UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,
STATE OF NEW JERSEY, ex rel.
STEVE GREENFIELD, et al.,
Plaintiffs,

v.

MEDCO HEALTH SYSTEMS, INC.,
ACCREDO HEALTH GROUP, INC.,
and HEMOPHILIA HEALTH
SERVICES, INC.,
Defendants.

CIVIL NO. 12-522(NLH)(AMD)

OPINION

APPEARANCES:

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HILLMAN, District Judge

This *qui tam* action concerns claims by plaintiff Steve Greenfield that defendants violated the federal False Claims Act, as well as twenty-four state and city statutes regulating false claims, relating to pharmaceutical products for hemophilia. Currently before the Court is the motion of defendants to dismiss plaintiff's third amended complaint. For the reasons expressed below, defendants' motion will be granted in part and denied in part.

BACKGROUND

Pursuant to the motion to dismiss plaintiff's second amended complaint ("SAC") filed by defendants Medco Health Systems, Inc., Accredo Health Group, Inc., and Hemophilia Health Services, Inc. ("HHS"),[1] the Court dismissed all of plaintiff's claims. Plaintiff was granted leave, however, to file a third amended complaint if he could do so consistent with the direction provided by the Court. Believing that he has addressed the deficiencies in his SAC, plaintiff has filed a third amended complaint ("TAC"). Because the

[1]According to plaintiff's complaint, Medco provides pharmacy services to private and public employers, health plans, labor unions, government agencies, and those under Medicare Part D prescription drug plans; Accredo is a wholly owned subsidiary of Medco, and provides specialty pharmacy services to patients with complex conditions; and HHS is a subsidiary of Accredo, and it provides hemophilia therapy management programs in the United States.

majority of plaintiff's TAC is the same as his prior complaint, the Court will restate a summary of his claims from the prior Opinion:

Plaintiff's claims against defendants are lodged pursuant to 31 U.S.C. §§ 3729 and 3720.[2] Plaintiff alleges that defendants submitted false claims for payment from the United States, as well as payment from various states in violation of their false claim laws, because defendants falsely certified their compliance with the Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b) (referred herein as the Anti-Kickback statute, or "AKS").[3] Plaintiff contends that in his capacity as an area vice-president of Accredo, he learned of defendants' fraudulent practices related to their efforts to

[2]A private individual, otherwise known as a relator, may bring a civil action in the name of the United States to enforce § 3729 of the FCA and may share a percentage of any recovery resulting from the suit. U.S. ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 305 (3d Cir. 2011) (citing 31 U.S.C. § 3730(b) & (d)). Because it was filed as a *qui tam* action, the entire case was filed under seal in order to allow the United States and interested states to investigate whether they wished to intervene in the action and prosecute plaintiff's claims on their behalf. See 31 U.S.C. § 3730(b)(2). Neither the United States government nor any of the states listed in the complaint chose to intervene in the action. Accordingly, the complaint was unsealed, and from that point on the case has been publically accessible.

[3]Plaintiff is not asserting an independent claim under the AKS. The AKS is a criminal statute that does not provide for a private cause of action. If an entity falsely certifies its compliance with the AKS, that false certification can serve as a basis for a civil FCA violation. See 31 U.S.C. §§ 3729–3733.

maintain and increase sales of their products to treat hemophilia.

As described in plaintiff's complaint, hemophilia is a rare bleeding disorder, and those with the disorder have little or no "clotting factor." Treatment for hemophilia is typically either "on-demand," where a patient receives factor replacement therapy to stop a bleed, or "prophylactic," where a patient receives factor replacement therapy to prevent a bleed. Clotting factor products are expensive, with the annual cost for the treatment of one patient ranging from $50,000 to $100,000 or more. As a result, New Jersey law requires health benefit providers to contract with state-authorized hemophilia home care providers to provide hemophilia patients with their necessary treatment regimen. There are four major state-authorized hemophilia providers in New Jersey, and Accredo is one of them.

The Hemophilia Association of New Jersey, Inc. ("HANJ") was created to coordinate and provide treatment to hemophilia patients. HANJ is a tax exempt entity that, through grants, funds referral entities and makes recommendations to the state for competitive providers. HANJ formed Hemophilia Services, Inc. ("HSI"), also a tax exempt organization, which works with treatment centers, insurers, and participating home care vendors to provide case management services for the hemophilia population in New Jersey. Essentially, HSI receives charitable donations, which it grants to

HANJ, and HANJ provides insurance and other financial assistance to individuals with hemophilia.

