 2016), in which the alleged Anti-Kickback Statute violations were dismissed because penalizing the defendant's generalized promotion of a drug "would effectively criminalize all promotion of medical goods and services." *Id*. at *18. Further, the *Celgene* court noted that "there [was] no evidence that speakers did anything other than convey truthful scientific information about the drugs." *Id*. Relators note that *Celgene* was decided at the summary judgment stage, and that it in essence rejects Defendant's argument that Relator's allegations would effectively criminalize the promotion of prescription drugs.

We are satisfied that Relators' allegations are sufficient to state a claim. Moreover, we find that Relators' allegations do not give rise to a concern that the Anti-Kickback Statute would be penalizing a "general promotion" of Vfend. Relators have alleged that Pfizer told its sales representatives to use *misleading* materials in order to encourage physicians to prescribe Vfend. (SAC ¶ 126.) Relators allege that Defendant "illegally promoted" Vfend, telling physicians to "choose Vfend first." (*Id*. ¶ 127.) Clearly, Realtors' allegations that Defendants' marketing tactics utilized deceit and misrepresentations distinguish this case from *Celgene*. In addition, contrary to Defendant's assertions, Relators alleged that Defendant paid physicians in order to encourage them to prescribe a particular drug. Furthermore, Relators allege that "[i]n addition to paying the aforementioned speaking fees to doctors for convincing other doctors to prescribe Vfend off label," Pfizer established a program "created to reward doctors who are willing to do whatever it takes to write Vfend." (*Id*. ¶¶ 187-88.) For the same reasons that we found Relators' claims sufficient to meet Rule 9(b)'s pleading requirements in our previous Memorandum, we find that Relators have sufficiently met the pleading requirements here.

2. Safe Harbor Regulation

Defendant argues that its financial arrangements with physicians, consultants, and promotional speakers fall within the Department of Health and Human Services' safe harbor regulation found at 42 C.F.R. § 1001.952. Defendant argues that under the safe harbor regulation, Defendant's payments for physicians' services do not constitute "illegal remuneration." Defendant bears the burden of proving that its conduct was protected by the safe harbor regulations. *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 95 (3d Cir. 2009). Relators argue that it is impossible for Defendant to prove that it is entitled to the safe harbor protection at the pleadings stage.

In order for Defendant to be protected by the safe harbor regulation for "personal services and management contracts," it must prove all seven of the elements listed. The elements are as follows:

> (1) The agency agreement is set out in writing and signed by the parties.
> (2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.
> (3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.
> (4) The term of the agreement is for not less than one year.
> (5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.
> (6) The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law.
> (7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

42 C.F.R. § 1001.952.

In its brief, Defendant mentions only elements 1, 2, 5, and 7. *See* Def.'s Mot. 22 (noting the elements as "set out in writing, specifies the services to be provided, aggregate compensation is consistent with fair market value, and aggregate services do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services"). In addition, Defendant does not affirmatively state how it satisfies each of the seven elements. Rather, Defendant merely asserts that Relators did not "identify any contractual arrangement that failed to comply with the personal services safe harbor . . . ." (Def.'s Mot. 23.) Relators argue that this is insufficient. Specifically, Relators argue that the fifth element is not

met because the payments Defendant made to physicians were specifically made to increase the volume of prescriptions for Vfend.

