No. 24-2180

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA *ex rel.* ADVENTIST HEALTH SYSTEM OF WEST, Relator, on behalf of the State of California and other States,

Plaintiff-Appellant,

v.

ABBVIE INC., *et al.*,

Defendants-Appellees.

On Appeal from the United States District Court for the Central District of California, No. 2:21-cv-04249-DSF-SK
Hon. Dale S. Fischer, District Judge

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1(a), Defendants-Appellees AbbVie Inc., Allergan Sales, LLC, Allergan U.S.A., Inc., AstraZeneca LP, AstraZeneca Pharmaceuticals LP, Genzyme Corporation, Novartis Pharmaceuticals Corporation, Sandoz Inc., Sanofi-Aventis U.S. LLC, and Sanofi US Services Inc. (collectively, "Appellees") state as follows:

Allergan USA, Inc. is 100% owned by Allergan Sales, LLC. Allergan Sales LLC is 51.8% owned by Allergan Holdings, Inc. and 48.2% owned by Allergan Holdco US, Inc. AbbVie Inc. (Ticker ABBV) has no parent corporation, and there is no publicly traded corporation that owns 10% or more of its stock.

AstraZeneca LP merged into AstraZeneca Pharmaceuticals LP on December 31, 2018. AstraZeneca Pharmaceuticals LP is an indirectly wholly owned subsidiary of AstraZeneca PLC, a publicly traded company (NASDAQ: AZN). No other publicly held corporation owns 10% or more of the voting interest in AstraZeneca Pharmaceuticals LP.

Novartis Pharmaceuticals Corporation is a wholly owned subsidiary of Novartis Finance Corporation and an indirect, wholly-

owned subsidiary of Novartis AG. Novartis AG ordinary shares trade on the SIX Swiss Exchange under the symbol NOVN and its American Depository Shares trade on the New York Stock Exchange under the ticker symbol NVS.

Sandoz Inc. is an indirect, wholly-owned subsidiary of Sandoz Group AG. Sandoz Group AG ordinary shares trade on the SIX Swiss Exchange under the symbol SDZ and its American Depository Shares trade on OTCQX under the symbol SDZNY. There are no publicly traded companies between Sandoz Inc. and Sandoz Group AG.

Sanofi-Aventis U.S. LLC is a wholly-owned subsidiary of Sanofi US Services Inc. Sanofi US Services Inc. and Genzyme Corporation are wholly-owned subsidiaries of Aventis Inc., a wholly-owned subsidiary of Sanofi Foreign Participations B.V., which is a wholly-owned subsidiary of Sanofi SA. Genzyme Corporation, Sanofi US Services Inc., and Sanofi-Aventis U.S. LLC are wholly-owned indirect subsidiaries of Sanofi SA, a publicly traded foreign corporation. No other publicly traded corporation owns 10% or more of their stock.

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INTRODUCTION

This appeal concerns an attempt by Adventist Health System/West (Adventist) to end-run the Supreme Court's decision in *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011). *Astra* analyzed Section 340B of the Public Health Service Act, which allows certain healthcare providers known as "covered entities" to buy prescription drugs at deeply discounted prices. The 340B statute is implemented through form agreements between drug manufacturers and the Secretary of the U.S. Department of Health and Human Services (HHS). As *Astra* made clear, the 340B statute does not allow covered entities to sue manufacturers that allegedly fail to provide the required discounts, regardless of the particular cause of action a covered entity may try to assert. Instead, covered entities that believe they have been overcharged must utilize the statute's exclusive administrative enforcement mechanism.

Adventist, an operator of covered entities, has tried to plead around *Astra*'s holding by couching 340B overcharge claims against Appellees, a group of pharmaceutical manufacturers, as alleged violations of the False Claims Act (FCA). Courts have rejected similar efforts by covered entities to circumvent *Astra* and the 340B statute's administrative-enforcement

regime by dressing up overcharge claims as other purported causes of action. The District Court properly determined that Adventist's FCA claims run afoul of *Astra* and dismissed this action with prejudice.

JURISDICTION

The District Court had jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1367(a) and 31 U.S.C. § 3732(a), (b).

Adventist asserts that the District Court had jurisdiction under 28 U.S.C. § 1345, which confers jurisdiction over "civil actions … commenced by the United States, or by any … officer thereof expressly authorized to sue by Act of Congress." *See* Br. 2. But this action was not commenced by the United States, *see U.S. ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 937 (2009) (holding that United States is not a party to a qui tam action unless it intervenes), and this Court has held that a qui tam relator is not an "officer" of the United States, *U.S. ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 749–59 (9th Cir. 1993).[1]

[1] If Adventist is an "officer" of the United States, then the Appointments Clause bars this action. That Clause requires "Officers of the United States" to be "appoint[ed]" by the President, "the Courts of Law," or "the Heads of Departments." U.S. Const. art. II, § 2. Relators like Adventist appoint themselves. Accordingly, insofar as Adventist claims to be an "officer of the United States," this action is unconstitutional. *See U.S. ex rel. Zafirov v. Fla. Med. Assoc., LLC*, 2024

The District Court granted Appellees' motion to dismiss with prejudice on March 18, 2024, and entered final judgment on March 21, 2024. Adventist timely filed its notice of appeal on April 1, 2024. This Court has jurisdiction over this appeal pursuant to 28 U.S.C. § 1291.

ISSUES PRESENTED

1. Whether the District Court properly dismissed Adventist's claims that Appellees violated their 340B pricing obligations as barred under the Supreme Court's decision in *Astra*.

2. Whether Adventist's claims are subject to dismissal for the additional, independent reason that they fail to satisfy the FCA's falsity element.

STATEMENT OF THE CASE

A. The 340B Statutory Framework

Congress created the 340B Drug Pricing Program to assist indigent and uninsured patients in 1992. *See* Veterans Health Care Act of 1992,

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WL 4349242, at *18–19 (M.D. Fla. Sept. 30, 2024) (holding that FCA relators are "officer[s] of the United States" "improperly appointed" under Article II); *see also U.S. ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 449–50 (2023) (Thomas, J., dissenting) (describing "substantial" arguments that "Congress cannot authorize a private relator to wield executive authority to represent the United States' interests in civil litigation"); *id.* at 442 (Kavanaugh, J., and Barrett, J., concurring) (agreeing with Justice Thomas on this point).

Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967 (codified at 42 U.S.C. § 256b). The 340B statute requires participating manufacturers of "covered outpatient drugs" to offer discounted "ceiling" prices when selling those drugs to "covered entit[ies]," a statutorily-defined subset of public or not-for-profit hospitals and other healthcare providers. 42 U.S.C. § 256b(a)(1), (4). The Health Resources and Services Administration (HRSA), a component of HHS, administers the 340B program. ER-33.

Manufacturers must participate in the 340B program to qualify for reimbursement of their drugs under Medicaid and Medicare Part B, 42 U.S.C. § 1396r-8(a)(1). To confirm their participation, manufacturers execute a standard-form Pharmaceutical Pricing Agreement (PPA) with HHS. *See* 42 U.S.C. § 256b(a)(1); *Astra*, 563 U.S. at 113. The PPA provides that "the amount to be paid" by a covered entity for each unit of a manufacturer's drugs under the program may not exceed a set "ceiling price." 42 U.S.C. § 256b(a)(1). That "ceiling price" is derived using quarterly pricing data that manufacturers submit to the Centers for Medicare & Medicaid Services (CMS) under the federal Medicaid Drug Rebate Program. 42 U.S.C. § 256b(a)(1). Manufacturers report their

drugs' "average manufacturer prices" (AMP) and "best prices" to CMS, and CMS uses those figures to calculate the drugs' respective "unit rebate amount[s]," or URAs. *Id.* §§ 256b(a)(2), 1396r-8(c), (k); 42 C.F.R. § 10.10(a). A drug's 340B ceiling price is equal to its AMP minus its URA, on a two-quarter lag (*e.g.*, Q1 AMP and Q1 URA are used to set the Q3 ceiling price). 42 U.S.C. § 256b(a)(2); 42 C.F.R. § 10.10(a). "Calculation of a manufacturer's 'average' and 'best' prices … is a complex enterprise requiring recourse to detailed information about the company's sales and pricing." *Astra*, 563 U.S. at 115.

