UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA ex rel. KASSIE WESTMORELAND, Plaintiff, v. AMGEN, INC.; INTERNATIONAL NEPHROLOGY NETWORK renamed INTEGRATED NEPHROLOGY NETWORK, a d/b/a of DIALYSIS PURCHASING ALLIANCE, INC.; and ASD HEALTHCARE, Defendants.	)	CIVIL ACTION NO. 06-10972-WGY

MEMORANDUM

YOUNG, D.J. September _20, 2010

I. INTRODUCTION

Relator Kassie Westmoreland ("Relator") brings her Fourth Amended Complaint against Amgen, Inc. ("Amgen"), International Nephrology Network ("INN"), and ASD Healthcare ("ASD") (collectively, the "Defendants"), alleging that the Defendants violated the federal False Claims Act. The Defendants move to dismiss Relator's Fourth Amended Complaint.

A. Procedural Posture

Relator filed the original qui tam action in June 2006. In September 2009, the United States filed a Notice of Non-

Intervention At This Time. Fifteen States and the District of Columbia (collectively, the "States"), filed a separate complaint in intervention in October 2009, and filed a First Amended Complaint in December 2009. Several states, subsequently, voluntarily dismissed their cases against the Defendants. In March 2010, the Defendants moved to dismiss both Relator's and the States' complaints.

In a memorandum and order dated April 23, 2010, this Court dismissed parts of Relator's Third Amended Complaint based on the first-to-file bar; dismissed the States' First Amended Complaint and the remainder of Relator's Third Amended Complaint because neither stated a "false claim"; and dismissed AmerisourceBergen Corporation ("ABC") and AmerisourceBergen Speciality Group ("ABSG") as parties to the action. United States ex rel. Westmoreland v. Amgen, --- F. Supp. 2d --, 2010 WL 1634315 (D. Mass. April 23, 2010). The Court entered a final judgment to that effect on April 26, 2010.

Shortly thereafter, Relator filed a motion for reconsideration and a motion for leave to file an amended complaint.[1] On May 26, 2010, the Court denied Relator's motion for reconsideration, and amended its previous final judgment with respect to Relator to reflect a dismissal without prejudice and with leave to file a motion for leave to file an amended

[1] The States chose instead to appeal to the First Circuit.

complaint. The Court also granted Relator's motion for leave to file an amended complaint. On May 27, 2010, Relator filed the Fourth Amended Complaint at issue here.

B. Facts As Alleged[2]

First, Relator claims that the Defendants caused legally and factually false claims to be presented to the federal government by encouraging providers to claim reimbursement for dosages of Aranesp that were medically unnecessary or never administered.[3]

Second, Relator claims that the Defendants induced providers to purchased Aranesp by giving kickbacks to them, which led to the submission of false claims. Such kickbacks caused providers falsely and expressly to certify compliance with the anti-kickback statute in their Medicare Enrollment forms, as providers knew that they were, and would, continue accepting kickbacks from the Defendants. One such kickback was "excess overfill," i.e.,

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[2] Relator's Fourth Amended Complaint is substantially similar to her Third Amended Complaint, except that it drops the claims the Court previously held to be barred by the first-to-file rule and contains additional factual allegations that the providers' certifications of compliance with the anti-kickback statute were knowingly false when made and that the Defendants encouraged providers to bill for medically unnecessary or unadministered dosages of Aranesp.

[3] The Medicare Claim Form requires providers expressly to certify that the dosages administered were "medically indicated and necessary" and that the number of units claimed were actually administered. Moreover, 42 U.S.C. § 1395y(a)(1)(A) makes explicit that services are covered only when "reasonable and necessary" for the diagnosis, prevention, or treatment of illness or injury.

dosages of liquid Aranesp in excess of the amount necessary to allow a provider to withdraw the labeled dosage. Amgen's inclusion of excess overfill in its single-dose vials was, in effect, a built-in free sample. The free overfill created the potential for providers to profit from excess reimbursement and constituted an illegal kickback. Relator also alleges that INN and ASD offered other kickbacks to providers in the form of sham consulting agreements, all-expense paid retreats, free services, and discounts.

Third, Relator claims that Amgen reported an inflated Average Sales Price ("ASP") to the Medicare Program by failing to include in its ASP calculation the excess overfill built into Aranesp vials. This omission caused Medicare to overpay reimbursement claims.

