No. 22-593

In the Supreme Court of the United States

UNITED STATES EX REL. DEBORAH SHELDON, PETITIONER

v.

ALLERGAN SALES, LLC

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether a defendant "knowingly" violates the False Claims Act, 31 U.S.C. § 3729, when it acts consistently with an objectively reasonable interpretation of the governing legal requirement, publicly informs the agency of its interpretation, and the agency does not warn it away from that interpretation.

2. Whether petitioner is entitled to relief before this Court when the judgment below is supported by two independent holdings, one of which petitioner has not challenged before this Court.

RULE 29.6 STATEMENT

Allergan Sales, LLC is owned by Allergan Holdings, Inc. and Allergan Holdco US, Inc., which are privately held corporations. Allergan Holdco US, Inc. and Allergan Holdings, Inc. are owned by Allergan, Inc. and Allergan Puerto Rico Holdings, Inc. Allergan, Inc. is owned by Allergan Finance, LLC and LifeCell Corporation who has non-voting rights. Allergan Puerto Rico Holdings, Inc. is owned by Allergan W.C. Holding Inc., which is owned by Allergan Arkana LLC, which is owned by Allergan Pharma, Inc. Ownership of Allergan Pharma, Inc., is split between various entities. LifeCell Corporation is owned by Allergan Holdco US, Inc. The ultimate parent of all Allergan entities is AbbVie Inc., a publicly held company. No publicly held corporation other than AbbVie Inc., owns more than 10% of respondent's stock.

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OPINIONS BELOW

The order of the en banc court of appeals (Pet. App. 1a–2a) is reported at 49 F.4th 873. The panel decision (Pet. App. 3a–81a) is reported at 24 F.4th 340. The opinion of the district court (Pet. App. 82a-140a) is reported at 499 F. Supp. 3d 184.

INTRODUCTION

Petitioner alleges that respondent Allergan defrauded the government by incorrectly reporting the "Best Price" for its drugs under Medicaid, used in calculating rebates to the government, because Allergan did not aggregate discounts it offered to separate entities involved in drug distribution, and instead reported the lowest price charged to an individual customer. The Medicaid Rebate Statute defines "Best Price" as "the lowest price available from the manufacturer * * * to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity." 42 U.S.C. § 1396r-8(c)(1)(C)(i). After carefully examining the statute and applicable regulations and guidance, the district court

concluded that "the plain and natural reading of the provision" is the one Allergan advocated, that "Best Price means the lowest price made available by the manufacturer, including all price concessions, to any one of the listed entities, but not to multiple entities." Pet. App. 131a; see also *id.* at 26a (court of appeals panel majority concluding that "is the best reading of that text"); *id.* at 33a ("the best interpretation" of statute).

As petitioner acknowledges, Pet. 12, the district court dismissed petitioner's False Claims Act complaint on *two* distinct grounds: First, it dismissed because petitioner had failed to plausibly plead the *falsity* element of the False Claims Act, because "differences in interpretation growing out of a disputed legal question are [] not false under the FCA." Pet. App. 126a (quoting *United States ex rel. Wilson* v. *Kellogg Brown & Root, Inc.*, 525 F.3d 370, 377 (4th Cir. 2008) (internal quotation marks omitted)). Thus, "claims based on Allergan's interpretation cannot qualify as objective falsehoods or constitute false statements under the FCA." Pet. App. 137a. Second, the court also dismissed because petitioner had not adequately pleaded the *scienter* element that respondent Allergan Sales had "knowingly" violated the False Claims Act, because "the FCA does not reach * * * claims based on reasonable but erroneous interpretations of a defendant's legal obligations." Pet. App. 127a (quoting *United States ex rel. Purcell* v. *MWI Corp.*, 807 F.3d 281, 287-288 (D.C. Cir. 2015)). That is because "[w]here there are legitimate grounds for disagreement over the scope of a" regulatory obligation, "the claimant cannot be said to have knowingly presented a false claim." *Ibid.* (quotation omitted); see also *id.* at 138a. As petitioner notes, the district court's "latter [holding] was at the heart of the [court of appeals] panel decision." Pet. 6. An equally divided en banc court then affirmed the district court's judgment. Pet. App. 1a-2a.

