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. **April 3, 2019**

Moving for reconsideration of the denial of its motion to dismiss the complaint, Bristol-Myers Squibb (BMS) contends that we erroneously determined that relator Ronald J. Streck adequately pled the falsity and knowledge elements of his "service fee scheme" claim under the False Claims Act (FCA), 31 U.S.C. § 3729-33. Recognizing that we could have been clearer, we now clarify the rationale for our ruling.

As alleged in Streck's amended complaint, BMS engaged in two schemes, each at different times, to fraudulently reduce the rebates it owed the states under the Medicaid program.[1] BMS challenges only our ruling regarding the "service fee scheme." It argues that we improperly applied the "warned away" doctrine in determining whether Streck sufficiently alleged the falsity element of a False Claims Act cause of action. It maintains that a failure to follow a proposed rule of a government agency cannot constitute a violation of a regulation because the proposed rule does not have the force and effect of a statute or regulation.

[1] Because the parties are familiar with the facts and the background, we recite only those facts necessary to address the reconsideration motion. A more detailed recitation of the facts is set forth in our opinion on the motion to dismiss. *United States ex rel. Streck v. Bristol-Myers Squibb Co.*, No. 13-7547, 2018 WL 6300578 (E.D. Pa. Nov. 29, 2018).

Background

Medicaid requires drug companies to provide the states rebates on their Medicaid sales of outpatient drugs. *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652 (2003). The rebate for generic drugs is a percentage of the Average Manufacturer Price (AMP), the average price wholesalers pay the manufacturer for a drug. For branded drugs, it is the lesser of (1) a percentage of AMP and (2) the difference between the "best" or lowest price other purchasers pay the manufacturer for the drug and the AMP. 42 U.S.C. §§ 1396r–8(c)(1)(A)(ii), (3)(A)(i)-(ii), (k)(1)(A) (2010). On a quarterly basis, the manufacturer calculates the AMP for each drug and reports it to the Center for Medicaid and Medicare Services (CMS), which then calculates the rebate owed.[2] Thus, AMP is the critical component of the rebate calculation.

Payments from wholesalers are included in AMP, but bona fide service fees are not. *Id.* § 1396r-8(k)(1)(B)(ii); 42 C.F.R. § 447.504(c)(14) (2007). The exclusion of bona fide service fees lowers AMP, decreasing the difference between AMP and the best price, which yields a lower rebate.[3]

Streck alleges that from January 2014 through March 2016, BMS engaged in its "service fee scheme" to underreport AMP and lower the rebate it owed.[4] He contends that BMS employed "price appreciation" clauses in its service agreements with wholesalers to disguise its price increases as bona fide service fees so it could improperly

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[2] First Am. Compl. (ECF No. 59-1) at ¶¶ 11-12. *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 April 3, 2019).

[3] First Am. Compl. at ¶¶ 30-31.

[4] *Id.* at ¶ 22.

exclude them from AMP.[5] Those provisions required distributors to reduce the service fees they charged BMS by the amount of additional revenue they realized by selling inventory at the new higher price.[6] In short, so Streck avers, instead of factoring price increases into AMP, BMS defined them as bona fide service fees in order to underreport AMP.[7]

Analysis

BMS argues that we clearly erred in ruling that Streck adequately alleged a false claims cause of action with respect to the service fee scheme. If BMS is correct, reconsideration is warranted. *Roberts v. Ferman*, 826 F.3d 117, 126 (3d Cir. 2016) (quotation omitted).

A traditional false claim cause of action "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)). To state a false claim cause of action, the relator must allege (1) the defendant presented a claim for payment to the United States; (2) the claim was false; (3) the defendant knew the claim was false; and (4) the false statement was material to the decision. *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011) (citation omitted); *Petratos*, 855 F.3d at 487.

[5] *Id.*

[6] *Id.* at ¶ 74.

[7] *Id.* at ¶¶ 36–37.

Falsity

To plead falsity, Streck had to allege that BMS's AMP calculations did not comply with a material statute, regulation, or contractual provision. *Wilkins*, 659 F.3d at 305. BMS claims that Streck did not identify any statute or regulation that prohibited treating price appreciation credits as bona fide service fees.[8] Streck cites CMS's 2012 proposed rule which specifically stated that "price appreciation credits[ ] do not meet the definition of a bona fide service fee." Medicaid Program; Covered Outpatient Drugs, 77 Fed. Reg. 5318, 5332 (Feb. 2, 2012).

