E-FILED

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	CV 10-3165-GHK (SSx)	Date	July 10, 2014
Title	*United States of America, et al., ex rel. Brown v. Celgene Corporation*		

Presiding: The Honorable	**GEORGE H. KING, CHIEF U.S. DISTRICT JUDGE**	
Beatrice Herrera	N/A	N/A
Deputy Clerk	Court Reporter / Recorder	Tape No.

Attorneys Present for Plaintiff:	Attorneys Present for Defendant:
None	None

Proceedings: **(In Chambers) Order re:** (1) Defendant's Motion to Dismiss [Dkt. No. 106]; (2) Defendant's Motion to Strike Paragraph 88 of Third Amended Complaint [Dkt. No. 108]

This matter is before us on (1) Defendant's Motion to Dismiss Plaintiff-Relator's Third Amended Complaint ("TAC") and (2) Defendant's Motion to Strike Paragraph 88 of TAC. We have considered the papers filed in support of and in opposition to these Motions and deem them appropriate for resolution without oral argument. L.R. 7-15. As the Parties are familiar with the facts, we will repeat them only as necessary. Accordingly, we rule as follows:

I. Background

Plaintiff-Relator Beverly Brown ("Brown") brought this *qui tam* action against Defendant Celgene Corporation ("Celgene") on April 27, 2010. The District of Columbia, the city of Chicago, the named state plaintiffs, and the United States have declined to intervene. Brown's TAC alleges that Celgene defrauded government-funded heathcare programs—including Medicare, Medicaid, TRICARE, the VA, and the Federal Employees Health Benefits Program—by systematically promoting the drugs Thalomid and Revlimid[1] for non-reimbursable off-label uses and paying illegal kickbacks to physicians.

[1] Thalomid, which was banned in the United States in the 1960s for causing birth defects, was approved by the FDA for the limited purpose of treating a skin disease associated with leprosy in 1998. (TAC ¶ 2). In 2006, the FDA also approved Thalomid for treating newly diagnosed patients with multiple myeloma ("MM"), a plasma cell cancer, in combination with another drug, dexamethasone. (*Id.* ¶ 11). This approval was contingent on the placement of a black box warning that Thalomid caused birth defects and increased the risk of venous thromboembolism (blood clots that form within veins). (*Id.* ¶¶ 11, 97). Celgene developed Revlimid, a derivative of Thalomid, in 2005. (*Id.* ¶ 9). The FDA approved Revlimid for treating a relatively uncommon subtype of the blood disorder myelodysplastic syndrome ("MDS"), an early stage of cancer. In 2006, Revlimid, in combination with dexamethasone, was also approved for MM patients who had received at least one prior therapy. (*Id.* ¶ 9). In light of the

Brown was employed by Celgene from 2001 to 2011 as a pharmaceutical sales representative (though she was given technical titles like Immunology Specialist and Hematology Oncology Consultant), and she received bonuses based on the amount of Thalomid and Revlimid sold in her district. (TAC ¶ 26). Brown alleges that Celgene's unlawful promotion of Thalomid and Revlimid for unapproved uses caused "federal, state, and local government health care programs . . . to pay for millions of prescriptions that never would have been submitted for reimbursement but for Celgene's activities." (TAC ¶ 18). Based on these allegations, Brown asserts violations of the Federal False Claims Act ("FCA"), several analogous state false claims statutes,[2] and California's Insurance Frauds Prevention Act.

Celgene now moves to dismiss Brown's TAC in its entirety under Rule 12(b)(6) for failure to state a claim and under Rule 9(b) for insufficient particularity. In the alternative, if we do not dismiss the entire TAC, Celgene seeks to dismiss certain classes of claims that it asserts cannot give rise to FCA liability as a matter of law. Celgene also argues that some of the state law claims are subject to dismissal, in whole or in part, for various independent reasons. Finally, Celgene moves to strike Paragraph 88 of the TAC on the grounds that it contains inflammatory and irrelevant allegations.

II. Motion to Dismiss

A. Legal Standard

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a complaint must set forth "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). It must contain factual allegations sufficient to "state a claim to relief that is plausible on its face." *Id.* at 570. In considering a motion to dismiss, we must accept the allegations of the complaint as true and construe them in the light most favorable to the plaintiff. *Cousins v. Lockyer*, 568 F.3d 1063, 1067 (9th Cir. 2009). We need not accept as true, however, legal conclusions "cast in the form of factual allegations." *W. Mining Council v. Watt*, 643 F.2d 618, 624 (9th Cir. 1981). "In sum, for a complaint to survive a motion to dismiss, the non-conclusory 'factual content,' and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief." *Moss v. U.S. Secret Serv.*, 572 F.3d 962, 969 (9th Cir. 2009).

---

known risk of birth defects and blood clots, "the FDA mandated that [Celgene] implement a restricted distribution system requiring physicians to follow specific procedures before prescribing [Thalomid and Revlimid]." (*Id.* ¶ ¶ 13, 92, 94).

[2] The Parties have stipulated to the dismissal of Count Thirteen of the TAC, violation of the Maryland False Health Claims Act. They have also stipulated to narrow many of the other state claims based on the enactment date of the states' statutes. [*See* Dkt. No. 111].