Petitioner now seeks review of the scienter decision, noting that "[t]he question presented in this petition was the sole issue decided by the panel majority" below, Pet. 25, and that issue is now before this Court in *United States ex rel. Schutte* v. *SuperValu, Inc.*, No. 21-1326, and *United States ex rel. Proctor* v. *Safeway, Inc.*, No. 22-111. Petitioner argues this Court should grant review to resolve "uncertainty regarding the FCA's scienter requirement," Pet. 14, or at least "hold th[e] petition pending the Court's decisions in *Schutte* and *Proctor*." Pet. 32.

For three reasons, the petition should be denied, and there is no basis for holding this case pending the outcome of *Schutte* and *Proctor*. *First*, petitioner seeks review only of the district court's *scienter* holding. See Pet. i; Pet. 14 ("Certiorari should be granted to resolve a circuit split and uncertainty regarding the FCA's scienter requirement"); *id.* at 25 (the "key issue" is "what is the role subjective intent plays in FCA scienter in the face of an ambiguous legal requirement"). But the judgment below is supported by an independent *second* holding that petitioner's petition does not challenge, much less does it demonstrate that the issue is the subject of a circuit split or otherwise meets this Court's traditional criteria for review. See S. Ct. R. 10. *Second*, before the district court, petitioner *affirmatively invoked* the very *Safeco* standard she now criticizes. Petitioner has therefore waived her claim that the district court's decision to apply *Safeco* in this case was error. *Third*, as both the district court and the Fourth Circuit panel majority concluded, Allergan's interpretation of the governing legal standard is the "plain and natural reading" of the relevant provisions, Pet. App. 131a, "and in fact the best interpretation," *id.* at 33a. Far from demonstrating that Allergan's interpretation of the governing provisions is clearly wrong, petitioner does not even quote the governing statute and regulations, or reproduce those provisions in the petition

or appendix, see Pet. App. 141a-143a. Further review is not warranted.

STATEMENT

A. Statutory and Regulatory Background

1. Medicaid authorizes federal financial assistance to states that reimburse certain costs of medical treatment. *Pharm. Research & Mfrs. of Am.* v. *Walsh*, 538 U.S. 644, 650 (2003). For drugs to qualify for federal reimbursement, a manufacturer must enter into an agreement with the Secretary of Health and Human Services ("HHS") to provide rebates to states on Medicaid sales of covered drugs (the "Medicaid Rebate Agreement"). 42 U.S.C. § 1396r-8(a)(1). The manufacturer reports to CMS the "Average Manufacturer Price" and "Best Price" for its covered drugs, after which CMS calculates a quarterly "Unit Rebate Amount." *Id.* § 1396r-8. Federal payments to each state are reduced by rebates the state receives from manufacturers. *Id.* § 1396r-8(b)(1)(B).

Section 1927 of the Social Security Act (the "Medicaid Rebate Statute") defines "Best Price" as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the U.S." *Id.* § 1396r-8(c)(1)(C)(i). The legislative history of the provision states that the provision's purpose was to ensure Medicaid "ha[s] the benefit of the same discounts on single source drugs that other large public and private consumers enjoy," H.R. Rep. No. 101-881 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108, to prevent "discrimination" against Medicaid by ensuring that Medicaid receives "the lowest price that the manufacturer makes available to other purchasers." 136 Cong. Rec. S12961 (1990) (statement of Sen. Pryor).

The Medicaid Rebate Agreement similarly provides that "'Best Price' means * * * the lowest price at which

the manufacturer sell*s* the Covered Outpatient Drug to any purchaser in the United States." C.A.J.A. 213, Rebate Agmt. § I(d) (2002). CMS regulations track the statutory definition: "Best price means * * * the lowest price available from the manufacturer * * * to any [specified] entity in the United States." 42 C.F.R. § 447.505(a) (2007). A 1991 Medicaid Program Release similarly explained that Best Price means "the single best price * * * at which any package size of the product was sold." C.A.J.A. 245 (emphasis added).