According to plaintiff's complaint, Medco, through Accredo and HHS, made charitable contributions in the amount of $500,000 or more to HSI from 2007 through 2009, with the intent to buy influence and induce referrals to the defendants. Plaintiff claims that when defendants informed HANJ that their charitable contributions would be decreasing, HANJ's response demonstrated the quid quo pro arrangement between defendants' donations and HANJ's funneling of patients to defendants' products. For example, in October 2009, the director of HANJ, Elena Bostick, sent an email to Craig Mears, president of Accredo/HHS, explaining the ramifications of the reduced funding, including the elimination of the $5,000 a month donation from Critical Care Services, a company which Accredo acquired in 2009. Bostick stated:

> 1. New Jersey has four HTC's--none of which has 340B designation.[4]
> 2. New Jersey has the lowest % of individuals with hemophilia on Medicaid.
> 3. New Jersey has enacted legislation which insures access to care, access to all hemophilia products, and to the providers of those products. This did not occur by

[4] "HTCs" are state-recognized hemophilia treatment centers. (SAC ¶ 68.) "340B designation" refers to the 340B Drug Pricing Program, which is a federal program that provides significant savings on outpatient drugs to qualified participants. (SAC ¶ 82, n.34.)

accident.

4. HANJ's insurance Grant Program currently covers 65 individuals with hemophilia. 49 of these are your customers.
5. The State Dept. of Health reimburses less than 50% of the cost of the insurance Grant Program. The balance of this cost must be borne by HANJ/H.S.I.
6. Grants to NJ HTC's, for the fiscal year ended 6/30/09, exceeded $500,000. These dollars enabled our centers to continue to function despite shortfalls in government funding. It also alleviated the need for HTC's to explore 340B as a funding solution.

(SAC ¶ 79, Ex. P.) Bostick concluded that Accredo/HHS's elimination of Critical Care's pledge to HSI "seriously compromises the necessary level of funding required to continue to provide these services." (Id.)

Over the next year defendants allegedly discussed the business ramifications of their reduced contributions to HANJ/HSI on the sale of their hemophilia products. According to plaintiff's complaint, in a meeting in October 2010, Bostick again related HANJ's arrangement with defendants in which defendants would make donations to HANJ/HSI, which would in turn fund insurance for patients who used defendants' factor products. Patients with insurance plans funded by the charitable contributions of defendants would not be referred to any other competitor hemophilia product. (SAC ¶ 87.) If defendants reduced their contributions to HANJ/HSI, patients would be referred to competitors. (Id. ¶ 89.)

In March 2011, HSI president Jerry Seltzer sent a letter to its members, stating:

> As you are aware insurance costs continue to rise in the State of New Jersey. Over the past ten years a successful partnership between Hemophilia Services, Inc. (HSI), the State of New Jersey and the "authorized" home care providers, who participate in the HSI program, has been able to "subsidize" the cost of Insurance Policies for our "uninsured" patient population.
>
> Unfortunately, due to insufficient funding for this groundbreaking program, the ability for HSI to continue to support this program is now in jeopardy for the balance of 2011. One of our key providers (HHS/Accredo) has continued to significantly reduce its financial support for this program over the last two years. In the recent past, HSI, in cooperation with the Hemophilia Association of New Jersey (HANJ), and with a restructuring of the "patient criteria" for obtaining Insurance Policies, was able to absorb the additional cost no longer funded by HHS/Accredo. It should be noted that the cost to purchase Insurance Policies for our patient population in 2010, alone, approached one million dollars.
>
> However, I am writing at this time to advise you that, beginning January 2011, HHS/Accredo has chosen to reduce its financial support so significantly, that as a major participant, this reduction has placed the Insurance Program in jeopardy of being phased out, and ceasing to exist in the foreseeable future.
>
> If you are a client of HHS/Accredo or a participant in HSI's Insurance Program, on behalf of the HSI Board, I request that you IMMEDIATELY contact Craig Mears, President of HHS/Accredo. . . .
>
> It should be noted that if we do not receive a commitment from HHS/Accredo to restore financial support for the coming year (2011), "sadly" we will have to notify the State of NJ that the very successful Insurance Program for our uninsured patient population is in danger of being "phased out" due to lack of funds. . . .

(SAC ¶ 92, Ex. I-1.)

As a result of Seltzer's letter, approximately 75 Accredo/HHS

clients expressed their concern over the funding cuts by sending letters to Accredo/HHS. Plaintiff claims that Accredo/HHS then began to analyze the loss of business they had already experienced, and could continue to experience in the future, due to HANJ/HSI's reaction to defendants' reduced donations. Defendants' business analysis questions included whether there was a quantifiable return on investment if they increased contributions from $175,000 to $350,000 and what was the likely business deterioration to the New Jersey market share if contributions were not increased. (SAC ¶ 96.) Based on this analysis, plaintiff contends that Accredo convinced Medco to restore funding to $350,000, with Mears explaining that when they reduced their contributions to HANJ/HSI, they saw a decline in business because HANJ/HSI wanted defendants to fund the insurance for patients using defendants' products. Of the 72 patients HSI provided insurance for, 58 were Accredo patients, and HANJ/HSI wanted Accredo to pay an equivalent amount. (Id. ¶ 98.) Plaintiff contends that Medco "found the additional money" to increase the donations so that they would not lose business and maintain the referrals to their hemophilia products. (Id. ¶ 99, quoting Accredo vice-president Bruce Scott, "[O]kay, so we're at the point where they understand that we are willing to continue and willing to increase our contribution back to 350K and it is clear to them that we are not willing to contribute to an

organization that is placing us in an unfavorable position with patients.”).