B. Brown Adequately Alleges the Elements of an FCA Claim

The FCA was enacted as a remedial statute to combat fraud on the government. *See United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968). To this end, the statute is broadly construed to reach "all fraudulent attempts to cause the Government to pay out sums of money." *Id.* at 233; *see also Cook Cnty., Ill. v. U.S. ex rel. Chandler*, 538 U.S. 119, 129 (2003) ("Congress wrote expansively, meaning to reach all types of fraud, without qualification, that might result in financial loss to the Government" (internal citation and quotation marks omitted)). The FCA is violated, *inter alia*, when a person "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). To state a claim under § 3729(a)(1)(A), a relator must allege: "(1) a false or fraudulent claim (2) that was material to the decision-making process (3) which defendant presented, or caused to be presented, to the United States for payment or approval (4) with knowledge that the claim was false or fraudulent." *Hooper v. Lockheed Martin Corp.*, 688 F.3d 1037, 1047 (9th Cir. 2012). Celgene moves to dismiss the TAC in its entirety on the grounds that (1) it fails to adequately allege that any claims were materially false or fraudulent; and (2) it does not plausibly plead that Celgene's misconduct caused any false claims to be submitted to the government.

1. Claim Falsity

Celgene first argues that Brown's FCA claims fail as a matter of law because she has failed to allege any cognizable "false or fraudulent claims." "An actual false claim is the *sine qua non* of an FCA violation." *Cafasso v. General Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011) (internal quotation marks and alterations omitted). The false claims "contemplated by the FCA take many forms." *Id.* This case involves "implied false certifications." A claim is false under an implied certification theory when it contains no express statement regarding compliance with a statute or regulation but, by the very fact that it has been submitted, falsely implies compliance with any statutory or regulatory precondition to obtaining the requested government benefit. *See Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 996-98 (9th Cir. 2010) (recognizing that the FCA "contemplates an implied false certification claim"); *see also Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001) ("An implied false certification claim is based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment."). In essence, the implied false certification theory is one of fraud by omission—the claim is false because the claimant has failed to disclose a statutory or regulatory violation that would make it ineligible for reimbursement. "Put another way, if a [claimant] is asking for payment, it is fair to assume that she has done everything necessary to merit reimbursement. If she has not, there is a problem." *United States v. Speqtrum, Inc.*, __ F. Supp. 2d __, 2014 WL 2620981, at *8 (D.D.C. June 13, 2014); *see also U.S. ex rel. Willard v. Humana Health Plan of Texas, Inc.*, 336 F.3d 375, 382 (5th Cir. 2003) ("Implied certification amounts to nothing more than an alternative expression of the well-accepted idea that billing the government for something not delivered may constitute a false claim.").

To adequately allege false claims based on an implied false certification theory, a relator must

"provide a reasonable basis to infer that (1) the [claimant] explicitly undertook to comply with a law, rule or regulation that is implicated in submitting a claim for payment[3] and that (2) claims were submitted (3) even though the [claimant] was not in compliance with that law, rule, or regulation." *Ebeid*, 616 F.3d at 998. Here, Brown alleges that Celgene caused claims to be submitted that (a) falsely implied they were for reimbursable, medically accepted uses, and (b) falsely implied compliance with the Anti-Kickback Statute.

As an initial matter, Celgene contends that Brown has failed to adequately allege any false claims because Brown's TAC "never once refers to a certification, or even uses the word 'certify.'" (Mot. 7). Although Celgene is correct that a claim can only be legally false if it expressly or implicitly certifies compliance with a statutory or regulatory condition of payment, a relator need not use the words "certification" or "certify" to state a claim. The Ninth Circuit has expressly held that "there is no special significance to the term 'certification,'" and we should not regard it as somehow "talismanic." *U.S. ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1172 (9th Cir. 2006). Moreover, in *Ebeid*, the Ninth Circuit reiterated that a complaint need only make "allegations that the government paid claims because it believed [claimants were] in compliance with laws upon which payment was conditioned" to raise an implied false certification theory—the phrase "implied false certification" does not need to actually appear in the complaint. 616 F.3d at 999 n.5; *accord U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 313 (3d Cir. 2011) (holding that a complaint need not allege that a claimant certified compliance to adequately plead a false claim under an implied certification theory). We therefore reject Celgene's formalistic argument that Brown's FAC claim fails simply because the TAC does not label the allegedly false claims as "implied false certifications."[4]

Celgene also appears to suggest that Brown's claims fail because she does not allege that any implied certifications were made *by Celgene*. This argument misses the point. Of course Celgene did not itself falsely certify compliance with any condition of payment. This is because it did not itself submit any claims to the government. But FCA liability is not limited to claimants. *See* 31 U.S.C. § 3729(a)(1)(A) (imposing liability on those who knowingly *cause* false claims to be submitted for payment). The FCA has a far broader reach. *See Neifert-White Co.*, 390 U.S. at 232 ("[T]he [False Claims] Act was intended to reach all types of fraud, without qualification, that might result in financial

[3] Where, as here, the claims at issue are reimbursements for medical items or services and the "law, rule or regulation" is a federal insurance program's coverage limitations, this element is essentially self-satisfying. *See, e.g.*, *Ebeid*, 616 F.3d at 996-97 (recognizing that by submitting a Medicare reimbursement form, a claimant implicitly certifies that claim is for a covered item or service).

[4] In its Statement of Interest Regarding Defendant's Motion to Dismiss, the Government likewise disagrees with Celgene's argument, noting that whether a complaint explicitly alleges any express or implied certification of compliance is "irrelevant." "Rather, the core question for 'falsity' under the False Claims Act is whether the government received a claim for payment from a healthcare provider for an item or service that was not legally reimbursable." (U.S. Stmt. of Interest 6).

loss to the Government."). Accordingly, even though Celgene did not itself falsely certify compliance with any legal condition of payment, it is still susceptible to liability because it allegedly caused claimants to implicitly make such false certifications and thereby caused the submission of false claims. *See, e.g., U.S. ex rel. Bergman v. Abbot Labs.*, 2014 WL 348583, at *7 (E.D. Pa. Jan. 30, 2014) ("An FCA violation occurs under implied false certification when a defendant . . . *causes to be submitted* a request for payment without disclosing that it is in violation of a regulation that affect[s] its eligibility for payment."). That the claimants themselves may not have been aware of their non-compliance makes no difference—the claims would still be false. *See U.S. ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377, 390 (1st Cir. 2011) (explaining that the "Supreme Court has long held that a non-submitting entity may be liable under the FCA for knowingly causing a submitting entity to submit a false or fraudulent claim, and it has not conditioned this liability on whether the submitting entity knew or should have known about a non-submitting entity's unlawful conduct").