2. The rulemaking history confirms the interpretation that "Best Price" means the best price received by a single customer. During the 2006-2007 rulemaking, a manufacturer noted that ambiguous language in one passage of the proposed rule's preamble could be read to "suggest[] that CMS views best price as the net amount realized by the manufacturer on a sale rather than the lowest price to a particular customer." C.A.J.A. 239. Numerous manufacturers and the industry trade group submitted comments expressing the uniform view that "[t]he statutory definition of best price," which "[t]he proposed rule adopt[ed]," "has always been interpreted to mean the single lowest price to a particular customer." *Ibid.*; accord C.A.J.A. 271 ("BP is the single lowest price at which the manufacturer sells the product to a single customer"); C.A.J.A. 285 (Medicaid Rebate Statute makes clear "it is not appropriate to consider discounts other than the discounts offered to one customer when determining best price, for those other discounts are never available to that customer"). They notified the agency that consistent with the traditional understanding of the statute and regulation, the "preamble language must be read to mean that Best Price is the lowest price realized by the manufacturer net of all price concessions to a specific Best Price-eligible customer." C.A.J.A. 305. In the final rule, the agency did not contradict that understanding.

3. Recognizing Medicaid's complexity, the Rebate Agreement provides that where the statute and regulations are unclear or silent, manufacturers should "make reasonable assumptions in [their] calculations of * * * Best Price, consistent with the requirements and intent of [the Medicaid Rebate Statute], Federal regulations, and the terms of [the Agreement]." C.A.J.A. 217, Rebate Agmt. §II(i). CMS has consistently reaffirmed the need for manufacturers to make such reasonable assumptions in determining Best Price. *E.g.*, 81 Fed. Reg. 5170, 5174 (Feb. 1, 2016); 72 Fed. Reg. 39,142, 39,191 (July 17, 2007).

B. Proceedings Below

1. Petitioner's husband[1] worked for Forest Laboratories, LLC and Forest Pharmaceuticals, Inc., both later acquired by respondent Allergan.[2] C.A.J.A. 63, Am. Compl. ¶55. Petitioner alleges that Allergan paid rebates and price concessions to separate customers along drugs' distribution chains, but failed to account for the combined amount of all concessions in calculating Best Price, which petitioner alleged resulted in the submission of false pricing reports to the government. C.A.J.A. 63, Am. Compl. ¶56. Petitioner contends that in calculating "best price," Allergan was required to aggregate all price concessions received by all parties involved in distribution. Petitioner alleges that this improperly reduced the rebates Allergan was required to pay to participating states under the Rebate Statute, which resulted in the federal government paying more for these drugs than it would have had Allergan accurately reported Best Price. C.A.J.A. 63, Am. Compl. ¶56.

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[1] Relator Troy Sheldon died after filing this action and his wife was substituted as plaintiff. C.A.J.A. 321.

[2] For clarity, all respondent entities will be referred to as "Allergan."

2. Allergan moved to dismiss. It argued that neither the Medicaid Rebate Statute nor governing regulations required Allergan to aggregate price concessions to unrelated entities when calculating best price. And at minimum, Allergan argued that its position was objectively reasonable. Allergan argued that "differences in interpretation growing out of a disputed legal question are * * * not false under the FCA." Allergan Mot. To Dismiss 17, Dkt. 72-1 (quoting *Wilson*, 525 F.3d at 377). Allergan separately argued that, by analogy to this Court's decision in *Safeco Ins. Co.* v. *Burr*, 551 U.S. 47 (2007), "a defendant does not possess the scienter necessary to impose FCA liability where it acts based on an objectively reasonable, but ultimately incorrect, interpretation of an ambiguous statute or regulation." Allergan Mot. To Dismiss 19 (citing *Purcell*, 807 F.3d at 288).

In opposing Allergan's scienter argument, petitioner explicitly agreed that "[t]he FCA does not * * * reach those claims made based on reasonable but erroneous interpretations of a defendant's legal obligations." Pet. Opp. to Mot. to Dismiss 24, Dkt. 79 (quoting *Purcell*, 807 F.3d at 287). It likewise agreed that a defendant would not be liable under the FCA if it could demonstrate that "(1) the statute was ambiguous; (2) the defendant's interpretation of that ambiguity was objectively reasonable; and (3) the defendant was not 'warned away' from that interpretation." *Ibid.* Petitioner argued that Allergan had not demonstrated those three factors were met because Allergan's interpretation of "Best Price" was objectively unreasonable and in any event, it had been "warned away" from that reading. *Id.* at 25-26.