Plaintiff claims that defendants knew that their arrangement with HANJ/HSI was an illegal kickback scheme, because the arrangement evidences defendants’ control over a charity, the lack of independence between defendants and the charity, defendants’ financial interest in the donations, and the connection between the donations and referrals, all of which violate the Anti-Kickback statute, as interpreted by the Office of Inspector General in its Advisory Opinion 10-19. (SAC ¶¶ 101-107.) Plaintiff contends that in addition to providing gifts, in the form of dinners, lunches, refrigerators, and equipment to patients that exceed the safe harbor amount ($10 per item/$50 limit per year), in order to influence the patient’s continued use of Accredo, this quid pro quo scheme between defendants and HANJ/HSI is a violation of the AKS, which has therefore caused defendants to falsely certify their compliance with the AKS, a violation of the False Claims Act.

In his TAC, plaintiff has added several additional allegations to further articulate and bolster his claims that defendants provide charitable donations and gifts in order to unlawfully induce federal and state Medicare and Medicaid recipients’

continued use of their hemophilia products.[5] Defendants have again moved to dismiss plaintiff's complaint in its entirety, arguing essentially the same bases as their prior motion to dismiss plaintiff's SAC. Plaintiff has opposed defendants' motion.

DISCUSSION

A. Subject matter jurisdiction

This Court has jurisdiction over plaintiff's federal claims under 28 U.S.C. § 1331, and supplemental jurisdiction over plaintiff's state law claims under 28 U.S.C. § 1367.

B. Standard for Motion to Dismiss

When considering a motion to dismiss a complaint for failure to state a claim upon which relief can be granted pursuant to Federal Rule of Civil Procedure 12(b)(6), a court must accept all well-pleaded allegations in the complaint as true and view them in the light most favorable to the plaintiff. Evancho v. Fisher, 423 F.3d 347, 351 (3d Cir. 2005). It is well settled that a pleading is sufficient if it contains "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Under the liberal federal pleading rules, it is

[5] Defendants helpfully point out the differences between plaintiff's SAC and TAC, which plaintiff does not object to: Plaintiff's new allegations are contained in paragraphs 66-73, 115-116, 119, 123, and 129; and plaintiff has deleted reference to the CMPL.

not necessary to plead evidence, and it is not necessary to plead all the facts that serve as a basis for the claim. Bogosian v. Gulf Oil Corp., 562 F.2d 434, 446 (3d Cir. 1977). However, "[a]lthough the Federal Rules of Civil Procedure do not require a claimant to set forth an intricately detailed description of the asserted basis for relief, they do require that the pleadings give defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." Baldwin Cnty. Welcome Ctr. v. Brown, 466 U.S. 147, 149-50 n.3 (1984) (quotation and citation omitted).

A district court, in weighing a motion to dismiss, asks "'not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claim.'" Bell Atlantic v. Twombly, 550 U.S. 544, 563 n.8 (2007) (quoting Scheuer v. Rhoades, 416 U.S. 232, 236 (1974)); see also Ashcroft v. Iqbal, 556 U.S. 662, 684 (2009) ("Our decision in Twombly expounded the pleading standard for 'all civil actions' . . . ."); Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009) ("Iqbal . . . provides the final nail-in-the-coffin for the 'no set of facts' standard that applied to federal complaints before Twombly.").

Following the Twombly/Iqbal standard, the Third Circuit has instructed a two-part analysis in reviewing a complaint under Rule 12(b)(6). First, the factual and legal elements of a claim should be separated; a district court must accept all of the complaint's

well-pleaded facts as true, but may disregard any legal conclusions. Fowler, 578 F.3d at 210 (citing Iqbal, 129 S. Ct. at 1950). Second, a district court must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a "'plausible claim for relief.'" Id. (quoting Iqbal, 129 S. Ct. at 1950). A complaint must do more than allege the plaintiff's entitlement to relief. Id.; see also Phillips v. Cnty. of Allegheny, 515 F.3d 224, 234 (3d Cir. 2008) (stating that the "Supreme Court's Twombly formulation of the pleading standard can be summed up thus: 'stating . . . a claim requires a complaint with enough factual matter (taken as true) to suggest' the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element").

A court need not credit either "bald assertions" or "legal conclusions" in a complaint when deciding a motion to dismiss. In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1429-30 (3d Cir. 1997). The defendant bears the burden of showing that no claim has been presented. Hedges v. U.S., 404 F.3d 744, 750 (3d Cir. 2005) (citing Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991)).

Finally, a court in reviewing a Rule 12(b)(6) motion must only

consider the facts alleged in the pleadings, the documents attached thereto as exhibits, and matters of judicial notice. S. Cross Overseas Agencies, Inc. v. Kwong Shipping Grp. Ltd., 181 F.3d 410, 426 (3d Cir. 1999). A court may consider, however, "an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document." Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993). If any other matters outside the pleadings are presented to the court, and the court does not exclude those matters, a Rule 12(b)(6) motion will be treated as a summary judgment motion pursuant to Rule 56. Fed. R. Civ. P. 12(b).