As set forth above, Brown alleges two categories of legally false claims—both of which are cognizable under the FCA. We now address Brown's two theories of legal falsity in turn.

a. Claims for Uses That Are Not Medically Accepted are "False"

First, Brown alleges that claims were false because they were for off-label uses that are not covered by Medicare and Medicaid. Whether an off-label, non-FDA-approved use is covered by these government programs turns on whether such use is a "medically accepted indication." An indication is "medically accepted" for purposes of the Medicaid statute if it is "supported by one or more citations" in any of the statutorily recognized drug compendia. 42 U.S.C. §§ 1396r-8(k)(6). Until January 1, 2009, Medicare Part D defined "medically accepted indication" in the same way as the Medicaid statute. Since January 1, 2009, Medicare Part D has also covered off-label uses that are part of an anti-cancer chemotherapeutic regimen if the use is (i) "supported by one or more citations" in certain compendia (including the three compendia recognized in the Medicaid statute) *and* not identified "as not indicated in one or more such compendia" or (ii) "medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in [certain] publications." *See* 42 U.S.C. §§ 1395w-102(e)(4), 1395x(t)(2)(B).[5]

Brown alleges that Celgene promoted Thalomid and Revlimid for uses that are not "medically accepted" and thereby knowingly caused false claims to be submitted for reimbursement. Celgene argues that its allegedly unlawful off-label promotion cannot support an FCA claim premised on an implied certification theory because (i) improper promotion does not violate any condition of payment, and (ii) Brown has failed to adequately allege that the off-label uses Celgene promoted were not reimbursable.

[5] The Parties do not dispute that the other government healthcare programs have materially similar coverage standards for off-label, non-FDA-approved uses. (TAC ¶ 61); *see also Strom ex rel. U.S. v. Scios, Inc.*, 676 F. Supp. 2d 884, 885 n.1 (N.D. Cal. 2009).

This first argument misses the point. While it may be true that an FCA claim cannot be predicated on off-label promotion alone, here Brown alleges not only that Celgene engaged in off-label promotion, but also that Celgene's promotion caused false claims to be submitted for reimbursement. That Celgene's off-label promotion itself does not violate a condition for payment is therefore immaterial. It is enough that Brown alleges that non-reimbursable claims that violated statutory conditions of payment resulted from Celgene's misconduct. In other words, the falsity here lies in the submission of non-reimbursable claims, not in Celgene's off-label promotion alone. And courts are in broad agreement that a claim for reimbursement from Medicare or Medicaid is "false" when it is statutorily ineligible for such reimbursement. *See, e.g.*, *Ebeid*, 616 F.3d at 1001 (recognizing that because certification of compliance with Medicare regulations may be inferred from the submission of a Medicare claim, regulations that set forth conditions of payment may serve as the basis for an implied false certification); *Mikes*, 274 F.3d at 700 (holding that a medical provider's reimbursement claim is false when it violates express statutory requirements for reimbursement); *Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975) (finding that claims for services that were not covered by Medicare were false); *U.S. ex rel. Colquitt v. Abbott Labs.*, 864 F. Supp. 2d 499, 530 (N.D. Tex. 2012) ("Medicare claims for expenses that are not covered and are ineligible for payment are false claims."); *Strom*, 676 F. Supp. 2d at 891 ("Because [Medicare] permits reimbursement only for 'reasonable and necessary' treatments, a prescription of [a drug] in a context where it is not 'reasonable' or 'necessary' would be statutorily ineligible for reimbursement. This satisfies the FCA's requirement of a 'false' statement."). In sum, Celgene's argument that the TAC insufficiently explains "what legal requirement was violated here" is unconvincing. The legal premise underlying Brown's theory is clear—she alleges that claims were false because they violated the Medicare/Medicaid statutes' requirements for reimbursement. Such claims are false for purposes of the FCA. Accordingly, so long as Brown has plausibly alleged that claims submitted as a result of Celgene's off-label promotion were, in fact, non-reimbursable, she will have sufficiently alleged the falsity element of her FCA claim.

Second, Celgene maintains that its off-label promotion cannot serve as a predicate for a false claim because Brown has failed to plausibly allege that it promoted non-reimbursable uses. We disagree. Brown identifies 19 off-label uses of Thalomid and 9 off-label uses of Revlimid that Celgene promoted. (TAC ¶¶ 63, 82, 86). She alleges that these 28 off-label, non-FDA-approved uses were not covered by federal healthcare programs because they were not "medically accepted" within the meaning of the Medicaid and Medicare statutes. (TAC ¶¶ 63, 64). Celgene counters that Brown's "blanket assertion" that the compendia did not provide adequate support for these 28 uses "is not remotely plausible." (Mot. 8). As support for this proposition, Celgene asks that we take judicial notice of excerpts from DrugDex (one of the statutorily approved compendia) that purportedly "indisputably support numerous off-label indications" identified in the TAC. (Mot. 8-9).

