UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA ex rel, ADVENTIST HEALTH SYSTEM/WEST, et al., Plaintiff/Relator, v. ABBVIE, INC., et al., Defendants.	2:21-cv-4249-DSF-SKx Order GRANTING Motion to Dismiss (Dkt. 122)

Plaintiff/Relator Adventist Health System/West has brought this False Claims Act case on behalf of the United States and numerous states. Relator claims that the Defendant pharmaceutical companies presented, or caused to be presented, false claims to the federal and state governments when the Defendants failed to comply with the drug pricing requirements of the 340B Drug Pricing Program (340B Program) found in 42 U.S.C. § 256b. Defendants now move to dismiss the complaint.

I. BACKGROUND

The 340B Program was created in 1992 and implements a ceiling price for certain outpatient drugs when those drugs are sold to certain providers known as "covered entities." Drug manufacturers are required to participate in the 340B Program if their products are to be purchased using Medicaid or Medicare Part B funds. The Health Resources and Services Administration (HRSA) of the Department of Health and Human Services (HHS) administers the 340B Program.

The price ceiling applicable to the 340B Program is set by statute in 42 U.S.C. § 256b(a)(1). In certain circumstances where a drug manufacturer increases the price of a drug faster than the general rate of inflation, the statutory ceiling price can fall below zero. The crux of this case is the way in which the Defendants are alleged to have dealt with this situation.

The long-held policy position of HRSA has been the so-called "penny pricing" policy: when the statutory ceiling price of a drug falls to at or below zero, the manufacturer is to charge covered entities no more than $0.01. However, this policy was not implemented in a binding, final regulation until 2019. In the absence of a binding regulation, Defendants are alleged to have priced their drugs that would otherwise be subject to the penny pricing policy at levels above $0.01 – sometimes far above. This pricing was apparently arrived at in several ways, although Defendants conspicuously fail to explain in their filings in this case why or how they believe that these approaches are justified by § 256b(a)(1) other than to argue that § 256b(a)(1) contemplates some positive, non-zero payment.[1]

The thrust of Relator's case is reasonably simple: Defendants caused false claims to be submitted to the federal and state government

[1] Defendants belabor the point that the penny pricing policy was allegedly not mandatory prior to 2019. But, as Relator stresses, there is a strong argument that the statutory language of § 256b(a)(1) does not authorize any pricing over $0.01 regardless of the existence of a regulation. Nor is there anything in § 256b(a)(1) to suggest that it would allow a manufacturer to set a 340B Program ceiling price using a formula unilaterally chosen by the manufacturer. In addition, it is not immediately clear that lack of an explicit, binding regulation would be a defense to an FCA claim where the government provided clear expectations for submitted claims and Defendants nonetheless submitted claims without disclosing that those claims did not comport with the government's stated expectations. Cf. Defendant Sanofi's explicit disclosure that it was not complying with the penny pricing policy and explaining its alternative approach. Bueker Decl., dkt. 124-10, Page ID 2178-2187.

when they overcharged 340B Program covered entities through their failure to comply with the formula specified in § 256b(a)(1). Relator argues that the statutory language compelled Defendants to charge, at best, no more than $0.01 for the drugs at issue and Defendants knowingly failed to comply with the statutory requirement when they utilized pricing formulas not found in § 256b(a)(1).

In addition to arguing that the complaint fails to allege falsity and scienter adequately, Defendants claim that Relator cannot bring a *qui tam* FCA action because the allegations in the complaint were previously publicly disclosed and Relator is not an "original source." Defendants further argue that the Supreme Court's holding in Astra USA, Inc. v. Santa Clara County, 563 U.S. 110 (2011), prohibits enforcement of the 340B Program requirements through the mechanism of the FCA.

II. LEGAL STANDARD

Rule 12(b)(6) allows an attack on the pleadings for failure to state a claim on which relief can be granted. "[W]hen ruling on a defendant's motion to dismiss, a judge must accept as true all of the factual allegations contained in the complaint." Erickson v. Pardus, 551 U.S. 89, 94 (2007) (per curiam). Allegations contradicted by matters properly subject to judicial notice or by exhibit need not be accepted as true, Produce Pay, Inc. v. Izguerra Produce, Inc., 39 F.4th 1158, 1161 (9th Cir. 2022); and the court is "not bound to accept as true a legal conclusion couched as a factual allegation." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" Id. (alteration in original) (quoting Twombly, 550 U.S. at 557).

A complaint must "state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570. This means that the complaint must plead "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. "The plausibility standard is not akin to a

'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." Id. There must be "sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively . . . and factual allegations that are taken as true must plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation." Starr v. Baca, 652 F.3d 1202, 1216 (9th Cir. 2011).

III. ANALYSIS

While Defendants argue for dismissal on several grounds, the Court need address only the application of Astra because it requires dismissal of all claims.