Fourth, Relator claims that the Defendants caused providers to make or use false statements material to payment of a claim, including false statements as to: the medical necessity of administered Aranesp, units administered, and compliance with the anti-kickback statute.

Fifth, Relator claims that the Defendants conspired to violate the False Claims Act by agreeing to engage in the above fraudulent conduct with an intent to defraud the government.

II. ANALYSIS

The Defendants move to dismiss the Fourth Amended Complaint

(the "Complaint"), contending that Relator's claims are barred by the first-to-file rule[4] and fail to meet the requirements of Federal Rules of Civil Procedure 9(b) and 12(b)(6).

A. Legal Standards

1. Motion to Dismiss Standard

A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) challenges a complaint on the basis that it fails to state a claim upon which relief can be granted. To survive a motion to dismiss under this Rule, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). A pleading that merely offers "labels and conclusions" or a "formulaic recitation of the elements of a cause of action" is insufficient. Id. at 555. Since the False Claims Act creates a statutory tort, the inquiry focuses on whether Relator has alleged facts that fit within the

[4] With respect to the first-to-file bar, the Defendants merely rehash arguments previously rejected by the Court in Westmoreland, 2010 WL 1634315. Amgen again contends that Relator ought not be allowed to rely on allegations that Amgen provided kickbacks in forms other than overfill to support her conspiracy claim. Meanwhile, INN and ASD argue that Relator's claims regarding their provision of kickbacks in forms other than overfill have previously been alleged. The Court holds that none of Relator's claims are barred by the first-to-file rule for the reasons previously explained in Westmoreland. Id. at *4, *7. It will now turn to the Defendants' arguments regarding Relator's failure to plead a plausible claim for relief.

specific contours of the statute.[5]

Further, the heightened pleading requirement of Federal Rule of Civil Procedure 9(b) applies to fraud claims brought under the False Claims Act. United States ex rel. Gagne v. City of Worcester, 565 F.3d 40, 45 (1st Cir. 2009). Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b).

2. Liability Under the False Claims Act

The False Claims Act (the "Act") imposes liability upon persons who knowingly present or cause to be presented to the government a false claim for payment. 31 U.S.C. § 3729(a)(1) (2008), amended by 31 U.S.C. § 3729(a) (2009). To state a federal claim under the so-called "presentment" theory, "an individual must allege that the accused: (1) knowingly presented or caused to be presented, (2) a false claim, (3) to the United

[5] Relator argues that the Defendants' motions to dismiss should be reviewed based on the standard for reconsideration because the Court implicitly performed a Rule 12(b)(6) review of the claims before granting Relator leave to file the Fourth Amended Complaint. See Glassman v. Computervision Corp., 90 F.3d 617, 623 (1st Cir. 1996) (holding that standard for futility for filing an amended complaint is same as that under Rule 12(b)(6)). This Court, however, stated that the Defendants would be allowed to file motions to dismiss and has not expressly ruled on the Defendants' present Rule 12(b)(6) arguments because Relator's Third Amended Complaint was dismissed primarily on the basis of the first-to-file bar and failure to state a "false claim." Therefore, the Court will analyze Defendants' motions under the standard for Federal Rule of Civil Procedure 12(b)(6).

States government, (4) knowing its falsity, (5) which was material, (6) seeking payment from the federal treasury." United States ex rel. Hutcheson v. Blackstone Med., Inc, 694 F. Supp. 2d 48, 61 (D. Mass. 2010) (citing United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 225 (1st Cir. 2004) and United States v. Data Translation, Inc., 984 F.2d 1256, 1267 (1st Cir. 1992)).

The Act also imposes liability upon persons who knowingly make or cause to be made a false record or statement material to a false claim, as well as persons who conspire to "defraud the Government by getting a false or fraudulent claim allowed or paid." 31 U.S.C. §§ 3729(a)(2) and (a)(3) (2008). Unlike presentment liability under subsection (a)(1), these theories of liability do not require proof that false claims were actually submitted to the government. Gagne, 565 F.3d at 46 (citing Allison Engine Co. v. U.S. ex rel. Sanders, 128 S. Ct. 2123, 2129-31 (2008)). Instead, liability under subsection (a)(2) requires proof the defendant caused a false statement to be made for the purpose of getting a false claim paid. In addition, conspiracy liability under subsection (a)(3) requires that the defendants intended to defraud the government by getting false claims paid and agreed that the false statement would have a material effect on the government's decision to pay. Gagne, 565 F.3d at 46; see 31 U.S.C. §§ 3729(a)(2) and (a)(3).