Because drugs' AMPs, best prices, and URAs are calculated on a quarterly basis, so are 340B ceiling prices. *See* 42 U.S.C. § 256b(a)(1). And because many factors impact AMP, best price, and URA, these variables—and the resulting 340B ceiling price—can and do vary quarter by quarter. *See County of Santa Clara v. Astra USA, Inc.*, 257 F.R.D. 207, 211 (N.D. Cal. 2009) (noting that ceiling prices vary over time "even for the very same drug" and even if the formula remains the same).

In any given quarter, if a drug's URA is equal to or greater than its AMP, the 340B ceiling price formula can calculate to zero.[2] Yet the 340B statute does not specify what non-zero price manufacturers are required to offer to covered entities in this situation.

B. The Affordable Care Act's Amendments to the 340B Statute

For nearly twenty years after the 340B statute's enactment, HRSA lacked rulemaking authority to implement the statute, prompting concerns that HRSA "lack[ed] the oversight mechanisms and authority to ensure that 340B entities pay at or below the ceiling price." Daniel R. Levinson, HHS OIG, No. OEI-05-02-00072, Deficiencies in the Oversight of the 340B Drug Pricing Program, at ii, 15 (Oct. 2005), *available at* https://tinyurl.com/33ba3bp7. Congress responded to those concerns in the 2010 Patient Protection & Affordable Care Act, Pub. L. No. 111-148, §§ 7101–02, 124 Stat. 119, 821–27 (2010) (ACA), which "strengthen[ed] and formalize[d] HRSA's enforcement authority" and "provide[d] for

[2] At all times relevant to this action, a drug's URA could not be *greater* than its AMP, meaning that the 340B ceiling price formula could not yield a negative number. *See* 42 U.S.C. § 1396r-8(c)(2)(D); *see also* 42 C.F.R. § 447.509(a)(5). After January 1, 2024, however, drugs' URAs may exceed their AMPs. *See* 42 U.S.C. § 1396r-8(c)(2)(D).

more rigorous enforcement" of the 340B program's requirements, *Astra*, 563 U.S. at 116, 121–22.

The ACA required HRSA to institute a comprehensive administrative process for adjudicating and remedying violations of 340B pricing requirements, with resulting determinations subject to judicial review. Congress directed the Secretary of HHS to "promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, … including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process." 124 Stat. at 826 (codified at 42 U.S.C. § 256b(d)(3)(A)). It further provided that "[t]he administrative resolution of a claim or claims under the regulations promulgated [here] under … shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." *Id.* (codified at 42 U.S.C. § 256b(d)(3)). Potential remedies included the payment of "refunds to covered entities in the event [of] an overcharge," along with "imposition of … civil

monetary penalties" for intentional overcharges. *Id.* at 824–25 (codified at § 256b(d)(1)(B)(ii), (vi)).

In addition to mandating these "formal procedures for resolving overcharge claims," *Astra*, 563 U.S. at 116, the ACA bolstered HRSA's oversight of 340B pricing in other ways. The statute empowered HRSA to audit manufacturers' compliance with the 340B statute. 124 Stat. at 824 (codified at § 256b(d)(1)(B)(v)). Likewise, it tasked HRSA with creating a comprehensive "system … to verify the accuracy of ceiling prices calculated by manufacturers … and charged to covered entities," including development of "precisely defined standards and methodology for the calculation of ceiling prices," "regular[]" comparison of "the ceiling prices calculated by [HRSA] with the quarterly pricing data … reported by manufacturers," periodic "spot checks of sales transactions," and investigation and "corrective action" of "any pricing discrepancies … identified." *Id.* (codified at § 256b(d)(1)(B)(i)).

Shortly after the ACA was enacted, the Supreme Court had the opportunity to gauge the strength and exclusivity of HRSA's new enforcement authority. In *Astra*, the Court held that court actions by covered entities alleging manufacturer overcharges were fundamentally

"incompatible with the statutory regime." 563 U.S. at 113. As the Court explained, HRSA has exclusive authority to adjudicate and enforce alleged violations of the 340B statute's pricing requirements, leaving "no auxiliary enforcement role" for covered entities. *Id.* at 117.

C. HRSA's Role as Final Arbiter of 340B Ceiling Prices

To effectuate the ACA's command that it develop a system to verify manufacturers' ceiling price calculations, HRSA added a pricing component to its 340B OPA Information System (OPAIS), a database that aggregates information about 340B program participants and drugs.[3] *See* HRSA, *340B Office of Pharmacy Affairs Information System* (May 2024), https://www.hrsa.gov/opa/340b-opais; HRSA, Off. of Pharm. Affairs, OMB No. 0915-0327, *Welcome to 340B OPAIS*, https://340bopais.hrsa.gov/.

Since 2019, HRSA has required manufacturers to report 340B ceiling price data to HRSA through OPAIS on a quarterly basis. *See 340B Office of Pharmacy Affairs Information System*, https://www.hrsa.gov/opa/340b-opais. HRSA also acquires quarterly manufacturer pricing data

[3] "OPA" is the Office of Pharmacy Affairs, the HRSA office that takes the lead in program administration. ER-33.

from CMS. It then compares the CMS-submitted data to the manufacturer-submitted data and uses the CMS-submitted data to independently calculate ceiling prices. *See* 82 Fed. Reg. 1210, 1218 (Jan. 5, 2017); *see also, e.g.*, HRSA, 340B OPAIS Pricing Component User Guide for Manufacturer Users, at 43–44 (2024) ("User Guide").[4] OPAIS automatically flags any pricing discrepancies and conveys them to the manufacturer. *See* User Guide at 43–44. "[I]f the manufacturer is able to conclusively show why [the data it submitted] is more accurate than the HRSA data points," HRSA may rely on the manufacturer-submitted data. *Id.* at 44. But absent such a showing, HRSA publishes the ceiling price data based on the data it received from CMS. *Id.* at 43.

After adjudicating any data discrepancies, HRSA publishes the official 340B ceiling price on OPAIS for covered entities to access. HRSA is thus "the final authority of the 340B ceiling price." *Id.*

D. HRSA's Penny Pricing Policy and 2019 Final Rule

In addition to publishing ceiling prices, HRSA took action to develop and publish "precisely defined standards and methodology for

[4] *Available at* https://340bpricingsubmissions.hrsa.gov/Help/Manufacturer/Resources/PDFUserGuides/340BManufacturerUserGuide.pdf.

the calculation of ceiling prices." 124 Stat. at 824 (codified at § 256b(d)(1)(B)(i)). As relevant here, HRSA developed a "penny pricing" regulation applicable where the 340B ceiling price formula yields a ceiling price of less than one cent. In such situations, HRSA dictated that the ceiling price is one penny per unit—thus, "penny pricing." *See* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. 61,563, 61,564 (Nov. 30, 2018) ("Final Rule"); 42 C.F.R. § 10.10(b).

HRSA's Final Rule on penny pricing did not become effective until January 1, 2019, however. 83 Fed. Reg. at 61,563. Before then, HRSA addressed penny pricing only through non-binding guidance.

