381 F.Supp.3d 932
United States District Court,
N.D. Illinois, Eastern Division.

UNITED STATES, EX REL.
Ronald J. STRECK, Plaintiff,
v.
TAKEDA PHARMACEUTICALS
AMERICA, INC., et al., Defendants.

Case No. 14 C 9412
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Signed 04/03/2019

Synopsis

Background: Relator brought qui tam False Claims Act (FCA) action against drug manufacturers for allegedly defrauding Medicaid via their calculations of rebates owed under Medicaid Drug Rebate Program (MDRP), with one manufacturer allegedly discounting prices, resulting in reduced rebate, to account for payments to drug wholesalers for services, and other manufacturer allegedly lowering service fees it paid to wholesalers, fees not deductible from sales prices to reduce rebate, by offsetting service fees with price-appreciation credits (PACs) for wholesalers' excess inventory profits. Manufacturers filed motions to dismiss for lack of subject-matter jurisdiction and failure to state claim.

Holdings: The District Court, Harry D. Leinenweber, J., held that:

FCA first-to-file bar did not apply;

FCA public disclosure bar did not apply;

relator adequately alleged scienter element of his claims; and

relator pleaded fraud with sufficient particularity.

Motions denied.

Procedural Posture(s): Motion to Dismiss for Failure to State a Claim; Motion to Dismiss for Lack of Subject Matter Jurisdiction.

Attorneys and Law Firms

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MEMORANDUM OPINION AND ORDER

Harry D. Leinenweber, Judge

I. BACKGROUND

The relator, Ronald J. Streck ("Relator"), a former executive of a network of drug regional wholesalers, brings this *qui tam* action against Defendants, Astellas ***934** Pharma US, Inc. ("Astellas") and Eli Lilly and Company ("Lilly"). The action is being brought on behalf of the United States and 26 states. Neither the United States nor any of the states has sought to intervene.

The underlying facts of the case are not in dispute. The case involves the allegation that Astellas and Lilly defrauded Medicaid in violation of the False Claims Act and corresponding state statutes, when they calculated certain rebates owed under the Medicaid Drug Rebate Program ("MDRP"). This program is designed to offset the cost of prescription drugs dispensed to Medicaid patients. Participating manufacturers must pay the government a rebate of a portion of the proceeds of their drug sales that are covered by a state's Medicaid plan. The base for computation of the rebate is the Average Manufacturer's Price ("AMP"), which is the average price wholesalers pay participating manufacturers for drugs. The lower the AMP, the lower the rebate that the manufacturer must pay to the government. This case involves two separate methods that the defendants employed to lower their AMPs, which in turn lowered the rebates that they paid under the MDRP. The Relator contends that these methods, or "schemes," constitute fraud on the government and violate the False Claims Act.

According to the Complaint, Astellas, from April 1, 2005 through March 31, 2010, entered into agreements with drug wholesalers under which the wholesalers would provide "core services" to Astellas of real value to it, and in return, Astellas agreed to pay the wholesaler a payment of a percentage of gross purchases. These services included, among others, contract administration; inventory and sales reports; returns processing; and inventory management. The wholesale agreement allowed Astellas to account for these payments as discounts from its sales price which reduced its AMP, which in turn resulted in a reduced rebate under the MDRP. The Complaint classifies Astellas as a "Discount Defendant."

With respect to Lilly, the Complaint alleges what the Complaint describes as the "service fee scheme." According to the Complaint, Lilly adopted a method to reduce its AMP by deducting "price-appreciation credits" ("PACs") from the service fees it agrees to pay its wholesalers for performing services such as previously described as services performed by Astellas' wholesale customers. PACs were created to inhibit drug wholesalers from speculative buying to build up stocks of drugs in the hope that the manufacturers would increase their prices in the future. Such increases would enable a wholesaler to sell its extra inventory at a profit. To deter this practice manufacturers, such as Lilly, began to insert so-called

"clawback" provisions in their agreements with their wholesalers, which obligated the wholesalers to return their profits to the manufacturer. The clawback provisions, instead of providing for cash payments for these excess inventory profits, were structured so that the manufacturer received credits for these profits, known as "price appreciation credits" ("PAC"), which were used to offset the service fees the manufacturer paid to the wholesaler. By statute and regulation, however, the service fees incurred by a manufacturer, provided they are bona fide, are not deductible from its sale price when calculating its AMP. So, the service fee "scheme," as alleged in the Complaint, charges that Lilly, knowing that service fees were not deductible from its sales price, lowered its service fees by deducting the PACs, thereby increasing its profits without raising its AMP.