Under all theories of liability, however, a "false" claim must be alleged. A claim may be factually false, legally false under an express certification theory, or legally false under an implied certification theory. A factually false claim is one in which the goods or services provided are neither correctly described nor ever provided. Hutcheson, 694 F. Supp. 2d at 62. A legally false claim occurs when a party represents compliance with a statute or regulation as a condition to payment, without actually complying with such statute or regulation. Id. A claim is legally false under an express certification theory when the party making the claim for payment expressly represents compliance with a statute or regulation. Id. A claim is legally false under the implied certification theory when a claimant makes no express statement regarding compliance with a statute or regulation, but by submitting a claim for payment, implies that it has complied with any preconditions of payment expressly contained in the relevant statutes or regulations. Id.

B. The Merits

1. Liability Based on the Overfill Theory

a. Excess Overfill as Kickback

The Complaint alleges that by offering excess overfill as an inducement to purchase Aranesp, the Defendants caused providers falsely and expressly to certify compliance with the anti-

kickback statute[6] in their Medicare enrollment forms.[7] The Defendants, however, contend that there was no violation of the anti-kickback statute when providers accepted free overfill, and thus there was no false certification of compliance.[8]

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[6] The federal anti-kickback statute states, in pertinent part:

> Whoever knowingly and willfully solicits or receives any renumeration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . in return for purchasing . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program . . . shall be guilty of a felony.

42 U.S.C. § 1320a-7b(b)(1)(B)(2006).

[7] To be eligible for Medicare reimbursement, providers must sign a certification on Form CMS-855A or Form CMS-855I, which contain nearly identical language. The certification on Form CMS-855A reads:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all application conditions of participation in Medicare.

[8] In its brief, Amgen argues that the Defendants cannot be liable because the Defendants did not knowingly and wilfully violate the anti-kickback statute. In the context of false certification liability, however, the salient issue is not whether the Defendants themselves violated the anti-kickback statute, but rather whether the Defendants caused **the providers** to violate the statute. This is because the enrollment agreement requires that the provider certify that the provider, itself, will comply with the anti-kickback statute.

First, the Defendants contend that alleged excess overfill contained in Aranesp vials cannot constitute a kickback as matter of law. Amgen argues that overfill contained in Aranesp vials cannot be "excessive" because the Federal Drug Administration (the "FDA") requires drug manufacturers to include overfill in their injectable products, there is no legal standard prescribing the maximum amount of overfill that can be included in a product, and the FDA approved the 16.8% overfill in Aranesp products. Amgen thus reasons that Aranesp overfill is part and parcel of the product and does not constitute "renumeration" under the anti-kickback statute. Such assertions are contrary to the allegations in the Complaint and the law.

Relator adequately alleges that Amgen was providing built-in free samples of Aranesp because the only legitimate purpose of overfill is to allow a provider to withdraw the labeled dosage, and Aranesp vials contained more overfill than necessary to do so.[9] Under the anti-kickback statute, "renumeration" is broadly defined as "transfers of items or services for free or for other than fair market value." 42 U.S.C. § 1320a-7a(i)(6). Excess overfill is in effect free doses of Aranesp, which create the

[9] The Complaint also alleges that the 19% overfill included in some vials was never disclosed to or approved by the FDA. Compl. ¶ 131. Thus, contrary to the Defendants' assertion, it is factually disputed whether the amount of overfill complied with all existing, known, and identified legal standards.

potential for providers to profit from Medicare reimbursement.[10] Compl. ¶¶ 116-55. Amgen's own marketing spreadsheets detailing the profit to be gained from overfill support this allegation. See Compl. ¶¶ 165, 168, and Ex. E.

