IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel*. RONALD J. STRECK	:	
v.	:	
BRISTOL-MYERS SQUIBB COMPANY	:	**CIVIL ACTION NO. 13-7547**

MEMORANDUM OPINION

Savage, J. **November 29, 2018**

In this *qui tam* action brought under the False Claims Act (FCA), 31 U.S.C. § 3729-33, and various state false claims laws,[*] relator Ronald J. Streck, a pharmacist and lawyer who once served as the chief executive officer of an association of prescription drug manufacturers,[1] alleges that Bristol-Myers Squibb (BMS) fraudulently manipulated the calculation of the Medicaid rebate it owed. As a result, BMS paid substantially less than it owed from 2007 to 2016.

In moving to dismiss, BMS argues that Streck fails to state an FCA claim because he offers no plausible basis for concluding that (1) it violated any regulatory requirement; (2) it acted with the requisite scienter; and (3) any purported violations were material. Alternatively, BMS contends that Streck's allegations of fraud do not satisfy Rule 9(b)'s heightened pleading requirements.[2]

We conclude that Streck has alleged sufficient facts to state a false claims cause of action. He alleges facts which, if proven, will establish that BMS knowingly or, at least, recklessly reported and paid lower rebates than it owed. Therefore, we shall deny BMS's motion to dismiss.

Background

The purpose of the Medicaid Drug Rebate Program (Program) is to ensure that Medicaid "should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy." H.R. REP. No. 101–881, at 96 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108. The Program provides for "a rebate mechanism in order to give Medicaid the best price for which a manufacturer sells a prescription drug to any public or private purchaser." *Id.* To qualify for Medicaid payments, drug companies must provide rebates to state Medicaid programs on the companies' Medicaid sales of outpatient prescription drugs. *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652 (2003).

The crucial component of the rebate calculation is the Average Manufacturer Price ("AMP"). AMP is the price a wholesaler pays the manufacturer on a per-unit basis for a drug. 42 U.S.C. § 1396r–8(k)(1)(A) (2010). *See also United States ex rel. Streck v. Allergan, Inc*. (*Streck I*), 894 F. Supp. 2d 584, 588 (E.D. Pa. 2012). The manufacturer calculates the AMP for each drug and reports it to the Center for Medicaid and Medicare Services (CMS) on a quarterly basis.[3] CMS relies on the AMP provided by the manufacturer to determine the amount of the rebate the manufacturer owes the states.[4]

For brand name drugs, the rebate is calculated as the greater of (1) the difference between the "best" or lowest price other purchasers pay the manufacturer for the drug and the AMP, or (2) a percentage of the AMP. 42 U.S.C. § 1396r–8(c)(1)(A)(ii). The generic drug rebate is a percentage of the AMP. *Id.* § 1396r-8(c)(3)(A)(i)-(ii). The percentage for brand name drugs is currently 23.1 percent, and for generic drugs, 13 percent.[5] *Id.* § 1396r–8(c)(1)(B)(i)(6), (3)(B)(iii).

In calculating AMP, a manufacturer must include all discounts offered to distributors. *Id.* § 1396r-8(k)(1)(B)(ii). A discount decreases AMP, reducing the difference between AMP and the best price and resulting in a lower rebate the manufacturer must pay.[6] A manufacturer must also include additional payments from distributors in calculating AMP. *Id.* § 1396r-8(k)(1)(B)(ii). *See also* Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170, 5228 (Feb. 1, 2016). Additional payments raise AMP, increasing the difference between AMP and the best price and resulting in a greater rebate.[7]

Streck contends that BMS engaged in two practices, each at a different time, that fraudulently lowered the AMP it reported. The schemes were embodied in its distribution service agreements. These agreements required the distributors to perform various services for BMS in the distribution process.[8] In return, BMS paid them a percentage of the total sales price of all drugs they purchased, reducing the AMP.[9]

Through the discount scheme, BMS underreported AMP by mischaracterizing service fees as discounts in order to deduct them from AMP. Through the service fee scheme, BMS underreported AMP by offsetting price increases against service fees owed to distributors in order to avoid including the increases in AMP.

Discount Scheme

According to Streck, from January 1, 2007, through December 31, 2013, BMS fraudulently underreported AMP by improperly deducting service fees from the price.[10] The agreements described services provided by the distributors, including inventory management, warehousing goods, distributing products, accounting and other services,[11]

for which BMS paid a percentage of the total sales of drugs purchased from BMS.[12] The parties calculated this fee as a 1.33% reduction of the invoice price.[13]

Streck contends these discounts were "bona fide service fees."[14] Unlike discounts and price increases, bona fide service fees are excluded from AMP. 42 C.F.R. § 447.504(c)(14) (2007). Thus, by characterizing fees paid for inventory, warehousing, distribution, and accounting services as discount fees rather than bona fide service fees, BMS reported lower AMPs because it deducted the amount of the fee from the price the distributors paid for the drug, reducing the rebate.[15]

Service Fee Scheme

From January 1, 2014, through March 31, 2016, BMS employed "price appreciation" clauses in its service agreements to disguise its price increases as service fees.[16] These provisions required distributors to reduce the service fee they charged BMS by the amount of additional revenue they realized by selling already purchased stock at the new higher price.[17] If BMS increased the price of a drug, the agreements required the distributor to credit BMS for "any value realized by Distributor as a result of that change (*e.g.*, appreciation on Distributor's Actual Inventory based on any change in [price].)"[18] In other words, when BMS increased the price of a drug, BMS decreased the service fee it owed by the amount of the distributor's units of inventory of that drug, multiplied by the amount of the price increase.[19] Streck avers that instead of factoring price increases into AMP, BMS defined them as service fees in order to underreport AMP.[20]

Standard of Review

A Rule 12(b)(6) motion tests the sufficiency of the allegations contained in the complaint. To survive a Rule 12(b)(6) motion, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

A conclusory recitation of the elements of a cause of action is not sufficient. *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008). The plaintiff must allege facts necessary to make out each element. *Id.* (quoting *Twombly*, 550 U.S. at 563 n.8). In other words, the complaint must contain facts which, if proven later, support a conclusion that a cause of action can be established.

In considering a motion to dismiss under Rule 12(b)(6), the court must first separate the factual and legal elements of a claim, accepting the well-pleaded facts as true and disregarding legal conclusions. The court next determines whether the facts alleged, if proven, show that the plaintiff has a plausible claim for relief. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009) (quoting *Iqbal*, 556 U.S. at 679). In making this determination, all well-pleaded allegations of the complaint must be accepted as true and interpreted in the light most favorable to the plaintiff, and all inferences must be drawn in the plaintiff's favor. *See McTernan v. City of York*, 577 F.3d 521, 526 (3d Cir. 2009).

A court may consider only the complaint, exhibits attached to the complaint, matters of public record and undisputedly authentic documents to the extent the plaintiff bases its claims upon them. *Hartig Drug Co., Inc. v. Senju Pharm. Co., Ltd.*, 836 F.3d 261, 268 (3d Cir. 2016) (*citing Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010)).

In the context of an FCA claim, a plaintiff must 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 v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156 (3d Cir. 2014) (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) and citing *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998-99 (9th Cir. 2010)). It is not enough to describe "a mere opportunity for fraud." *Id.* at 158. The plaintiff must allege sufficient facts to establish "a plausible ground for relief." *Id.* (quoting *Fowler*, 578 F.3d at 211).

Statutory Scheme for AMP Calculations

Legislative and regulatory history reveals that the government has been concerned with manufacturers seeking ways to artificially reduce rebates. To curb drug manufacturers' persistent efforts to manipulate the calculation of AMP to reduce rebates, Congress has tightened the definition of AMP and CMS has issued regulations limiting what can be deducted from AMP.

Prior to 2007, Congress had defined AMP as follows:

> The term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, 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, after deducting customary prompt pay discounts.

42 U.S.C. § 1396r-8(k)(1) (1997).

In 2007, Congress eliminated customary prompt pay discounts as a deduction:

> Subject to subparagraph (B) [excluding customary prompt pay discounts], the term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, 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. § 1396r-8(k)(1)(A) (2007).

In October 2007, CMS issued regulatory guidance for calculating AMP:

> AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. AMP shall be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation.
> . . .
>
> Sales, rebates, discounts, or other price concessions excluded from AMP. AMP excludes--
> . . .
>
> Bona fide service fees;
> . . .
>
> AMP includes cash discounts except customary prompt pay discounts extended to wholesalers, free goods that are contingent on any purchase requirement, volume discounts, chargebacks, incentives, administrative fees, service fees, distribution fees (except bona fide service fees), and any other rebates, discounts, or other price concessions, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to the retail pharmacy class of trade.