The first written reference to penny pricing came from a 2006 report from the HHS Office of Inspector General (OIG), which obliquely referenced penny pricing while acknowledging that the practice was "not officially stated in regulation or guidance." Daniel R. Levinson, HHS OIG, No. OEI-05-02-00073, Review of 340B Prices, at 3 n.21 (July 2006), *available at* https://tinyurl.com/255e565r. HRSA, for its part, first issued a written penny pricing policy in a nonbinding November 2011 policy release. *See* ECF 124-1 (HRSA, Release No. 2011-2, Clarification of

Penny Pricing Policy (Nov. 21, 2011)); *see also* ECF No. 1 ¶ 98 (Adventist's original complaint citing this policy release). The 2011 policy release contained a few sentences regarding penny pricing and stated that manufacturers "should charge $0.01 per unit," without explanation. ECF 124-1 at 1. HRSA did not publish the 2011 policy release in the Federal Register or solicit public comment before finalizing it; the release could be found only on HRSA's website.

Nearly four more years passed before HRSA sought to codify its penny pricing guidance in binding regulations. In a 2015 proposed rule, HRSA correctly described its existing 340B policies as mere "guidelines," stated it was aware that not all manufacturers were following its nonbinding guidance, and acknowledged that a formal standard was needed to "allow HRSA to enforce [penny pricing] in a manner that would *require*" a manufacturer to charge a penny. 80 Fed. Reg. 34,583, 34,586 (June 17, 2015) (emphasis added); 82 Fed. Reg. at 1228.

The rulemaking process itself was a prolonged exercise; HRSA reopened the public comment period after it had ended and solicited additional feedback on potential alternatives to penny pricing. *See* 81 Fed. Reg. 22,960, 22,960–61 (Apr. 19, 2016). Then, after finalizing the

penny pricing regulation, HRSA repeatedly delayed the Final Rule's effective date, explaining that more time was needed to "examine important substantive issues arising from the … final rule" and "provide affected parties sufficient time to make needed changes to facilitate compliance." 82 Fed. Reg. 45,511, 45,512 (Sept. 29, 2017); *see also* 82 Fed. Reg. 12,508 (Mar. 6, 2017); 82 Fed. Reg. 14,332 (Mar. 20, 2017); 82 Fed. Reg. 22,893 (May 19, 2017); 83 Fed. Reg. 25,943 (June 5, 2018); 83 Fed. Reg. 55,135 (Nov. 2, 2018); 83 Fed. Reg. at 61,563.

The penny pricing Final Rule finally took effect on January 1, 2019. 83 Fed. Reg. at 61,563. Rejecting demands from some stakeholders that the rule apply retrospectively, HRSA concluded that retroactive application "would be administratively burdensome and difficult to implement." 82 Fed. Reg. at 1211; 83 Fed. Reg. at 61,563.

E. Adventist's FCA Action and the District Court's Dismissal

Adventist filed this qui tam action in 2021. ECF No. 1. It alleged that Appellees failed to provide penny pricing for certain drugs both before and after the Final Rule's effective date and thus allegedly "overcharged" Adventist and other covered entities for these drugs, which in turn led to "false" claims being submitted for reimbursement from

government payors. *Id.* ¶¶ 6, 8. Specifically, Adventist asserted that Appellees "charged [c]overed [e]ntities … unlawfully inflated prices for their drugs" in circumstances where Appellees should have charged a "per-unit penny price." *Id.* ¶¶ 137, 145. The United States and the state governments named as putative plaintiffs in the complaint declined to intervene. ECF Nos. 39, 43.

After Appellees moved to dismiss, Adventist filed an amended complaint. *See* ECF Nos. 94–95; ER-11–131. Like the original complaint, the amended complaint asserted that Appellees knowingly reported inaccurate ceiling prices for their drugs and "overcharged" covered entities for those drugs. *E.g.*, ER-19 (alleging that "the correct Ceiling Price calculation for these drugs was $0.01," but "instead of following the … statutory formula," Appellees "illegally overcharged 340B Covered Entities" drug prices greatly exceeding $0.01 per unit); ER-22–24 (purporting to "identify dozens of [Appellees'] drugs that should have been subject to a $0.01 Ceiling Price, but which were sold to Covered Entities at a significantly higher price"). Adventist claims that Appellees failed to provide penny pricing for certain drugs, both before HRSA's Final Rule took effect and in the first two quarters following its January

2019 effective date. ER-48–49; ER-57–58; ER-76–77; ER-84–85. Adventist alleges that this failure to offer penny pricing violated the 340B statute and that Appellees' alleged "overcharge[s]" of covered entities caused the covered entities to submit inflated "false" claims for Medicaid and Medicare reimbursement. ER-99–129.

Appellees again moved to dismiss. ECF Nos. 122–23. Among other arguments, they explained that Adventist's claims were barred under the Supreme Court's decision in *Astra*, which held that covered entities are precluded from challenging overcharges outside the exclusive 340B enforcement regime. ECF No. 123 at 30–36. Appellants also explained that Adventist had failed to plausibly establish falsity: Before January 1, 2019, manufacturers were not required to comply with penny pricing, and after January 1, 2019, HRSA ratified and published ceiling prices. *Id.* at 36–42.[5]

Concluding that Adventist's claims were barred in light of *Astra*, the District Court dismissed Adventist's claims with prejudice. ER-4–10. The court explained that under *Astra*, Congress's decision to vest HRSA

[5] Appellees also explained that Adventist's claims were precluded by the FCA's public disclosure bar and that Adventist had failed to plead fraud with particularity. ECF No. 123 at 14–30, 44–51.

with exclusive authority to adjudicate 340B overcharge disputes means that covered entities cannot sue manufacturers for purported pricing violations. ER-8–9. That conclusion applied "equally" to Adventist's suit, where Adventist's "falsity" theory depends on Appellees' purported "noncompliance with the statutory requirements of the 340B Program." *Id.* Finding *Astra* dispositive, the court did not reach Appellees' other arguments for dismissal. ER-10.

Adventist timely appealed. ER-3; ER-132–35.

SUMMARY OF THE ARGUMENT

The District Court correctly dismissed Adventist's claims.

First, the Supreme Court's decision in *Astra* makes clear that covered entities cannot sue manufacturers to redress manufacturers' alleged noncompliance with the 340B statute's pricing requirements. This rule applies no matter the label on the lawsuit—as the Supreme Court put it, "no matter the clothing in which [covered entities] dress their claims." 563 U.S. at 114 (cleaned up). *Astra* explained that allowing covered entities to sue manufacturers for overcharges would both contradict Congress's choice to grant HRSA exclusive authority to adjudicate purported violations of the 340B statute through a specific

administrative enforcement scheme and hamper HRSA's ability to administer the 340B program on a uniform, nationwide basis. *See id.* at 117–22. These considerations apply fully here. The crux of Adventist's claims is that Appellees failed to comply with the 340B statute's pricing requirements. Those claims cannot proceed under *Astra*.

Adventist tries to dodge this conclusion, but its arguments come up short. Adventist contends that *Astra*'s rule is limited to the common-law contract claims at issue in that case. But *Astra*'s holding is expressly about the substance of a covered entity's allegations, not the form of its claims, and subsequent decisions have applied *Astra* to dismiss statutory causes of action.