Thus, the essential crux of Relator's allegations is not that the amount of overfill was illegal in and of itself, but rather that Amgen: (1) gave excess Aranesp to providers for which the providers did not pay; (2) advocated that providers bill Medicare for the free doses; and (3) induced providers to purchase Aranesp and make false certifications of compliance with the anti-kickback statute. See United States v. Bay State Ambulance and Hosp. Rental Serv. Inc, 874 F.2d 20, 29 (1st Cir. 1989) ("The gravamen of Medicare Fraud is inducement. Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient."). Such allegations are sufficient to state a claim that the Defendants gave kickbacks in the form of overfill to providers, and thus caused them falsely and expressly to certify compliance with the anti-kickback statute.

Second, the Defendants argue that because overfill cannot constitute a kickback, they could not have caused providers to

[10] Overfill even has value independent of potential Medicare reimbursement. For example, a provider could administer excess overfill to a patient who pays out of pocket and charge the patient for the dosage.

violate the anti-kickback statute simply by advising them that Medicare reimburses for units administered regardless of the presence or absence of overfill. That is, the Defendants contend that giving providers accurate information regarding Medicare reimbursement cannot constitute a kickback in and of itself. As discussed above, however, the Complaint contains adequate allegations that excess overfill may constitute a kickback and that the Defendants avidly marketed the value of excess overfill to providers. It is also disputed whether the Defendants were giving accurate reimbursement information when they advised providers that they could properly bill for free overfill.[11]

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[11] The Defendants' argument that Medicare reimburses for excess overfill - dosages that do not represent an expense to the provider - appears flawed. The Defendants point to a letter from Centers for Medicare and Medicaid Services (the "Center") written in response to the Defendants' request for deposition testimony of a Center employee, which states that "CMS has never issued a policy on the topic of 'overfill'. . . and that "[its] policy is to reimburse suppliers for the total number of units administered . . . assuming that the beneficiary's receipt of a drug is reasonable and necessary." Amgen's Mem. Supp. Mot. Dismiss 4 (citing Mayer Decl., Ex. 1 at 2).

The Complaint, however, alleges that overfill is not reimbursable by Medicare. See, e.g., Compl. ¶¶ 140, 157 (stating that Medicare will only permit a claim for reimbursement up to the **labeled** amount on the vial, and would not reimburse a claim related to overfill) (emphasis added). In support, Relator points to the Medicare Reimbursement Policy Manual (the "Manual"), which states that "the cost of the drug . . . [for which reimbursement is sought] must represent an expense to the physician." Rel.'s Mem. Opp'n Amgen's Mot. Dismiss 3 and Ex. A. Relator also cites to a Medicare Proposed Rule which appears to clarify the just-mentioned policy, stating that "[a]ny excess, free product (that is, overfill) is provided without charge to the provider. In accordance with our policy, providers may not bill Medicare for overfill harvested from containers." Rel.'s

b. Knowingly False Express Certification

This Court previously dismissed Relator's Third Amended Complaint for failure to allege a "false" claim because Relator did not allege that providers' certifications of compliance with the anti-kickback statute were knowingly false when made, i.e., "that when the providers signed the enrollment forms, they knew that they would be accepting kickbacks from the Defendants in violation of the anti-kickback statute." Westmoreland, 2010 WL 1634315, at *10; see id. at *8 (stating that no specific form of certification is required for express certification theory "so long as the statement of compliance is knowingly false when it was made.").

Since then, Relator has amended the Complaint in an attempt to remedy this deficiency. Relator now pleads that: as of November 2009, the majority, i.e., 70%, of all Medicare-eligible medical providers had re-enrolled in Medicare since 2003; that most medical providers had enrolled in the Provider Enrollment Chain and Ownership System ("PECOS") since 2003; that such PECOS

Mem. Opp'n Amgen's Mot. Dismiss 4 (citation omitted). A plain reading of the Manual suggests that because providers do not pay for excess overfill, it is not reimbursable by Medicare. The Defendants have not pointed to any regulation directly to the contrary.

Thus, drawing all inferences in favor of Relator, the Complaint adequately pleads an overfill kickback scheme in which the Defendants provided excess overfill to providers and encouraged them to profit therefrom by improperly billing Medicare.

enrollments and Medicare re-enrollments took place after the Defendants had begun giving kickbacks to providers; and that when providers signed these forms and certified future compliance with the anti-kickback statute, they knew they would be accepting kickbacks from the Defendants. Compl. ¶¶ 371-80; see supra, n.6. The Defendants argue that such pleading is insufficient to support the contention that the providers' statements were "knowingly false when made" because the Complaint does not identify particular providers who signed certifications knowing that they would be accepting kickbacks. INN's Mem. Supp. Mot. Dismiss 5.