42 C.F.R. § 447.504(a), (h)(19), (i)(1) (2007).

Hence, after October 2007, bona fide service fees were explicitly excluded from the AMP calculation. To avoid uncertainty, CMS defined bona fide service fees as:

> [F]ees paid by a 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. § 447.502 (2007).

During the comment period, CMS clarified that to determine whether a distributor has passed on a fee, it was adopting the presumption applicable in the Medicare "average sales price" (ASP) context. "If a manufacturer has determined that a fee paid meets the other elements of the definition of 'bona fide service fee,' then the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on . . . ." Medicare Program; Revisions to Payment Policies, 71 Fed. Reg. 69624, 69669 (2006). *See also* Medicaid Program; Prescription Drugs, 72 Fed. Reg. 39142, 39182 (2007) (adopting ASP reporting rules).

In 2010, the Patient Protection and Affordable Care Act (ACA) changed the statutory definition of AMP. In doing so, the ACA included fees for inventory management and distribution in the definition of bona fide service fees, and specifically excluded them from AMP.

> (1) Average manufacturer price
>
> (A) In general
>
> Subject to subparagraph (B), the term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by—
>
> (i) wholesalers for drugs distributed to retail community pharmacies; and
>
> (ii) retail community pharmacies that purchase drugs directly from the manufacturer.
>
> (B) Exclusion of customary prompt pay discounts and other payments
>
> (i) In general
>
> The average manufacturer price for a covered outpatient drug shall exclude
>
> (I) customary prompt pay discounts extended to wholesalers;

> (II) bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);
>
> . . .
>
> Notwithstanding clause (i), any other discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies shall be included in the average manufacturer price for a covered outpatient drug.

42 U.S.C. § 1396r–8(k)(1).

Recognizing that the ACA legislation superseded regulatory authority and had become the controlling law on how to calculate AMP, CMS repealed 42 C.F.R. § 447.504, which had previously governed such calculations. Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs, 75 Fed. Reg. 69591, 69593 (Nov. 15, 2010). On February 2, 2012, CMS proposed a new rule to clarify what was excluded from AMP and to address possible fraud in using bona fide service fees to disguise discounts. In the proposal, CMS expressed that it "continue[s] to be concerned that these fees could be used as a vehicle to provide discounts, as opposed to fees at 'fair market value' for bona fide services. Thus, to avoid potential fraud concerns, we are retaining our definition [of bona fide service fees]." Medicaid Program; Covered Outpatient Drugs, 77 Fed. Reg. at 5332. The proposed rule further specified that "retroactive price adjustments, sometimes also 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." *Id.*

The final rule adopted four years later retained the four-part definition of bona fide service fees. 42 C.F.R. § 447.502 (2016). It defines excludable bona fide service fees as fees paid by a manufacturer to "an entity" that: (1) "represent fair market value" of (2) a "bona fide, itemized service actually performed on behalf of the manufacturer" (3) the manufacturer "would otherwise perform (or contract for) in the absence of the service arrangement," and (4) "are not passed on in whole or in part to a client or customer of an entity." *Id*. As the ACA had previously articulated, bona fide service fees include, but are not limited to, "distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs." *Id.*

CMS did not define "fair market value." Instead, it characterized the determination as "by nature subjective" and encompassing "a range of values" because "manufacturers should retain flexibility in determining whether service fees are paid at fair market value in light of constant changes in the pharmaceutical marketplace." Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. at 5179, 5180.

Regarding price appreciation credits, CMS explained in comments accompanying the final rule why such credits "would likely not meet the definition of bona fide service fee." Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. at 5225. According to CMS:

> Based on our experience with the program, it is our understanding that price appreciation credits are not issued for the purposes of payment for any service or offset for a bona fide service performed on behalf of the manufacturer, but rather are issued by the manufacturer to adjust (increase)

> the wholesaler's purchase price of the drugs in such instances when the drugs were purchased at a certain price and are remaining in the wholesaler's inventory at the time the manufacturer's sale price of the drug increased. In such situations, these credits would amount to a subsequent price adjustment affecting the average price to the manufacturer and should be recognized for purposes of AMP in accordance with [42 C.F.R.] § 447.504(f).

Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. at 5228.

This history of the governing regulatory and statutory framework reflects a continuing concern with drug manufacturers' attempts to manipulate AMP. Congress began to limit what manufacturers may consider in calculating AMP when it excluded prompt pay discounts from AMP, as of January 1, 2007. Later that year, when delineating the discounts includible in AMP, CMS excluded bona fide service fees. In 2010, Congress specified what fees were bona fide service fees that are not includible in AMP. In 2012, amidst concerns that manufacturers continued to deduct certain bona fide service fees, CMS issued guidance stating that price appreciation credits were not bona fide service fees that can be excluded from AMP.

Streck I **District and Appellate Court Decisions**

Additional guidance came in 2012 when Judge Robreno addressed allegations similar to those Streck makes here. In *Streck I*, Streck had brought FCA claims against two groups of pharmaceutical manufacturers, "Discount Defendants" and "Service Fee Defendants."[21] He alleged that each set of defendants engaged in a scheme that functioned like those he describes here. There, he alleged that Discount Defendants characterized certain bona fide service fees as discounts which they deducted from AMP, and Service Fee Defendants required wholesalers to credit any inventory price increases against their service fees, "effectively hid[ing] the true price paid by wholesalers" and reducing AMP. *Streck I*, 894 F. Supp. 2d at 589. Defendants moved to dismiss, arguing

primarily that Streck had failed to plead scienter in light of the ambiguous regulatory framework.[22]

Observing that the 2007 CMS guidance for calculating AMP constituted a "definitive change" to the existing regulatory framework, Judge Robreno began his analysis of the claims against Discount Defendants by dividing them into those that arose before and after that point. *Id.* at 594. As for the pre-2007 claims, he found that "[t]here was simply no guidance – within the statute itself, regulations, or from the courts – of what types of services could be discounted and what types of services should be excluded from AMP calculations." *Id.* at 596. Thus, nothing "warned [Discount Defendants] away from the view [they] took," and they had not acted with the recklessness required to give rise to an FCA claim. *Id.* (quoting *Safeco Ins. Co. of Am. V. Burr*, 551 U.S. 47, 70 (2007)).

The 2007 regulations removed any uncertainty about including bona fide service fees in AMP. As Judge Robreno found, "[w]ith the 2007 change in the law, some statutory guidance put Discount Defendants on notice that fees that were at one time allowed to be included within AMP were no longer allowed." *Id.* at 597. He noted that "the CMS regulations promulgated in October 2007 confirmed this significant change [in the calculation of AMP] by delineating the specific types of discounts allowed under AMP calculations and also confirming that a fee known as a bona fide service fee could not be included within Discount Defendants' AMP calculations." *Id.* The question became whether Streck's allegations plausibly showed that "Discount Defendants were at least reckless in concluding that their service agreements were not for bona fide services" such that Discount Defendants could characterize the service fees as discounts and include them in AMP. *Id.*

In answering this question, Judge Robreno observed that the complaint lacked any "facts that state the service fees paid under the contracts are a fair market value for the services rendered by the wholesalers to Discount Defendants," but that this absence was "not fatal" at the motion to dismiss stage because Streck had pleaded "other facts" that plausibly demonstrated Defendants had in fact contracted for bona fide services in their agreements with wholesalers. *Id.*

These "other facts" included indications in "several of the agreements themselves . . . that wholesalers believed the service fees to be bona fide service fees, despite Discount Defendants' conclusion that they were discounts." *Id.* (quoting the language of the agreements, including the wholesaler's warranties that "the fees are bona fide fees for service" and that "the payments are a bona fide fee for service provided under this agreement"). Indeed, Judge Robreno concluded that Discount Defendants' classification of the fees as "discounts" could itself serve as evidence of their culpable mental state. Because Service Fee Defendants had contracts for similar services with their wholesalers, and those Defendants had admitted "that such services were bona fide services," Discount Defendants had shown "a sense of awareness to call the service fees discounts" not only "in the face of the change in the statutory and regulatory landscape in 2007," but also "in the face of other manufacturers and wholesalers stating otherwise . . . ." *Id.* at 597-98. Consequently, Judge Robreno denied the motion to dismiss as to the post-2007 discount scheme claims. *Id.* at 598.