Adventist also contends that the District Court's decision is contrary to this Court's precedent. Quite the opposite: Binding precedent limits relators' ability to bring FCA actions based on claims, like Adventist's, that Congress specified must be resolved in a different forum. Adventist also overlooks the basic principle that specific statutory enforcement mechanisms displace more general remedies that might otherwise be available. And the cases Adventist clings to are inapposite; they simply recognize that the FCA often may be used to assert claims

premised on violations of other statutes that lack their own private rights of action. As *Astra* makes clear, the 340B statute does not merely lack a private right of action. It creates a regime in which HRSA has exclusive enforcement authority and enforcement is channeled into a comprehensive and specific administrative scheme. The District Court's decision is tied to the unique features of the 340B statute; it does not threaten the availability of FCA claims in other contexts.

Second, Adventist's claims fail for the additional, independent reason that they do not satisfy the FCA's "falsity" element. The regulation on which Adventist bases its claims became effective only on January 1, 2019. And HRSA's system of price reporting and verification renders implausible Adventist's allegation that each manufacturer failed to charge penny prices when required after that date.

This Court should affirm.

STANDARD OF REVIEW

This Court "review[s] de novo an order granting a motion to dismiss for failure to state a claim under [Rule] 12(b)(6)," reversing only if the allegations, taken as true, "state a plausible claim for relief." *Fort v. Washington*, 41 F.4th 1141, 1144 (9th Cir. 2022). A claim is facially

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." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). In making this determination, the court "accept[s] as true all well-pleaded allegations of material fact, and construe[s] them in the light most favorable to the non-moving party." *Daniels-Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998 (9th Cir. 2010). Only well-pleaded factual allegations count; the Court does not credit "allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *Id.*

This Court is not limited to the District Court's reasoning; it "may [instead] affirm the district court's dismissal on any ground that is supported by the record." *Espy v. J2 Global, Inc.*, 99 F.4th 527, 540 (9th Cir. 2024).[6]

[6] This brief raises Appellees' challenge to Adventist's pleading of the FCA's falsity element as an alternative ground for affirmance if the Court opts to address it in addition to, or instead of, the *Astra* issue. Appellees' other arguments for dismissal would remain to be considered in the event of a remand.

ARGUMENT

I. The District Court Correctly Concluded that *Astra* Bars Adventist's Claims.

The District Court determined that the Supreme Court's decision in *Astra* bars Adventist's claims as a matter of law. That conclusion was correct, and this Court should affirm.

A. *Astra* Forbids Suits, Like This One, by Covered Entities Seeking to Enforce the 340B Statute.

Astra makes clear that covered entities may not sue manufacturers for purported violations of the 340B statute that are subject to HRSA's exclusive adjudicative authority, "no matter the clothing in which [covered entities] dress their claims." 563 U.S. at 114 (cleaned up). This holding disposes of the present action. Though Adventist has tried to "dress [its] claims" in FCA garb, *id.*, Adventist's theory rests on alleged ceiling price overcharges. Because Congress vested HRSA with sole authority to adjudicate and address such violations, *see id.* at 117, 119–22, this action cannot proceed.

Astra involved claims by Santa Clara County, an operator of covered entities, against pharmaceutical manufacturers that Santa Clara accused of charging its covered entities prices exceeding the statutory ceiling. *Id.* at 113, 116. Santa Clara did not purport to sue

directly under the 340B statute, which lacks its own private right of action. *See id.* at 116. Rather, Santa Clara pleaded contract claims, claiming to be a third-party beneficiary of the manufacturers' PPAs with HHS and alleging that the manufacturers overcharged it in violation of the 340B statute and the PPAs. *Id.* This Court initially held that such claims could proceed. *County of Santa Clara v. Astra USA, Inc.*, 588 F.3d 1237, 1249 (9th Cir. 2009).

The Supreme Court reversed, holding that actions by covered entities to enforce manufacturers' 340B obligations were fundamentally "incompatible with the statutory regime." *Astra*, 563 U.S. at 113. Prioritizing "substance" over form, the Court concluded that Santa Clara's action was, at bottom, a "suit[] to enforce § 340B"—even if pleaded as a contract claim. *Id.* at 114.

As the Court explained, Congress made a considered choice to grant HHS (and its sub-agency HRSA) exclusive authority to redress violations of 340B pricing requirements through a comprehensive administrative scheme. Congress did not respond to reports alleging noncompliance with the 340B statute by "inviting 340B entities to launch lawsuits in district courts across the country." *Id.* at 121. To the contrary, the legislature

"opted to strengthen and formalize HRSA's enforcement authority," directing "HRSA to create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits of manufacturers." *Id.* at 121–22.

The Court directed that the 340B statute's administrative "adjudicative framework"—not lawsuits by covered entities—is "the proper remedy for covered entities complaining of overcharges and other violations of the [statute's] discounted pricing requirements." *Id.* (quotation marks omitted); *see also Prince George's Hosp. Ctr. v. Advantage Healthplan Inc.*, 985 F. Supp. 2d 38, 49 (D.D.C. 2013) (In *Astra*, "the Supreme Court found that the existence of an extra-judicial dispute resolution system … was conclusive evidence that Congress had foreclosed third parties from bringing … lawsuits to enforce the terms of the statute." (quotation marks omitted)).

Astra's holding also acknowledged the federal government's concern that permitting covered entity claims to be brought directly in court would lead to inconsistent administration of the program. As the Solicitor General explained in the Government's brief, "confer[ring] broad enforcement rights on covered entities would be inconsistent with

Congress's decision to vest authority to enforce the Medicaid Rebate and 340B programs in the government[] and would undermine HHS's ability to administer both programs." Br. for the U.S. as Amicus Curiae Supporting Petitioners at 21, 29–30, *Astra*, 563 U.S. 110 (No. 09-1273), 2010 WL 4717264 (Nov. 19, 2010).[7] The Supreme Court agreed:

> 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. Recognizing the County's right to proceed in court could spawn a multitude of dispersed and uncoordinated lawsuits by 340B entities. With HHS unable to hold the control rein, the risk of conflicting adjudications would be substantial.

563 U.S. at 120 (footnote omitted). The technical and complex nature of the 340B program exacerbated this concern. As the Court put it, "HHS can use its expertise to ascertain and balance the competing interests" of stakeholders in the 340B program, whereas "[c]ourts as first-line decisionmakers are not similarly equipped to deal with the whole picture." *Id.* at 120 n.6; *see also Am. Hosp. Ass'n v. HHS*, 2021 WL 616323, at *6 (N.D. Cal. Feb. 17, 2021) (dismissing a covered entity's claims under *Astra* and observing that agency "decisionmakers [have]

[7] The government's amicus brief in this case does not acknowledge its arguments before the Supreme Court in *Astra*.

intimate familiarity, technical knowledge, and understanding of the nuances inherent in the 340B Program").

Astra's prohibition on private enforcement of the 340B statute applies with full force in this case. Just as in *Astra*, Adventist has "based its suit on allegations that the manufacturers charged more than the § 340B ceiling price," 563 U.S. at 118: it claims that Appellees "illegally ignored the statutory Ceiling Pricing formula" and "illegally overcharged 340B Covered Entities." *E.g.*, ER-19; ER-24.[8] These alleged ceiling price violations raise precisely the sort of "overcharge" disputes that Congress entrusted exclusively to HHS and its exclusive administrative regime. *See Astra*, 563 U.S. at 116, 122; 42 U.S.C. § 256b(d)(3).

The District Court thus was correct to conclude that "the underlying rationale of *Astra*" applies equally here. ER-8. Adventist seeks to redress purported 340B violations, this time by way of the False Claims Act, "[b]ut spreading the enforcement burden … is hardly what Congress contemplated when it centralized enforcement in the government" and "assigned no auxiliary enforcement role to covered entities." *Astra*, 563 U.S. at 117, 119 (quotation marks omitted). "Far

[8] *See also* ER-40; ER-41; ER-42; ER-47–48; ER-56, ER-75–76; ER-84.

from assisting HHS," suits brought by covered entities like Adventist threaten the agency's ability to uniformly administer the 340B program, presenting a sizable risk of "conflicting" determinations by courts that "are not similarly equipped" to adjudicate overcharge disputes. *Id.* at 120 & n.6. This Court should reject Adventist's attempt to evade the 340B statute's exclusive administrative enforcement provisions.