The DrugDex excerpts proffered by Celgene, however, do not undermine Brown's allegations that Celgene promoted non-reimbursable off-label uses. Whether or not any particular use is "supported" by the compendia is a complex, case-by-case inquiry not susceptible to resolution on a motion to dismiss, and expert testimony is often necessary to discern whether a mention in a

compendium in fact constitutes sufficient support. *See United States v. King-Vassel*, 728 F.3d 707, 717 (7th Cir. 2013); *Abbott Labs.*, 2014 WL 348583, at *9 n.8 (finding that the compendia did not "resolve as a matter of law (or fact) whether TriCor was marketed for medically unnecessary uses"); *United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 16 (D. Mass. 2008) (finding that it was unable to assess whether DrugDex entry supported drug's off-label use based on preliminary record at motion to dismiss stage). As the Government explained in its Statement of Interest:

> Evaluation of whether a compendium citation supports use of a drug for a particular indication involves a factual inquiry that should not be resolved at the motion to dismiss stage. Specifically, resolution of the question whether a particular use which a manufacturer is promoting is "supported by" a compendium citation depends on the exact use being promoted, the content of the compendium citation with respect to that exact use, and the scope and outcome of the studies as described in the compendium. Moreover, some studies which a compendium cites may well indicate that a particular off-label use has shown little to no efficacy in treating a medical condition or presents serious safety concerns for a particular patient population. . . . This Court should find that the factual record at the motion to dismiss stage is insufficient to make such a determination.

(U.S. Stmt. of Interest 6-7). In sum, the DrugDex excerpts are of little help in resolving this Motion because we cannot draw any broad, generally applicable inferences from them. The extent to which DrugDex supports any particular off-label use promoted by Celgene, if any, is a fact-specific inquiry that we are ill-suited to resolve without a more developed evidentiary record.

Celgene's argument to the contrary is belied by its own evidence. It tells us that we can easily determine whether DrugDex supports any broad category of uses by "referenc[ing] . . . a simple numerical rating." (Reply 7). Citing the *Medicare Benefits Policy Manual*, Celgene professes that all uses categorized as Class I, IIa, or IIb are supported by DrugDex. But the analysis in fact requires additional steps. For one thing, the *Medicare Benefits Policy Manual* "is a guide for intermediaries in applying the Medicare statute and reimbursement regulations and does not have the binding effect of law or regulation." *Nat'l Med. Enters. v. Bowen*, 851 F.2d 291 (9th Cir. 1988). In any event, the Manual itself states that a DrugDex rating of I, IIa, or IIb only constitutes support "in general." (Def's RJN Ex. 19, § 50.4.5). The Manual therefore contemplates exceptions and does not set forth a bright-line rule. This is because uses categorized by DrugDex as Class IIb are "indicated in some, *but not most*, cases." *See* DrugDex Recommendation and Evidence Ratings Reference. Almost all the uses that Celgene contends have "indisputable support" are categorized as Class IIb. That these uses have medical acceptance in "some, but not most, cases" does nothing to undermine the plausibility of Brown's allegation that Celgene promoted Thalomid and Revlimid for non-reimbursable uses. Given that these uses had only limited support in DrugDex in certain narrow circumstances, Celgene's alleged aggressive, misleading off-label marketing could easily have caused claims for non-reimbursable uses.

Moreover, consistent with the Medicare statute as of January 1, 2009, the Manual explains that off-label uses are only covered when they are both supported by one or more compendia *and* "**not** listed as unsupported, not indicated, not recommended, or equivalent terms" in any of the other compendia. (Def's RJN Ex. 19, § 50.4.5). In other words, for any claims submitted after January 1, 2009, the DrugDex compendium alone cannot be used to determine whether any particular use was reimbursable. Before we could conclude that the DrugDex excerpts undermine Brown's allegations, we would also have to survey the relevant entries in the other compendia to ensure that they were either supportive or neutral. In sum, while the DrugDex entries might allow us to determine that certain narrow uses prior to January 1, 2009 had medical support, this fact says nothing about whether the off-label uses promoted by Celgene caused false claims to be submitted to the government. The DrugDex entries proffered by Celgene are therefore insufficient to resolve Brown's claims at this early stage.

At bottom, Celgene's argument on this point seems to conflate pleading requirements with Brown's ultimate burden to prove her claims. *See U.S. ex rel. Fox Rx, Inc. v. Omnicare, Inc.*, 2013 WL 2303768, at *6 (N.D. Ga. May 17, 2013). Our job at this stage is not to test the sufficiency of the evidence underlying Brown's allegations or to resolve factual disputes about the meaning of that evidence. *See id.* So long as Brown alleges facts plausibly suggesting that the uses at issue were not "medically accepted," we must accept her allegations as true. Brown's allegations meet this plausibility threshold here. The TAC alleges, *inter alia*: (i) that the FDA has only approved Thalomid and Revlimid for limited purposes (¶¶ 79-81, 84-85); (ii) that there are many serious safety risks attendant with Thalomid and Revlimid use (¶¶ 89-104, 153); (iii) that Celgene purposely concealed these risks (¶¶ 116-128) and used misleading, unreliable studies to suggest that off-label uses had medical support (¶¶ 154-176, 192-199); and (iv) that Celgene even tried to improperly influence the compendia by bribing physicians who worked on them (¶¶ 65, 249). These allegations are sufficient to give rise to a plausible inference that Celgene promoted off-label uses that were not supported by the compendia.[6] *See Starr v.*