II. STATUTORY AND REGULATORY HISTORY

Since the adoption of the MDR Program in the 1990s, Congress and the Center for ***935** Medicare and Medicaid Services of the Department of HHS ("CMS") have adopted comprehensive statutes and regulations that govern the calculation of the AMP. In 1991 Congress defined AMP as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." 42 U.S.C. § 1396-8(k)(1). In 2006, Congress directed CMS to promulgate a regulation to clarify the requirements for determining the AMP. CMS responded with a regulation that, among other things, prohibited the inclusion of "bona fide service fees" ("BFSF") in the calculation of the AMP. BFSF were defined as:

> fees paid by manufacturer to an entity; that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. *Id.* at § 447.502 (2007).

The regulation also required the manufacturer to adjust the AMP for a specific rebate period if cumulative discounts, rebates, or other arrangements subsequently adjusted the prices that the manufacturer actually realized from the wholesaler.

In 2010, Congress enacted the Patient Protection and Affordable Care Act, a/k/a "Obama Care" (the "ACA"). As a result, CMS withdrew its 2007 regulation to account for the changes brought about by the ACA. Manufacturers were directed to comply with the ACA's statutory requirements, which included a prohibition of deducting fees paid for distribution service and inventory management fees from the AMP calculation.

In 2012, CMS proposed a regulation that largely tracked the 2007 regulation in defining service fees. CMS specifically mentioned PACs in the preamble to that proposed regulation. It said, "retroactive price adjustments, sometimes known as price appreciation credits, do not meet the definition of a bona fide service fee as they do not reflect any service or offset of a bona fide service performed on behalf of the manufacturer." 77 Fed. Reg. 5318,5332 (Feb. 2, 2012). However, the regulation adopted in 2016, did not mention PACs.

III. PREVIOUS LITIGATION

A. Streck I

The relator commenced his litigation in 2008 when he filed a *qui tam* action in the Eastern District of Pennsylvania. ("*Streck I*"). Both Astellas and Lilly, together with a number of other drug manufacturers, were named as Defendants. The government declined to intervene in the case against Astellas and Lilly and a number of other manufacturers. Streck then voluntarily dismissed Astellas and Lilly and some of the other defendants, from *Streck I*. However, the remaining Defendants, including both discount defendants and service fee defendants, moved to dismiss the Complaint, contending that the statutory and regulatory requirements governing the AMP were ambiguous, that their interpretations were reasonable, and therefore that the complaint should be dismissed for failing plausibly to plead scienter. The District Court denied the motion with respect to the discount defendants but granted the motion with respect to the service fee defendants. The discount defendants then settled with the relator and the relator appealed the dismissal of the service fee defendants to the Third Circuit. That court affirmed the dismissal in a non-precedential opinion. *U.S. v. Allergan, Inc.*, 746 Fed. Appx. 101 (3rd Cir. 2018).

*936 B. Streck II

In 2013, Streck filed a new lawsuit in the Eastern District of Pennsylvania, *U.S. ex rel. Streck v. Bristol-Myers Squibb Company* ("BMS") ("*Streck II*"), against several drug manufacturers including BMS. Streck dismissed all Defendants from the case save BMS. BMS, according to the Complaint, engaged in both the service fee scheme and the discount fee scheme. The Complaint charged that "[a]t various times [BMS] deducted service fees from the calculation of the AMP and at other times it deducted the price appreciation credits from the service fees, when it did not deduct the service fees from the calculation of the AMP." Recently the District court denied BMS's motion to dismiss concluding that the complaint plausibly alleged falsity, scienter, and materiality, and complied with Rule 9(b).

C. Streck III

The relator filed this suit in 2014 on behalf of the United States and 28 states plus the District of Columbia, against various defendants, including Astellas and Lilly ("*Streck III*"). In January 2018, the federal government notified the Court that it was declining to intervene with respect to Astellas and all other defendants save Lilly, which it was continuing to investigate. The relator then voluntarily dismissed all defendants except Astellas and Lilly. Defendants filed a motion to dismiss, after which the Relator filed a first amended complaint. The relator in this complaint, as was

the case with his previous complaints, alleged that Astellas and Lilly improperly accounted for service fees paid to wholesalers and, in doing so, improperly reduced their AMPS, which in turn improperly reduced their rebate obligations. Astellas also is alleged to have wrongfully treated all service fees it paid to wholesalers as deductions in computing its AMP (a "Discount Defendant"). Lilly is alleged to have wrongfully deducted price appreciation credits from the service fees it paid to manufacturers, improperly reducing its AMP. ("Service Fee Defendant").