B. Adventist's Efforts to Evade *Astra* Fail.

Adventist cannot escape the conclusion that *Astra*'s binding logic bars its FCA claims. In arguing otherwise, Adventist overlooks on-point case law, misconstrues prior FCA precedents, and mischaracterizes both Appellees' position and the District Court's holding.

1. *Astra*'s Reasoning Is Not Limited to Common-Law Claims.

Adventist seeks to confine *Astra*'s reach to common-law causes of action, contending that it is inapplicable to statutory claims. *See* Br. 24–27; *see also* U.S. Br. 10–12. But *Astra*'s holding was not so limited. It turned on Congress's decision to assign exclusive enforcement authority to HHS, not on the particular cause of action asserted. The Court's ruling did not turn on whether Santa Clara qualified as a third-party beneficiary of the PPA or whether Santa Clara had adequately made out

a contract claim. *Astra* instead held that because "Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities," suits by those entities claiming overcharges were barred. 563 U.S. at 117.

Courts in this Circuit have already applied *Astra* to toss out covered entity attempts to bypass the 340B statute's administrative procedures by suing under another statute. In *American Hospital Association v. HHS*, the court dismissed covered entities' claims that HHS had violated the Administrative Procedure Act by not pursuing enforcement actions against manufacturers that had limited their transfer of drugs at 340B prices to third-party contract pharmacies. 2021 WL 616323, at *3–4.[9] Like the FCA, the APA creates a cause of action and often can be used to enforce requirements in other laws that lack their own right of action.

[9] The 340B program has exploded in scope in recent years; in 2022, total 340B purchases reached *$53.7 billion*. *2022 340B Covered Entity Purchases*, HRSA.gov (Sept. 2023), https://tinyurl.com/4xfrpycp. This explosive growth has been driven in large part by contractual relationships between covered entities and for-profit pharmacy chains with which covered entities partner to sell drugs acquired at 340B prices. *See Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 700 (3d Cir. 2023). These "contract pharmac[y]" arrangements allow covered entities and pharmacies to buy low, sell high, and "divvy up the [resulting] spread." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 457 (D.C. Cir. 2024).

See 5 U.S.C. § 702; *Glacier Park Found. v. Watt*, 663 F.2d 882, 885 (9th Cir. 1981). Nonetheless, the court rejected the covered entities' efforts to "creatively recast" their true aim of "enforc[ing]" 340B statutory "requirements against the various allegedly non-complying drug companies." *Am. Hosp. Ass'n*, 2021 WL 616323, at *5–6.

Likewise, in *AIDS Healthcare Foundation v. Apexus LLC*, the court held that a covered entity's claims under California's Unfair Competition Law ("UCL") could not proceed on allegations that the defendant failed to negotiate discounted drug prices under the 340B statute's "[p]rime [v]endor [p]rogram." 2023 WL 3149268, at *1, *2–3 (C.D. Cal. Apr. 10, 2023). The UCL, too, expressly confers statutory standing and provides a right of action that can be used to enforce other laws under which private plaintiffs cannot sue directly. *See* Cal. Bus. & Prof. Code § 17204; *Kasky v. Nike, Inc.*, 45 P.3d 243, 249 (Cal. 2002). But these features did not spare the UCL claim from dismissal; it remained in substance a "claim[] to enforce Section 340B." *AIDS Healthcare*, 2023 WL 3149268, at *3;[10]

[10] This Court recently affirmed in a non-precedential decision. 2024 WL 3886974 (9th Cir. Aug. 21, 2024). The Court agreed that *Astra* barred the covered entity's common-law claims and affirmed the dismissal of the UCL claims on other grounds. *See id.* at *3.

see also Mosaic Health Inc. v. Sanofi-Aventis U.S., LLC, 714 F. Supp. 3d 209, 215–16, 218 n.2 (W.D.N.Y. Feb. 1, 2024) (expressing "serious doubts about the viability of … [covered entities'] backdoor attempt to use the antitrust laws to enforce [their] preferred interpretation of the 340B statute"), *appeal docketed*, No. 24-598 (2d Cir. Mar. 4, 2024).

Adventist fails to mention these authorities. Instead, it protests that *its* statutory claims are somehow different, contending that Appellees' supposed "violations of the statutory Ceiling Price formula is [sic] … just one link in the chain establishing FCA liability." Br. 32.[11] This argument ignores that alleged ceiling price violations are the *key* link in the chain here; they underpin Adventist's entire theory of why claims submitted to government payors were supposedly "false." *U.S. ex rel. Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011) ("An actual false claim is the *sine qua non* of an FCA violation."

[11] Adventist's reliance (at Br. 36) on a statement at *Astra*'s oral argument by counsel for the manufacturers gets it nowhere. This Court is bound by the Supreme Court's decision, not counsel's remarks. Indeed, whatever may have been suggested about qui tam actions, the Court seemed unconvinced. Tr. of Oral Argument at 16, *Astra*, 563 U.S. 110 (No. 09-1273), 2011 WL 161901 (Jan. 19, 2011) (Justice Ginsburg: "Well, to the extent that you're objecting to the disruption of the Secretary, there is disruption when it's a private party bringing a False Claims Act [case].").

(cleaned up)); *see, e.g.*, ER-19; ER-24. Adventist's FCA claims of course require proof of additional elements beyond the alleged 340B overcharges, such as scienter. Br. 29–32. But the same was true of Santa Clara's claims, which required it to show, for example, that it was a third-party beneficiary of the PPA. *See Astra*, 563 U.S. at 116–17. Adventist cannot deny that its claims require adjudication of ceiling price disputes that Congress directed HHS—and not the courts—to resolve in the first instance, and the presence of additional elements is irrelevant.

2. Adventist's Appeals to Precedent Fail.

Adventist also contends that the District Court's holding cannot be squared with this Court's precedent involving FCA claims based on wage-and-hour violations. Br. 15–19; *see also* U.S. Br. 16–17; Anti-Fraud Coalition Br. 11–14. Adventist did not make this argument before the District Court. It is accordingly forfeited. *See Villanueva v. California*, 986 F.3d 1158, 1164 n.4 (9th Cir. 2021) (applying the "general rule against entertaining arguments on appeal that were not presented or developed before the district court" (quoting *In re Mercury Interactive Corp. Sec. Litig.*, 618 F.3d 988, 992 (9th Cir. 2010))). In any event, the

cases Adventist cites are distinguishable, and other controlling authorities support affirmance.

Adventist argues that *United States ex rel. Plumbers & Steamfitters Local Union No. 38 v. C.W. Roen Construction Co.*, 183 F.3d 1088 (9th Cir. 1999), "rejected" arguments similar to those Appellees raised below. Br. 18–19. *C.W. Roen* concluded that FCA liability on an implied false certification theory could lie based on violations of the Davis-Bacon Act's wage requirements, despite that act's extensive "regulatory scheme." 183 F.3d at 1091 (quotation marks omitted). But the regulations implementing the Davis-Bacon Act *themselves* "state explicitly" that a federal contractor's false certifications of compliance with that act can give rise to FCA liability. *Id.* at 1092 (citing 29 C.F.R. § 5.5(a)(3)(D)). Neither the 340B statute, the PPA, nor any implementing regulation contains any comparable provision.