C. Pleading standard under Fed. R. Civ. P. 9(b)

Because the complaint in this case alleges violations of the federal FCA, plaintiff's allegations with respect to these claims must satisfy the heightened pleading requirements of Fed. R. Civ. P. 9(b). Even though many courts in this district and throughout the country have often applied the heightened Rule 9(b) pleading requirements to assess the viability of FCA claims, the standard for analyzing the sufficiency of a FCA complaint was not specifically addressed by the Third Circuit Court of Appeals until recently, after the parties in this case filed their briefs.

In Foglia v. Renal Ventures Management, LLC, 754 F.3d 153,

155-56 (3d Cir. 2014), the Third Circuit explained that the "Fourth, Sixth, Eighth, and Eleventh Circuits have held that a plaintiff must show 'representative samples' of the alleged fraudulent conduct, specifying the time, place, and content of the acts and the identity of the actors," while the "First, Fifth, and Ninth Circuits, however, have taken a more nuanced reading of the heightened pleading requirements of Rule 9(b), holding that it is sufficient for a plaintiff to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." Foglia, 754 F.3d at 155-56 (citations and quotations omitted). Considering that "the purpose of Rule 9(b) is to provide defendants with fair notice of the plaintiffs' claims," the Third Circuit adopted "the more 'nuanced' approach followed by the First, Fifth, and Ninth Circuits." Id. at 156-57 (citations and quotations omitted).

Thus, in order to survive a motion to dismiss and satisfy the standards of Rule 9(b), a plaintiff asserting claims under the FCA "must provide particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." Id. at 158-59 (citations omitted). "Describing a mere opportunity for fraud will not suffice," and, instead, a plaintiff must provide "sufficient facts

to establish a plausible ground for relief." Id. at 159 (citations omitted).

D. Analysis

In the prior Opinion assessing the sufficiency of plaintiff's FCA claims in his second amended complaint, the Court focused on whether defendants' conduct alleged by plaintiff was tied to payment from the United States government. This is because to establish a prima facie FCA violation under section 3729(a)(1), a plaintiff must prove that "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent."[6] U.S. ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 304-05 (3d Cir. 2011) (citations omitted).[7]

[6] As discussed in detail below, there are two categories of false claims under the FCA: a factually false claim and a legally false claim." U.S. ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 304-05 (3d Cir. 2011) (citation omitted). Plaintiff in this case relies upon the "legally false" category to support his claims.

[7] As explained in U.S. ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 303-304 (3d Cir. 2011), on May 20, 2009, Congress enacted the Fraud Enforcement and Recovery Act of 2009 (FERA), Pub.L. No. 111–21, 123 Stat. 1617 (2009), which amended the FCA and re-designated 31 U.S.C. § 3729(a)(1) as 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(2) as 31 U.S.C. § 3729(a)(1)(B). Further explanation of this change is contained in the Court's prior Opinion.

To demonstrate that defendants knowingly submitted false claims for payment by the federal government, plaintiff argued that his SAC met the Rule 9(b) standard because "the facts plead in the Complaint show that the Defendants offer and give[] substantial inducements to HANJ/HSI that support hemophilia patients, disguised as 'charitable donations' when, in fact, such donations are prohibited 'remuneration' under the AKA because they are intended to induce referrals of hemophilia patients who receive benefits from Federal health care programs." (Docket No. 42, Op. at 16.) To demonstrate that defendants' alleged "prohibited remuneration" was connected to patients who receive benefits from the federal government, plaintiff pointed to the following allegations in his SAC:

> The Complaint identifies and alleges that there were approximately 646 hemophilia patients in New Jersey as of the first quarter of 2011 and Defendant Hemophilia Health Services (HHS) had 401 of these individuals as active patients, or approximately 62% of the New Jersey Market [Complaint ¶ 71]. In addition, the Complaint also alleges and states that HANJ/HSI had 77 insurance recipients of which 59 were HHS clients [Complaint ¶ 83, Exhibit G-4]. Therefore, on the face of the Complaint itself, of the 401 HHS hemophilia patients, only 59 had private insurance, leaving the remaining 342 as part of the population that were beneficiaries of a Federal Health Care Program [Complaint ¶¶ 8, 9, 11, and 70].

Plaintiff also referred to Exhibit N to his SAC, which is a chart of Medco's hemophilia patients, listing the amount of factor

each uses, each patient's insurer, and the "gift" provided to them, such as snacks, lunches and dinners. A few of these patients are listed as federal Medicare recipients.