With respect to Service Fee Defendants, the issue was "not whether those Defendants had service agreements for bona fide services," but "whether those service agreements could properly contain what Plaintiff avers were retroactive price

adjustments" disguised as reduced service fees. *Streck I*, 894 F. Supp. 2d at 599. He determined that Streck had failed to plead how price appreciation credits "change[ ] in any way the price paid to the manufacturer for the drug by the wholesaler." *Id.* at 600. Noting "the dearth of guidance on price appreciation credits" (at least during the period at issue), Judge Robreno found that Service Fee Defendants had not acted "unreasonabl[y], let alone reckless[ly]," in concluding "that the 'price paid to the manufacturer' under AMP is just that, the price initially paid to the manufacturer by the wholesaler." *Id.* He further explained:

> This does not include any additional profits manufacturers' claw back after a price increase because the price actually paid for the drugs does not change. The price credit certainly cuts into the wholesaler's *additional* profits from a price increase. But the price credit does not appear to alter the wholesaler's initial profits and, therefore, does not alter the price [the] wholesaler paid for the drug.

Id. (emphasis in original).

Judge Robreno found that this "dearth of guidance" provided cover for the Service Fee Defendants. *Id.* "Even assuming that these price credits or retroactive price adjustments were not permissible as a payment method for service fees, there was simply no statutory or regulatory guidance to that effect for Service Defendants to consider." *Id.* In fact, the only contrary guidance appeared seven months after Streck had filed his last amended complaint when, on February 2, 2012, CMS issued the proposed rule advising that "retroactive price adjustments, sometimes also 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." *Id. See also* Medicaid Program; Covered Outpatient Drugs, 77 Fed. Reg. at 5332. In light of this lack of regulatory guidance, Judge Robreno decided that Streck had not alleged facts to

support an inference that Service Fee Defendants "engaged in 'the unjustifiably high risk of violating the statute necessary for reckless liability.'" Thus, he dismissed the price appreciation claims against the Service Fee Defendants. *Streck I*, 894 F. Supp. 2d at 600 (quoting *Safeco Ins. Co. of Am.*, 551 U.S. at 70).

Streck appealed the dismissal of the claims against Service Fee Defendants. On August 16, 2018, the Third Circuit Court of Appeals affirmed the dismissal and issued a non-precedential opinion. *United States ex rel. Streck v. Allergan* (the *Streck Appeal*), No. 17-1014, 2018 WL 3949031, at *1, -- F. App'x – (3d Cir. Aug. 16, 2018) (unpublished opinion). The panel framed the issue as "whether the District Court properly dismissed [Streck's complaint] for failure to allege the [Service Fee Defendants] acted with the required mental state." *Id.* at *3. In resolving this issue, the panel first analyzed whether the regulatory framework "unambiguously required price-appreciation credits to be added to the price paid by wholesalers." *Id.* at *4. It observed that under the service agreements the initial value paid to acquire drugs does not include price appreciation credits. *Id.* at *5. Rather, in order to activate the credit, the wholesaler must distribute the drug to a third party after the manufacturer has increased the price of the drug beyond that paid by the wholesaler. *Id.* In addition, the credit's value depends not only on the price the wholesaler initially pays the manufacturer, but also on "the ultimate price" the former obtains from its buyer. *Id.*

The panel acknowledged that "a price-appreciation credit that remits value back to the manufacturer could be considered a component of the cumulative value a manufacturer receives for a drug." However, it found that the lack of any temporal language indicating an "initial" versus "cumulative" price rendered the pre-2012 regulatory

framework "ambiguous" and counseled against finding either interpretation objectively unreasonable. *Id.*

To complete its analysis, the panel also considered whether Service Fee Defendants "were warned away from th[eir] interpretation by available guidance." *Id.* Reviewing the pre-2012 regulatory landscape, the court rejected Streck's contention

> that the guidance available during the relevant period should be read as imposing a continuing duty on a manufacturer to revise AMP to include any profits received throughout the course of the business relationship with a wholesaler. By inference, this would include a price-appreciation credit, which constitutes value obtained by a manufacturer after an initial sale.

Id.

The court found "that price-appreciation credits were not specifically addressed by the CMS until 2012" when it issued the proposed rule explaining that such 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." *Id.* at *6. *See also* Medicaid Program; Covered Outpatient Drugs, 77 Fed. Reg. at 5332. The court noted that even "[t]his statement by the CMS, however, did not unambiguously foreclose the possibility that price-appreciation credits could be excluded from AMP under a different theory." *Streck Appeal*, 2018 WL 3949031, at *6. The Third Circuit commented that the final 2016 rule, with its detailed explanation as to why "price appreciation credits would likely not meet the definition of a bona fide service fee," "strikes us as far clearer on the issue of price-appreciation credits" than the earlier 2012 proposed rule. *Id.* at *6 n.5 (quoting Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. at 5228). Accordingly, it found that the Service Fee Defendants' "reasonable interpretation of an ambiguous statute was inconsistent with the reckless disregard Streck was required to

allege at [the motion to dismiss] stage of the litigation." Accordingly, it affirmed Judge Robreno's dismissal of the Service Fee claims. *Id.*

Analysis

Traditional FCA Claim Under 31 U.S.C. § 3729(a)(1)(A), (B), (D)

To state a false claim cause of action, the relator must allege "(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." *United States ex rel. Pilecki-Simko v. Chubb Inst.*, 443 F. App'x 754, 759 (3d Cir. 2011) (quoting *U.S. ex rel. Willis v. United Health Grp., Inc.*, No. 10–2747, 659 F.3d 295, 305 (3d Cir.2011)). Thus, a traditional claim "includes four elements: falsity, causation, knowledge, and materiality." *United States ex rel. Petratos v. Genentech, Inc.*, 855 F.3d 481, 487 (3d Cir. 2017) (citing *Universal Health Servs., Inc. v. United States ex rel. Escobar*, -- U.S. --, 136 S. Ct. 1989, 1996 (2016)).

1. Falsity

Streck alleges that BMS made express false certifications to the government when it underreported AMP.[23] "Under the 'express false certification' theory, [a claimant] is liable under the FCA for falsely certifying that it is in compliance with' a material statute, regulation, or contractual provision." *United States ex rel. Whatley v. Eastwick College*, 657 F. App'x 89, 94 (3d Cir. 2016) (quoting *Wilkins*, 659 F.3d at 305). Here, Streck alleges that BMS falsely certified that it had provided accurate information as required by its Rebate Agreement with Medicaid and 42 C.F.R. § 447.510, which provides that manufacturers must calculate AMP pursuant to 42 C.F.R. § 447.502.[24]

a. Discount Scheme

Streck contends BMS, using the discount scheme, improperly deducted bona fide service fees. He argues such fees were explicitly excluded from AMP. *See* 42 U.S.C. § 1396r–8(k)(1)(B)(i)(II); 42 C.F.R. § 447.504(h)(19), (i)(1); Medicaid Program; Covered Outpatient Drugs, 77 Fed. Reg. at 5332. Since 2007, the regulatory framework has excluded from AMP any fees that: (1) "represent fair market value" of (2) a "bona fide, itemized service actually performed on behalf of the manufacturer" (3) that the manufacturer "would otherwise perform (or contract for) in the absence of the service arrangement," and (4) that "are not passed on in whole or in part to a client or customer of an entity." 42 C.F.R. § 447.502 (2007). BMS argues that it properly characterized service fees in its distributor agreements as includible discounts because they did not "represent fair market value" and were "not passed on in whole or in part" by the distributors. *See id.*

i. Fair Market Value

CMS has described the determination of fair market value as "by nature subjective" and encompassing "a range of values." Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. at 5180. Given the inherent flexibility in the fair market value analysis, courts appear reluctant at the pleadings stage to conclude that service fees were not bona fide because the complaint lacks sufficient allegations of fair market value. *See United States ex rel. Arnstein v. TEVA Pharm. USA, Inc.*, No. 13 Civ. 3702, 2016 WL 750720, at *21 (S.D.N.Y. Feb. 22, 2016) ("fair import" of allegations was that speaker fees paid to physicians were not at fair market value where complaint alleged the speeches were "devoid of substance"); *Streck I*, 894 F. Supp. 2d at 597 (complaint "devoid of facts"

attesting to fair market value of services nonetheless survived motion to dismiss where the plaintiff pleaded "other facts" showing that the services were bona fide).