3. The district court dismissed the complaint under Rule 12(b)(6), concluding that petitioner had failed to plausibly plead either falsity or scienter. Pet. App. 140a. After carefully examining the governing statute and regulatory framework, *id.* at 130a-132a, the district court

concluded that "the plain and natural reading of the provision is that Best Price means the lowest price made available by the manufacturer, including all price concessions, to any one of the listed entities, but not to multiple entities." *Id.* at 131a. The district court noted that although petitioner had "cherry-picked" agency statements in an attempt to support its reading, *id.* at 135a, she had failed to identify "a single example where [the agency] explicitly state[d] that manufacturers must aggregate discounts to different customers along the supply chain in a given sale." *Id.* at 136a. Allergan thus offered an interpretation that was at least "objectively reasonable." *Id.* at 130a. Under Fourth Circuit precedent, "[t]o satisfy the [falsity] element of an FCA claim, the statement * * * must represent an objective falsehood," which did not include "differences in interpretation growing out of a disputed legal question." *Id.* at 125a-126a (quoting *Wilson*, 525 F.3d at 376-377); accord *id.* at 137a. In addition, because Allergan was not "warned away" from that interpretation, petitioner had separately failed to plausibly allege that "[Allergan] acted with the requisite scienter." *Id.* at 138a-139a.

4. A panel of the court of appeals affirmed. Pet. App. 3a-81a. Writing for the majority, Judge Wilkinson agreed with the district court that Allergan's "reading of the statute is both objectively reasonable and in fact the best interpretation." *Id.* at 33a; accord *id.* at 26a. The majority explained that "[t]he plain language here indicates that Best Price is one offered to a single entity," reasoning that "both 'price' and all of the entities listed are singular, joined by the disjunctive 'or,'" and "'any' usually means a single member in a class if used with singular nouns." *Id.* at 22a (citation omitted). Thus, "[t]his linguistic construction (singular nouns plus the disjunctive) strongly advises against aggregating discounts to multiple entities." *Ibid.* The panel majority concluded that petitioner's reading

was counter-textual, "cobbling together bits and pieces" of numerous parties' prices "to fashion a price never 'available' to any actual entity." *Id.* at 25a.

The majority rejected petitioner's argument, advanced for the first time on appeal, that the *Safeco* standard was inapplicable to the FCA scienter inquiry. Noting that this Court had tasked courts "with 'strict enforcement' of the FCA's 'rigorous' scienter requirement," Pet. App. 12a, the majority emphasized that "*Safeco*'s standard duly ensures that defendants must be put on notice before facing liability for allegedly failing to comply with complex legal requirements." *Id.* at 19a. "Such 'clarity in regulation is essential to the protections provided by the Due Process Clause of the Fifth Amendment,' especially when, as here, defendants are faced with 'damages that are essentially punitive in nature,'" *id.* at 20a (quoting *Vt. Agency of Nat. Res.* v. *United States ex rel. Stevens*, 529 U.S. 765, 784 (2000)), to ensure "the government 'provide[s] a reasonably clear standard of culpability to circumscribe the discretion of the enforcing authority and its agents.'" *Ibid.* (quoting *United States* v. *Hoechst Celanese Corp.*, 128 F.3d 216, 224 (4th Cir. 1997)).

The majority also rejected petitioner's argument that Allergan had been warned away from its reading, noting that agency guidance did not "sp[eak] directly to whether manufacturers were required to aggregate discounts given to separate entities on the supply chain." *Id.* at 28a. Rather, Allergan reasonably relied on the agency's direction that "in the absence of specific guidance, manufacturers should 'make reasonable assumptions in their calculations of … Best Price,'" *id.* at 30a (quoting Rebate Agreement), which the agency had reaffirmed "*nine* times" in Best Price rulemaking, *ibid.* The majority thus concluded that "the district court correctly dismissed Sheldon's complaint for failure to allege scienter." *Id.* at 32a. Because the panel "h[e]ld that [Allergan] did not act

knowingly under the FCA, [it] ha[d] no occasion to address the district court's holding as to falsity." *Id.* at 11a n.2.

