UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OFAMERICA, ex rel. FRANK SOLIS,

Plaintiffs,

v.

MILLENNIUM PHARMACEUTICALS, INC., SCHERING-PLOUGH CORP., and MERCK & CO.,

Defendants.

No. 2:09-cv-03010-MCE-EFB

MEMORANDUM AND ORDER

This lawsuit was originally filed under seal on November 4, 2009, pursuant to the qui tam provisions of the Federal False Claims Act, 31 U.S.C. § 3729, et seq. ("FCA"), against Defendants, who are pharmaceutical companies, include Millennium Pharmaceuticals, Inc., Schering-Plough Corp., and Merck and Co. ("Defendants" unless otherwise indicated). The so-called "Relator" Plaintiff, Frank Solis, a former sales employee who at various points worked for all three Defendants ("Relator" or "Plaintiff") claims that the companies fraudulently marketed and/or promoted the use of two drugs, Integrilin and Avelox, for so called "off label" uses not approved by the Food and Drug

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Administration.[1] In so doing, according to Relator, Defendants "caused" physicians to improperly prescribe the drugs and, consequently, to submit false claims to Medicare, Medicaid and TRICARE (United States Military Healthcare) for federal reimbursement, which the government allegedly paid without knowing the claims were ineligible. Following a three-year investigation, the United States and all twenty-four states named in the initial complaint chose not to intervene, and Relator's Complaint was subsequently unsealed on December 20, 2012.

In response to Motions to Dismiss previously filed on behalf of each of the Defendants, Relator filed a First Amended Complaint ("FAC") on June 27, 2013. The viability of Plaintiff's FAC was then attacked through three separate motions. Defendants Schering-Plough Corp. ("Schering-Plough") and Merck & Co. ("Merck") filed a joint Motion to Dismiss for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1)[2] on grounds that Relator's complaint was barred by the FCA's so-called "public disclosure" bar. Defendant Millenium Pharmaceuticals, Inc. ("Millenium") subsequently joined in that motion. Additionally, two other motions, one filed jointly by Schering-Plough and Merck and the other by Millenium, argued that the various causes of action pled in the FAC are substantively deficient in contravention of Rule 12(b)(6). By Memorandum and Order filed March 26, 2014, this Court granted Defendants' Rule 12(b)(1) motion on grounds that Relator's "combination use" allegations were precluded under the FCA's so-called "public disclosure" bar precluding suits whose allegations have already been disclosed. Because Relator's FAC contained other allegations beyond combination use, however, including assertions pertaining to a completely different drug, Avelox, as well as allegations of fraud, improper billing, and

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[1] Off-label use of a drug occurs when it is used either for a purpose not approved by the FDA, of where non-indicated dosing regimens for the drug are promoted.

[2] All further references to "Rule" or "Rules" are to the Federal Rules of Civil Procedure unless noted otherwise.

impermissible kickbacks, the Court permitted Relator to file a Second Amended Complaint ("SAC") omitting the combination use allegations.

Relator's SAC was filed on April 5, 2014. Presently before the Court is a Motion to Dismiss pursuant to Rule 12(b)(6) filed on behalf of Defendants Schering-Plough and Merck (hereinafter referred to collectively as "Moving Defendants"). Moving Defendants further seek dismissal of Relator's FCA claims under Rule 9(b) for failure to plead fraud with particularity. As set forth below, Moving Defendants' Motion is DENIED.

BACKGROUND

Integrilin is a drug that helps reduce blood clots and thereby helps to prevent heart attacks and death in patients suffering from acute coronary syndrome ("ACS"). ACS is an umbrella term covering a variety of diseases related to clotting in the coronary arteries that supply blood to the heart muscle, including unstable angina ("UA"), mild heart attacks known as non-ST–segment elevation myocardial infarctions ("NSTEMI"), and more severe heart attacks called ST-segment elevation myocardial infarctions ("STEMI"). Avelox, on the other hand, is an antibiotic approved by the Food and Drug Administration ("FDA") for treating adult patients with infections caused by a few susceptible strains of microorganisms.