Here, Streck alleges facts in support of a finding that the services were at fair market value. Most significantly, he pleads that BMS's own consultant concluded that BMS was paying fair market value for the services set forth in its distributor agreements.[25] BMS counters that this conclusion reached in 2013 and implemented in 2014 has no bearing upon the value of services distributors provided between 2007 and 2013, the period of the discount scheme. BMS ignores that Streck alleges the agreements the consultant evaluated did not materially differ from those in place during the scheme.[26] Indeed, as Streck points out, BMS and its distributors agreed upon the parties' "independen[ce]" of each other "in the operation of their own respective businesses," as well as the sufficiency of the consideration paid for the services.[27] They did so as "sophisticated market players" transacting at arms' length to reach "a deal representing fair market value."[28] *See In re Hechinger Inv. Co. of Del., Inc.*, 278 F. App'x 125, 129 (3d Cir. 2008) (stating that fair market value may be determined by looking at "the amount that a willing buyer would pay, and a willing seller accept, in an arm's length transaction").

If the allegations are proven, a reasonable jury could infer that the fees BMS paid for services under its agreements with its distributors between 2007 and 2013 constituted fair market value.

ii. Not Passed On

If distributors passed on the fees at issue, in whole or in part, to its customers, BMS could properly treat them as discounts includible in AMP rather than as excludable

bona fide service fees. *See* 42 C.F.R. § 447.502. Streck alleges that distributors did not pass on the fees set forth in their agreements with BMS.

CMS guidance provides that "the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on . . . ." Medicare Program; Revisions to Payment Policies, 71 Fed. Reg. at 69669. Indeed, Streck points to evidence that BMS so presumed. According to Streck, BMS ceased the discount scheme in 2013 after its consultant confirmed the fair market value of the services. A jury might reasonably infer that this cessation indicates that BMS already believed that the fees for these services otherwise met the definition for bona fide service fees, including that the fees were not passed on, and that BMS was waiting only on a formal confirmation of fair market value before finally treating the service fees as bona fide.[29] Notably, BMS made no similar inquiry into whether the fees were passed on, bolstering the inference that BMS did not question that they were not. In addition, one can infer that distributors would keep, rather than pass on to customers, fees that the distributors earned for services they provided to BMS under the distribution agreements.[30]

Streck has sufficiently alleged that the service fees were bona fide and improperly deducted from AMP. He alleges facts that support a finding that the fees constituted fair market value and that they were not passed on by distributors. BMS's own consultant determined that the fees were paid at market rates in an exchange between sophisticated entities operating at arms' length. He argues that a jury may infer that the fees were not passed on by distributors because the other elements of a bona fide service fee have been established and because common sense dictates that distributors were not likely to pass on to customers fees that they had earned for themselves. These allegations are

enough to state a false certification claim because they show BMS's treatment of bona fide service fees as discounts was inconsistent with the definition set forth in 42 C.F.R. § 447.502.

b. Service Fee Scheme

Streck claims that BMS's offsetting of price appreciation credits against bona fide service fees directly conflicted with 2012 guidance from CMS on how to interpret the definition of bona fide service fees laid out in 42 C.F.R. § 447.502. Although proposed only, this CMS rule warned that "retroactive price adjustments, sometimes also 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." Medicaid Program; Covered Outpatient Drugs, 77 Fed. Reg. at 5332.

The clear and plain text of the 2012 proposed rule specified that "price appreciation credits[ ] do not meet the definition of a bona fide service fee . . . ." Medicaid Program; Covered Outpatient Drugs, 77 Fed. Reg. at 5332. It is true that from the Third Circuit's perspective, the prohibition against treating such credits as bona fide service fees became "far clearer" in the final rule. But, that observation was based upon the additional explanation provided with the 2016 rule and not on any ambiguity or vagueness in the 2012 rule itself. *See Streck Appeal*, 2018 WL 3949031, at *6 n.5. Indeed, the court's language does not impart that the 2012 rule was not clear. Instead, it became "clearer" in 2016.

BMS correctly points out that the 2012 proposed rule was not binding.[31] Nonetheless, "a proposed regulation constitutes a body of informed judgment to which courts may draw on for guidance in the interpretation of relevant statutes . . . ." *Bolton v.*

C.I.R., 694 F.2d 556, 560 n.10 (9th Cir.) (citing *Ricards v. U.S.*, 652 F.2d 897, 902 n.12 (9th Cir. 1981)). *See also Streck I*, 894 F. Supp. 2d at 600 (noting that proposed rule constituted "guidance" as to whether price appreciation credits were "permissible as a payment method for service fees"); *Markham v. Salina Concrete Prods., Inc.*, No. 10–1104–JTM, 2010 WL 5093769, at *3 (D. Kan. Dec. 8, 2010) (proposed regulations may "provide guidance to interpreting" statutes). Proposed rules and regulations also "have some authority as an indication of administrative practice." *Farmar v. U.S.*, 689 F.2d 1017, 1025 (Ct. Cl. 1982) (citing *Farmers Coop. Co. v. Birmingham*, 86 F. Supp. 201, 229 (N.D. Iowa 1949)), *rev'd and remanded on other grounds*, *C.I.R. v. Engle*, 464 U.S. 206 (1984). Here, 42 C.F.R. § 447.502, which sets forth the definition of bona fide service fees, was admittedly silent as to whether price appreciation credits were included in the definition and excludible from AMP. However, the 2012 rule constituted a pronouncement that price appreciation credits were not bona fide service fees and must be included in AMP. Thus, the proposed rule warned BMS away from its erroneous interpretation of § 447.502. *See also Rountree Cotton Co. v. C.I.R.*, 113 T.C. 422, 428 n.4 (1999) ("Petitioner's concern about the absence of final regulations is also less compelling where, as here, some guidance was provided by the issuance of proposed regulations.").

Streck has pleaded facts sufficient to satisfy the element of falsity. As alleged, BMS used the discount and service fee schemes to reduce the rebates it owed. BMS's certification that it had provided accurate AMP calculations was false.

2. Scienter

An essential element of an FCA cause of action is scienter. The plaintiff must plead facts which, if proven, establish that the defendant acted knowingly, that is, with knowledge of the falsity of the claim. *Petratos*, 855 F.3d at 487.

"Knowingly" is defined to "(A) mean that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require[s] no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(A)–(B) (2009). For liability to attach in a case revolving around an interpretation of a statute or regulation, the defendant's interpretation must have run "a risk of violating the law substantially greater than the risk associated with a reading that was merely careless." *Streck I*, 894 F. Supp. 2d at 593 (quoting *Safeco Ins. Co. of Am.*, 551 U.S. at 70). *See also K & R Ltd. P'ship v. Mass. Hous. Fin. Agency*, 530 F.3d 980, 983 (D.C. Cir. 2008) (applying standard from *Safeco*, a case under the Fair Credit Reporting Act, in FCA context). "[T]he FCA does not reach an innocent, good-faith mistake about the meaning of an applicable rule or regulation. Nor does it reach those claims made based on reasonable but erroneous interpretations of a defendant's legal obligations." *Streck Appeal*, 2018 WL 3949031, at *3 (quoting *United States ex rel. Purcell v. MWI Corp*., 807 F.3d 281, 287-88 (D.C. Cir. 2015)).

Where a defendant claims, as BMS does, that its interpretation of the law was reasonable at the time even though it was later found to be erroneous,[32] we ask three questions: "(1) whether the relevant statute [or regulation] was ambiguous; (2) whether a defendant's interpretation of that ambiguity was objectively unreasonable; and (3)

whether a defendant was 'warned away' from that interpretation by available administrative and judicial guidance." *Id.* (citing *Purcell*, 807 F.3d at 288). The first two considerations present purely legal questions; the third, a factual one. *Purcell*, 807 F.3d at 288-89.

If the statute or regulation was unambiguous, scienter is established and the inquiry ends. If the statute or regulation was ambiguous, but the defendant's interpretation was unreasonable, scienter is established. On the other hand, if the defendant's interpretation of an ambiguous statute or regulation is not objectively unreasonable, we proceed to the third question.