With regard to the fifth element, at the very least, Relators' allegations call into question whether the compensation Defendant paid to physicians and pharmacists was "consistent with fair market value in arms-length transactions." 42 C.F.R. § 1001.952 (5). Relators allege the following in the SAC: Defendant "gave its sales representatives large budgets to compensate physicians to promote Vfend's efficacy for various off label uses" (SAC ¶ 167); Defendant gave "pharmacists gifts in exchange for insights into what medications physicians were using" (*id*.); Defendant paid physicians bills for "travel, first-rate lodging, extravagant meals and entertainment" (*id*. ¶ 173); Defendant paid "in kind" kickbacks to physicians (*id*. ¶ 174); Defendant created "sham" speaker programs where Defendant paid doctors to convince other doctors to prescribe Vfend (*id*. ¶ 175); Defendant established an annual entertainment budget to impress physicians' business (*id*. ¶ 176); Defendant paid physicians $1,500 for each training session (*id*. ¶ 179); and Defendant paid one physician $44,800.35 in one year alone to promote Vfend to other physicians (*id*. ¶ 180). Absent any argument to the contrary by Defendant, we are compelled to conclude that Relators' allegations call into question whether the types of compensation that Defendant paid to its medical agents was actually consistent with a fair market value. Accordingly, at this point Defendant's actions do not meet the safe harbor requirements.

D. FCA Liability

Defendant contends that in light of the recent Supreme Court decision in *Universal Health Services, Inc. v. United States*, 136 S. Ct. 1989 (2016), Relators' allegations that Defendant concealed clinical trial data pertaining to Vfend are insufficient to state a claim under the FCA. Defendant argues that Relators must rely on an implied certification theory in asserting

their FCA claim because Relators' SAC does not allege that their reimbursement claims contained false statements. Relators argue that they need not rely on an implied certification theory to state a claim under the FCA. Realtors maintain that they alleged FCA liability under the fraudulent inducement theory.

"Under a fraudulent inducement theory, although [a defendant's] subsequent claims for payment made under the contract [are] not literally false, because they derived from the original fraudulent misrepresentation, they, too, [become] actionable false claims." *U.S. ex rel. Longhi v. United States*, 575 F.3d 458, 468 (5th Cir. 2009) (internal quotation marks omitted). Under the "implied certification theory," a defendant would be liable under the FCA if "a claimant seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment." *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011) (citation omitted). The Eighth Circuit distinguishes the two theories as follows:

> [*Escobar*] was about implied false certifications, claims for payment that do not say anything untrue but are misleading because of what they leave out, whereas [the relator's] claims are based on the rule that when a government contract is secured through fraud, claims for payment later submitted under the contract can count as false claims even if they are not fraudulent themselves. Because the fraud that matters for [the relator's] theory is whatever [the defendant] initially induced the government to enter into the ongoing relationship, not any misrepresentations—implicit or explicit—in the claims for payment themselves, the Court's analysis of when such claims can be actionably misleading is irrelevant here.

Olson v. Fairview Health Servs. of Minn., 831 F.3d 1063, 1079 n.20 (8th Cir. 2016) (citation and internal quotation marks omitted).

Defendant argues that Relators must rely on an implied certification theory in an attempt to establish falsity because Relators did not allege that their claims contained expressly false statements. Relators argue that they did allege that Defendant made false representations in its

New Drug Application to obtain FDA approval of Vfend to treat Candida infections, which was needed to allow Pfizer to obtain government reimbursement. For the following reasons, we find that Relators have sufficiently stated a claim under the fraudulent inducement theory.[2]

1. Falsity

"Under fraudulent inducement, FCA liability attaches to each claim submitted to the government under a contract so long as the original contract was obtained through false statements or fraudulent conduct." *Weston*, 840 F.3d at 499 (citation and internal quotation marks omitted). We find, as we did in our previous Memorandum, that Relators have alleged that 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." *Pfizer*, 2016 WL 807363, at *10 (internal quotation marks omitted). Furthermore, Relators' SAC alleges the following: that Pfizer submitted "a false and misleading New Drug Application ("NDA") to the Food and Drug Administration ("FDA") for approval of Vfend" (SAC ¶ 3); that "[a]fter the FDA's rejection of the Empiric Therapy indication for Vfend and its limited approvals in 2002 and 2004, Pfizer could only maximize its Vfend sales by marketing Vfend for a broad range of off-label uses and by misrepresenting and concealing key aspects of the 608 Candida Study" (*id*. ¶ 67); that "[t]he net effect of Pfizer's misrepresentations about the efficacy of Vfend in treating C. glabrata is that the medical community was misled into believing that Vfend was the antifungal drug of choice . . . In fact, those patients were more likely to die with Vfend." (*id*. ¶ 153); and that "Pfizer made these false and misleading survival rate claims about Vfend . . . ." (*id*. ¶ 149). In addition, Relators specifically allege that "Pfizer