Defendants, Astellas and Lilly, have once again filed Motions to Dismiss, one, for lack of jurisdiction pursuant to Rule 12(b)(1) and, two, for failure to state a claim pursuant to Rule 12(b)(6).

IV. THE RULE 12(B)(1) MOTION

According to Defendants' Rule 12(b)(1) Motion, *Streck III* runs afoul of two provisions of the Federal False Claim Act: Section 3750(b)(5), the so-called "first to file bar," and Section 3750(e)(4)(A), the "public disclosure" bar. Accordingly, the court does not have jurisdiction.

The basis for the first to file bar claim is that at the time the Relator filed this suit against Astellas and Lilly, Streck I was a pending action in a Pennsylvania District Court. Section 3750(b)(5) states "[w]hen a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." Defendants, in arguing for dismissal, argue that *Streck I* was filed on October 28, 2008, and *Streck III* was filed on November 24, 2014, while *Streck I* was still pending (it was not over until the Third Circuit affirmed the dismissal in 2018). They also contend that the two actions are "related," citing *U.S. ex rel. Chovanec v. Apria Healthcare Group Inc.*, 606 F.3d 361, 365 (7th Cir. 2010), because they rely upon essentially the same factual scenarios.

The Relator contends however that, at the time of the filing of *Streck III*, Astellas and Lilly had been voluntarily dismissed from *Streck I* and been out of the case for over three years prior to the filing of *Streck III*. He also cites *Covanec for* the ***937** test of relatedness: whether the two actions are "materially similar," *i.e.,* whether the two cases have the material facts in common. He argues that the defendants are different, the service agreements upon which the alleged frauds are based are different, and the actual drug purchases are different, although the general scheme may be common.

The Relator is correct on his first point: because Astellas and Lilly had been dismissed but not on the merits, *i.e.*, without prejudice, a dismissal here, as sought by defendants, would, in effect, constitute a "dismissal with prejudice" and would insulate defendants from any future *qui tam* actions based on the two schemes. Such a result that would be contrary to the approach the Supreme Court took in *Kellogg Brown & Root Services, Inc. v U.S. ex rel. Carter*, —— U.S. ——, 135 S. Ct. 1970, 1978, 191 L.Ed.2d 899 (2015). In *Kellogg Brown & Root*, the relator's case was dismissed without prejudice under the first to file bar because a previous *qui tam* case having similar claims was pending and was considered to be a related case. While the relator's appeal of

the dismissal was pending, the so-called related case was dismissed for want of prosecution. The relator immediately filed a new complaint, which the court again dismissed on the basis of the first to file bar, because the relator's first case was pending on appeal. The relator then voluntarily dismissed the appeal and filed a new complaint which was against dismissed, but this time with prejudice. On appeal to the Supreme Court, the case was reversed and remanded to remove the "with prejudice" provision as being error, because it was based on an improper interpretation of the word "pending." The Supreme Court said:

> [n]ot only does petitioners' argument push the term "pending" far beyond the breaking point, but it would lead to strange results that Congress is unlikely to have wanted. Under petitioners' interpretation, a first-filed suit would bar all subsequent related suits even if that earlier suit was dismissed for a reason having nothing to do with the merits.
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> [w]e hold that a qui tam suit under the FCA ceases to be "pending" once it is dismissed. We therefore agree ... that the dismissal with prejudice ... was error.

The point the Supreme Court was making was that Congress would not have wanted a dismissal, which was not on the merits, to act as a bar to a subsequent effort to recover funds for the government which may have been lost due to fraud. Here, like in *Kellogg, Brown & Root,* the claims against Astellas and Lilly were dismissed without reaching the merits.

The Relator also makes the additional point that the first to file bar is not jurisdictional. *U.S. ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112 (D.C. Cir. 2015); *U.S. ex rel. Berkowitz v. Automation Aids*, No. 13 C 08185, 2017 WL 1036575, at *10 (N.D. Ill. Mar. 16, 2017).

The Defendants' second basis for dismissal is the prior public disclosure bar. This provision of the False Claims Act reads as follows:

> The court shall dismiss an action or claim under this section, unless opposed by the Government. If substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed - (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report hearing audit, or investigation, or (iii) from the news media. Unless the action is brought by the Attorney General ***938** or person bringing the action is an original source of the information.