Adventist also invokes *United States ex rel. Sutton v. Double Day Office Services, Inc.*, 121 F.3d 531 (9th Cir. 1997). *See* Br. 15–18. *Sutton*, which pre-dated *Astra*, involved FCA claims alleging that a moving company that had "contract[ed] with the United States for moving federal employees" had underpaid its workers in violation of the Service Contract

Act, which "requires government contractors to pay service employees minimum wages and benefits determined by the Secretary of Labor." 121 F.3d at 533. In deciding whether the Secretary's "exclusive right to enforce[]" the Service Contract Act precluded Sutton's FCA claims, the Court focused on whether Sutton sought "the equivalent of [Service Contract Act] damages under the guise of another statute." *Id.* Because Sutton sought to recover damages based on the amount the government paid for *moving services* under its federal contracts, rather than damages equal to his lost wages, the Court reasoned that his FCA claims could proceed. *Id.* at 533–34.

Here, by contrast, Adventist's FCA claims plainly seek to recover for ceiling price "overcharges" that can only be redressed in a 340B administrative proceeding. The reimbursement metric for the bulk of the supposed false claims at issue is "actual acquisition cost," meaning that an alleged overcharge to a covered entity translates into an equivalent overcharge by the covered entity to the government. *See* ER-42; ER-72–73; ER-93–97. Adventist's own brief further highlights the direct relationship between the government's supposed "harm[]" and

Adventist's alleged overpayments. As Adventist itself explained, Appellees' purported misconduct:

> harmed the government in three ways: … [1] If a Covered Entity acquires a drug at an inflated price, that inflated price is passed directly through to Medicaid; … [2] critical access hospitals bill Medicare at 101% of their drug costs, meaning Defendants' overcharges to critical access hospitals are passed directly through to Medicare; [and] [3] Defendants have overcharged government-funded 340B Covered Entities … [and] the government is harmed because it directly pays fraudulently inflated ceiling prices."

Br. 7–8. Because Adventist seeks to recover "the equivalent of [340B overcharges] under the guise of another statute," *Sutton*, 121 F.3d at 533, *Sutton* is inapplicable here.

This action is instead far more akin to *United States v. Universal Fruits & Vegetables Corp.*, 370 F.3d 829, 833–36 (9th Cir. 2004), in which this Court recognized that when Congress channels claims through a specific adjudicative body, those claims cannot be brought via the FCA in federal district court. In *Universal Fruits*, the United States asserted FCA claims premised on an importer's fraudulent attempt to avoid paying customs duties. 370 F.3d at 831–32. The importer contended that 28 U.S.C. § 1582(3)—which grants the Court of International Trade "exclusive jurisdiction" over civil actions by the United States to recover

customs duties related to imports—precluded the government's FCA claims. *Id.* at 832.

This Court agreed. Because "the measure of the government's damages" was "essentially a tally of the duties it claim[ed the importer] owed," any distinction between FCA damages and customs duties was "illusory," such that "the government's claim [was], at bottom, a customs claim." *Id.* at 834. "If the government could bring an FCA claim in district court whenever a party fraudulently withholds customs duties," the Court of International Trade's exclusive jurisdiction "would become a virtual nullity: The government could simply recast the withheld duties as damages and proceed in district court under the FCA." *Id.* at 836.

So too here. Allowing Adventist to "recast" purported 340B overcharges as FCA damages and sue manufacturers in federal court would render HHS's "exclusive" authority to adjudicate overcharge claims in a comprehensive administrative regime "a virtual nullity." *Id.*

Universal Fruits, which goes unmentioned in Adventist's brief, thus belies Adventist's claim that "it is unclear whether *any court anywhere has ever* interpreted a statute as impliedly abrogating the FCA." Br. 20 (emphasis in original). So does the line of cases holding that relators

cannot bring FCA cases premised on violations of the Civil Monetary Penalties Law, which grants the HHS Secretary exclusive authority "to levy civil monetary penalties and assess treble damages against medical providers who file false or otherwise improper claims for payment in certain federal healthcare programs." *U.S. ex rel. Grayson v. Genoa Healthcare*, 2011 WL 2670079, at *5 (W.D. Wash. July 6, 2011); *see, e.g., U.S. ex rel. Greenfield v. Medco Health Sys., Inc.*, 2014 WL 4798637, at *8 n.8 (D.N.J. Sept. 26, 2014); *U.S. ex rel. Gonzalez v. Fresenius Med. Care N. Am.*, 2010 WL 1645969, at *8 (W.D. Tex. Jan. 21, 2010).[12]

Characterizing the District Court's decision as an impermissible "implied repeal[]," Adventist also argues that "there is no basis to discern an implied exclusion [from FCA liability] for misconduct involving the 340B program." Br. 20, 23. This assertion again ignores Congress's deliberate choice to vest HHS with exclusive authority to adjudicate disputes regarding manufacturers' 340B pricing obligations through a comprehensive administrative scheme specifically tailored to the 340B

[12] Adventist's amicus (but, tellingly, not Adventist itself) claims that several out-of-Circuit decisions have "expressly opine[d] on the viability of FCA actions relating to the 340B program." Anti-Fraud Coalition Br. 23. But *none* of the cited cases assessed *Astra*'s impact on the viability of FCA claims alleging violations of the 340B statute.

program. *See supra* part I.A. The 340B statute does not "repeal" the FCA; it merely forecloses an FCA cause of action for one limited type of statutory violation—340B drug price overcharges—that Congress chose to address through a separate, more specific remedial mechanism. And for all its bluster about "implied repeals," Adventist's brief fails to acknowledge settled authority holding that statutes providing for specific enforcement mechanisms tailored to a particular program may indeed limit the remedies otherwise available under more general statutes.

For example, in *Middlesex County Sewerage Authority v. National Sea Clammers Association*, the Supreme Court held that plaintiffs could not sue under 42 U.S.C. § 1983—notwithstanding that statute's express cause of action to redress violations of other federal laws—for violations of two federal environmental statutes. 453 U.S. 1, 19 (1981). The Court concluded that the environmental statutes' "comprehensive enforcement mechanisms" demonstrated Congress's intent "to supplant any remedy that would otherwise be available under § 1983." *Id.* at 20–21. Other binding decisions have since reached similar holdings, embodying the "cardinal rule of statutory interpretation that a specific limitation takes precedence over a general grant of authority," *Branch v. Umphenour*, 936

F.3d 994, 1003 (9th Cir. 2019).[13] This case is in precisely the same vein, given that the Supreme Court has already held that Congress's chosen administrative regime for 340B overcharge enforcement is exclusive. *See Astra*, 563 U.S. at 114, 120–22.