[2] After *Escobar*, appellate courts have analyzed relators' FCA claims under the fraudulent inducement theory. *See, e.g., Weston Educ., Inc.*, 840 F.3d 494, 499 (8th Cir. 2016); *Olson*, 831 F.3d at 1074 (8th Cir. 2016).

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" by "[f]alsely cit[ing] the 608 Study as evidence that Vfend was more effective . . . despite the fact that, as Pfizer well knew, the 'primary endpoint' of the 608 study upon which its claims were based was totally invalid for that purpose," and "[m]isrepresenting the 608 Study results to add credibility to Pfizer's illegal marketing of Vfend . . . to falsely suggest that Vfend was suitable for 'Empiric Therapy.'" (*Id*. ¶ 69.)

We find that Relators have sufficiently established the element of "falsity" pursuant to the FCA. We agree that Relators alleged that Defendant withheld or concealed adverse test results from the FDA, however Relators have *also* alleged that Pfizer made expressly false statements to the FDA for approval of Vfend in order to induce Medicare and Medicaid payments. Therefore, the falsity element is satisfied.

2. Materiality

The Supreme Court refined the FCA's definition of materiality in *Escobar*. 136 S. Ct. 2002 ("We now clarify how that materiality requirement should be enforced."). The Court noted that "[u]nder any understanding of the concept, materiality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Id*. at 2003 (citation and internal quotation marks omitted). The Court held that "[t]he materiality standard is demanding" and "cannot be found where noncompliance is minor or insubstantial." *Id*. Relators argue that the results of the 608 Study that Pfizer presented to the FDA for approval of Vfend for Candida infections were material to the FDA's subsequent approval. Defendant cites the First Circuit's decision in *D'Agostino v. ev3, Inc*., 845 F.3d 1 (1st Cir. 2016) in arguing against materiality. Similar to this case, the court in *D'Agostino* was analyzing a relator's fraudulent inducement

theory under the FCA. *Id*. at 7-10. The court held that the relator's alleged false representations did not have a tendency to influence the FDA into approving the drug. *Id*. The court held that the relator's allegations that the defendant's false representations "could have" influenced the FDA were insufficient to make the false representations material. *Id*.

Here, Relators alleged that the misrepresentations that Defendant made in its application to the FDA in 2004 did in fact cause the FDA to approve Vfend to be used to treat Candida infections. Unlike the relator in *D'Agostino*, Relators here provide factual allegations that demonstrate how Defendant's misrepresentations caused the FDA to approve Vfend for Candida infections. Relators allege in their SAC that in 2002, the FDA rejected Pfizer's application to approve Vfend to treat serious Candida infections. (SAC ¶ 56.) Relators allege that the FDA refused to approve Vfend to treat Candida infections because the 608 Study showed that Vfend was not as effective as another antifungal drug, to which Vfend was being compared. (*Id*.) In 2004, Pfizer again attempted to obtain FDA approval for Vfend in treating Candida infections. (*Id*. ¶ 68.) Relators allege that this second time, however, Pfizer misrepresented the 608 Study by doing the following: falsely citing the 608 study as evidence that Vfend was more effective than other anti-fungal medications in treating Candida infections, claiming that the 608 Study revealed that Vfend was effective in treating a Candida infection despite the fact that the 608 Study showed the opposite results, misrepresenting the 608 Study results to add credibility to Pfizer's illegal marketing tactics, and supporting the publication of "ghost written" articles in medical journals, which cited the 608 Study as evidence that Vfend should be used to treat Candida infections. (*Id*. ¶ 69.) We find that Relators have pled sufficient facts to demonstrate that Defendant's misleading and false statements were material to the FDA's approval of Vfend for treating Candida infections.