Liability under the False Claims Act requires a false claim. Karvelas, 360 F.3d at 232. Thus, a party's presentation of a false claim is a central element that must be alleged. Id. In cases where the defendant directly presents the claim to the government, the plaintiff must provide details identifying particular false claims submitted, including who filed the claims, the content of the claims, when such claims were submitted, where such claims were submitted, and how much it sought in payment. Id.

In situations such as here, where the defendant induced third parties to file false claims, however, a "more flexible" standard applies. United States ex rel. Duxbury v. Ortho Biotech Products, 579 F.3d 13, 29 (1st Cir. 2000). A relator can satisfy

Rule 9(b) by providing "factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim." Duxbury, 579 F.3d at 29 (citing United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 732-33 (1st Cir. 2007)(internal quotation marks omitted)). This more flexible standard is appropriate because before conducting full discovery, a plaintiff whistleblower, such as Relator, likely would not have access to provider enrollment forms submitted by third party providers.

Here, Relator has provided factual and statistical evidence supporting the conclusion that since the Defendants began giving kickbacks, providers involved in the Defendants' Aranesp kickback scheme have likely re-enrolled and made knowingly false statements on their re-enrollment forms. In addition to the allegations outlined above regarding the percentage of providers who have re-enrolled since 2003, Relator has pled (1) that over half of Aranesp revenue comes from reimbursement by Medicare and Medicaid; (2) that the great majority of dialysis and kidney disease patients are covered by such programs (and thus their doctors are enrolled in Medicare); (3) that there are many situations where providers must submit new enrollment forms, including cases of acquisition, merger, consolidation, changes of ownership, changes to basic Medicare information and enrollment with another fee-for-service contractor; and (4) factual details

regarding specific providers and clinics that were offered kickbacks. See Compl. ¶¶ 8, 58-59, 94-96, 371-80, 388.

Although Relator cannot identify each particular instance of a knowingly false certification, the Complaint as a whole is sufficiently particular to strengthen the inference of fraud beyond possibility. Rost, 508 F.3d at 732 ("Rule 9(b) may be satisfied where, although some questions remain unanswered, the complaint as a whole is sufficiently particular to pass muster under the [False Claims Act]."); see U.S. ex. Rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 49 (D. Mass. 2001) (Saris, J.) (stating that where relator does not have direct access to information regarding the alleged false claims and "where the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible").

2. Liability Based on Overdosing & False Billing Theories

a. Sufficiency of Factual Pleading

Next, the Defendants argue that Relator's theories of liability regarding providers' claims for reimbursement for doses of Aranesp that were never administered or medically unnecessary are not sufficiently supported by particularized allegations. They argue that Relator does not identify specific instances in which particular providers either rendered medically unnecessary dosages of Aranesp to patients or falsely billed Medicare for

dosages never administered.

Relator, however, provides allegations regarding the Defendants' active encouragement of providers to bill for medically unnecessary or unadministered overfill at clinic visits and at seminars sponsored by the Defendants. Moreover, a central component of the Defendants' marketing scheme was advertising the profit to be gained from billing for all overfill and encouraging providers to do so, even though it is nearly impossible consistently to withdraw and administer all of the overfill in an Aranesp vial. See Compl. ¶¶ 149-58, 168-69, 171, 197, 361-65.

Further, the Complaint contains allegations regarding particular medical providers who submitted legally and factually false claims at the Defendants' encouragement. Relator pleads that the Defendants advised doctors at Balboa Nephrology ("Balboa") to capture all overfill profit, which led Balboa to issue a standing order for doctors to write Aranesp orders for an amount that was 10% more than the standard dosage that otherwise would have been administered for **every** patient, and a standing order that Medical Assistants were to administer as much Aranesp in the vial as possible. Compl. ¶¶ 218-21. Relator also alleges that California Kidney Group ("California Kidney") billed Aranesp 15% over the labeled dosage even though it is not actually possible to withdraw 15% overfill from a single dose vial, and sought reimbursement for dosages of Aranesp above the amount

intended to be administered to the patient. Id. ¶¶ 232, 236-37; see also id. ¶¶ 255-60 (alleging that "Amgen's encouragement of [Portland Hypertension & Nephrology ("PHN")] to administer overfill to patients who would otherwise have received the labeled dosage amount caused [PHN] to submit claims for Aranesp dosing that was not medically necessary"); id. ¶ 282 (alleging that Nephrology Associates of Syracuse administered extra Aranesp to bill for extra product, not because patients required the additional medication).