[6] In support of its argument that Brown has failed to adequately allege that the off-label uses were not medically accepted, Celgene relies heavily on *U.S. ex rel. Simpson v. Bayer Corp.*, 2014 U.S. Dist. LEXIS 51342 (D.N.J. Apr. 11, 2014). In *Simpson*, although the court decided that it "need not determine which off-label uses of [the drug] the 2000 DrugDex actually supports," it nevertheless concluded that the relator's complaint did "not plausibly allege that the off-label uses of [the drug] that [defendant] promoted lacked medical acceptance." 2014 U.S. Dist. LEXIS 51342, at *33. The court instructed the relator to "point to specific statements in the 2000 DrugDex entry to demonstrate that it does not support each individual off-label use." *Id.*, at *35. Without more specific allegations regarding the compendium entry, the court said it could not "reasonably infer which uses [were] not 'reasonable and necessary' under Medicare." *Id.* We decline to follow *Simpson*. *Simpson* essentially requires relators in Brown's position to "prove a negative." This approach would necessitate a complaint of several hundred pages in this case—this cannot be what is required. We cannot reasonably expect Brown to describe the relevant entries in each of the four statutorily recognized compendia for all 28 off-label uses. *See, e.g., U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) ("To require these details at pleading is one small step shy of requiring production of actual documentation with the complaint . . . and [is] significantly more than any federal pleading rule contemplates."). At

Baca, 652 F.3d 1202, 1216-17 (9th Cir. 2011) ("The standard at this stage of the litigation is not that plaintiff's explanation must be true or even probable. The factual allegations of the complaint need only 'plausibly suggest an entitlement to relief.'" (internal citation omitted)). Based on the foregoing, Brown's first theory of claim falsity—premised on claims for non-reimbursable off-label uses—has been sufficiently alleged.

b. Claims Resulting from Kickbacks Are "False"

Brown's second theory of claim falsity is premised on violations of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b).[7] The AKS prohibits any person from offering any kind of remuneration to induce the purchase, order, or recommendation "of any item or service for which payment may be made in whole or in part under a Federal health care program." *Id.* Here, Brown alleges that Celgene violated the AKS by using financial incentives to induce physicians to promote and prescribe Thalomid and Revlimid for off-label uses. (TAC ¶¶ 235-249). Celgene argues that Brown's claims premised on AKS violations fail as a matter of law because AKS compliance was not a condition of payment prior to May 23, 2010. We reject this argument.

All claims that result from unlawful kickbacks are false for purposes of the FCA. On May 23, 2010, Congress amended the AKS to make this abundantly clear. *See* 42 U.S.C. § 1320a-7b(g) ("[A] claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]."). Celgene takes this amendment to mean that prior to May 23, 2010, AKS compliance was not a condition of payment. Celgene is wrong. The amendment merely clarified existing law; it did not change it. *See U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 52 (D. Mass. 2011) ("The amendment's legislative history . . . evinces Congress' intent to clarify, not alter, existing law that claims for payment made pursuant to illegal kickbacks are false under the False Claims Act."). Prior to this clarifying amendment, courts consistently held that non-compliance with the AKS rendered a claim non-payable and that a FCA claim

---

this stage, general allegations regarding the lack of compendia support suffice (so long as such allegations are plausible in light of the full context of the complaint). Moreover, for some of the uses allegedly promoted by Celgene, such as for colorectal cancer, Brown alleges that "there is no evidence" Thalomid provides any benefit "at any stage of disease, either alone or with other agents." (TAC ¶ 164; *see also, e.g.*, ¶ 195). For these uses that allegedly have a complete and categorical lack of support, it is hard to see how Brown could provide additional details to make her allegations meet Celgene's high standard of plausibility.

[7] Brown's TAC also asserts violations of the Stark Law, 42 U.S.C. § 1395nn, which prohibits a physician from making a referral to an entity that furnishes designated health services for payment if the physician has a financial relationship with that entity. In her Opposition, however, Brown does not respond to Celgene's argument that her Stark Law theory fails as a matter of law because Celgene does not furnish "designated health services" within the meaning of the statute. Accordingly, Brown's FCA claims are **DISMISSED** to the extent they are premised on violations of the Stark Law.

could therefore be premised on an AKS violation. *See, e.g., U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 313-14 (3d Cir. 2011); *U.S. ex rel. McNutt v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005); *United States v. Rogan*, 459 F. Supp. 2d 692, 714 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008); *U.S. ex rel. Ortega v. Columbia Healthcare, Inc.*, 240 F. Supp. 2d 8, 13 n.5 (D.D.C. 2003).

And, as the Government notes in its Statement of Interest, the conclusion of these courts is consistent with sound policy and the "premise underlying the payment scheme in federal health insurance programs." (U.S. Stmt. of Interest 10, 12); *see also Westmoreland*, 812 F. Supp. 2d at 53 ("[T]he conclusion that compliance is precondition of payment is rendered inescapable when the purpose of the Anti-Kickback Statute is considered within the context of the Medicare statute."). Given that these programs only pay for "reasonable and necessary" items and services, 42 U.S.C. § 1395y(a)(1), they clearly would not pay for claims tainted by kickbacks. The integrity of such claims would be undermined by the possibility that the drugs were prescribed to benefit the provider financially, not because they were "reasonable and necessary" for treatment. (*See* U.S. Stmt. of Interest 10 (explaining the "clear" "rationale for non-payment of kickback-tainted claims"); *see also Wilkins*, 659 F.3d at 314 ("[T]he Government does not get what it bargained for when a [claimant] is paid by CMS for services tainted by a kickback.").

Accordingly, certification of compliance with the AKS may be properly inferred from providers' submission of Medicare/Medicaid claims. Because the government would not knowingly reimburse kickback-tainted claims, any claims resulting from Celgene's alleged kickbacks constitute false claims.