Even assuming a defendant reasonably interpreted the ambiguous statute, scienter may still be established because "a jury might still find knowledge if there was interpretive guidance 'that might have warned [the defendant] away from the view it took.'" *Id.* at 288 (quoting *K & R Ltd.*, 530 F.3d at 983 and citing *Safeco Ins. Co. of Am.*, 551 U.S. at 70). *See United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1155 (11th Cir. 2017) ("scienter is not determined by the ambiguity of a regulation, and can exist even if a defendant's interpretation is reasonable") (citing *United States ex rel. Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1053–54 (8th Cir. 2002)). Because this inquiry turns on the determination of facts, a court should not resolve an FCA claim at the motion to dismiss stage where the plaintiff plausibly alleges that the defendant proceeded with its interpretation in the face of contrary guidance. *See United States ex rel. Nevyas v. Allergan, Inc*., Civ. A. No. 09-432, 2015 WL 4064629, at *6 (E.D. Pa. July 2, 2015) (the defendant's "reasonable interpretation of the law and applicable regulatory framework may well be a defense to liability, but it is not appropriate

at the motion to dismiss stage when there are reasonable interpretations to the contrary"); *cf. United States ex rel. Walker v. R&F Props. of Lake Cty., Inc.*, 433 F.3d 1349, 1358 (11th Cir. 2005) (reversing summary judgment in favor of FCA defendant due to existence of guidance contrary to its interpretation of Medicare regulations); *Minn. Ass'n of Nurse Anesthetists*, 276 F.3d at 1054-56 (same).

Streck points to "interpretive guidance that might have warned [BMS] away from the view it took" with respect to both schemes. *Purcell*, 807 F.3d at 288-89 (quotations and citations omitted). Hence, even assuming the ambiguity of the underlying statutes and rules governing the calculation of AMP and the objective reasonableness of BMS's interpretation of them, the motion to dismiss fails because BMS was warned away from its interpretation.

a. Discount Scheme

The statutory definition of AMP was silent on the treatment of bona fide service fees as discounts when the discount scheme began. 42 U.S.C. § 1396r-8(k)(1)(A). BMS's treatment of such fees as discounts was therefore not objectively reasonable. However, in 2007, Congress excluded prompt pay discounts. *Compare* 42 U.S.C. § 1396r-8(k)(1) (1997), *with* 42 U.S.C. § 1396r-8(k)(1)(B) (2007). "This discount had been explicitly allowed since AMP's inception and its exclusion . . . signaled the pharmaceutical industry that the types of discounts allowed within the AMP calculation had narrowed significantly." *Streck I*, 894 F. Supp. 2d at 596. In October 2007, CMS "confirmed this significant change by delineating the specific types of discounts allowed under AMP calculations and also confirming that a fee known as a bona fide service fee could not be included within . . . AMP calculations." *Id. See* 42 C.F.R. § 447.504(a), (h)(19), (i)(1). As

discussed earlier, the CMS regulation established the four-part test to determine which service fees were bona fide. *Id.* § 447.502.

In 2010, the ACA amended the definition of AMP to exclude fees for inventory management and distribution services as bona fide service fees. 42 U.S.C. § 1396r–8(k)(1)(B)(i)(II). Fees for these services were included in BMS's distribution agreements and treated as deductions from AMP by BMS.[33] For instance, under sections 2.1 through 2.7 of the sample agreement, the distributor agreed to provide services "with regard to inventory," including maintaining inventory of BMS products within an agreed upon range.[34] The distribution agreements also incorporated BMS's promotion and service agreement and chargeback agreement.[35] The promotion and service agreement required distributors to promote BMS's good will to the distributor's customers, promote BMS's products to customers in the distributor's trading area, conduct featured sales drives of BMS's products, note shortages of and damage to delivered products, and rotate inventory on a first-in, first-out basis.[36] The chargeback agreement required distributors to maintain and report accurate distribution records and submit a "negative chargeback" when accepting a return of previously charged back drugs.[37]

BMS persisted in deducting the discounts it gave in exchange for these services from AMP. It argues that, in accordance with the default rule to include fees in AMP calculations," *see* 42 U.S.C. § 1396r–8(k)(1), it "viewed the fees it paid to distributors as a reduction off of the list price of the drugs it sold to distributors and phrased it that way in the agreements."[38]

In March 2011, notwithstanding the clear language in the agreements, BMS began a two-year search for a consultant to analyze whether it was paying fair market value for

the services the distributors provided.[39] *See* 42 C.F.R. § 447.502 (setting forth payment of fair market value as a component of a bona fide service fee). From then throughout the remainder of 2013, BMS continued to deduct the discounts from AMP. It did not stop until the consultant formally confirmed that the discounts represented fair market value for the services.[40]

In the meantime, on July 3, 2012, Judge Robreno issued his opinion denying the Discount Defendants' motion to dismiss claims arising after January 1, 2007. *Streck I*, 894 F. Supp. 2d at 596-98. Although Streck had voluntarily dismissed BMS prior to that time, Judge Robreno's opinion was a red flag, warning BMS that the regulatory framework did not support its deducting the discounts. Explaining the 2007 changes to the calculation of AMP, including the four-prong test for evaluating bona fide service fees, Judge Robreno concluded: "[A]s the law from 2007 onward provided guidance that such bona fide service fees were to be excluded in AMP calculations, Plaintiff pleads sufficient facts to plausibly show that Discount Defendants were at least reckless in their AMP calculations." *Id.* at 598.

Streck has alleged facts presenting a plausible claim that BMS acted recklessly in continuing to deduct the discounts from AMP in the face of guidance to the contrary. Indeed, the 2007 CMS regulation defining bona fide service fees, coupled with the 2010 ACA amendment of that definition to include the exact types of fees set forth in the distribution agreements, "might have warned [BMS] away from the view it took." *Purcell*, 807 F.3d at 288-89 (quotations and citations omitted). Judge Robreno's opinion in *Streck I* merely reinforced these earlier warnings.

One could infer that BMS knew its interpretation was incorrect because it waited two years to hire a consultant to evaluate the value of the services while it continued to deduct them, knowing that the consultant would later confirm their fair market value. In other words, a jury could infer that BMS purposefully delayed hiring a consultant so it could reap the benefits of the deduction for two additional years and later claim it had been acting reasonably while continuing to deduct the fees. A jury could consider this delay as evidence that BMS knew that it would likely have to stop deducting the fees after receiving an evaluation from a consultant. Indeed, this is what ultimately happened. Only after the consultant formally confirmed that BMS was paying market rates for them did BMS stop deducting the service fees. Thus, these facts show that Streck has plausibly alleged scienter as to the discount scheme.

b. Service Fee Scheme

The statutory definitions of AMP and bona fide service fees in place at the start of the service fee scheme in 2014 was silent as to price appreciation credits. *See* 42 U.S.C. § 1396r–8(k)(1) (2010); *see also* 42 C.F.R. § 447.502 (2007). As the Third Circuit found in the *Streck Appeal*, this silence rendered the statute ambiguous, and BMS's interpretation of it to permit exclusion of price appreciation credits from AMP was not objectively unreasonable. 2018 WL 3949031, at *5. However, as we have observed, in February 2012, CMS had proposed a new rule directly addressing such credits, stating "retroactive price adjustments, sometimes also 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." Medicaid Program; Covered Outpatient Drugs, 77 Fed. Reg. at 5332. Later that year, in *Streck I*, Judge

Robreno called the treatment of price appreciation credits as bona fide service fee offsets "contrary" to the proposed rule. 894 F. Supp. 2d at 600. He further opined that a drug manufacturer that conflated the two after the promulgation of the proposed rule possibly[41] "acted at least recklessly . . . ." *See id.* (finding that the date of the proposed rule constituted "the earliest" that liability might arise).

At that point, BMS knew that CMS did not consider price appreciation credits bona fide service fees. Nonetheless, BMS proceeded with the service fee scheme. Although the Third Circuit in the *Streck Appeal* expressed its belief that the proposed rule became "far clearer" in its final form, Streck has plausibly pleaded that the earlier version warned BMS that it had misinterpreted the requirement to include price appreciation credits in AMP. *See Purcell*, 807 F.3d at 288-89.

c. Government Knowledge Inference

BMS argues that the government knowledge inference precludes a finding of scienter.[42] It supports its arguments with facts that are not alleged in the First Amended Complaint.