With respect to Integrilin, FDA approval was first obtained in May 1998 by a company named COR Therapeutics, Inc. ("COR"), which thereafter promoted the drug along with Defendant Schering-Plough. In February of 2002, Defendant Millennium acquired COR and thereby obtained the right to co-promote Integrilin. In September of 2005, Defendant Millennium transferred its right to market Integrilin within the United States to Defendant Schering-Plough, thereby relinquishing any responsibility for the drug after a period of less than four years. Schering-Plough later merged with Merck in November of 2009 to form a new company, also known as Merck. In addition to

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Integrilin, Schering-Plough and Merck (but not Millenium) also market, sell and distribute Avelox. SAC, ¶ 2.

The allegations incorporated within Relator's initial complaint included contentions that Moving Defendants facilitated the presentation of false reimbursement claims by doctors and hospitals. According to Relator, Defendants promoted the prescription of Integrilin in particular, in combination with other drugs, without properly disclosing the dangers implicit in such combinations. As already stated, those allegations have already been adjudicated in Moving Defendants' previous Rule 12(b)(1) Motion to Dismiss. Relator's SAC, however, also alleges other allegedly improper uses of Integrilin, including its off-label early use for STEMI patients, despite the fact that such early use is "extremely dangerous, off-label and fraudulent." SAC, ¶ 5, 11. Relator further claims that Defendants violated the so-called Anti-Kickback Statute ("AKS"), which prohibits a drug company from knowingly and willfully offering or paying remuneration to purchase goods or services for which payment may be made by a federal healthcare program. See 42 U.S.C. § 1320a-7b(b). Relator alleges that Defendants violated the AKS by "funnel[ing] millions of dollars" in grants, honoraria, and meals to physicians in order to induce Integrilin prescriptions and to drive "off label" sales, all in violation of the AKS. See SAC, ¶¶ 6-7, 151-55.

Relator Solis was a pharmaceutical sales representative for Millennium covering the Los Angeles area between July 2003 and September of 2005, and as part of his duties he promoted the sale of Integrilin. After Schering-Plough acquired the exclusive U.S. marketing rights for Integrilin from Millenium in late 2005, he transitioned to employment for Schering-Plough, where he also promoted Integrilin. Then, in November of 2009, after the Schering/Merck merger, he became a Merck sales representative. Relator was terminated by Merck on March 9, 2010.

Plaintiff's 144-page SAC alleges causes of action for federal false claims based on the AKS (Counts One and Two), false claims for causing the submission of off-label billings (Count Three and Four), and false claims for the fraudulent promotion of Integrilin

(Count Five). Plaintiff's claims are all rooted in the federal FCA, but additional causes of action based on corresponding state law statutory provisions are also made on behalf of both California (Count Seven) and 27 other states (Counts Eight through Thirty Four).

In now requesting dismissal under Rule 12(b)(6), Moving Defendants argue that Relator has failed to adequately allege the submission of any false claim under the FCA, either with respect to alleged "off-label" promotion of Integrilin or with regard to any FCA violation predicated on the AKS.

STANDARD

A. Motion to Dismiss Under Rule 12(b)(6)

On a motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6), all allegations of material fact must be accepted as true and construed in the light most favorable to the nonmoving party. Cahill v. Liberty Mut. Ins. Co., 80 F.3d 336, 337–38 (9th Cir. 1996). Rule 8(a)(2) "requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957)). A complaint attacked by a Rule 12(b)(6) motion to dismiss does not require detailed factual allegations. However, "a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Id. (internal citations and quotations omitted). A court is not required to accept as true a "legal conclusion couched as a factual allegation." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Twombly, 550 U.S. at 555). "Factual allegations must be enough to raise a right to relief above the speculative level." Twombly, 550 U.S. at 555 (citing 5 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1216 (3d ed. 2004) (stating that the

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pleading must contain something more than "a statement of facts that merely creates a suspicion [of] a legally cognizable right of action.")).

Furthermore, "Rule 8(a)(2) . . . requires a showing, rather than a blanket assertion, of entitlement to relief." Twombly, 550 U.S. at 555 n.3 (internal citations and quotations omitted). Thus, "[w]ithout some factual allegation in the complaint, it is hard to see how a claimant could satisfy the requirements of providing not only 'fair notice' of the nature of the claim, but also 'grounds' on which the claim rests." Id. (citing 5 Charles Alan Wright & Arthur R. Miller § 1202, supra, at 94, 95). A pleading must contain "only enough facts to state a claim to relief that is plausible on its face." Id. at 570. If the "plaintiffs . . . have not nudged their claims across the line from conceivable to plausible, their complaint must be dismissed." Id. However, "[a] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and 'that a recovery is very remote and unlikely.'" Id. at 556 (quoting Scheuer v. Rhodes, 416 U.S. 232, 236 (1974)).