It would be almost impossible at this stage for Relator to access the medical records of each clinic and specify particular instances wherein the dosage claimed was unnecessary or never administered. See Parke-Davis, 147 F. Supp. 2d at 49 (explaining that pleadings all occurrences of fraud in a complex fraudulent scheme would be "ungainly if not impossible" especially in cases where relator "does not reasonably have pre-discovery access to patient-specific information"). Here, Relator has described a marketing scheme focused on exploiting the profit providers could gain from claiming reimbursement for all overfill, and has detailed instances where providers have successfully encouraged particular providers to bill for unadministered or unnecessary overfill. Relator has thus provided pleading adequate to meet the requirements of Rule 9(b).

b. Causation

The Defendants also argue that they did not cause the submission of false claims simply by marketing overfill because a provider's independent decision to administer medically unnecessary dosages of Aranesp or bill for unadministered Aranesp "constitutes an intervening cause that breaks any chain of proximate causation extending from Amgen." Amgen's Mem. Supp. Mot. Dismiss 9.

In United States ex rel. Franklin v. Parke-Davis, the court rejected a similar argument. 147 F. Supp. 2d 39. There, the defendant drug manufacturer claimed that although it allegedly marketed an off-label use, it was the physicians who wrote off-label prescriptions and submitted the claims for reimbursement. The defendant then argued that it did not cause the submission of false claims because the doctors' professional medical judgments in seeking reimbursement for off-label prescriptions constituted an intervening cause. In response, Judge Saris stated that "an intervening source only breaks the causal connection when it is unforeseeable," and reasoned that, "the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud." Parke-Davis, 147 F. Supp. 2d at 52-53.

Similarly, the Complaint here describes a fraudulent scheme the intended and foreseeable consequence of which was the

submission of legally and factually false claims. The Defendants did not merely advise providers that overfill could be administered to patients. Rather, the Defendants allegedly encouraged providers to bill for unnecessary and unadministered dosages of overfill, instructed providers to bill for almost all overfill contained in the vial even though it was not possible to withdraw such a dosage, and even taught providers to include overfill quantities on patient charts when it was never administered. See, e.g., Compl. ¶¶12-13, 150, 156-58, 197. The Defendants knew that their actions "would, if successful, result in the submission by [providers] of compliance certifications required by Medicare that [the defendants] knew would be false." United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 244 (3d Cir. 2004) (holding that where device manufacturers used kickbacks to induce hospitals to use their orthopedic products, hospitals' submissions of Medicare claims were not intervening causes). Further, Amgen's contention that they only gave providers accurate reimbursement information is factually disputed because the Complaint alleges that Amgen misled providers into believing that overfill is reimbursable.

Therefore, the Complaint alleges adequately that the Defendants' proximately caused the submission of claims for units of Aranesp that were medically unnecessary or never administered.

3. False Claims Caused by INN and ASD

INN and ASD contend that the Complaint does not contain particularized facts supporting the conclusion that the misconduct of INN or ASD caused false claims to be submitted to Medicare. As discussed supra in section II.B.1.b., an actual claim for payment is a central element of False Claims Act "presentment" liability that must be pled with particularity pursuant to Federal Rule of Civil Procedure 9(b).[12] The First Circuit has held that a relator can satisfy Rule 9(b) by providing "factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim." Duxbury, 579 F.3d at 29 (citing Rost, 507 F.3d at 733 (internal quotation marks omitted). When pursuing a claim under the "causes to be presented" prong, pleading a "connecting causal link" between the defendant's actions and the submission of claims strengthens the inference that false claims were submitted. See Rost, 507 F.3d at 732 n.9. One example of such a causal link, which the First Circuit has cited approvingly, is the type alleged in Parke-Davis. See id., 507 F.3d at 732 n.9. There, the pleadings described the defendant pharmaceutical company's efforts "to

[12] Relator is not required to prove the submission of false claims to hold INN and ASD liable under 31 U.S.C. §§ 3729(a)(2) and (a)(3). Gagne, 565 F.3d at 46 (citing Allison Engine, 128 S. Ct. at 2129-31).

coach doctors on how to conceal the off-label nature of the prescription." Parke-Davis, 147 F. Supp. 2d at 46.