With regard to plaintiff's charitable donation claims, the Court previously found that plaintiff failed to satisfy Rule 9(b), finding, "Accepting as true that defendants' charitable contributions to HANJ/HSI were intended to induce referrals to defendants' hemophilia treatment products, and that defendants' actions demonstrated prohibited control over the charity's use of its donations, the facts pleaded in plaintiff's complaint are not sufficient, under his Rule 9(b) burden, to show that any of those contributions are tied to federal funds. To the contrary, the quid pro quo scheme between HANJ/HSI and defendants alleged by plaintiff appear to demonstrate that defendants' contributions were used by HANJ/HSI to avoid the need to avail themselves of any federal benefits program." (Docket No. 42, Op. at 17.)

The Court further found that "plaintiff's math (and his corresponding assumption that federal funds are implicated) is too attenuated and derivative to state a viable claim under the heightened Rule 9(b) standard, and even under the regular Rule 8(a) standard. There are no factual allegations to support the conclusion that the remaining 352 HHS patients were under a federal

prescription drug program. This data simply fails to demonstrate with the requisite degree of clarity and certainty a connection between defendants' alleged kickback scheme with HANJ/HSI and payments from the federal government." (Id. at 19.)

The Court, however, noted that "352 HHS patients were not privately insured through funding from the kickback scheme alleged leaves open the question of what kind of financial assistance these patients received, especially when considering the high medical costs associated with the treatment of hemophilia." (Id. at 20.) Accordingly, the Court granted plaintiff leave to file a third amended complaint to comply with Rule 9(b), and more concretely plead that defendants' charitable contributions were intended to, and did, induce referrals of patients receiving federal support to defendants' products. (Id.)

With regard to plaintiff's excessive gifts claims, the Court found that plaintiff's opposition brief better articulated his claim than his complaint. (Id. at 23.) In his brief, plaintiff argued that defendants maintained billing privileges with Medicare and signed a provider agreement form 855s, wherein defendants agreed that payment by Medicare is conditioned upon compliance with the anti-kickback statute. Because defendants' gifts were not considered "nominal," and were intended to induce patient use of

defendants' hemophilia products, plaintiff claimed that these gifts violate the AKS, and the prescriptions stemming from the illegal gifts resulted in payments by the federal government in violation of the FCA. In other words, plaintiff claimed that defendants were paid by Medicare for the prescriptions procured by illegal kickbacks to Medicare patients. (Id. at 24.)

The Court found that even though plaintiff's complaint demonstrated that defendants give certain non-nominal gifts to patients whose prescriptions are paid for by Medicare, that fact alone was not sufficient under Rule 9(b) to make the leap that the gifts were violations of the AKS, and that defendants expressly and falsely certified compliance with AKS when they received payment from federal funds for prescriptions resulting from those illegal gifts.[8] (Id.) As with his claims concerning charitable donations, the Court granted leave to plaintiff to reassert his claims based on the alleged excessive gifts.

In addition to the direction to plaintiff with regard to his charitable donation and excessive gifts claims, the Court also

[8] Plaintiff also claimed that these gifts exceed the nominal amount permitted under the Civil Monetary Penalty Law, 42 U.S.C. § 1320a-7(a), and that defendants' violation of the CMPL served as a basis for his FCA claims. The Court explained that a violation of the CMPL cannot serve as the basis for a FCA claim. Plaintiff has removed the references to the CMPL in his third amended complaint.

advised plaintiff that if he chose to file a third amended complaint he needed to better articulate whether his allegations concerning gifts provided to Medco patients on Medicare exceeding the maximum dollar amount permitted by the AKS was an allegation of a separate illegal scheme or somehow related to the allegations concerning charitable donations. (Id. at 19 n.10.) The Court also advised that plaintiff must properly allege specific conduct by Medco, separate from Accredo/HHS, as well as properly plead his claims that the three entities conspired with each other. (Id. at 21 n.11.)

In their current motion, defendants argue that plaintiff's third amended complaint has not cured any of the deficiencies found by the Court. Plaintiff contests defendants' position and argues that his TAC satisfies the Rule 9(b) standard for all his claims. The Court finds that plaintiff's revised complaint, along with the Rule 9(b) standard recently adopted by the Third Circuit, permits some of his claims to proceed.

1. FCA violation claims - Counts One and Two

Plaintiff's TAC appears to allege a two-part illegal scheme perpetrated by defendants to induce referrals to their hemophilia products. One part of the alleged scheme is defendants' charitable contributions to HANJ/HSI: the more defendants donate to HANJ/HSI,

the more referrals to defendants' products.[9] The second part of the alleged scheme concerns excessive gifts: once the charitable donations have funneled patients to defendants' products, defendants ensure the hemophilia patients' continued use of these products by providing them with excessive gifts.