B. Pleading Fraud Claims

Rule 9(b) requires that "in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." To meet the requisite particularity standards on a case like the present one, which asserts claims under the federal FCA, Relator's allegations must be accompanied by the "who, what, when, where, and how of the misconduct charged." Ebeid ex rel. U.S. v. Lungwitz, 616 F.3d 993, 998 (9th Cir. 2010) (quoting Vess v. Ciba-Geigy Corp., U.S., 317 F.3d 1097, 1106 (9th Cir. 2003)). In the Ninth Circuit, "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 also submitted." Ebeid, 616 F.3d 998-99.

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ANALYSIS

A. FCA Claims

To state a false certification claim giving rise to FCA liability, a relator must establish four elements: 1) a false statement or fraudulent course of conduct; 2) made knowingly; 3) causing; 4) the government to pay out money. Hendow v. University of Phoenix, 461 F.3d 1166, 1174 (9th Cir. 2006). Under this framework, an FCA claim can be based on the allegation that a party "has falsely certifie[d] compliance with a statute or regulation as a condition to government payment." Id. at 1171. Under the terms of the FCA statute, however, a defendant need only "cause to be presented" a false claim. 31 U.S.C. § 3729(a)(1) (2006). Under Ninth Circuit precedent, this extends to any third person or entity, even if that party was not the one who actually submitted the claims, as long as the party "knowingly assisted in causing the government to pay claims grounded in fraud." United States v. Mackby, 261 F.3d 821, 827 (9th Cir. 2001). FCA liability requires only "some degree of participation in the claims process." United States v. President & Fellows of Harvard College, 323 F. Supp. 2d 151, 186-87 (D. Mass. 2004) (citing Mackby). Whether or not a defendant's conduct is a substantial factor in causing the presentation of false claims is a question of fact. United States ex rel. Franklin v. Parke-Davis, 2003 WL 22048255 at *5 (D. Mass. 2003).

As indicated above, Relator herein argues that Moving Defendants had the requisite involvement in the submission of claims they knew were false in two different ways: 1) improper marketing of Integrilin for off-label uses; and 2) using kickbacks, bribes and other remuneration in contravention of the AKS to influence doctors to prescribe Integrilin. The sufficiency of Relator's SAC with respect to both of those contentions will now be addressed.

B. Relator's Off-Label Allegations

Relator alleges that Moving Defendants caused the submission of false claims by "presenting physicians with false information about off-label uses of Integrilin and

encouraging physicians to prescribe Integrilin for such uses and procure the drug for such uses which were not approved by the FDA or any relevant drug compendium." SAC, ¶ 157. According to Relator, such improper promotion "caused physicians and facilities to submit numerous bills for Integrilin that were ineligible for reimbursement under Medicaid, Medicare, and TRICARE because the drug [was] used for an off-label use." Id.; see also id. at ¶ 163 (Defendants made "false and fraudulent representations "to physicians that Integrilin was safe and effective for use in off-label patient populations."). Relator claims that the off-label uses advocated by Moving Defendants "threatens patient safety." Id. at ¶ *8.*

The FDA has approved Integrilin for the treatment of ACS in two different ways. First, it is approved as a drug therapy for UA and NSTEMI patents "who are to be managed medically or with percutaneous coronary intervention ('PCI"), a procedure through which blocked coronary arteries are opened or widened by inflating a tiny balloon inserted into the artery by using a catheter. Second, Integrilin is approved "for the treatment of patients undergoing PCE." Id. at ¶ 3.