Where the government knows and approves of the facts underlying the allegedly false claim, the government knowledge inference doctrine precludes a finding of scienter. *U.S. Dep't of Transp. ex rel. Arnold v. CMC Eng'g*, 567 Fed. App'x 166, 170 n.9 (3d Cir. 2014) (*United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 951–52 (10th Cir. 2008)). *See also United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 756 (3d Cir. 2017) ("The 'government knowledge inference' helps distinguish, in FCA cases, between the submission of a false claim and the knowing submission of a false claim – that is, between the presence and absence of scienter.") (quoting *United States ex rel. Burlbaw*

v. Orenduff, 548 F.3d 931, 951 (10th Cir. 2008)). The inference applies when "(1) the government agency knew about the alleged false statement(s), and (2) the defendant knew the government knew." *Id.* (quotations omitted). But, "'mere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance,' and even actual knowledge that certain requirements were violated 'is not dispositive.'" *Smith v. Carolina Med. Ctr.*, 274 F. Supp. 3d 300, 319 (E.D. Pa. 2017) (citing *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 110-12 (1st Cir. 2016)). Rather, the "two-prong test is necessary because knowledge by the government, without more, cannot negate the scienter requirement." *Spay*, 875 F.3d at 757.

In *Universal Health Services, Inc. v. United States ex rel. Escobar*, the Supreme Court made clear that a court may consider the existence of the government knowledge inference at the motion to dismiss stage. 136 S. Ct. at 2004 n.6. "*Escobar* did not, however, alter the fundamental procedural rule that 'a district court ruling on a motion to dismiss may not consider matters extraneous to the pleadings.'" *Id.* (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997)) (additional citations omitted). Accordingly, a district court should not infer government knowledge where "defendants rely on allegations outside the complaint[ ] . . . ." *Id. See also United States ex rel. Grubea v. Rosicki, Rosicki & Assocs., P.C.*, No. 12–CV–7199, 2018 WL 3091255, at *14 (S.D.N.Y. June 23, 2018) ("these unsubstantiated assertions about what [the government] must have known relate to facts beyond the scope of the complaints and cannot be resolved at the pleading stage"), *reconsideration denied by* 13-cv-1467 2018, WL 3866711 (S.D.N.Y. Aug. 14, 2008).

BMS posits in its motion to dismiss that:

> The government knew of Streck's allegations since 2008 and investigated those allegations; Bristol-Myers cooperated in that investigation; CMS has continued receiving AMP-based rebates from Bristol-Myers without taking regulatory action or requiring a restatement or revision of AMP regarding that treatment; and Bristol-Myers knew of the government's knowledge of its purported mistreatment of bona fide service fees and miscalculation of AMP.[43]

None of these facts are set forth in the First Amended Complaint. They are subject to proof. At this stage, we do not consider them. Accordingly, we decline to dismiss the claims based on the government knowledge inference.

3. Materiality

To be actionable under the FCA, the misrepresentation about compliance with statutory or regulatory requirements must be material to the decision to pay. The FCA defines material as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). It is a demanding standard. *Escobar*, 136 S. Ct. at 2003. The FCA does not encompass "minor or insubstantial" violations. *Escobar*, 136 S. Ct. at 2003 (quoting *Allison Engine Co., Inc. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008) and citing *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 543 (1943)).

The government's designation of compliance with a particular regulation as a condition of payment does not establish materiality. *Id.* Nor does the fact that the government could decline payment if it knew of the violation. *Id.* Nevertheless, both may serve as evidence of materiality. *Id.* Other evidence of materiality may include a history of refusal to pay claims due to noncompliance with the particular regulation. *Id.* On the other hand, regular payment of claims notwithstanding actual knowledge of

noncompliance may be evidence of a lack of materiality, provided the government had not signaled a coming change in its position. *Id.* at 2003-04.

BMS argues that even though the government had actual knowledge of BMS's flawed AMP calculation methodology, it continued to accept rebates based upon that methodology without ever taking regulatory action against BMS.[44] *Cf. id.* ("if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material"). As BMS argues:

> [S]ince 2008, the government has had "actual knowledge" of Streck's theory of fraud against Bristol-Myers as well as dozens of other manufacturers, has thoroughly investigated his allegations, and yet has continued receiving AMP-based rebates from these manufacturers without taking regulatory action against Bristol-Myers regarding this AMP issue, requiring a restatement of AMP on this issue, or even intervening in this or Streck's prior case.[45]

BMS's argument rests upon facts which do not appear in the First Amended Complaint. Streck alleges only that "[a]fter an initial investigation, the United States and various states declined to intervene."[46] However, it is well-established that "the Government can choose not to intervene in a *qui tam* action for a number of reasons, many of which can be unrelated to the merits of the case." *United States ex rel. Class v. Bayada Home Health Care, Inc.*, No. 16-680, 2018 WL 4566157, at *11 (E.D. Pa. Sept. 24, 2018) (citing *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 n.17 (11th Cir. 2006)) (additional citations omitted). Here, why the government declined to intervene is unknown.

"Although a relator in a *qui tam* action faces a demanding standard at the motion-to-dismiss stage with respect to pleading materiality, she is not required to make allegations regarding past government action." *United States ex rel. Prather v. Brookdale*

Senior Living Cmtys., Inc., 892 F.3d 822, 834 (6th Cir. 2018). As the Sixth Circuit has explained:

> [W]e must construe the complaint in the light most favorable to the plaintiff. Inferring from the absence of allegations regarding past government action . . . that this means the [relevant] requirement is not material is an inference adverse to the relator and in favor of the defendant. This improperly inverses the pleading standard.

Id. at 834. *See also United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 906-07 (9th Cir. 2017) ("[T]he parties dispute exactly what the government knew and when, calling into question its 'actual knowledge.' Although it may be that the government regularly pays this particular type of claim in full despite actual knowledge that certain requirements were violated, such evidence is not before us.").

BMS's claim that CMS continued to accept rebates from BMS without requiring a restatement or revision or taking other regulatory action is a matter for trial. Accordingly, it does not factor into the materiality analysis at this stage.

Materiality requires that the information must potentially influence "the other party's course of action." *Escobar*, 136 S. Ct. at 2001. Where a plaintiff pleads that the amount of payment depends on information the defendant provides to the government, the course of action "is the Government's decision to reimburse [or otherwise pay or accept payment] at a particular price point." *United States ex rel. Rahimi v. Rite Aid Corp.*, No. 2:11-cv-11940, 2018 WL 1744796, at *7 (E.D. Mich. Apr. 11, 2018) (slip opinion) (quoting *Escobar*, 136 S. Ct. at 2001). *See also United States ex rel. Luke v. Healthsouth Corp.*, No. 2:13–cv–01319–APG–VCF, 2018 WL 3186941, at *6 (D. Nev. June 28, 2018) (slip opinion) ("alleged manipulation of the criteria by which payment is determined" satisfied materiality requirement at pleading stage).

In *Rahimi*, the district court held that the relator had plausibly pleaded materiality where he alleged that Rite Aid had misreported to Medicaid Part D the "usual and customary charges to the general public" (U&C) for its prescription drugs in an attempt to inflate its reimbursements from CMS. *Id.* at *1-2. It found the materiality requirement was satisfied even though almost all of the involved state programs paid claims "based on the lower of U&C and one or more other price metrics" and, as such, the relator did not "identify a single instance in which Rite Aid's alleged noncompliance with U&C rules actually caused Medicare Part D and the federal-state Medicaid program . . . to pay excessive amounts." *Id.* at *7. Nonetheless, it sufficed that the relator had pleaded "that inflating the U&C would have the 'natural tendency to influence, or be capable of influencing,' the amounts reimbursed by CMS." *Id.* (quoting 31 U.S.C. § 3729(b)(4)).

The district court in *Luke* reached a similar conclusion. The relator alleged that the defendant, an operator of rehabilitation hospitals, had deflated its patients' functional independence measure (FIM) in order to inflate its reimbursement from Medicare. *Id.* at *1, *6. The relator noted the "FIM score is put directly into the software that CMS uses to determine what services a facility like [the defendant's] is expected to provide to patients, and CMS bases the amount of prospective Medicare payments in part on the FIM. The lower the FIM, the higher the reimbursement payment." *Id.* The court found that the relator had "plausibly alleged materiality because he ha[d] alleged manipulation of the criteria by which payment is determined." *Id.*

Here, as in *Rahimi* and *Luke*, Streck alleges manipulation of the criteria by which payment is determined. He argues that "[t]he dollar values of the rebates paid by each manufacturer to Medicaid are based on the [AMP] of each distinct prescription drug"

reported by the manufacturer.[47] Indeed, Streck alleges that the Program is "entirely predicated" on the "manufacturer's provision of accurate AMP pricing information to CMS at the outset of the process."[48] Because the size of the rebate owed by the manufacturer increases as AMP increases, underreporting of AMP has the direct result of lowering the manufacturer's rebate obligations.[49] Where the amount owed or received depends upon data supplied by the defendant, misstatement of that data is material because it directly influences the final amount. Therefore, we conclude Streck satisfies the materiality element.