2. Causation

Celgene next attacks the sufficiency of the causation element of Brown's FCA claim. It contends that Brown has not plausibly alleged that it caused the submission of false claims. Courts borrow general tort law principles to analyze the FCA's causation element. *See U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3d Cir. 2004). Under these principles, Celgene may be liable for false claims submitted by others if its conduct was a substantial factor in bringing about the false claims and such claims were a foreseeable and natural consequence of its conduct. *See id.*; *U.S. ex rel. Humane Soc. of U.S. v. Hallmark Meat Packing Co.*, 2013 WL 4713557, at *11 (C.D. Cal. Apr. 30, 2013).

Here, there is a plausible causal connection between Celgene's conduct and the submission of false claims. The causal chain is straightforward: (1) Celgene allegedly fraudulently promoted Thalomid and Revlimid for non-reimbursable, off-label uses to physicians, (2) this off-label marketing caused physicians to write off-label prescriptions, and (3) many of these non-reimbursable prescriptions were submitted to government payors for reimbursment. Brown's allegations sufficiently raise an inference of both proximate and but for causation. As the Government explains in its Statement of Interest, "a defendant drug manufacturer could reasonably foresee that a comprehensive marketing scheme involving [a] large number of salespeople furnishing large numbers of physicians with

information about off-label use of a drug in a manner which is not a medically accepted indication could cause providers to prescribe the drug for those off-label indications." (U.S. Stmt. of Interest 14). Indeed, such prescriptions were not only foreseeable, they were an intended consequence of Celgene's alleged fraudulent scheme. (*See, e.g.*, TAC ¶ 19). We can likewise reasonably infer that Celgene's alleged misleading marketing was a substantial factor in at least some physicians' decisions to prescribe Thalomid and Revlimid for non-reimbursable uses. Finally, given that "a large percentage of Revlimid and Thalomid prescriptions are paid for by Medicare," Celgene could likewise reasonably foresee that these off-label prescriptions would result in false claims for reimbursement. (TAC ¶ 252).

Celgene argues that we should instead presume that physicians based their prescription decisions on their own independent medical judgment and the needs of their patients, not any conduct by Celgene.[8] We disagree. That physicians exercised their independent judgment does not defeat the causal connection here—Brown specifically alleges Celgene manipulated physicians' judgment with misleading articles and studies such that they could not make "objective and informed decisions." (*See, e.g.*, TAC ¶ 176); *see also, e.g.*, *U.S. ex rel. Nathan v. Takeda Pharms. North Am., Inc.*, 2011 WL 3911095, at *5 (E.D. Va. Sept. 6, 2011), *aff'd*, 707 F.3d 451 (4th Cir. 2013) (noting that causation will be sufficiently pled, notwithstanding independent judgment of physicians, where there are allegations "that the judgment of [the] physician was altered or affected by the defendant's fraudulent activities"). While we certainly cannot infer that *no* Thalomid and Revlimid prescriptions for off-label uses would have been written absent Celgene's alleged misconduct, this does not mean that Brown has not plausibly alleged that at least *some* doctors were substantially influenced by Celgene's marketing. To suggest that Celgene's alleged expansive, multi-faceted efforts to create an off-label market for Thalomid and Revlimid did not cause physicians to prescribe Thalomid or Revlimid for non-reimbursable uses strains credulity. It is implausible that a fraudulent scheme on the scope of that alleged by Brown would be entirely feckless. Accordingly, "[r]ather than showing a lack of proximate causation, [Celgene's] argument presents a question . . . regarding the total number of prescriptions that were attributable to [Celgene's] actions." *See In re Neurontin Mktg. & Sales Prac. Litig.*, 712 F.3d 21, 39 (1st Cir. 2013). Such an argument about the potential scope of Celgene's liability is premature at this stage. *See Strom*, 676 F. Supp. 2d at 894 ("While there may . . . be factual disputes as to which claims, if any, were the result of Defendants' fraudulent activity, it is not Plaintiff's burden to prove such causation at the pleading stage."). Thus, Brown has sufficiently alleged that Celgene caused the submission of false

[8] Celgene makes a lot out of the fact that the TAC includes anecdotes of some physicians rebuffing Celgene's advances. Because of these anecdotes, Celgene suggests that "the only inference that can be drawn from the Complaint[]. . . is that physicians did *not* prescribe Thalomid or Revlimid for off-label uses because of Celgene's alleged promotion." (Resp. to U.S. Stmt. of Interest 5-6). This is a fatuous argument. Brown explicitly alleges that in her experience these doctors who were not convinced by Celgene's fraudulent practices "were the exception." (TAC ¶ 159). That the TAC includes the details of these "exceptional" interactions to highlight the wrongfulness of Celgene's alleged practices does not mean that we should infer that Celgene's marketing efforts were wholly unsuccessful—particularly given that Brown alleges otherwise.

claims.[9]

3. The TAC Satisfies Rule 9(b)

Finally, Celgene argues that the TAC should be dismissed in its entirety for failing to satisfy Rule 9(b)'s heightened pleading requirements. Because the FCA sounds in fraud, Brown's TAC must be pled with particularity. *See Bly-Magee v. California*, 236 F.3d 1014, 1018 (9th Cir. 2001). "Rule 9(b) requires a party to state with particularity the circumstances constituting fraud or mistake, including the who, what, when, where, and how of the misconduct charged." *Ebeid*, 616 F.3d at 998. In an FCA case, the "use of representative examples is simply one means of meeting the pleading obligation." *Id.* The relator is not required to "identify representative examples of false claims." *Id.* Particularly where, as here, the defendant is alleged to have induced third parties to submit false claims, the relator cannot reasonably be expected to allege details about the individual claims that were submitted. *See, e.g., U.S. ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 29 (1st Cir. 2009). Instead, it is sufficient 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.* (adopting Fifth Circuit's standard set forth in *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180 (5th Cir. 2009)). In short, to comply with Rule 9(b), Brown's allegations of fraud must be "specific enough to give [the defendant] notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." *Bly-Magee*, 236 F.3d at 1019 (internal citation and quotation marks omitted). Brown's TAC meets this standard.

