8-16-2018

Ronald Streck v. Allergan Inc

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

_____

No. 17-1014

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UNITED STATES OF AMERICA; THE STATE OF CALIFORNIA; THE STATE OF CONNECTICUT; THE STATE OF DELAWARE; THE STATE OF FLORIDA; THE STATE OF GEORGIA; THE STATE OF HAWAII; THE STATE OF ILLINOIS; THE STATE OF INDIANA; THE STATE OF LOUISIANA; THE COMMONWEALTH OF MASSACHUSETTS; THE STATE OF MICHIGAN; THE STATE OF MONTANA; THE STATE OF NEVADA; THE STATE OF NEW HAMPSHIRE; THE STATE OF NEW JERSEY; THE STATE OF NEW MEXICO; THE STATE OF NEW YORK; THE STATE OF NORTH CAROLINA; THE STATE OF OKLAHOMA; THE STATE OF RHODE ISLAND; THE STATE OF TENNESSEE; THE STATE OF TEXAS; THE COMMONWEALTH OF VIRGINIA; THE STATE OF WISCONSIN; THE DISTRICT OF COLUMBIA, ex rel. RONALD J. STRECK

v.

ALLERGAN, INC.; AMGEN, INC.; ASTRAZENECA PHARMACEUTICALS LP; AZTRAZENECA LP; BIOGEN IDEC INC., BRADLEY PHARMACEUTICALS INC. n/k/a FOUGERA PHARMACEUTICALS, INC.; CEPHALON, INC.; EISAI, INC.; GENZYME CORPORATION; MALLINCKRODT INC. n/k/a MALLINCKRODT LLC; NOVO NORDISK, INC.; RELIANT PHARMACEUTICALS, INC; SEPRACOR n/k/a SUNOVION PHARMACEUTICALS INC.; UPSHER-SMITH LABORATORIES, INC.

Ronald J. Streck,
Appellant

_____

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. Civil No. 2-08-cv-05135)
District Judge: Honorable Eduardo C. Robreno

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Argued
April 12, 2018

_____

Before: CHAGARES, VANASKIE, *Circuit Judges*, and BOLTON,* *District Judge*

(Filed: August 16, 2018)

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OPINION**

VANASKIE, *Circuit Judge.*

This appeal concerns allegations that several drug manufacturers underpaid Medicaid rebates to the States under the Medicaid Drug Rebate Program ("MDRP"), 42 U.S.C. § 1396r-8, in violation of the False Claims Act ("FCA"), 31 U.S.C. § 3729, and its state counterparts. Specifically at issue in this *qui tam* action is whether Appellees knowingly violated the FCA by excluding certain credits they received from their customers in calculating a drug's "Average Manufacturer Price." Concluding that Appellees' decision to exclude these credits from the calculation of a drug's "Average Manufacturer Price" reflected a reasonable interpretation of the pertinent MDRP statutory provisions, we will affirm the District Court's order granting the Appellees' joint motion to dismiss.

I.

As we write principally for the benefit of the parties, we recite only the essential facts and procedural history. The following facts are generally taken from the Fourth

*The Honorable Susan R. Bolton, Senior District Judge, United States District Court for the District of Arizona, sitting by designation.

** This disposition is not an opinion of the full Court and pursuant to I.O.P. 5.7 does not constitute binding precedent.

Amended Complaint and are assumed to be true for the purposes of this opinion. *See Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (citation omitted).

Appellees (the "Service Fee Defendants" or "SFDs") consist of nine drug manufacturers.[1] All nine manufacturers participated in the MDRP during the relevant time period. The MDRP helps to offset the cost of prescription drugs dispensed to Medicaid patients. Participating manufacturers must pay the states a rebate for their drugs that are covered by a state's Medicaid plan. A central component for calculating the amount of the rebate is the drug's "Average Manufacturer's Price," or "AMP." Under the applicable versions of the MDRP, AMP is generally defined as the price wholesalers pay participating manufacturers for drugs. The lower the AMP, the lower the rebate manufacturers must pay the states.