Plaintiff contends that this scheme violates the FCA because: (1) many of these hemophilia patients, having been referred through and induced by illegal kickbacks to use defendants' products, are recipients of federal Medicare and Medicaid assistance, (2) federal funds therefore pay defendants for these illegally procured prescriptions, (3) in order to be paid from government funds, defendants have to certify that they have complied with the anti-kickback laws (on Provider Agreement CMS Form 855s), and (4)

[9] As discussed in the prior Opinion and restated here, the quid pro quo scheme alleged by plaintiff in his SAC focused almost entirely on how defendants' donations would fund private insurance, and that private insurance would pay for defendants' hemophilia products, referral to which being a result of defendants' donations. No federal funds were implicated there. Moreover, the Court found that it was a too broad assumption that if the HANJ/HSI-funded insurance programs did not cover a Medco/Accredo/HHS customer, Medicare or Medicaid must be paying. In his TAC, plaintiff has slightly shifted focus to the goodwill generated by defendants' donations. The part of this claim that is now actionable is that the charitable donations - or kickbacks - illegally induced HANJ/HSI to refer patients to defendants' products, defendants track these patients and secure their continued use of defendants' products through excessive gifts, and there is evidence that some of these patients are Medicaid and Medicare recipients.

defendants have presented claims to the government for reimbursement knowing that they violated the anti-kickback laws.

There are two main issues relating to the viability of these alleged FCA violations. The first is whether defendants' signing of Provider Agreement CMS Form 855s can serve as a predicate for a false certification claim under the FCA. If so, the second issue is whether plaintiff's allegations satisfy Rule 9(b) so far as they tie defendants' conduct to claims for federal funds.[10]

Provider Agreement CMS Form 855s provides, "I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. 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 supplier's compliance with all applicable conditions of participation in Medicare." (TAC ¶ 123.) Defendants argue that Form 855s cannot support an express certification claim under the FCA because it is forward-looking; i.e., it can only support claims

[10] Issues concerning plaintiff's state law claims are addressed below.

where defendants knew when they signed the form that they would be accepting payment in violation of the anti-kickback statute. (Def. Br. at 21, citing cases.) In contrast, plaintiff cites numerous cases in his complaint that support his position. (See TAC ¶ 121, n.50.)

A legally false claim under the FCA comes in two types: express false certification and implied false certification. U.S. ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 305 (3d Cir. 2011) (citation omitted). "Under the 'express false certification' theory, an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds." Wilkins, 659 F.3d at 305. The more expansive "implied false certification" liability "attaches when a claimant seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment. Thus, an implied false certification theory of liability is premised '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.'" Id. (citation omitted).

With regard to the Form 885s issue, a recent case in the

Southern District of Texas surveyed how courts in many of the circuits have addressed the use enrollment forms with similar language to Form 885s to support a legally false claim under the FCA. It determined that the "implied false certification theory" has been adopted in most courts, and has been applied to the use of enrollment agreements such as Form 855s in FCA cases. U.S. ex rel. Ruscher v. Omnicare, Inc., 2014 WL 2618158, *19 (S. D. Tex. June 12, 2014). The rationale of the courts is that "in signing the enrollment agreement, a provider both promises ongoing compliance with the AKS and is put on notice that future payments are conditioned on keeping that promise. As a result, when the provider subsequently seeks payment, it is implicitly certifying that it kept that promise to comply with the AKS." Ruscher, 2014 WL 2618158 at *19. The Ruscher court then found that "the legion of cases endorsing the use of enrollment agreements and embracing the application of an implied false certification theory more persuasive than the three Northern District of Illinois cases that Defendants cite for the proposition that forward-looking promises can never qualify as false certifications." Id.; see also U.S. ex rel. Kester v. Novartis Pharmaceuticals Corp., --- F. Supp. 2d ---, 2014 WL 4230386, *12 (S.D.N.Y. August 7, 2014) ("Other courts have held that a party's submission of a CMS form with language

that is virtually identical to the certification contained in CMS Form 855S renders a claim 'false,' where the party was allegedly violating the AKS in connection with the underlying transaction that is the subject of that claim.").

The abundance of caselaw that permits the use of enrollment forms such as Form 855s to serve as the basis for a legally false certification claim under the FCA supports the same result in this case. Thus, defendants' motion to dismiss plaintiff's FCA claims based on their argument that plaintiff cannot support his FCA claims through the use of Form 885s must be denied.[11]

The question remains, however, whether plaintiff has adequately pleaded his FCA claims, particularly with regard to tying defendants' conduct to reimbursement from federal funds. The Court finds that under the standard announced in Foglia, along with the additional pleadings in plaintiff's TAC, plaintiff's FCA claims contained in Counts One and Two may proceed.

Foglia set forth two elements of viable FCA claim. First,

[11] Defendants argue that plaintiff has pleaded an express false certification claim and is foreclosed from asserting an implied false certification claim, which is the theory used to support the use of Form 885s as a predicate for a FCA claim. The Court does not read plaintiff's TAC to assert either an express or an implied false certification specifically, but rather a false certification claim generally, and finds that plaintiff's TAC is sufficient in this regard.

plaintiff has articulated the "particular details of a scheme to submit false claims": defendants' charitable donations are illegal kickbacks to garner referrals to defendants' products, and the patients funneled to defendants by the charitable donation kickbacks are given excessive gifts by defendants to secure their continued use of defendants' products. See Foglia, 754 F.3d at 158. Second, plaintiff has demonstrated in his pleadings "a strong inference that claims were actually submitted" for reimbursement for these illegally procured patient prescriptions from federal funds. See id. This element is supported by plausible statistical inferences, along with documents showing that several of defendants' customers are Medicare or Medicare recipients (e.g., plaintiff's exhibits Q and N).