The SAC goes on to allege that Moving Defendants intentionally promoted the early, off-label use of Integrilin for STEMI patients before undergoing PCI, and for treating other cardiovascular problems not approved by the FDA. Id. at ¶¶ 5, 11, 43-44. Relator pleads facts which purport to show that Moving Defendants systematically worked to convince doctors to prescribe Integrilin off-label. Id. at ¶¶ 56, 60. Relator alleges, for example, that, based on his own personal information and knowledge, Defendants trained their representatives to induce physicians to ask about off-label uses of Integrilin and to provide off-label information to physicians even if they did not request such information. Id. at ¶¶ 29, 48-49, 62. Moving Defendants went so far as to identify and cultivate "key opinion leader" physicians ("KOLs") who frequently used Integrilin for off-label uses and could induce other doctors to do so. Id. at ¶ 63. The SAC specifically identifies KOLs who were so targeted. Id. at ¶¶ 64-71. Moving Defendants thereby promoted prescriptions written for off-label uses that were both inappropriate and

"extremely dangerous". Id. at ¶ 5. Relator claims that Moving Defendants did this despite several studies showing that the off-label uses were associated with a risk of major bleeding. Id. at ¶¶ 58-59. Therefore, according to Relator, many of the prescriptions Moving Defendants promoted were ineligible for reimbursement and were therefore false when submitted to the government for payment. Significantly, too, Relator cites figures indicating that Moving Defendants' allegedly improper promotional activities were successful. According to Relator, for example, Integrilin outpatient use substantially increased by the end of 2009, with this increase being "entirely attributable to an increase in patients receiving Integrilin for off-label purposes." Id. at ¶ 148.

Moving Defendants correctly point out that "off-label marketing of an approved drug is itself not inherently fraudulent." See, e.g., In re Actimmune Mktg LItig, 614 F. Supp. 2d 1037, 1051 n.6 (N.D. 2009). "Merely alleging off-label marketing . . . is not sufficient, without more, to plead a false claims act violation." U.S. ex rel. Rost v.Pfizer, Inc., 253 F.R.D. 11, 16-17 (D. Mass. 2008). Nonetheless, examination of the SAC reveals allegations that Moving Defendants promoted Integrilin for uses they knew were inappropriate and dangerous. SAC, ¶¶ 5, 157. For purposes of a motion to dismiss, such allegations must be taken as true. Twombly, 550 U.S. at 556. Relator's allegations are therefore sufficient to survive scrutiny at the pleadings stage of this litigation. Moreover, given the considerable detail provided in the SAC about Defendants' allegedly fraudulent marketing of Integrilin, the Court finds that the particularity requirements of Rule 9(b) are also satisfied.

In advocating dismissal, Moving Defendants contend that Medicare pays a flat fee for inpatient hospital care based on broad diagnostic categories. Moving Defendants consequently argue that such single-price billing based on the condition at issue, regardless of the actual treatment being provided, makes Integrilin use irrelevant to the medical services being invoiced. This factual defense, however, does not change the viability of Relator's pleadings. It presents factual issues not proper for determination as a matter of law in the context of a motion to dismiss.

Similarly, while Moving Defendants also claim that a physician's independent decision to prescribe Integrilin trumps any promotional activities that may have preceded that decision, that fact also does not obviate Moving Defendants' potential liability, given the allegations in the SAC as described above. As discussed above, to incur FCA liability Defendants need only play some role in submitting a false claim; they need not play the only role.

For all of these reasons, Relator's SAC sufficiently alleges actionable FCA activity with respect to off-label use to survive Moving Defendants' Motion to Dismiss.

C. Relator's Kickback Allegations

To state a viable FCA violation based on kickback claims in contravention of the AKS, Relator must show that Moving Defendants: 1) knowingly and willfully, 2) offered or paid remuneration, 3) to induce another to purchase a good or service, 4) for which payment may be made by a federal healthcare program. 42 U.S.C. § 1320a-7b(b)(2)(B). Claims influenced by kickbacks are false because "courts, without exception, agree that compliance with the Anti-Kickback Statute is a precondition of Medicare payment, such that liability under the False claims Act can be predicated on a violation of the Anti-Kickback Statute." U.S. ex rel. Westmoreland v. Amgen, Inc., 812 F. Supp. 2d 39, 54 (D. Mass. 2010); see also United States ex rel. Hutcheson v. Blackstone Medical, Inc., 647 F.3d 377, 392 (1st Cir. 2011) (claims seeking payment for services induced by kickbacks are false, and the FCA imposes liability when a defendant knowingly causes such a claim to be presented).