The government has filed its notice of opposition to dismissal on this ground. The government's right to object was created in a 2010 amendment to the False Claims Act,

so the objection only applies to claims arising on or after March 23, 2010. The government however has taken no position as to claims arising prior to that date. The issue is whether a refiling of a case against two defendants who were originally named in a prior suit but who were dismissed without prejudice, *i.e.,* not on the merits, warrants dismissal with prejudice because of the public disclosure bar. The answer here should be the same as the answer was to the motion to dismiss a *qui tam* suit with prejudice under the first to file bar. Why should a possible claim under False Claims Act be dismissed with prejudice because the claim had been previously dismissed for reasons other than the merits? If Streck was the original source of the false claims alleged against Astellas and Lilly in *Streck I*, then why would he not be the original source in *Streck III*, which is essentially the same case as *Streck I* but with considerably more detail pled with respect to Astellas and Lilly? What we have is a *qui tam* action filed against Defendants in *Streck I*, which was dismissed against Astellas and Lilly on Relator's motion for reasons other than the merits. *Streck III*, a refiling of *Streck I*, which at the time was no longer pending against Astellas and Lilly, if dismissed because of the public disclosure bar, would amount to a dismissal with prejudice, and would raise the same question the Supreme Court posed in *Kellogg Brown & Root*, "[w]hy would Congress want the abandonment of an earlier suit to bar a later potentially successful suit that might result in a large recovery for the Government?" *Id.* at 1978.

The cases cited by Defendants do not require a different result. In *U.S. ex rel. Lisitza v. Par Pharm. Companies, Inc.*, No. 06 C 06131, 2017 WL 3531678 (N.D. Ill. Aug. 17, 2017), an alleged prescription-switching scheme, was well known to the government at least four years before the Relator filed his suit. In *U.S. ex rel. Bogina v. Medline Indus., Inc.*, No. 11 C 05373 2015 WL 1396190 (N.D. Ill. Mar. 25, 2015), involved a second complaint by a different relator, that basically parroted the allegations of an earlier complaint. The fact that Streck was the same Relator involved in both *Streck I* and *Streck III* is the difference. The Rule 12(b)(1) Motion is denied.

V. THE RULE 12(b)(6) MOTION

The Defendants have moved to dismiss the *qui tam* action under Rule 12(b)(6) and also for lack of specificity under Rule 9(b). With respect to Lilly, the Defendant asks the Court to follow the Third Circuit's decision in *Streck I* which was a "non-precedential" decision. The Third Circuit decision does not help Astellas because it concerned only "service fee" defendants and not "discount defendants." *See Allergan*, 746 Fed. Appx. at n.2.

The Third Circuit's decision in favor of the service fee defendants was based on its conclusion that the applicable requirements for calculating the AMP failed to specify whether the AMP is the "initial price" or the "cumulative price" realized by the manufacturer. The court began its analysis by noting that the PCA imposes liability on any person who "knowingly" makes a false claim to the government. 31 USC § 3729(a)(1)(A). A person acts "knowingly" if he or she "acts in reckless disregard of the truth or falsity of ... information." § 3729(b)(1)(A)(iii). The court in part relied upon the Supreme Court's decision in *Safeco Ins. Co.*

of Am. v. Burr, 551 U.S. 47, 127 S. Ct. 2201, 167 L.Ed.2d 1045 (2007), which suggested three inquiries as to whether a decision was based on a ***939** reasonable, but erroneous interpretation of a statute: (1) whether the relevant statute was ambiguous; (2) whether a defendant's interpretation of that ambiguity was objectively unreasonable; and (3) whether a defendant was "warned away" from the interpretation by available administrative and judicial guidance. *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 127 S. Ct. 2201, 167 L.Ed.2d 1045 (2007); *United States ex rel. Purcell v. MWI Corp*, 807 F.3d 281, 287-88 (D.C. Cir. 2015). The Third Circuit found that the definition of AMP was ambiguous with regard to price appreciation credits, by noting that nowhere did a statute or a regulation address PACs. It agreed that PACs could be considered a component of the cumulative value that the manufacturer receives for a drug, but it noted that neither the word "initial" nor the word "cumulative" appears before "price" in the statute and regulation. The court agreed with the District Court that the "price paid to the manufacturer" could be read as referring to the price initially paid by the wholesaler because the versions of the statute and regulations lacked "temporal" limitations when referring to "price." Whether there was any guidance that could have warned the manufacturers about their use of PACs, the Court noted that the CMS as well as OIG suggested that there was significant confusion regarding what to include in an AMP calculation, and PACs were not addressed by the CMS until 2012, and even then it did not do so definitively, when it expressed its belief in a non-binding preamble that PACs should not be considered a service fee. The court further noted that the ensuing regulation, which was not adopted until 2016, did not mention PACs.