Celgene cannot reasonably suggest that the 100-plus pages in the TAC do not give adequate notice of the misconduct alleged—as a direct participant in Celgene's off-label promotion, Brown "sets out the particular workings of a scheme that was communicated directly to [her] by those perpetrating the fraud." *Grubbs*, 565 F.3d at 191; *see also U.S. v. Kaplan, Inc.*, 517 F. App'x 534, 536 (9th Cir. 2013). In addition to detailed, particularized factual allegations regarding Celgene's fraudulent marketing scheme, Brown also "suppl[ies] reasonable indicia that false claims were actually submitted." *Ebeid*, 616 F.3d at 999. She notes, for example, that by Celgene's own estimates "Medicare and Medicaid paid for the majority of Thalomid and Revlimid prescriptions." (TAC ¶¶ 27, 252). Taken together with her allegations that industry analysts estimate that "almost all" of Celgene's sales are for off-label uses and that she never was trained to market the drugs on-label (*id.* ¶¶ 7, 131), it is easy to infer that claims for non-reimbursable, off-label uses were submitted to Medicare and Medicaid. Brown also alleges that Celgene's fraudulent marketing scheme specifically targeted government payors because of the drugs' high cost. (*See, e.g., id.* ¶¶ 94, 218-221, 250-256). For example, Celgene sales representatives urged physicians to enroll their patients in Medicare. (*Id.* ¶ 219). In addition, "[u]nder

[9] Celgene also insists that Brown's allegations are insufficient to satisfy the causation element because she has not identified any specific examples of a physician prescribing Thalomid or Revlimid as a result of Celgene's off-label promotion or kickbacks. Because this boils down to a particularity argument, we address it in the section that follows.

the guise of giving away free drugs," Celgene allegedly marketed Thalomid and Revlimid for unapproved uses to cancer patients "just prior" to their enrollment in government health care plans. (*Id.* ¶¶ 208, 211). As a direct result of this scheme, Brown alleges that false claims were submitted to Medicare. (*Id.* ¶ 210).

Accordingly, although she does not provide the details of any representative false claim caused by Celgene's alleged misconduct, Brown's TAC contains sufficient "indicia that false claims were actually submitted." *Ebeid*, 616 F.3d at 999; *see also Duxbury*, 579 F.3d at 29-30; *Abbot*, 2014 WL 348583, at *12. In fact, "[i]t would stretch the imagination to infer the inverse." *See Grubbs*, 565 F.3d at 192. To conclude that Brown's allegations do not reasonably suggest that false claims were actually submitted would require far more strained leaps of logic. We would have to believe that: (i) while Celgene went to the trouble of systematically implementing a multi-pronged fraudulent scheme to create an off-label market for Thalomid and Revlimid, (ii) these alleged fraudulent practices did not sway physicians to write prescriptions for off-label uses; but (iii) Celgene nevertheless maintained its ineffectual fraudulent scheme for years and years. *See id.*

Based on the foregoing, Celgene's Motion is **DENIED** insofar as it seeks to dismiss Brown's federal FCA claim. Brown has plausibly—and with particularity—stated a claim for relief under the federal FCA.

C. State Law Claims

Celgene argues that all of Brown's non-California state law claims should be dismissed because Brown "fails to allege any connection to or knowledge of activities in those other states." (Mot. 19). This argument is not well taken. Brown's TAC makes allegations about Celgene's nationwide, systemic practices, not California-specific allegations. There is no reason to conclude that Celgene's alleged misconduct was limited to California.

Celgene also suggests that all of Brown's state law claims should be dismissed because she did not adequately follow these states' pre-filing requirements. Specifically, Celgene contends that Brown did not properly disclose her allegations to the state governments and prematurely unsealed her complaint before the states declined to intervene. As an initial matter, there is no reason to conclude that Brown did not adequately comply with both of these pre-filing requirements. (*See* TAC ¶ 19 (noting that Brown "disclosed her findings to . . . the states prior to filing this action); Dkt. No. 59 (notification of the states' declination prior to unsealing)). In any event, these pre-filing requirements are "solely for the benefit of the government," *U.S. ex rel. Maxfield v. Wasatch Constructors*, 2005 U.S. Dist. LEXIS 10162, at *2 (D. Utah May 27, 2005), and here the State Plaintiffs have indicated that Brown substantially complied with their pre-filing requirements and should not be procedurally barred from continuing this litigation. (*See* States' Jt. Stmt. of Interest 8).

Finally, Celgene contends that several of Brown's state law claims fail as a matter of law for various independent reasons. We now address each of these arguments in turn.

1. Minnesota Claim (Count 17) and Colorado Claim (Count 5)

Celgene argues that Brown's Minnesota and Colorado claims are procedurally barred by these states' first-to-file provisions. Celgene is correct. These states' first-to-file provisions are modeled on the materially identical first-to-file bar in the federal FCA. They provide that "[w]hen a person brings a [*qui tam*] action, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5); *see also* Minn. Stat. § 15C.05(b); Colo. Rev. Stat. Ann. § 25.5-4-306(2)(3). This jurisdictional bar is "exception-free." *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1183 (9th Cir. 2001). It "bars later-filed actions alleging the same material elements of fraud described in an earlier suit, regardless of whether the allegations incorporate somewhat different details." *Id.* at 1189. The first-to-file bar serves two purposes: "to promote incentives for whistle-blowing insiders and to prevent opportunistic successive plaintiffs." *Id.* at 1187. In sum, the first-to-file bar discourages piggyback claims that would provide no additional benefit to the government, "since once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds." *Id.* at 1189 (quoting *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 234 (3d Cir. 1998)).