Defendants argue that plaintiff has not provided specific proof regarding: the presentment of claims to the federal government, which defendant presented what claim,[12] documentation

[12] Defendants argue that plaintiff has not lodged any specific claims relating to Medco's conduct, but instead clumps the three defendants together. Plaintiff's claims against Medco are sufficient in that he claims that Medco holds the purse strings for the charitable donations, and Medco's sales representatives provide the excessive gifts. The discovery process will flush out the three entities' individual conduct, and defendants may make the appropriate motions should it be determined that any of these entities had no involvement in the circumstances of plaintiff's claims.

for those claims, the substantive nature of the claims, or any other details about particular reimbursements from federal funds. Under Foglia, plaintiff is not required to do any of these things at the pleading stage, particularly because such specific proofs are usually inaccessible to a *qui tam* plaintiff. "[R]equiring this sort of detail at the pleading stage would be 'one small step shy of requiring production of actual documentation with the complaint, a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates.'" Foglia, 754 F.3d at 156 (quoting United States ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009)). Ultimately, the purpose of a *qui tam* plaintiff's complaint is to provide defendants with fair notice of his FCA claims. See id. Plaintiff has done so in his third amended complaint.

2. FCA conspiracy and state law claims

Even though the Court has found that plaintiff may proceed with his two FCA counts, two other aspects of his complaint cannot go forward. First, plaintiff's conspiracy count is inadequately pleaded, and second, plaintiff's state law claims are wholly unsupported.

a. FCA conspiracy - Count Three

Plaintiff claims that the three defendants conspired to commit the FCA violations. Defendants argue that plaintiff's conspiracy claim fails because a parent company cannot be held to conspire with its subsidiaries.[13] Plaintiff contests defendants' position.

In order to state a conspiracy claim under the FCA, a plaintiff must allege "(1) a conspiracy to get a false or fraudulent claim allowed or paid; and (2) an act in furtherance of the conspiracy." U.S. ex rel. Lampkin v. Johnson & Johnson, Inc., 2013 WL 2404238, *5 (D.N.J. 2013) (citing U.S. ex rel. Atkinson v. PA. Shipbuilding Co., 473 F.3d 506, 514 (3d Cir. 2007); 31 U.S.C. § 3729(a)(3)). Critically, "[t]he essence of a conspiracy under the Act is an agreement between two or more persons to commit fraud." Id. (citation omitted).

In this case, even though plaintiff claims that Medco is the master of the alleged scheme, perpetrated by Accredo and HHS, what is lacking to support a conspiracy claim are allegations describing an agreement between the three entities to submit false claims. As pleaded by plaintiff, each entity allegedly engaged in conduct that related to the other and resulted in FCA violations. This interaction, however, as described by plaintiff in his complaint,

[13] Defendants also argue that plaintiff has not made any allegations that would support piercing Medco's corporate veil. The Court does not need to address this argument.

appears to be because of their relationship as a parent company and wholly owned subsidiaries, rather than an explicit agreement to commit fraud on the government.

The intra-corporate conspiracy doctrine, raised by defendants, contemplates the ramifications of this type of parent/subsidiary relationship. The doctrine provides that a wholly owned subsidiary is deemed incapable of conspiring with its parent company, and it has long been applied to conspiracy claims generally. See Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752, 777 (1984). The Supreme Court explained the reasoning of the doctrine:

> A parent and its wholly owned subsidiary have a complete unity of interest. Their objectives are common, not disparate; their general corporate actions are guided or determined not by two separate corporate consciousnesses, but one. They are not unlike a multiple team of horses drawing a vehicle under the control of a single driver. With or without a formal "agreement," the subsidiary acts for the benefit of the parent, its sole shareholder. If a parent and a wholly owned subsidiary do "agree" to a course of action, there is no sudden joining of economic resources that had previously served different interests, and there is no justification for § 1 scrutiny.

Copperweld, 467 U.S. at 771 (applying doctrine to anti-trust conspiracies).

The Third Circuit has applied the doctrine in several contexts, see, e.g., General Refractories Co. v. Fireman's Fund Ins. Co., 337 F.3d 297, 313 (3d Cir. 2003) (citing Heffernan v.