Congress's specific decision to consolidate 340B enforcement before HHS in a unique administrative regime subject to its own procedures and limitations thus trumps the FCA's general provision for civil actions brought in the name of the United States. Straining against this well-established principle, Adventist insists that as a "*qui tam* relator," it "'effectively stands in the shoes of the government,'" which retains "substantial control" over FCA actions, Br. 28, 34 (quoting *Kelly*, 9 F.3d at 748); *see also id.* at 17, 33–35; U.S. Br. 15–16. But that argument fails

[13] *See, e.g., City of Rancho Palos Verdes v. Abrams*, 544 U.S. 113, 122–27 (2005) (Telecommunications Act of 1996, with its "scheme of expedited judicial review and limited remedies," "precluded resort to § 1983"); *Smith v. Robinson*, 468 U.S. 992, 1012 (1984) (plaintiff could not "circumvent" the Education of the Handicapped Act's administrative remedies through a § 1983 action), *superseded by statute on other grounds*; *Ahlmeyer v. Nev. Sys. of Higher Educ.*, 555 F.3d 1051, 1058 (9th Cir. 2009) ("The comprehensive remedial scheme of the ADEA demonstrates that Congress intended [it] to serve as the exclusive means for pursuing claims of age discrimination in employment."); *Okwu v. McKim*, 682 F.3d 841, 846 (9th Cir. 2012) ("By drafting a comprehensive remedial scheme for employers' violations of ADA Title I, Congress manifested an intent to preclude § 1983 remedies.").

to meet the point. The 340B statute lodges exclusive enforcement authority "in *HHS*" through a specific administrative scheme, not to the government writ large through any and all mechanisms that might otherwise be available. *Astra*, 563 U.S. at 117, 120 (emphasis added); *see also* 42 U.S.C. § 256b(d). Accordingly, even if a relator in some sense "stands in the shoes of the government," Br. 17, Adventist's attempt to litigate 340B overcharge claims in court rather than raising them in the administrative regime specified by Congress runs afoul of the 340B statute as authoritatively interpreted in *Astra*.[14]

3. Adventist's Concerns about the Impact of the District Court's Decision Are Misplaced.

Adventist and its amici argue that the District Court's decision would have "pernicious ramifications" and would bar "virtually *every* FCA lawsuit" premised on false certification of compliance with legal or contractual requirements. Br. 37 (emphasis in original); *see id.* at 38–41; U.S. Br. 18–19; Anti-Fraud Coalition Br. 18–22. This misplaced

[14] The *exclusive* nature of the 340B enforcement regime for covered entity overcharge claims distinguishes this action from the cases Adventist cites for its contention that "FCA liability is not barred by the fact that the government *also* has an administrative remedy." Br. 34 n.4 (emphasis added); *see also id.* at 19 & n.3.

alarmism betrays a basic misunderstanding of *Astra*, the District Court's decision, and Appellees' arguments.

Again: *Astra* and the District Court's decision applying it do not turn on the mere fact that the 340B statute lacks a private right of action. Both decisions instead turn on Congress's choice to direct disputes over manufacturers' compliance with 340B statutory pricing obligations to an *exclusive administrative enforcement regime*. Contrary to Adventist's suggestion, the 340B statute does not just decline to create its *own* private right of action while remaining agnostic about whether some *other* right of action can be used to enforce it. It grants HRSA sole enforcement authority, exercised through an exclusive administrative process. Adventist overlooked this distinction below, and its error persists here. *See, e.g.*, ECF No. 135 at 38, 41–42.

Despite Adventist's sky-is-falling rhetoric, Appellees are not asking this Court to depart from prior case law about the viability of FCA claims alleging violations of other statutes—*e.g.*, the Stark Law, the Anti-Kickback Statute, or the Federal Food, Drug, and Cosmetic Act—that contain no private right of action. *See* Br. 37–41; *see also id.* at 19 & n.3; U.S. Br. 18–19. Appellees' position is much narrower and specific to the

340B statute, which expressly channels covered entities' overcharge claims through HRSA's exclusive enforcement scheme. Complying with controlling Supreme Court precedent in the unique context of the 340B program would not have the sweeping ramifications that Adventist and its amici decry.

Indeed, the District Court's order dismissing Adventist's claims was carefully circumscribed. The court took pains to confine its holding to qui tam actions asserting noncompliance with 340B statutory requirements, finding simply "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." ER-9. The court reserved ruling on whether the government itself could bring an FCA action premised on purported violations of the 340B statute. ER-9–10 ("express[ing] no opinion" on that question).[15] And it even reserved ruling

[15] The government thus cannot credibly claim (*see* U.S. Br. 2) that the District Court's holding is inconsistent with the government's position in *Astra*, where it told the Court that although in its view "*the government, in coordination with HHS*" could pursue FCA claims premised on 340B statutory violations, this "in no way suggests that the 340B Program allows for private suits by thousands of covered entities." Br. for the U.S. as Amicus Curiae Supporting Petitioners at 30 & n.11, *Astra*, 2010 WL 4717264 (emphasis added); *see also id.* at 26.

on whether covered entities could assert FCA claims that relate to the 340B program but allege fraud that—unlike Adventist's overcharge allegations—goes beyond "noncompliance with statutory language." ER-9.

Affirming the District Court's dismissal of Adventist's claims thus would not remotely "eviscerate the *qui tam* provisions of the FCA," Br. 40. It would simply respect Congress's decision, in the unique context of the 340B program, to grant HHS exclusive "authority to oversee compliance with" that program. *Astra*, 563 U.S. at 117.

II. Adventist's Claims Also Fail for Lack of Falsity.

"[A]n actual false claim" is the sine qua non of a False Claims Act violation, *Cafasso*, 637 F.3d at 1055 (quoting *U.S. ex rel. Aflatooni v. Kitsap Physicians Serv.*, 314 F.3d 995, 1002 (9th Cir. 2002)), and claims are not "false" under the FCA unless they violate some "controlling authority." *U.S. ex rel. Stenson v. Radiology Ltd.*, 2024 WL 1826427, at *2–3 (9th Cir. Apr. 26, 2024); *see also U.S. ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 901 (9th Cir. 2017) (false claims must fail to disclose the "violation of a material statutory, regulatory, or contractual requirement" (quoting *Universal Health Servs., Inc. v. U.S. ex rel.*

Escobar, 579 U.S. 176, 180 (2016))). Adventist did not and cannot plausibly allege that Appellees overcharged 340B entities in violation of any such controlling standard. Its failure to adequately plead falsity provides an independent route to affirmance. *See U.S. ex rel. Silingo v. WellPoint, Inc.*, 904 F.3d 667, 678 (9th Cir. 2018) (noting that this Court "may affirm the dismissal on any ground supported by the record").

A. Alleging Falsity Requires Identifying the "Controlling Authority" that Renders the Claim False.

To state a false claim under the FCA, a relator must allege "a false statement or fraudulent course of conduct." *Campie*, 862 F.3d at 899 (quoting *U.S. ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2006)). "Claims are not false under the FCA unless they are furnished in violation of some controlling rule, regulation or standard." *Stenson*, 2024 WL 1826427, at *2 (quoting *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1026 (D. Nev. 2006)); *see also Escobar*, 579 U.S. at 190 (certification theories of FCA liability require noncompliance with material "statutory, regulatory, or contractual requirements"); *U.S. ex rel. Hanna v. City of Chicago*, 834 F.3d 775, 779 (7th Cir. 2016) (plaintiff must identify "the specific provisions of law whose violation made the

certification of compliance false"). "In the absence of controlling authority, there can be no violation." *Stenson*, 2024 WL 1826427, at *3.

To show that Adventist failed to plead falsity, Appellees thus "need only" demonstrate that the 340B statute "does not affirmatively establish the requirement of" penny pricing. *U.S. ex rel. Sheldon v. Forest Labs., LLC*, 2024 WL 3555116, at *32 (D. Md. July 23, 2024), *appeal docketed*, No. 24-1793 (4th Cir. Aug. 21, 2024); *see also U.S. ex rel. O'Neill v. Somnia, Inc.*, 339 F. Supp. 3d 947, 955 (E.D. Cal. 2018) ("Whether relator has sufficiently alleged falsity in this case depends upon the language of the regulation, since if none of the alleged conduct is contrary to what the regulations permit, there can be no violation."), *appeal docketed*, No. 23-15973 (9th Cir. July 7, 2023).