Contrary to INN and ASD's contention, the Complaint here pleads a similar connecting causal link between the Defendants' actions and the submission of false claims. First, the very essence of the overfill kickback scheme is that providers would be able to profit by claiming Medicare reimbursement for the free overfill contained in Aranesp vials. This is supported by the marketing materials used by all the Defendants, which show the amount of profit to be gained based on Medicare reimbursement rates. See, e.g., Compl. ¶¶ 156-59; 173-75. The Complaint also alleges that INN representatives encouraged providers on more than one occasion to submit false claims, and instructed providers to write down on claim forms that they had administered overfill dosages even when they did not do so because such a technique would "pass an audit" by Medicare. Id. ¶¶ 176, 197.

Further, the Complaint contains provider-specific pleadings linking INN and ASD's provision of various types of kickbacks and encouragement of overfill billing to particular providers' submission of false claims. See, e.g., Compl. ¶¶ 208-21 (alleging that Amgen and INN advised Balboa providers to bill for overfill, which led Balboa to issue a standing order to increase the Aranesp dosage administered to **every** patient so that Balboa could capture overfill profit); id. ¶¶ 222-31 (alleging that

Amgen and INN's encouragement of overfill billing caused Bronx Westchester Medical Group to bill Medicare and Medicaid for 15% overfill in each Aranesp dose even though it is not possible to withdraw this amount, resulting in over $12,500 of Medicare payments); id. ¶¶ 232-38 (alleging that INN instructed California Kidney Medical Group to bill for and record for doses of Aranesp in excess of the intended dose, causing California Kidney to submit claims for medically unnecessary and unadministered Aranesp); id. ¶¶ 312-50 (describing Amgen, INN, and ASD's provision of kickbacks in form of retreats, honoraria, and practice assessments to providers, which induced providers such as Balboa Nephrology and Rockland Renal Associates to purchase Aranesp). Finally, in addition to the above allegations, Relator provides factual and statistical information supporting the actual submission of claims for payment. The Complaint contains a table showing practice areas all over the country at which the Defendants conducted practice assessments, the percentage of patients at such practices with Medicare as their primary insurance, and the amount the practice spent on Aranesp after such practice assessments, as well as an exemplar table showing Aranesp claims of the Rockland Renal Associates billed to Medicare. Id. ¶ 388.

Therefore, Relator pleads adequately that the alleged misconduct of INN and ASD caused the submission of false claims.

The Complaint not only describes the Defendants' marketing scheme - a central purpose of which was to encourage providers to submit false claims in order to profit from purchasing Aranesp - but also provides factual and statistical information regarding claims for payment. Overall, the Complaint "does more than suggest fraud was possible." See Duxbury, 579 F.3d at 29-30 (internal quotation marks omitted); Cf. Rost, 507 F.3d at 732-33 (holding pleadings inadequate for presentment liability where complaint contained neither a connecting link between fraud and the submission of false claims nor factual or statistical evidence countering the possibility that doctors did not seek federal reimbursement, and where criminal investigation revealed that most patients taking drug for off-label uses paid out of pocket).

4. ASP Inflation by Failing to Report Excess Overfill

In Count IV, the Complaint alleges that Amgen inflated Aranesp's ASP by failing to report overfill contained in Aranesp. Amgen argues that this theory of liability fails as matter of law because overfill is not required to be included in ASP calculations under CMS regulations. Title 42 of the Code of Federal Regulations Section 414.804 states that ASP is calculated by dividing a manufacturer's total sales of the drug (after deducting price concessions) by the total number of units sold in one quarter. Amgen argues that nowhere does the ASP account for

overfill, as "unit" is defined by the labeled dosage sold. Thus, overfill in a vial could not factor into CMS's calculation.