Hunter, 189 F.3d 405, 411 (3d Cir. 1999)), and although the Third Circuit has not specifically applied the doctrine to FCA conspiracy claims, other courts have. See U.S. ex rel. Miller v. SSM Health Care Corp., 2014 WL 2801234, *5 (W.D. Wis. 2014) (citing Chilcott v. KBR, Inc., 09–CV–4018, 2013 WL 5781660 (C.D. Ill. Oct. 25, 2013) ("[T]he intra[-]corporate conspiracy doctrine bars FCA conspiracy claims where all the alleged conspirators are either employees or wholly-owned subsidiaries of the same corporation."); United States v. Gwinn, No. 5:06–cv–00267, 2008 WL 867927, at *24–25 (S.D.W. Va. Mar. 31, 2008) ("[T]he Court holds that the intra[-]corporate conspiracy doctrine applies to conspiracy claims against agents of a corporation brought under the False Claims Act."); United States ex rel. DRC, Inc. v. Custer Battles, LLC, 376 F. Supp. 2d 617, 651–52 (E.D. Va. 2005) (applying intra-corporate conspiracy doctrine to False Claims Act); United States ex rel. Fago v. M & T Mortgage Corp., 518 F. Supp. 2d 108, 117–18 (D.D.C. 2007) (same); United States ex rel. Fent v. L–3 Communications Aero Tech LLC, No. 05–cv–0265–CVE–SAJ, 2007 WL 3283689 (N.D. Okla. Nov. 2, 2007) (same)).

The intra-corporate conspiracy doctrine makes sense in the context of the FCA conspiracy claim alleged in this case, and it would seem appropriate to apply it here to bar plaintiff's FCA conspiracy claim. As pleaded by plaintiff, it appears that any

"agreement" between Medco, Accredo, and HHS to perpetrate the charitable donations/excessive gifts scheme comes from a complete unity of interest under one corporate consciousness.

Even without the specific application of the intra-corporate conspiracy doctrine, however, plaintiff's conspiracy allegations still fail for similar reasons resulting from his pleading deficiencies. Accepting as true that Medco, Accredo, and HHS provided prohibited kickbacks to HANJ/HSI for referrals and gave excessive gifts to patients, and they falsely certified compliance with the FCA in order to be paid by the federal government for the prescriptions based on those referrals and gifts, plaintiff's allegations demonstrate a parent company interacting with its subsidiaries in the course of conducting its business, albeit a business in violation of the FCA. Plaintiff's allegations are lacking in a depiction of an explicit agreement between the entities to conspire to violate the FCA, which is the essential element of a FCA conspiracy claim. Should discovery reveal evidence to support the existence of such an agreement, plaintiff may seek leave to amend his complaint to revive his conspiracy claim, but as it is pleaded in his third amended complaint, it cannot stand.

b. State law claims

In his third amended complaint, plaintiff claims that defendants' conduct has also violated the false claims statutes of twenty-four states.[14] Defendants have moved to dismiss plaintiff's state law claims on several bases.

In addition to the fact that plaintiff has not opposed defendants' motion to dismiss his state law claims, the Court finds that they are entirely unsupported. Other than a dozen states mentioned in Exhibit Q, the complaint is devoid of any allegation of defendants' conduct relating to the remainder of the twenty-four states. For the states listed in plaintiff's exhibit, other than New Jersey, the notation that a certain patient receives a particular state's Medicaid cannot, without more, create viable claims that defendants violated those states' false claims acts. For plaintiff's claim that defendants violated New Jersey's false claims act, plaintiff has described alleged conduct that occurred in New Jersey, but the gravamen of plaintiff's allegations concern defendants' illegal claims for federal funds, not New Jersey state funds. See N.J.S.A. 2A:32C-3(a), (b), (c) (providing that a person is liable to the State for a civil penalty if he knowingly

[14] Plaintiff's third amended complaint filed on the docket appears to have been scanned in with missing pages. Plaintiff shall refile a fourth amended complaint to comply with this Court's holdings, and to correct the technical errors.

causes gets a false or fraudulent claim paid or approved by the State).[15] Consequently, all of plaintiff's state law claims must be dismissed without prejudice to the right of plaintiff to seek leave to revive any of his state law claims should discovery reveal a basis to do so.

CONCLUSION

Through additional allegations and the Third Circuit's recently announced standard for analyzing False Claims Act violation claims pursuant to Rule 9(b), plaintiff's third amended complaint states viable claims for violations of the False Claims Act contained in Counts One and Two of his complaint, and these claims may proceed. Plaintiff's False Claims Act conspiracy claim and all his state law claims are not sufficiently pleaded and must be dismissed. Accordingly, defendants' motion to dismiss plaintiff's claims will be granted in part and denied in part. As noted above, plaintiff shall file a fourth amended complaint consistent with this Opinion to serve as a blueprint for the case

[15] Moreover, as defendants point out, the New Jersey false claims act was not effective until March 2008, it is not applied retroactively, and much of the conduct alleged by plaintiff occurs before that date. State ex rel. Hayling v. Correctional Medical Services, Inc., 28 A.3d 1246, 1250 (N.J. Super. Ct. App. Div. 2011) (holding that the NJFCA is not retroactively applicable to conduct occurring prior to its effective date).

going forward.

An appropriate Order will be entered.

Date: September 25, 2014
At Camden, New Jersey

s/ Noel L. Hillman
NOEL L. HILLMAN, U.S.D.J.