Appellant Ronald J. Streck was the CEO of Rx Distribution Network, a network of regional drug wholesalers. While in this role, Streck became familiar with the agreements that the SFDs entered into with various wholesalers. Before 2004, wholesalers commonly engaged in a practice of "speculative buying," stockpiling inventory acquired from drug manufacturers at one price. Wholesalers would then sit on the extra inventory until manufacturers increased their drug prices, at which time they would sell off any extra inventory at the higher price and retain the profits.

[1] These manufacturers are: Allergan, Inc., Amgen, Inc., Bradley Pharmaceuticals, Inc. n/k/a Fougera Pharmaceuticals, Inc., Eisai, Inc., Mallinckrodt, Inc. n/k/a Mallinckrodt LLC, Novo Nordisk, Inc., Reliant Pharmaceuticals, Inc., Sepracor, Inc. n/k/a Sunovian Pharmaceuticals Inc., and Upsher-Smith Laboratories, Inc.

In an effort to curb speculative buying, the SFDs negotiated clawback provisions with their wholesalers that, in essence, deprived wholesalers of their stockpiling profits. Rather than taking the form of cash payments, however, the clawbacks were structured as credits against service fees. Service fees, in turn, were payments owed by manufacturers to wholesalers under separate provisions of the agreements in exchange for services provided by wholesalers. Going forward, we will refer to the clawbacks as "price-appreciation credits." Price-appreciation credits reduced the amount manufacturers had to pay to wholesalers for the services rendered by wholesalers on behalf of the manufacturers, such as product distribution services. Stated otherwise, price-appreciation credits increased the value manufacturers received for the drugs purchased by wholesalers.

From 2004 to 2012, the SFDs excluded price-appreciation credits from their AMP calculations, thus reducing their AMPs and the rebates owed the states. The parties dispute whether they were permitted to do so. Streck contends they were not and that this practice resulted in fraudulently lower AMPs, and ultimately, fraudulently lower rebates to state Medicaid programs—in other words, false claims.

Streck initially filed this lawsuit in October 2008 on behalf of the United States and several states against two groups of defendants—the SFDs and several non-service fee drug manufacturers.[2] The United States and relevant states declined to intervene as to the SFDs. In December 2011, the SFDs jointly moved to dismiss Streck's Fourth

[2] The allegations against the other manufacturers involved a distinct scheme, not relevant to this appeal.

Amended Complaint (the "FAC"). The District Court granted the motion, concluding that Streck had failed to plead sufficient facts plausibly suggesting the SFDs had knowingly violated the FCA. Accordingly, the District Court dismissed all of Streck's claims against the SFDs with prejudice. The District Court also dismissed all of the states' claims against the SFDs with prejudice. However, the District Court dismissed all of the United States' claims against the SFDs without prejudice.

Streck and the remaining non-service fee defendants ultimately settled. At that point, all of Streck's claims against both the SFDs and the non-service fee defendants were finally adjudicated. Streck filed a Notice of Appeal with respect to the District Court's order dismissing his claims against the SFDs. The Third Circuit Clerk remanded the case to the District Court to determine whether certification pursuant to Federal Rule of Civil Procedure 54(b) was required before we could exercise jurisdiction over the appeal. On remand, Streck filed a Rule 54(b) motion, which the District Court granted.

II.

The District Court had jurisdiction pursuant to 28 U.S.C. §§ 1331, 1345, and 1367, and 31 U.S.C. § 3732. Although the parties do not dispute appellate jurisdiction, we must consider our jurisdiction *sua sponte*. *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 751 F.3d 150, 156 (3d Cir. 2014).

"The scope of our review concerning questions of our own jurisdiction is plenary." *Id.* As we explained in *In re Fosamax*:

> Pursuant to 28 U.S.C. § 1291, we have jurisdiction over appeals from final decisions of the district courts of the United States. Generally, an order which terminates fewer than all claims pending in an action or claims against fewer than all the parties to an action does not constitute a final order for purposes of 28 U.S.C. § 1291. However, under Rule 54(b) of the Federal Rules of Civil Procedure, a district court may convert an order adjudicating less than an entire action to the end that it becomes a final decision over which a court of appeals may exercise jurisdiction under 28 U.S.C. § 1291.

Id. at 156 (internal citations and quotation marks omitted). Put somewhat differently, "[o]btaining a final judgment [via Rule 54(b) certification] cures the jurisdictional defect of an otherwise premature appeal." *Id.* (citations omitted).