According to BMS, failure to adhere to a proposed rule does not constitute a violation of a statutory or regulatory provision. It argues that as a proposed rule, CMS's 2012 pronouncement could not and did not prohibit BMS from treating price appreciation credits as bona fide services fees. However, the proposed rule did not stand alone. When it issued the proposed rule, CMS declared that 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. It reminded the drug industry that to determine what constituted a bona fide service fee, it had to look to the definition in the Patient Protection and Affordable Care Act (ACA), 42 U.S.C. § 1396r–8(k)(1) (2010), and its implementing regulation, 42 C.F.R. § 447.502 (2007).[9] *Id.* Thus, although the proposed rule was not final, CMS declared that price appreciation credits were not bona fide service fees as defined by the ACA and its regulations.

[8] Def.'s Mot. for Recon. (ECF No. 117) at 2.

[9] 42 C.F.R. §§ 500 through 522 address "changes from the Affordable Care Act and other requirements pertaining to Medicaid payment of drugs." 42 C.F.R. § 447.500(b).

Although the ACA and its implementing regulations do not specifically address price appreciation credits, they convey that price appreciation credits are not bona fide service fees. First, they define bona fide service fees as those "paid *by* manufacturers *to* wholesalers" for services such as distribution, inventory management, and product stocking. *Id.* (emphasis added); *see also* 42 C.F.R. § 447.502 (providing substantially the same definition). As CMS noted in response to comments on the 2012 proposed rule, price appreciation credits "affect[ ] the average price *to* the manufacturer" paid *by* wholesalers. Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170, 5228 (Feb. 1, 2016) (emphasis added). Second, the regulations define bona fide service fees as fees paid for an "itemized service actually performed on behalf of the manufacturer." 42 C.F.R. § 447.502. 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 . . . ." Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. at 5228. Simply, they are not payments for services.

BMS ignores this definition of bona fide service fees. Instead, it construes the absence of any specific reference to "price appreciation credits" in the ACA or 42 C.F.R. § 447.502 as permitting the credits to be treated as bona fide service fees and excluded from AMP. But, as Streck observes, "statutory and regulatory definitions need not address every artifice industry can imagine; instead, it is the manufacturer's obligation to apply the principles of the applicable statutory and regulatory language to its own factual, in-the-field operations."[10] *See also* Medicaid Program; Covered Outpatient Drugs, 77

[10] Relator's Resp. to Mot. for Recon. (ECF No. 127) at 4-5.

Fed. Reg. at 5332 (noting "the rapidly changing market in which new types of arrangements arise").

Indeed, rather than providing examples of bona fide service fees when it announced the proposed rule in 2012, CMS directed drug manufacturers to the ACA and regulatory definition to determine which service fees were bona fide. *Id.* CMS believed the existing statutory and regulatory framework addressed the issue. Because the framework did not specifically reference "price appreciation credits," CMS offered the proposed rule as additional guidance or clarification. It explained: "We are not proposing to further define the type of fees used as examples in the definition of bona fide service fees because we believe that these terms can be read in concert with *the current definition of bona fide service fee.*" 77 Fed. Reg. at 5332 (emphasis added). It also directed the drug industry to the existing "specific examples of what could qualify as a bona fide service fee" in the ACA. *Id.* CMS's pronouncement reminded the industry of its existing regulatory obligations. It did not set forth a new one. *See id.*

BMS continued to treat price appreciation credits as excludable bona fide service fees, lowering AMP and reducing the rebates it owed. Once CMS restated that price appreciation credits were not bona fide service fees as defined in the ACA and its regulations, drug companies could not deduct them. Despite this declaration, BMS continued the service fee scheme. The AMP it reported to CMS was false. Thus, its rebate claims were false.