Here, Brown's Minnesota and Colorado claims were not added to Brown's complaint until May 3, 2013, several months after David Schmidt had already brought materially indistinguishable claims under these statutes in the Eastern District of Texas. *See* Fifth Am. Compl., *U.S. ex rel. Schmidt v. Celgene Corp.*, No. 4:11-cv-00094-RAS-DDB (E.D. Tex. Feb. 8, 2013). That Schmidt's action was later dismissed is immaterial. *See Lujan*, 243 F.3d at 1188 ("To hold that a later dismissed action was not a then-pending action would be contrary to the plain language of the statute and the legislative intent."). Thus, Brown's Minnesota and Colorado claims are **DISMISSED** as procedurally barred.

2. California Insurance Frauds Prevention Act Claim (Count 4)

Celgene moves to dismiss Brown's claim under California's Insurance Frauds Prevention Act ("IFPA") on the grounds that it is time-barred in its entirety. We agree. The IFPA requires that civil actions be brought within "three years after the discovery of the facts constituting the grounds for commencing the action." Cal. Ins. Code § 1871.7. Here, Brown did not seek leave to add her IFPA claim to her complaint until October 1, 2013. Given that her IFPA claim has the exact same factual predicates as her other claims (*see* TAC ¶ 278), we can assume that she had discovered the relevant facts for her IFPA claim at the very latest by April 27, 2010, when she filed her original Complaint. Her November 6, 2013 IFPA claim was therefore at least five months too late. Moreover, Brown's Opposition fails to address Celgene's SOL argument with respect to her IFPA claim. Accordingly, Brown's IFPA claim is **DISMISSED** as untimely.

3. New Mexico Claim (Count 22)

Celgene argues that Brown's New Mexico claim fails because she lacks statutory standing to assert it. New Mexico's Medicaid False Claims Act provides that a "private civil action may be brought by an affected person . . . on behalf of the person bringing suit and for the state." N.M. Stat. § 27-14-7(B). In a summary fashion, Celgene contends that Brown cannot fairly be construed as an "affected person" simply because she is a California resident and has no connection to the state of New Mexico. However, Celgene provides no basis for us to adopt this limited reading of "affected person." When Delaware's FCA contained similar "affected person" language, that statute defined "affected person" as an "employee or former employee" of the defendant. *See* Del. Code Ann. Tit. 6 § 1202(1) (2000). Brown would clearly qualify as an "affected person" under this definition. Given that Celgene's cursory, two-sentence argument offers no reason why we should adopt a more limiting reading of New Mexico's use of "affected person," we **DENY** its motion to dismiss Brown's New Mexico claim.

4. Washington Claim (Count 30)

Finally, Celgene moves to dismiss Brown's Washington claim because the TAC cites Rev. Code Wash. § 48.80.010, *et seq.*, the Washington Health Care False Claim Act, which does not permit *qui tam* actions. As Brown explains in her Opposition, her citation to the Health Care False Claim Act was a mere "scrivener's error," and she intended to cite the Medicaid Fraud False Claims Act, Rev. Code Wash. § 74.66.005. Because this miscitation appears to be little more than a good-faith clerical mistake, we shall deem Count 30 as asserting a claim under the Medicaid Fraud False Claims Act, Rev. Code Wash. § 74.66.005. Celgene's motion to dismiss Count 30 is **DENIED** on this ground.

D. Celgene's Alternative Request to Narrow Claims

As an alternative to complete dismissal, Celgene requests that we "narrow" Brown's causes of action by dismissing certain classes of claims that it purports cannot give rise to false claim liability as a matter of law. All of these arguments go to the potential scope of Celgene's liability, not to whether Brown has stated a claim under the federal and state FCA statutes. We disfavor motions to dismiss that only seek to "narrow," rather than eliminate a claim entirely. Accordingly, at this early stage we decline to consider Celgene's arguments, which at best would only result in piecemeal relief. To the extent that Brown seeks to recover for any claims that are time-barred or not false as a matter of law, Celgene can raise these arguments at summary judgment. Moreover, our decision here does not prevent Celgene from making arguments about the appropriate scope of discovery before the magistrate judge.

III. Motion to Strike

Under Federal Rule of Civil Procedure 12(f), a "court may strike from a pleading . . . any redundant, immaterial, impertinent, or scandalous matter." Although generally disfavored, a motion to strike is well-taken when "it is clear that the matter to be stricken could have no possible bearing on the

subject matter of the litigation." *LeDuc v. Kentucky Central Life Ins. Co.*, 814 F. Supp. 820, 830 (N.D. Cal. 1992). We have broad discretion to grant or deny a motion to strike. *See Whittlestone, Inc. v. Handi-Craft Co.*, 618 F.3d 970, 973 (9th Cir. 2010).

Celgene moves to strike Paragraph 88 of the TAC on the grounds that it contains inflammatory and irrelevant allegations. We agree. Although this historical material may be true, it is wholly irrelevant to this case, and Brown would in no way be prejudiced by its removal. Paragraph 88 of the TAC is hereby **STRICKEN**.

IV. Conclusion

As set forth above, Celgene's Motion to Dismiss is **GRANTED in part** and **DENIED in part**. In summary, Celgene's Motion to Dismiss is **DENIED** except insofar as it seeks to dismiss Brown's Minnesota, Colorado, and IFPA claims—these three claims are **DISMISSED**. Finally, Celgene's Motion to Strike Paragraph 88 of the TAC is **GRANTED**. Celgene **SHALL** answer the surviving portions of the TAC **within 14 days hereof**.

IT IS SO ORDERED.

-- : --

Initials of Deputy Clerk Bea