While it could be argued that Streck filed his Notice of Appeal prematurely, the District Court's subsequent certification of the matter pursuant to Rule 54(b) cured any jurisdictional defect. *See id.* Thus, we have appellate jurisdiction to consider the District Court's dismissal of Streck's claims against the SFDs.

III.

We now turn to the primary issue on appeal—whether the District Court properly dismissed the FAC for failure to allege the SFDs acted with the required mental state.[3] Our review of a decision granting motions to dismiss is plenary. *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 240 (3d Cir. 2004) (citations omitted).

[3] We note that our reasoning applies equally to Streck's claims brought under the federal FCA and the FCAs of the various states. Because we ultimately conclude that Streck failed to plead that the SFDs acted with the required mental state, we need not reach the SFDs' alternative argument that Streck waived appeal of his state-law claims.

As a preliminary matter, the parties dispute whether Streck's complaint should be governed by the pleading standard of Rule 8 or Rule 9(b). It makes no difference whether we assess Streck's allegations under either standard. Although under Rule 9(b), scienter may be pled generally, Rule 8 still requires FCA plaintiffs to plead facts sufficient to raise a plausible claim of fraud. *Cf. Ashcroft v. Iqbal*, 556 U.S. 662, 686–87 (2009) ("Rule 9 merely excuses a party from pleading discriminatory intent under an elevated pleading standard. It does not give him license to evade the less rigid—though still operative—strictures of Rule 8.") (citation omitted).

The FCA imposes liability on any person who "knowingly" makes a false claim to the government. 31 U.S.C. § 3729(a)(1)(A). As relevant here, a defendant acts "knowingly" if he or she "acts in reckless disregard of the truth or falsity of . . . information."[4] *Id.* § 3729(b)(1)(A)(iii). "Consistent with the need for a knowing violation, the 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." *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 287–88 (D.C. Cir. 2015) (internal

[4] At oral argument, Streck's counsel maintained that the FAC also contained allegations that the SFDs acted with deliberate ignorance. *See* Tr. 29:17–21; *see also id.* § 3729(b)(1) (explaining a defendant acts knowingly if he "acts in deliberate ignorance of the truth or falsity of . . . information"). We are not convinced. Allegations of deliberate ignorance demonstrate conduct and knowledge particularized to a given defendant. For the most part, the allegations in the FAC do not shed light on each SFDs' negotiations process. The one potential exception, which concerns the more specific allegations made against Eisai, Inc., was relinquished by Streck's counsel at oral argument. *See* Tr. 11:1–18.

citation omitted) (recognizing defense of reasonable, but erroneous, interpretation of ambiguous statute), *cert. denied*, 137 S. Ct. 625 (2017); *cf. Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 68–70 (2007) (recognizing similar defense to False Credit Reporting Act claim, which also requires showing of reckless disregard); *Long v. Tommy Hilfiger U.S.A., Inc.*, 671 F.3d 371, 374–75 (3d Cir. 2012) (recognizing similar defense to Fair and Accurate Credit Transactions Act claim, which also requires showing of reckless disregard).

Assuming the SFDs' decision to exclude price-appreciation credits was erroneous, we ask whether doing so during the relevant time period was objectively unreasonable. Basing a defense on a reasonable, but erroneous, interpretation of a statute includes three distinct inquiries: (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. *See Purcell*, 807 F.3d at 288 (observing that, even if a term is ambiguous and a defendant's interpretation of that term was reasonable, "a jury might still find knowledge if there is interpretive guidance that might have warned [the defendant] away from the view it took") (alteration in original) (citation and quotation marks omitted).

Applied here, we must first decide whether the MDRP's definition of AMP was ambiguous with regard to price-appreciation credits. This is a question of statutory interpretation, the principles of which are well-established. In *Long*, we explained:

> Our role is to give effect to Congress's intent, which we assume is expressed in the ordinary meaning of the statutory language. In analyzing whether the statutory language is unambiguous, we take account of the specific context in which that language is used, and the broader context of the statute as a whole. We also consider the overall object and policy of the statute, and avoid constructions that produce odd or absurd results or that are inconsistent with common sense.