Judge Wynn dissented. Pet. App. 34a-81a. He argued that "*Safeco*'s objective-recklessness test" was erroneous because it effectively "scrap[ped] two of the False Claims Act's three scienter standards," and its use was inconsistent with later decisions of this Court. *Id.* at 44a. He also argued that "even if *Safeco* applied, the majority erred by finding that [Allergan] wasn't 'warned away' from" not aggregating concessions in reporting Best Price. *Id.* at 37a. Judge Wynn separately concluded that the district court had erred in holding that petitioner had failed to plead falsity. *Id.* at 80a n.9.

5. The court of appeals granted Sheldon's petition for rehearing en banc. But after hearing argument, the equally divided en banc court vacated the panel opinion, and affirmed the judgment of the district court. Pet. App. 2a.

REASONS TO DENY THE PETITION

A. The Judgment Below Is Supported By The Unchallenged Holding That Allergan's Claims Were Not False

In addition to dismissing petitioner's complaint for failure to plead scienter, the district court *also* dismissed on the ground that under the False Claims Act, "the statement of conduct alleged must represent an objective falsehood." Pet. App. 125a (quoting *Wilson*, 525 F.3d at 376-377). Under that standard, "differences in interpretation arising out of a disputed legal question are [] not false under the FCA." *Id.* at 126a (quoting *Wilson*, 525 F.3d at 377). As the government acknowledged, whether disputed legal questions are "false" under the False Claims Act is a "separate question [from] whether [Allergan] vio-

lated the law knowingly." U.S. C.A. *Amicus* Br. 12. Before the court of appeals, both parties and the government as *amicus* analyzed the falsity and scienter issues separately. See Pet. C.A. Br. 21-38 (falsity), 38-46 (scienter); Allergan C.A. Br. 15-36 (falsity), 36-53 (scienter); U.S. C.A. *Amicus* Br. 9-19 (falsity), 19-27 (scienter). And both the panel majority and dissent considered the issues analytically distinct. See Pet. App. 11a n.2, 80a n.9. The district court relied on a different line of cases that addressed the meaning of "falsity" under the FCA rather than the statute's knowledge element.[3]

Petitioner has not sought review of the district court's falsity determination. While petitioner criticizes the district court's falsity ruling in passing, see Pet. 11, 12, petitioner pointedly did not include the falsity issue among the issues presented for review. See Pet. i; *id.* at 14 ("Certiorari should be granted to resolve a circuit split and uncertainty regarding the FCA's scienter requirement"); *id.* at 25 ("key issue" is "what is the role subjective intent plays in FCA scienter in the face of an ambiguous legal requirement"). The district court's falsity ruling thus is not properly presented for this Court's review. Cf. *Dep't of Treasury* v. *Fed. Labor Relat. Auth.*, 494 U.S. 922, 933 (1990) ("declin[ing] to consider" argument petitioner had raised in cursory fashion). And petitioner has made no effort to demonstrate that application of the "falsity" prong of the False Claims Act has divided the courts of appeals or otherwise satisfies this Court's criteria for review. S. Ct. R. 10. Thus, petitioner has presented no basis for disturbing the district court's judgment, which the en banc Fourth Circuit affirmed.

Because the judgment below will remain valid regardless of how this Court rules in *Schutte* and *Proctor*,

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[3] See Pet. App. 125a-126a (citing *Wilson*, 525 F.3d at 376-377; *Lamers* v. *City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999)).

the petition should be denied. This Court "reviews judgments, not statements in opinions." *Johnson* v. *De Grandy*, 512 U.S. 997, 1003 n.5 (1994) (quoting *California* v. *Rooney*, 483 U.S. 307, 311 (1987) (per curiam)). Accordingly, "[t]he question before an appellate Court is, was the judgment correct, not *the ground* on which the judgment professes to proceed." *Camreta* v. *Greene*, 563 U.S. 692, 717 (2011) (Kennedy, J., dissenting) (quoting *McClung* v. *Silliman*, 19 U.S. (6 Wheat.) 598, 603 (1821)). Because the district court's alternative holding independently supports the judgment below, there is no basis for disturbing the judgment below regardless of how this Court resolves the scienter issue in *Schutte*. See Stephen M. Shapiro, et al., *Supreme Court Practice* 6-148 (11th ed. 2019) (fact that "the decision below is correct regardless of how the Court resolves the question presented" counsels against review); see also Stephen G. Breyer, *Reflections on the Role of Appellate Courts: A View from the Supreme Court*, 8 J. App. Prac. & Process 91, 96 (2006) (noting that this Court is "not particularly interested" in resolving issues that "are not outcome determinative").