Reverse FCA Claim Under 31 U.S.C. § 3729(a)(1)(G)

To plead a reverse claim, the relator must allege "that the defendant did not pay back to the government money or property that it was obligated to return." *United States ex rel. Quinn v. Omnicare, Inc.*, 382 F.3d 432, 444 (3d Cir. 2004). However, since the 2009 amendment, "[a] false statement is no longer a required element, since the . . . FCA [now] specifies that mere knowledge and avoidance of an obligation is sufficient, without the submission of a false record, to give rise to liability." *United States ex rel. Customs Fraud Invest., LLC. v. Victaulic Co.*, 839 F.3d 242, 255 (3d Cir. 2016). *Compare* 31 U.S.C. § 3729(a)(1)(G) (2009) *with* 31 U.S.C. § 3729(a)(7) (1994). Here, Streck pleads that reducing the amount of the rebates BMS owed by decreasing reported AMP facilitated BMS's keeping money it should have paid to state Medicaid programs. These allegations plausibly state Streck's right to relief under a reverse claim because they demonstrate that BMS knowingly withheld money it owed to the state Medicaid programs. *Victaulic Co.*, 839 F.3d at 255; *Quinn*, 382 F.3d at 444.

Rule 9(b) Particularity Requirement

Because FCA claims sound in fraud, Streck must satisfy Rule 9(b)'s heightened pleading standard. An FCA plaintiff must 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 156 (quotation and citation omitted). "Describing a mere opportunity for fraud will not suffice." *Id.* at 158. Instead, a plaintiff must allege sufficient facts to establish "a plausible ground for relief." *Id.* (quoting *Fowler*, 578 F.3d at 211). Ultimately, the pleading must fulfill "Rule 9(b)'s purpose of giving the defendant[ ] fair notice of the claims against it." *United States ex rel. Ryan v. Endo Pharms., Inc.*, 27 F. Supp. 3d 615, 624 (E.D. Pa. 2014) (citing *Foglia*, 754 F.3d at 156-57), *aff'd sub nom*., *United States ex rel. Dhillon v. Endo Pharms., Inc.*, 617 F. App'x 208 (3d Cir. 2015).

BMS argues that Streck's First Amended Complaint lacks the requisite particularity because it fails to allege

> concrete facts or specifics as to how Bristol-Myers calculated AMP, who was involved in that calculation, what calculation or methodology was used, whether any one person knew of the alleged fraud, when or where any false AMP calculation was made or reported, or any other facts that could create a strong inference that false claims were actually submitted.[50]

For each scheme, Streck pleads the start and end dates, the statutory and regulatory provisions BMS violated, the frequency with which BMS reported AMP to CMS, the particular drugs for which BMS misreported AMP, and the amount Medicaid paid for these drugs.[51] In addition, he attaches a sample agreement between BMS and a wholesaler setting forth the services the latter provided, the amount of the fee, the BMS employee who executed the agreement and the mischaracterization of fees as discounts (under the discount scheme) and price appreciation increases as reduced fees (under the service fee scheme).[52] These detailed allegations satisfy the particularity requirement of

Rule 9(b). *Foglia*, 754 F.3d at 158; *Ryan*, 27 F. Supp. 3d at 624 (quotation and citation omitted).

State Law Claims

BMS contends that several of the state false claim acts' effective dates and other technical requirements, such as the need for state intervention or a written determination of "substantial evidence," bar or limit their application in this action.

Delaware and New Mexico Claims

The parties agree that in 2007, at the start of the discount scheme, Delaware and New Mexico only allowed an "affected person" to bring an action and required the state either to intervene or provide a written determination of substantial evidence that a violation occurred. Del. Code Ann. tit. 6, § 1203(b) (2000); N.M. Stat. § 27-14-7(B) (2004). They also agree that Delaware amended its statute, abolishing those requirements on July 16, 2009, and that the amendment does not apply retroactively. DEL. CODE ANN. tit. 6, § 1203(b)(1) (2009); *Wilson v. Triangle Oil Co.*, 566 A.2d 1016, 1018 (Del. Super. Ct. 1989), *aff'd sub nom.*, *Clark v. Sun Ref. & Mktg.*, 584 A.2d 1228 (Del. 1990); *United States ex rel. Conrad v. GRIFOLS Biologicals, Inc.*, No. 07-3176, 2010 WL 2733321, at *6 (D. Md. July 9, 2010). Streck concedes that neither Delaware nor New Mexico has intervened and that he has not obtained any written determinations of substantial evidence.[53] Therefore, we shall dismiss the New Mexico claim in full and the Delaware claim to the extent it reaches BMS's conduct prior to July 16, 2009.[54]

Texas Claim

Texas amended its Medicaid Fraud Prevention Act (MFPA) to dispense with the requirement for state intervention, effective May 4, 2007. *Compare* TEX. HUM. RES. CODE

ANN. § 36.104(b) (2005) ("If the state declines to take over the action, the court shall dismiss the action."), *with* TEX. HUM. RES. CODE ANN. § 36.104(b) (2007) ("If the state declines to take over the action, the person bringing the action may proceed without the state's participation."). As with the Delaware amendment, the Texas amendment only applies "to conduct that occurs on or after the effective date" of the act. 2007 Tex. Sess. Law Serv. Ch. 29 (S.B. 362). Streck argues that the word "conduct" refers not to BMS's operation of the schemes, but rather to Texas's 2017 decision not to intervene.[55]

If "conduct" refers to the defendant's conduct, only its conduct occurring after the effective date of the amended statute may provide the basis for liability, regardless of when the state declined to intervene. If "conduct" refers to the state's decision to decline to intervene, even the defendant's fraudulent acts or omissions occurring before the effective date may provide the basis for liability so long as Texas decided after the effective date not to intervene.

The Texas Supreme Court has not addressed whether "conduct" refers to the defendant's alleged misconduct or the state's decision not to intervene. Some district courts have interpreted the MFPA as applying to all of the defendant's conduct, including conduct occurring prior to the amendment's effective date, as long as Texas declines to intervene after the effective date of the amended statute. *See United States ex rel. Ruscher v. Omnicare, Inc.*, No. 4:08–cv–3396, 2014 WL 2618158, at *31 (S.D. Tex. June 12, 2014) (citing *United States ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472, 522 (S.D. Tex. 2011), *vacated in part on other grounds on reconsideration by* No. 4:08–CV–3396 (Sept. 5, 2014)); *King*, 823 F. Supp. 2d at 522*, vacated in part on other grounds on reconsideration by* No. 06-2662, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012).

The greater weight of authority precludes claims based on conduct that preceded the amendment. *Streck I*, 894 F. Supp. 2d at 605 (citing *United States ex rel. Wall v. Vista Hospice Care*, 778 F. Supp. 2d 709, 723-24 (N.D. Tex. Mar. 28, 2012); *United States ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112, 130 (D. Mass. 2011)). *See also United States ex rel. Bergman v. Abbot Labs.*, 995 F. Supp. 2d 357, 380 (E.D. Pa. 2014) (Jones, J.) ("the *Streck* court resolved the matter definitively for the Eastern District by allowing claims under the Texas statute to proceed without intervention if filed after the date of the amendment, but only as they pertain to fraudulent conduct occurring after the date of amendment"); *United States ex rel. Carroll v. Planned Parenthood Gulf Coast, Inc.*, 21 F. Supp. 3d 825, 838 (S.D. Tex. 2014) ("most courts have allowed Texas claims 'to proceed without intervention if filed after the date of the amendment, but only as they pertain to fraudulent conduct occurring after the date of amendment'"); *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 832-33 (S.D.N.Y. Mar. 31, 2017), *reversed and remanded on other grounds by* 246 F. Supp. 3d 772 (2d Cir. 2018) (same) (quoting *Carroll*, 21 F. Supp. 3d at 838).

Agreeing with our colleagues Judges Robreno and Jones, we hold that "conduct" in the MFPA refers to the defendant's conduct, not the state's decision not to intervene. Only claims based upon the defendant's conduct occurring after the MFPA's effective date may give rise to a false claims action. Thus, Texas claims based upon the defendant's conduct occurring before May 4, 2007 are not actionable.