Defendant also argues that since both the federal and state governments have continued to pay for Vfend despite Relators' allegations against Defendant, Relators cannot satisfy the materiality requirement. Defendant cites *Escobar*, which noted that "if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." 136 S. Ct. at 2003-04. Relators argue that there is no evidence that the government had actual knowledge of Pfizer's misrepresentations when making their decisions to pay for Vfend and that courts must take a holistic approach to determining materiality, since no one factor is dispositive.

On remand from the Supreme Court, the First Circuit in *Escobar* further defined what "actual knowledge" meant within the context of determining materiality. *Escobar*, 842 F.3d 103, 112 (1st Cir. 2016). The First Circuit noted that "mere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance." *Id*. Further, the court held that even if the government had actual knowledge that certain requirements were violated, "such knowledge is not dispositive." *Id*. at 110. Highlighting the Supreme Court's emphasis on "applying the holistic approach to determining materiality," the First Circuit ultimately held that the relators had satisfied the FCA's materiality requirement. *Id*. Defendant cites *D'Agostino* to support its argument that Relators' allegation against Pfizer in 2005 is sufficient to constitute "actual knowledge" of an FCA violation. The First Circuit in *D'Agostino* held that "[t]he fact that CMS has not denied reimbursement for [the drug] in the wake of [the relator's] allegations casts serious doubt on the materiality of the fraudulent representations that [the relator] alleges." *Id*. at 7. Both First Circuit cases were published after the Supreme Court's instructions on materiality in *Escobar*. As noted above, we distinguish the

facts in *D'Agostino* from the current case before us. We find, as the First Circuit found in *Escobar*, that Relators have satisfied the materiality requirement. Here, the SAC alleges that:

> Plaintiff United States, unaware of the false or fraudulent nature of the records and/or statements caused to be made and used by Pfizer, and in reliance on the accuracy thereof, has paid and approved, and continue to pay and approve, claims for Vfend that were ineligible for reimbursement and would not have been paid or approved if any part of the truth were known.

(SAC ¶ 211.)

The mere fact that the government has continued to pay and approve claims for Vfend even after Relators' allegations in 2005 is insufficient to establish that Relators' claims lack materiality. As the First Circuit held, mere knowledge of allegations regarding noncompliance is insufficient to prove actual knowledge of noncompliance. Moreover, Relators allege that the United States was "unaware of the false or fraudulent nature" of Pfizer's statements and actions, and therefore due to this ignorance, continued to pay for reimbursement claims for Vfend. Absent evidence that the government had actual knowledge of Defendant's fraud, we find the government's continued payments of Vfend claims insufficient to establish that Relators' claims fail for lack of materiality.

Accordingly, we find that Relators have sufficiently pled materiality.

3. Scienter

The Supreme Court in *Escobar* highlighted the FCA's scienter requirement, stating that "[w]hat matters is not the label that the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." 136 S. Ct. at 1996. Defendant argues that even assuming that Relators have satisfied the falsity and materiality requirements, they have failed to adequately allege scienter. Defendant argues that Relators' allegations are insufficient to prove that

Defendant knowingly violated the FCA. As support, Defendant argues that Relators admit that the swapped endpoints in the 608 Study were the result of Pfizer's mistake, and that Pfizer alerted the FDA as soon as it discovered its mistake.

We rejected this argument in our previous memorandum, and we reject that argument here. In our Memorandum denying Defendant's First Motion to Dismiss we stated the following;

> 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 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.

Pfizer, 2016 WL 807363, at *10.

We again determine that Relators' allegations are sufficient to allege that Defendant acted with the requisite scienter pursuant to the FCA. Accordingly, we find that Relators have stated a claim against Defendant under the FCA.

IV. CONCLUSION

For the foregoing reasons, Defendant's Second Motion to Dismiss will be denied.

An appropriate Order follows.

BY THE COURT:

R. BARCLAY SURRICK, J.