671 F.3d at 374–75 (citations and quotation marks omitted).

At issue here are several versions of the MDRP's definition of AMP. From 1997 through 2007, Congress defined AMP in the following way:

> 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) (current version at 42 U.S.C. § 1396r-8(k)(1)(A) (2018)). In 2007, Congress amended the definition of AMP as follows:

> Subject to subparagraph (B), [which excludes customary prompt pay discounts from AMP,] 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) (current version at 42 U.S.C. § 1396r-8(k)(1)(A) (2018)). Then, in 2010, Congress changed the statutory definition of AMP to read:

> Subject to subparagraph (B), [which excludes, *inter alia*, customary prompt pay discounts, bona fide service fees, reimbursements for unsalable goods, payments received from, and rebates or discounts provided to entities that do not conduct business as wholesalers or retail community

> pharmacies, and certain discounts provided by manufacturers from AMP,] 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.

42 U.S.C. § 1396r-8(k)(1)(A) (2010) (current version at 42 U.S.C. § 1396r-8(k)(1)(A) (2018)).

Each version of the statute calls for calculation of a drug's AMP as the average price paid by entities dealing directly with the manufacturer during the rebate period. Notably, each version of the statute recognized that certain matters could be excluded from the calculation of AMP, such as prompt pay discounts, thereby reducing AMP. No version of the statute addressed price-appreciation credits. The question here, then, is whether the statute unambiguously required price-appreciation credits to be added to the price paid by wholesalers.

Black's Law Dictionary defines "price" as "[t]he amount of money or other consideration asked for or given in exchange for something else; the cost at which something is bought or sold." *Price*, Black's Law Dictionary (10th ed. 2014). Per the SFD agreements with their wholesalers, however, price-appreciation credits are not part of the initial value given for the acquisition of a supply of drugs. Rather, a price-appreciation credit is only triggered once a drug is distributed by a wholesaler to a third party after the manufacturer has increased the price of the drug above the amount paid

by the wholesaler. Additionally, the value of a price-appreciation credit turns on the ultimate price the third party pays a wholesaler for a drug, not just the price a wholesaler initially pays a manufacturer for a stock of drugs.

Admittedly, a price-appreciation credit that remits value back to a manufacturer could be considered a component of the cumulative value a manufacturer receives for a drug. However, we note neither the word "initial" nor the word "cumulative" appears before "price" in any of the applicable versions of the statute. The absence of such temporal language gives us pause before concluding that "price" unambiguously refers to the cumulative price paid, rather than the initial price paid. In short, while the statute could be interpreted to include price-appreciation credits in the AMP calculation, the statute is—as the District Court observed—susceptible to multiple interpretations, one of which excludes the price-appreciation credits. In other words, the statute is ambiguous.

We next address whether it was objectively unreasonable to conclude that manufacturers could exclude price-appreciation credits from their calculations of AMP. The District Court determined that it was not. Specifically, the District Court reasoned that "price paid to the manufacturer" could be read as referring to the price initially paid to the manufacturer by the wholesaler. We agree. Once again, we are persuaded by the fact that the applicable versions of the statute lack temporal limitations when referring to "price."

We conclude by asking whether the SFDs were warned away from this interpretation by available guidance. In answering this question, we take judicial notice of numerous pieces of administrative guidance issued between 1991 and 2012 on which

the parties rely. *See Spellman v. Am. Barge Line Co.*, 176 F.2d 716, 720 (3d Cir. 1949); *see also Denius v. Dunlap*, 330 F.3d 919, 926–27 (7th Cir. 2003) (collecting cases). Streck contends that the guidance available during the relevant time 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. We disagree. Despite the fact that some of the guidance (such as Manufacturer Releases issued by the Centers for Medicare & Medicaid Services (the "CMS") during the 1990s) could be read to support Streck's interpretation, we cannot say that this guidance was so clear as to warn the SFDs away from an interpretation that excluded price-appreciation credits from AMP. Rather, we are convinced that the available scattershot guidance failed to articulate a coherent position on AMP and, specifically, price-appreciation credits.