In Astra, the Supreme Court considered "whether 340B entities, though accorded no right to sue for overcharges under the statute itself, may nonetheless sue allegedly overcharging manufacturers as third-party beneficiaries of the PPAs to which the manufacturers subscribed."[2] 563 U.S. at 113. The Supreme Court unanimously found they could not.

Defendants now argue that the same reasoning applies to the use of FCA *qui tam* actions by 340B covered entities. Perhaps surprisingly, the application of Astra to FCA claims appears to be a matter of first impression.

The most obvious difference between FCA *qui tam* claims and the third-party beneficiary contract claims considered in Astra is that a *qui tam* plaintiff is presenting the claims of the government, not those of the plaintiff itself. An FCA claim also has additional elements that

[2] A PPA is a "Pharmaceutical Pricing Agreement." "PPAs are not transactional, bargained-for contracts. They are uniform agreements that recite the responsibilities § 340B imposes, respectively, on drug manufacturers and the Secretary of HHS. Manufacturers' eligibility to participate in State Medicaid programs is conditioned on their entry into PPAs for covered drugs purchased by 340B entities." Id. at 113.

make it different in many cases from a direct attack on 340B program compliance – notably the requirements of falsity and scienter, as opposed to mere noncompliance. However, despite these differences, the underlying rationale of Astra applies as much to a *qui tam* FCA claim as to the third-party beneficiary claims considered in Astra.

The reasoning in Astra was three-fold. First, because the PPA contracts "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them," a third-party suit to enforce them would be "in essence a suit to enforce the statute itself." Id. at 118. Allowing such suits would therefore render the lack of a private right of action "meaningless." Id.

Second, it was telling that the suit was based explicitly on allegations that the manufacturer defendants charged more than the 340B ceiling price, "not that they violated any independent substantive obligation arising only from the PPAs," and the plaintiff "[r]epeatedly . . . acknowledged that § 340B is the source of the contractual term allegedly breached." Id. at 118-19.

Third, the statutory scheme showed that "spreading the enforcement burden" was "hardly what Congress contemplated" when it created the 340B Program. Id. at 119. "Far from assisting HHS, suits by 340B entities would undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." Id. at 120. And while it did appear that oversight and enforcement of the 340B Program was inadequate, "Congress did not respond to the reports of inadequate HRSA enforcement by inviting 340B entities to launch lawsuits in district courts across the country." Id. at 121. Instead, it directed HRSA to create a dispute resolution process within HRSA, and added disclosure requirements and enforcement powers. Id. at 121-22.

All of these considerations apply equally to Relator's FCA suit. Relator is explicit that the falsity of the claims at issue was due to Defendants' noncompliance with the statutory requirements of the

340B Program.[3] On this theory of falsity, the FCA adds nothing substantive to a direct enforcement action under the statute other than that Defendants must have acted knowingly, recklessly, or with deliberate ignorance. There is no indication that Astra would have been decided differently if the PPA contracts had required breaches to have been done with one of these states of mind.

Astra's concern about fragmented and inconsistent enforcement of the 340B Program is only slightly less for *qui tam* FCA actions as it was for the private PPA contract claims. *Qui tam* FCA cases do provide the government the option to intervene in the case and thus exercise more control than in a private breach of contract case; however this is imperfect and does not address the problem of state law FCA cases and the federal government's limited influence over them despite the federal HHS's responsibility for the 340B Program.

In sum, the Court finds that Astra bars FCA claims by a *qui tam* plaintiff where the allegation of falsity is that the defendants failed to comply with the statutory requirements of the 340B Program. The Court recognizes that the analysis would be more complicated if the FCA claim were brought directly by a federal or state government or if the claims involved fraud beyond noncompliance with statutory language, *e.g.*, submission of falsely certified data. The Court expresses

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[3] See, e.g., Opp'n, dkt. 135, at 44 ("Because Defendants Did Not Charge Either a Zero Price or a Penny Price, as Required by Statute, Their Claims Were False"); at 46 ("Stated another way, whether Defendants' prices were 'false' does not involve Defendants' state of mind. Rather, the question is whether Defendants' prices were correct or incorrect—i.e., did Defendants' prices comply with the law or fail to comply?"); at 49-50 ("In conclusion, when the statutory Ceiling Price formula yields a zero price, Defendants were statutorily required to report a zero price. However, given that HRSA issued written guidance permitting drug manufacturers to submit prices of $0.01 in such circumstances, Defendants cannot be accused of submitting false claims based on the use of penny prices. But, when Defendants elected to submit fabricated prices based on their own 'alternative calculation,' they submitted false Ceiling Prices.").

no opinion regarding such scenarios. Nor does the Court reach any of Defendants' alternative grounds for dismissal, such as the public disclosure bar.

IV. CONCLUSION

The motion to dismiss is GRANTED. Given that the dismissal is on purely legal grounds, leave to amend is not given. Judgment will be entered consistent with this order.

IT IS SO ORDERED.

Date: March 18, 2024

Dale S. Fischer
United States District Judge