Scienter

To plead scienter, Streck is required to allege that BMS acted with knowledge of the falsity of its rebate calculation. *Petratos*, 855 F.3d at 487. Knowledge means that

BMS "ran a risk of violating the law substantially greater than the risk associated with a reading that was merely careless." *United States ex rel. Streck v. Allergan, Inc*. (*Streck I*), 894 F. Supp. 2d 584, 593 (E.D. Pa. 2012) (quoting *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 70 (2007)). A defendant's erroneous, but reasonable, interpretation of its legal obligations is insufficient for liability. *United States ex rel. Streck v. Allergan* (the *Streck Appeal*), 746 F. App'x 101, 106 (3d Cir. Aug. 16, 2018) (quoting *Purcell*, 807 F.3d at 287-88).

Where a defendant maintains that its interpretation was reasonable at the time it submitted its claim, the court considers three factors in determining whether it acted with scienter: "(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 that interpretation by available administrative and judicial guidance." *Id.* (citing *Purcell*, 807 F.3d at 288).

What constituted bona fide services fees for purposes of calculating AMP was not ambiguous. Section 447.502 defines them as fees paid for "an itemized service actually performed on behalf of the manufacturer." There is nothing ambiguous about that definition.

Even if the definition was ambiguous and BMS's interpretation was objectively reasonable, BMS was warned away from its interpretation of bona fide service fees. Citing *Safeco*, BMS argues that the 2012 proposed rule was not "authoritative guidance" capable of warning it away from its reading that the ACA and C.F.R. definition of bona fide service fees encompasses price appreciation credits.[11] Whether the proposed rule

[11] Def.'s Mot. for Recon. at 8-9 (citing *Safeco Ins. Co. of Am.*, 551 U.S. at 70).

warned BMS away presents a question of fact. *Purcell*, 807 F.3d at 288-89. *See also United States ex rel. Nevyas v. Allergan, Inc*., Civ. A. No. 09-432, 2015 WL 4064629, at *6 (E.D. Pa. July 2, 2015). Here, a factual determination remains whether it had been warned away from its interpretation by CMS's declaration that price appreciation credits did not meet the definition of bona fide service fees in the ACA and 42 C.F.R. § 447.502. *Purcell*, 807 F.3d at 289.

In the *Streck Appeal*, the Third Circuit asked whether the Service Fee Defendants had been warned away from a similar alleged scheme "by available administrative and *judicial guidance*." 746 F. App'x at 106 (emphasis added). The administrative guidance in that case included the same 2012 proposed rule, CMS Manufacturer Releases, and a report from the Department of Health and Human Services "recommend[ing] appropriate changes in AMP calculation guidelines . . . ." *Id.* at 108-09. The Third Circuit concluded that because the proposed rule had been issued after the complaint had been filed and the regulatory landscape remained too confusing notwithstanding the other administrative guidance, it could not find that the defendants had been warned away from their exclusion of price appreciation credits from AMP. *Id.* However, it did not find any of this guidance insufficiently "authoritative."

Here, BMS also had the benefit of, but ignored, "judicial guidance" which had not been available to the defendants in the *Streck Appeal*. In 2012, before the service fee scheme began, Judge Robreno had warned in *Streck I* that the treatment of price appreciation credits as bona fide service fees was "contrary" to the proposed rule. 894

F. Supp. 2d at 600. He further warned that a drug manufacturer did so after the announcement of the proposed rule could have "acted at least recklessly . . . ."[12] *See id.*

Even if the definition of bona fide service fees in the ACA and implementing regulations was ambiguous, and BMS's interpretation was objectively reasonable, it was warned "by available administrative and judicial guidance" that price appreciation credits did not fit the definition. Therefore, we conclude Streck has alleged sufficient facts that, if proven, could permit a jury to find that BMS acted with scienter.

Conclusion

Streck has pled the falsity and scienter elements of his FCA claim. Thus, we shall deny BMS's motion to reconsider.

[12] In *Streck I*, because Streck filed the operative complaint prior to the promulgation of the proposed rule, Judge Robreno did not ultimately decide whether Service Fee Defendants had violated it. *Streck I*, 894 F. Supp. 2d at 589-90, 600.

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ORDER

NOW, this 3rd day of April, 2019, upon consideration of Bristol-Myers Squibb Company's Motion for Reconsideration (Document No. 117), the response, the reply, and the sur-reply, it is **ORDERED** that the motion is **DENIED**.

/s/TIMOTHY J. SAVAGE