As Moving Defendants point out, however, the FCA does not prohibit all business transactions between physicians and drug companies. See, e.g., United States v. Ctr. for Diagnostic Imaging, Inc., 787 F. Supp. 2d 1213, 1223 (W.D. Wash. 2011) (explaining that the "remuneration" element of an AKS claim must be assessed in light of the fair market value for the service rendered). Moving Defendants accordingly argue that because any remuneration they provided was reasonable and not excessive, Relator's kickback claims necessarily fail. The Court disagrees.

The SAC describes, in detail, Moving Defendants' alleged actions between 2002 and 2009 to convince physicians to write prescriptions of Integrilin for off-label uses. Those purported "kickback" activities included funding grants (SAC, ¶¶ 6,7), paying excessive speaker fees (Id. at ¶¶ 6, 7, 82-86, 99, 102, 104, 121, 133-34), providing honoraria (Id. at ¶¶ 7, 82, 104-106), furnishing meals (Id. at ¶¶ 7, 14, 82, 100, 102, 104-106, 114-16, 133-34), paying for attendance at Continuing Medical Education ("CME") seminars while retaining control of virtually every aspect of the events so as justify off-label use (Id. at ¶¶ 79-81) and funding preceptorships and advisory boards (Id. at ¶ 99). The SAC provides both dates and details of these alleged kickback activities, including separate and specific meals, which Relator alleges that these activities violated both the FCA and the AKS. Id. at ¶¶ 114-116, 117, 123, 125-29. The SAC further provides examples of rewarding high-prescribing doctors with excessive speaker fees. Id. at ¶¶ 83-86, 122, and alleges that certain hospitals were tracked in order to determine which "to target for expensive meals." Id. at ¶¶ 118-121. According to Relator, Moving Defendant's sale representatives were also instructed to send "invitations to lavish meals exclusively to targeted high volume prescribers or referral sources." Id. at ¶ 121. In light of all these activities, Relator alleges that the submissions of prescriptions for reimbursement were false because Defendants' illegal activities had influenced them. Id. at ¶¶ 22-23.

Again, while Moving Defendants deny these allegations and claim Relator has shown no excessive remuneration that would run afoul of the AKS, the facts of the SAC as alleged by Relator must be deemed true for purposes of ruling on a motion to dismiss. Additionally, as also enumerated above, the SAC need only show that Moving Defendants' alleged illegal promotional activity was a "substantial factor" in the submitting of false claims. Parke-Davis, 2003 WL 22048255 at *4-5. To state a viable FCA claim, Relator simply has to show that "one purpose" of the kickbacks is to induce prescriptions–it need not be the only purpose of the kickbacks. U.S. v. McClatchey, 217 F.3d 823, 835 (10th Cir. 2000). Nor is the fact that Moving Defendants failed to

directly present claims for payment an impediment to liability. Mackby, 261 F.3d at 827 ("a person need not be the one who actually submitted the claims forms in order to be liable").

The SAC plainly makes averments that survive a pleadings challenge, either with respect to Rule 12(b)(6) or Rule 9(b). Consequently, Moving Defendants' motion to dismiss the kickback allegations levied against them also fails.

D. State Law Claims

Moving Defendants argue that Relator's state FCA claims fail for the same reasons that his federal FCA claims cannot be sustained. Pl.'s Mem. In Supp. of Mot. to Dismiss, 19:26-27. Given the Court's finding, as enumerated above, that Relator's federal FCA claims survive, the sole reason advanced by Moving Defendants for dismissing the state law claims necessarily fails.

CONCLUSION

For all the reasons stated above, Moving Defendants' Motion to Dismiss, ECF No. 113, is DENIED.[3]

IT IS SO ORDERED.

Dated: March 27, 2015

MORRISON C. ENGLAND, JR, CHIEF JUDGE
UNITED STATES DISTRICT COURT

[3] The Court notes that Moving Defendants make a request for dismissal under 12(b)(1) for the first time in their reply brief. Because it is improper to consider arguments not raised until the reply, with no opportunity for the opposing party to respond, the Court disregards Moving Defendants' request in that regard. See Zamani v. Carnes, 491 F.3d 990, 997 (9th Cir.2007) ("district court need not consider arguments raised for the first time in a reply brief").