Remaining State Law Claims

The parties agree that several other state false claims acts became effective after the alleged start of the discount scheme on January 1, 2007, and that these acts do not

apply retroactively. These acts include those of Colorado, COLO. REV. STAT. § 25.5-4-303.5 *et seq.* (effective May 26, 2010); Georgia, GA. CODE ANN. § 49-4-168 *et seq.* (effective May 24, 2007); Iowa, IOWA CODE § 685.1 *et seq.* (effective March 10, 2010); Minnesota, MINN. STAT. § 15c.02 *et seq.* (effective July 1, 2010); New Jersey, N.J. STAT. ANN. § 2A:32-C1 *et seq.* (effective March 18, 2008); New York, N.Y. STATE FIN. LAW § 187 *et seq.* (effective April 1, 2007); Oklahoma, OKLA. STAT., tit. 63, § 5053.1 *et seq.* (effective November 1, 2007); and Rhode Island, R.I. GEN. LAWS § 9-1.1-1 *et seq.* (effective February 15, 2008). The parties agree that BMS's conduct prior to these effective dates may not serve as the basis for liability under the respective state statutes. Therefore, to the extent Streck asserts claims under these statutes before their effective dates, they are dismissed.

Conclusion

The First Amended Complaint states with particularity the elements of an FCA claim, including falsity, scienter and materiality. Therefore, we shall deny BMS's motion to dismiss.

/s/TIMOTHY J. SAVAGE

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* The government has declined to intervene. Notice of Election to Decline Intervention, ECF 17.

1 First Amended Complaint ¶ 44, ECF 59-1.

2 BMS also seeks to dismiss the state false claims counts on various technical grounds. While conceding that the court may dismiss Streck's counts for violation of state false claims laws to the extent those laws took effect after the conduct at issue, or require state intervention or written documentation of substantial evidence, he opposes the wholesale dismissal of his state law-based claims. Accordingly, he consents only to the dismissal of his New Mexico claim and the limitation of his Colorado, Delaware, Georgia, Iowa, Minnesota, New Jersey, New York, Oklahoma, Rhode Island and Texas claims to the dates when those states' false claims acts became effective or dispensed with the requirement for state intervention. The parties agree that effective dates and other technical requirements do not limit Streck's remaining claims under the false claims acts of California, Connecticut, the District of Columbia, Florida, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, North Carolina, Tennessee, Virginia, Washington and Wisconsin.

[3] *Id.* ¶ 11. *See* NAT'L HEALTH POLICY FORUM, THE BASICS: THE MEDICAID DRUG REBATE PROGRAM 3 (2009), *available at* https://www.nhpf.org/library/the-basics/Basics_MedicaidDrugRebate_04-13-09.pdf (last visited November 29, 2018).
[4] First Amended Complaint ¶ 12. *See* NAT'L HEALTH POLICY FORUM, THE BASICS: THE MEDICAID DRUG REBATE PROGRAM 3.
[5] Congress periodically updates the AMP percentages used to calculate the rebate for brand name and generic drugs. It established the current percentages in 2010. 42 § 1396r–8(c)(1)(B)(i)(6),(3)(B)(iii).
[6] First Amended Complaint ¶ 23.
[7] *Id.* ¶ 31.
[8] *Id*. ¶¶ 71-72.
[9] *Id*. ¶ 73.
[10] *See id.* ¶ 22.
[11] *Id*. ¶¶ 71-72.
[12] *Id*. ¶ 73.
[13] *Id*.
[14] *Id.* ¶¶ 23–29.
[15] *Id*. ¶ 27.
[16] *Id*. ¶ 22.
[17] *Id.* ¶ 74.
[18] *Id.* (quoting Inventory and Services Management Agreement § 2.4) (alteration in original).
[19] *Id.* ¶ 32.
[20] *Id.* ¶¶ 36–37.
[21] Although BMS was originally a defendant in *Streck I*, Streck voluntarily dismissed it before Judge Robreno issued his opinion on Defendants' motion to dismiss.
[22] In addition to the challenge under the pleading standards of Rule 8(a), Defendants argued that Streck failed to plead with the required specificity under Rule 9(b). Judge Robreno disagreed, concluding that notwithstanding the "absence of a specific false claim by Defendants" set forth in the complaint, its "ample facts describing the alleged scheme and details of contracts Defendants had with wholesalers" nonetheless advised Defendants of the "precise 'misconduct with which they are charged.'" *Streck I*, 894 F. Supp. 2d at 602 (quoting *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984)).
As BMS does here, Defendants also argued that several of the state false claim acts' effective dates and other technical requirements, such as the requirement to obtain a written determination of "substantial evidence" of a violation, barred or limited their application. *Id.* at 603. The court dismissed or limited Streck's claims in accordance with these requirements. *See id.* at 603-05.
[23] *See* First Amended Complaint ¶ 117. At oral argument, Streck's counsel confirmed Streck is proceeding upon an express rather than implied false certification theory of liability. Hearing on Motion to Dismiss Transcript at 54:4-5 (Oct. 2, 2018).
[24] *Id.* ¶¶ 119-120.
[25] *Id.* ¶ 82.
[26] *Id.* ¶ 83.
[27] *Id.* ¶ 80 (quoting Inventory and Services Management Agreement at 1, 6).
[28] *Id.* ¶ 79.
[29] *Id.* ¶¶ 96, 113.
[30] *See id.* ¶ 95.
[31] Mot. to Dismiss at 28, ECF 80 (citing *Public Citizen, Inc. v. Shalala*, 932 F. Supp. 13, 18 n.6 (D.D.C. 1996)).
[32] *See* Mot. to Dismiss at 32-36.
[33] First Amended Complaint ¶¶ 71-72.
[34] *Id.* Ex. A (Inventory and Services Management Agreement) at § II.
[35] *Id.* Ex. A (Inventory and Services Management Agreement) at § 2.6.
[36] *Id.* Ex. A (Promotion and Service Agreement for our Drug Wholesalers) at 1.
[37] *Id.* Ex. A (Primary Vendor Chargeback Agreement) at 5.
[38] Mot. to Dismiss at 38.
[39] First Amended Complaint ¶¶ 110-11.
[40] *Id.* ¶¶ 112-14.

[41] In *Streck I*, because Streck filed the operative complaint prior to the promulgation of the proposed rule, Judge Robreno did not ultimately decide the question of whether Service Fee Defendants had violated it. *Streck I*, 894 F. Supp. 2d at 589-90, 600.
[42] Mot. to Dismiss at 39-40.
[43] *Id.* at 39.
[44] *Id.* at 42.
[45] *Id.*
[46] First Amended Complaint ¶ 2.
[47] *Id.* ¶ 9.
[48] *Id.* ¶ 13.
[49] *Id.* ¶ 14.
[50] Mot. to Dismiss at 45-46.
[51] First Amended Complaint ¶¶ 22, 28-29, 39, 55-66, 76-124, 129, 137-38, 141-54, 157-58.
[52] *Id.* Ex. A (Inventory and Services Management Agreement).
[53] Resp. to Mot. to Dismiss at 41, ECF 83.
[54] *Id.*
[55] *Id.* at 42-43. *See also* Notice of Election to Decline Intervention.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	
***ex rel*. RONALD J. STRECK**	:	
	:	
v.	:	
	:	
BRISTOL-MYERS SQUIBB COMPANY	:	**CIVIL ACTION NO. 13-7547**

ORDER

NOW, this 29th day of November, 2018, upon consideration of Defendant Bristol-Myers Squibb Company's Motion to Dismiss Relator's First Amended Complaint (Document No. 82), the Relator's response, the defendant's reply, and after oral argument, it is **ORDERED** that the motion is **GRANTED IN PART and DENIED IN PART.**

IT IS FURTHER ORDERED as follows:

1. To the extent the motion seeks to dismiss claims under the laws of Colorado, Delaware, Georgia, Iowa, Minnesota, New Jersey, New Mexico, New York, Oklahoma, Rhode Island and Texas, the motion is **GRANTED**.

2. All claims under New Mexico law are **DISMISSED**.

3. All claims under Delaware law based on conduct occurring before July 16, 2009 and all claims under Texas law based on conduct occurring before May 4, 2007 are **DISMISSED.**

4. All claims based upon conduct occurring before the effective dates of the applicable laws of Colorado, Georgia, Iowa, Minnesota, New Jersey, New York, Oklahoma and Rhode Island are **DISMISSED.**

5. In all other respects, the motion is **DENIED**.

/s/TIMOTHY J. SAVAGE