Streck, on the other hand, asks the Court to follow *U.S. ex rel. Streck v. Bristol-Myers Squibb* (*Streck II*), No. No. 13-7547, 2018 WL 6300578 (E.D. Pa. Nov. 29, 2018), which found that BMS, as a service fee defendant during some of the time period in question, failed to heed the guidance given in 2012 by CMS where it opined that PACs did not meet the definition of a bona fide service fee. That court found that Streck had "plausibly" pled that BMS had been warned that it was incorrectly calculating its AMP by considering PACs as deductible from service fees. It therefore denied BMS's motion to dismiss the allegations relating to the Service fee scheme.

The BMS court also discussed the discount scheme. It was noted that the law and regulations prior to 2007 were silent as to how to treat bona fide service fees and whether they could be considered as discounts in calculating a manufacturer's AMP. However, in 2007 CMS identified certain specific types of discounts that were not allowed in calculating the AMP and further stated that bona service fees also could not be included in the calculation. In the 2010 regulation, inventory management and distribution services were specifically excluded from the AMP because these were considered to be bona fide service fees. In 2012 the district court in Pennsylvania (*Streck I*), as previously noted, denied a motion to dismiss brought by discount defendants, based on its conclusion that from 2007 onward CMS had provided guidance to manufacturers that they should not include bona fide service fees in the calculation of the AMP. *Streck I*, 894 F.Supp.2d at 598.

Thus, manufacturers were forewarned by both the CMS and a federal district court not to consider service fees as discounts.

The issue here is whether this Court should follow the Third Circuit (*Streck I*) or follow the Pennsylvania Eastern District Court (*Streck II*). Since the case is before the Court on a Motion to Dismiss where the Court should take all well pleaded facts as true, the balance tips in the favor of denial of the Rule 12(b)(6) Motions to Dismiss. The issue is admittedly ***940** clearer on the question of Discount defendants. As noted by the District Court Judge in *Streck II*, the CMS had clearly advised as early as 2010 that inventory management and distribution fees were bona fide service fees and were not to be considered in calculating the AMP. Earlier than that, the CMS regulations in 2007 stated that bona fide service fees were to have no effect on the computation of the AMP. In 2012, the District Judge in *Streck I* denied the discount defendant's motion to dismiss finding that a discount defendant was "reckless" for classifying service fees as discounts. The Court therefore finds that the Complaint adequately alleges sufficient facts to prove scienter with respect to Astellas and the discount scheme allegations in the Complaint.

With respect to the service fee Defendant Lilly, and apparently Astellas at times, the Court finds, in agreement with the District Judge in *Streck II,* that the preamble to the 2012 proposed regulation was sufficiently clear with respect to treatment of PACs, that, coupled with the wording of the 2007 regulation, which stated that a manufacturer "must adjust the AMP for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized" (72 DE R 39,242), were sufficient to have warned defendants away from including PACs in the computation of their AMPs. Thus, the Complaint, as with the discount defendant, Astellas, adequately alleges scienter with respect to Lilly, the service fee defendant. The issue of scienter can be revisited at the summary judgment stage when the Court will have a more complete record.

VI. RULE 9(b)

The Defendants lastly argue that the Complaint fails to satisfy Rule 9(b) due to lack of specificity with respect to the allegations of false AMP submissions. However, the Complaint clearly alleges that Astellas subtracted the service fees it paid from the prices it received from the wholesalers, thus treating these fees as "discounts." Furthermore, the service fees are clearly alleged to be "bona fide service fees." The Complaint also clearly alleges that Lilly deducted PACs from the bona fide service fees it contracted to pay to its wholesalers, thus reducing the total amount of money it paid for these service fees, which reduced its AMP. As explained by the district court in *Streck I*:

> In this case, while Plaintiff has not provided the exact claims filed by Defendants that are allegedly fraudulent, Plaintiff did provide specific contracts between Defendants and wholesalers. Plaintiff detailed how the alleged fraud occurred. Plaintiff specified the statutory and regulatory provisions violated, and also indicated that Defendants had to file the wire AMP reports with the Government "not later than 30 days after the last day of each rebate period under

> the agreement." 42 U.S.C. § 1396r-8(b)(3)(A)(i). This detail is sufficient to meet the particularity requirement of Rule 9(b) in this case.

U.S. ex rel. Streck v. Allergan, 894 F.Supp.2d 584, 602 (E.D. Pa. 2012).

The Court agrees and finds that the Complaint sufficiently provides details of the two alleged schemes to satisfy Rule 9(b). Therefore, the Motions to Dismiss under Rule 12(B)(6) and Rule 9(b) are denied.

VII. CONCLUSION

For the reasons stated herein, Defendants' Rule 12(b)(1) and Rule 12(b)(6) Motions to Dismiss are denied.

IT IS SO ORDERED.

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