As Relator points out, however, manufacturers are required to deduct "price concessions" from the numerator of the ASP, which include "free goods that are contingent on any purchase requirement." 42 C.F.R. § 414.804(a)(2)(i)(D). The Complaint alleges that excess overfill is a "free good" that should have been deducted from the total Aranesp sales. Compl. ¶¶ 353-57. Amgen's argument that overfill is part and parcel of the FDA-approved product and thus cannot be a "free good" with independent value is factually disputed, as discussed supra.

The Complaint also alleges that Amgen was aware that inclusion of excess overfill would affect the cost and sales of Aranesp because, for example, providers could pool together free overfill and reduce the number of vials they actually purchase. Id. ¶¶ 214, 357. Further, Relator alleges that Amgen was aware of the effect that overfill had on ASP because the Office of the Inspector General ("OIG") previously adjusted the ASP for one of Amgen's drugs, Epogen, to take into account the portion of excess overfill which could be administered from Epogen vials. In doing so, OIG explained that it adjusted Epogen's ASP because the "use of the additional Epogen [from overfill] would materially affect each provider's cost." Id. ¶¶ 355-56.

Drawing all reasonable inferences in favor of Relator, the

Complaint pleads adequately that Amgen inflated Aranesp's ASP by failing to report excess overfill, thereby causing false claims to be presented.

5. Conspiracy to Inflate ASP as to INN and ASD

Finally, INN and ASD contend that because it is the responsibility of the drug manufacturer to report an accurate ASP to CMS, INN and ASD could not be part of a conspiracy to inflate Aranesp's ASP. The text of the Section 3729(a)(3) subjects to liability any person who "conspires to defraud the Government by getting a false or fraudulent claim allowed or paid." 31 U.S.C. § 3729(a)(3). Liability under this subsection does not require presentment of a claim to the federal government nor an intent that the false record or statement be presented directly to the government. Allison Engine, 128 S. Ct. at 2129-31. As discussed supra, however, subsection (a)(3) does require that the defendants "intended to defraud the government" and "agreed that the false record or statement would have a material effect on the Government's decision to pay the false or fraudulent claim." Gagne, 565 F.3d at 46 (citing Allison Engine, 128 S.Ct. at 2130-31).

Moreover, general civil conspiracy principles apply to subsection (a)(3). United States v. President & Fellows of Harvard Coll., 323 F. Supp. 2d 151, 196 (D. Mass. 2004) (Woodlock, J.) (citing United States ex rel. Durcholz v. FKW

Inc., 189 F.3d 542, 545 n.3 (7th Cir. 1999)). Conspiracy liability requires only that "(1) the defendant conspired with one or more persons to get a false or fraudulent claim allowed or paid by the United States; and **(2) one or more conspirators performed any act** to effect the object of the conspiracy." Fellows of Harvard Coll., 323 F. Supp. 2d at 196 (emphasis added). Thus, contrary to INN and ASD's assertion, liability for the ASP inflation aspect of the conspiracy does not require their direct participation in submitting a false ASP to CMS.

Here, Relator pleads an overarching conspiracy among Amgen, INN, and ASD to defraud Medicare by providing kickbacks in various forms to providers as an inducement to purchase Aranesp, sharing confidential information gained from INN's practice assessments to better target each individual provider, and encouraging providers to bill for overfill even when it was never administered or medically unnecessary. Compl. ¶¶ 298-350. INN and ASD were avid in marketing the "economics" of overfill reimbursement, which relied on Aranesp's inflated ASP. Id. ¶¶ 172-75, 345(b), 348. In other words, it is an inflated ASP - which did not take into account free overfill - that allowed providers to profit from the overfill scheme. As Relator aptly argues, "[h]aving joined the conspiracy and knowing the centrality of ASP to reimbursement calculations, [INN and ASD] cannot now seek to avoid liability by claiming that it was only

Amgen that was responsible for submitting false ASP data." Rel.'s Mem. Opp'n INN 's Mot. Dismiss 14.

III. CONCLUSION

For the reasons stated above, the Court DENIED the Defendants' Motions to Dismiss Relator's Fourth Amended Complaint in their entirety on July 21, 2010.

/s/ William G. Young
WILLIAM G. YOUNG
DISTRICT JUDGE