We are particularly persuaded by two pieces of administrative guidance. First, in 2005, the Office of Inspector General, Department of Health and Human Services (the "OIG") was directed to "review the requirements for, and manner in which, AMPs [were] determined," and to "recommend appropriate changes" in AMP calculation guidelines to the Secretary of Health and Human Services (the "HHS Secretary"). Office of Inspector Gen., HHS, Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005 ("OIG Report") (2006), at i. The OIG issued its report in 2006. While the OIG Report was not concerned with price-appreciation credits specifically, the OIG concluded that "[e]xisting requirements for

determining certain aspects of AMPs are not clear and comprehensive, and manufacturers' methods of calculating AMPs are inconsistent." *Id.* The OIG went on to explain that, as far back as 1991, manufacturers used different methods to calculate AMP, such as "bas[ing] calculations on gross sales to wholesalers, net sales to wholesalers, or direct retail sales and retail sales reported by wholesalers." *Id.* at 4. The OIG also compiled the concerns of industry groups regarding administrative and service fees, and in particular, whether these fees should be included in AMP. Accordingly, in its recommendations, the OIG suggested that the HHS Secretary direct the CMS to "consider addressing issues raised by industry groups, such as: administrative and service fees . . . ." *Id.* at 12. In Appendix G to the Report, the CMS commented on a draft of the OIG's findings:

> The CMS acknowledges that the OIG has reported some confusion among drug manufacturers about what sales and price concessions must be included when calculating AMP. This is an extremely complex and technical topic that has been made more difficult due to changes in the chain of sales and the evolution of new entities, especially [pharmacy benefit managers]. For this reason, CMS had hoped that the OIG would have provided more specific recommendations for us to consider as we develop a proposed rule to address this topic. However, we appreciate the efforts of the OIG in the past, as well as this report, and we look forward to continuing to work with the OIG on this important issue.

Id. at App. G, 2. All told, the OIG Report suggests that there was significant confusion regarding what to include in AMP calculations, despite the existence of the administrative guidance from the 1990s on which Streck relies. The confusion appears to have been extensive enough to merit a recommendation that the CMS clarify the types

of payments that were excludable from AMP—a concern seconded by the CMS itself in its response to the Report.

Second, the guidance proffered by the parties reveals that price-appreciation credits were not specifically addressed by the CMS until 2012. In 2012, the CMS proposed a rule intended to clarify how manufacturers should calculate AMP. *See* Medicaid Program; Covered Outpatient Drugs ("2012 Proposed Rule"), 77 Fed. Reg. 5318 (proposed Feb. 2, 2012). The 2012 Proposed Rule explained that price-appreciation credits were likely not excludable from AMP as "bona fide service fees." 77 Fed. Reg. at 5332. This statement by the CMS, however, did not unambiguously foreclose the possibility that price-appreciation credits could be excluded from AMP under a different theory.[5]

[5] We also note a distinction between the 2012 Proposed Rule and the final rule issued by the CMS in 2016. *See* Medicaid Program; Covered Outpatient Drugs ("2016 Final Rule"), 81 Fed. Reg. 5170 (Feb. 1, 2016). In response to comments challenging the position on price-appreciation credits taken by the CMS in the 2012 Proposed Rule, the CMS wrote:

> We continue to believe that price appreciation credits would likely not meet the definition of bona fide service fee. 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 § 447.504(f).

In light of the OIG's recognition of confusion regarding the calculation of AMP during the relevant time period and the CMS's first express recognition of price-appreciation credits in 2012, we are convinced that Streck failed to plead that the SFDs were warned away from an interpretation of AMP that excluded price-appreciation credits. Although we are not prepared to say that this is the best interpretation of the statute, we nevertheless are confident that—at the very least—it was not objectively unreasonable to act in accordance with such an interpretation between the years of 2004 and 2012. Because this reasonable interpretation of an ambiguous statute was inconsistent with the reckless disregard Streck was required to allege at this stage of the litigation, we will affirm the District Court's dismissal of Streck's claims.[6]

IV.

For these reasons, we will affirm the order of the District Court dated July 3, 2012.

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81 Fed. Reg. at 5228. The 2016 Final Rule, which strikes us as far clearer on the issue of price-appreciation credits, was obviously unavailable to the SFDs during the relevant time period.

[6] As an alternative ground for affirmance, the SFDs contend that Streck failed to satisfy the heightened pleading requirements of Rule 9(b) for stating a claim for fraud. Because we conclude that the District Court properly dismissed the FAC on the ground that Streck failed to plead a plausible violation of the FCA, we decline to reach this issue.