B. Adventist Failed to Plausibly Allege Ceiling Price Violations for Claims Submitted before January 1, 2019.

1. The 340B Statute Does Not Compel Penny Pricing.

Adventist points to the 340B statute and PPA between HHS and manufacturers as the controlling standards requiring penny pricing. *See* ER-41. Nothing in the 340B statute or PPA "affirmatively establish[es]" such a requirement. *Sheldon*, 2024 WL 3555116, at *32.

The 340B statute repeatedly refers to "the amount required to be paid" to and the "prices" to be "charged" by the manufacturer. 42 U.S.C. § 256b(a)(1), (a)(10), (d)(1)(B)(i). It directs participating manufacturers to "charge" a "price" that does not exceed the ceiling price and defines that price by reference to a statutory formula: the drug's AMP minus its URA. 42 U.S.C. § 256b(a)(2); 42 C.F.R. § 10.10(a). These terms clearly contemplate that the ceiling price formula will yield a positive ceiling price. For that reason, neither HRSA nor Adventist has ever argued that the 340B statute can be applied to require manufacturers to provide their drugs to covered entities for free—at a "price" of zero. Instead, HRSA itself has long interpreted the statute to require a positive price generating a revenue transfer: "[W]hen the URA equals the AMP in the calculation of the 340B ceiling price, it is not reasonable for a manufacturer to set a 340B ceiling price to $0.00 per unit of measure." *See* 80 Fed. Reg. at 34,585; *see also* 82 Fed. Reg. at 1214 (HRSA noting that "a zero-dollar ceiling price would run counter to the statutory scheme").

There is no statutory language requiring, or even suggesting, what Adventist argues: that the statute *mandates* a penny price when the

prescribed formula calculates to zero or a negative number; the statute is silent as to what "price" to "charge" in that situation, and the words "penny," "cent," "$0.01," or "zero" appear nowhere in the statute. For this reason, the District Court was wrong to imply in dicta that the 340B statute may prohibit charging more than one penny per drug unit in circumstances where the ceiling price formula yields a negative or zero price. *See* ER-5 n.1. The PPA likewise does not include those words, and because PPAs "simply incorporate statutory obligations" and "contain no negotiable terms," *Astra*, 563 U.S. at 118, the PPA cannot otherwise impose penny pricing as a freestanding obligation.

2. The Agency's Nonbinding Guidance Did Not Compel Penny Pricing.

Non-binding guidance is not "controlling authority" that can serve as the basis for an FCA violation. *See Stenson*, 2024 WL 1826427, at *3*; see also U.S. ex rel. Rose v. Stephens Inst.,* 909 F.3d 1012, 1016 (9th Cir. 2018) (citing *Escobar*, 579 U.S. at 190); *U.S. ex rel. Loc. 342 Plumbers & Steamfitters v. Caputo Co.*, 321 F.3d 926, 933 (9th Cir. 2003) (no falsity

for failure to pay prevailing wage where no final agency action or contract established that obligation).[16]

As discussed above, HRSA first imposed an enforceable penny pricing requirement through a Final Rule effective January 1, 2019. Before that time, HRSA's informal penny pricing guidance was just that.

HRSA repeatedly has acknowledged as much. In its 2015 proposed penny pricing rule, HRSA recognized that not all manufacturers were following its informal guidance and that a regulation was necessary for penny pricing to be enforceable. *See* 80 Fed. Reg. at 34,586; 82 Fed. Reg. at 1228 (same). And when the Final Rule was ultimately published, it did not apply retroactively to ceiling price calculations for quarters before the effective date. *See* 82 Fed. Reg. at 1211.

Adventist's complaint thus failed to state a claim with respect to any prices charged before January 1, 2019.

[16] Because non-binding guidance by definition cannot constitute "controlling authority," the District Court was incorrect to suggest in dicta that failure to disclose noncompliance "with the government's stated expectations" regarding penny pricing could support FCA falsity even in the absence "of an explicit, binding regulation." ER-5 n.1.

C. Adventist Failed to Plausibly Allege Ceiling Price Violations Between January 1, 2019 and July 1, 2019.

The *Twombly/Iqbal* plausibility standard requires more than pleading facts that are "merely consistent with" liability. *Eclectic Props. E., LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 996 (9th Cir. 2014) (quoting *Iqbal*, 556 U.S. at 678). As this Court has explained, "[w]hen faced with two possible explanations, only one of which can be true and only one of which results in liability," and "plaintiffs … offer allegations that are merely consistent with their favored explanation but are also consistent with the alternative explanation," a court will dismiss. *Id.* (quoting *In re Century Aluminum Co. Sec. Litig.*, 729 F.3d 1104, 1108 (9th Cir. 2013)). Adventist thus was required to offer facts tending to exclude the possibility of alternative, innocuous explanations for Appellees' actions. *Id.* at 996–97. It failed to do so.

First, as Adventist acknowledged in its original complaint (but then scrubbed from its amended complaint), HRSA independently verifies Appellees' 340B price calculations and publishes ceiling prices to 340B covered entities through OPAIS. *See* ECF No. 1 ¶¶ 89, 111. Through that process, OPAIS identifies any discrepancies between manufacturer-submitted ceiling prices and the ceiling price HRSA calculates from data

provided by CMS. *See* User Guide at 43–44. If a discrepancy arises, the manufacturer can reconcile the discrepancy by "conclusively show[ing] why [such] data is more accurate than HRSA data points;" otherwise, HRSA publishes the ceiling price based on the *CMS* data. User Guide at 43–44. Within this system, as HRSA has explained, it is "the final authority" of the published 340B ceiling price. *Id.* at 43.

Adventist nevertheless alleges that each manufacturer charged ceiling prices in excess of a penny in violation of the new regulation during the first half of 2019, despite HRSA's direct oversight of 340B ceiling price reporting, verification, and publication. That is wholly implausible. HRSA did not rely solely on manufacturer-submitted ceiling prices. It independently calculated and verified manufacturers' ceiling prices based on the CMS-provided data. If manufacturers deviated from the statutory formula, OPAIS would have identified it, and HRSA would have published ceiling prices based on its own calculations, using CMS's data. Adventist's Amended Complaint ignores this reality.

Adventist's theory also assumes fraudulent conduct solely from the quarterly variations in Appellees' 340B ceiling prices. But these prices can and do change by quarter. *See Astra*, 257 F.R.D. at 211 (ceiling prices

vary over time "even for the very same drug" and even if the formula remains the same). For instance, a change in contracted price concessions that materially decreases the reported "best price" can result in a positive ceiling price one quarter and a penny price the next quarter. Adventist has offered no facts that exclude the alternative possibility that covered outpatient drugs moved in and out of penny pricing because of real-world factors.

Adventist also fails to explain why Appellees would comply with the penny pricing regulation as to only some of their products after the regulation took effect, or why they would do so episodically over time, as Adventist claims. For example, Adventist alleges that every Appellee correctly applied penny pricing for multiple drugs in Q1 2019 yet also claims that Appellees did not do so for other drugs until Q2 and/or Q3 2019. ER-48–49; ER-57–58; ER-76–77; ER-84–85. This, combined with the HRSA system of verification described above, tips the scale in favor of Appellees' alternative explanation for such price changes among quarters. Because Adventist failed to plausibly allege falsity with respect to claims submitted after the penny pricing regulation's effective date,

the dismissal of its claims may be affirmed on this independent basis as well.

CONCLUSION

For the foregoing reasons, this Court should affirm the District Court's judgment.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure Rule 32(a)(7)(C), I certify that this brief complies with the length limitations set forth in Rule 32(a)(7)(B)(i) because it contains 9,711 words, as counted by Microsoft Word, excluding the items that may be excluded under Rule 32(a)(7)(f).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared using Microsoft Word 365ProPlus in Century Schoolbook 14-point font.

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