There is no warrant for holding this case pending *Schutte* and *Proctor*. The en banc Fourth Circuit was already presented with both the scienter and falsity issues, as well as briefing on whether petitioner had satisfied the standard of pleading under Federal Rule of Civil Procedure 9(b). After full briefing about all issues and oral argument, the full court was equally divided, affirming the decision of the district court. There is no reason to believe this Court's decision in *Schutte* and *Proctor* would affect the Fourth Circuit's prior resolution of the legally distinct "falsity" issue.

B. Petitioner Waived Her Claim By Urging The *Safeco* Test On The District Court

Petitioner now contends that some courts of appeals have mistakenly held that "a relator cannot * * * meet any

of the three definitions of scienter if the defendant's conduct was consistent with a reasonable interpretation of an ambiguous legal requirement, unless authoritative guidance warned the defendant away from that interpretation." Pet. 2. But petitioner has waived any claim that the district court erred in applying that standard by urging that very rule on the court. Petitioner urged the district court to conclude that "[t]he FCA does not * * * reach those claims made based on reasonable but erroneous interpretations of a defendant's legal obligations." Pet. Opp. to Mot. to Dismiss 24, Dkt. 79 (quoting *Purcell*, 807 F.3d at 287). *Purcell* explicitly concluded that "subjective intent—including bad faith—is irrelevant when a defendant seeks to defeat a finding of knowledge based on its reasonable interpretation of a regulatory term." 807 F.3d at 290. Petitioner thus advocated the very rule it is now criticizing; it simply argued that Allergan had not satisfied the *Safeco* test.

A "cardinal rule of appellate review" is that "a party may not complain on appeal of errors that he himself invited or provoked the [district] court * * * to commit." *In re Bayer Healthcare & Merial Ltd. Flea Control Prods. Marketing & Sales Practices Litigation*, 752 F.3d 1065, 1072 (6th Cir. 2014) (quotations omitted). By urging an erroneous proposition of law on a court, the principle of waiver prevents a party from "later seeking to profit from the legal consequences of having the ruling set aside." *Ibid.*; accord *United States* v. *Mamoth*, 47 F.4th 394, 398 (5th Cir. 2022). This Court has written that doctrine counsels in favor of denying review to petitioners who have urged inconsistent positions below, observing that "there would be considerable prudential objection to reversing a judgment because" a lower court applied a rule that the party "itself requested." *City of Springfield, Mass.* v. *Kibbe*, 480 U.S. 257, 259 (1987) (per curiam) (dismissing

cert. as improvidently granted). To discourage gamesmanship, this Court has long barred parties from "asserting a claim in a legal proceeding that is inconsistent with a claim taken by that party in a previous proceeding." *New Hampshire* v. *Maine*, 532 U.S. 742, 749 (2001).

Had petitioner not lulled the district court into believing that the only relevant issue that petitioner saw was whether "[Allergan]'s reading of the [Medicaid Rebate] statute was objectively unreasonable," Pet. Opp. to Mot. to Dismiss 25, the district court would have had the opportunity and incentive to conclusively resolve the meaning of the governing legal standard. Had the district court known that petitioner would later argue that the "objective reasonableness" of Allergan's position was not enough to resolve this case, the district court might have undertaken a more definitive examination of the Medicaid Rebate Statute and regulations such that it would have concluded, like the panel majority, that Allergan's position was not merely reasonable but was "in fact the best interpretation." Pet. App. 33a; accord *id.* at 26a ("the best reading of that text"). There is no basis at this late stage to reward petitioner's sandbagging by remanding the case for further proceedings.

C. Allergan's Interpretation Of "Best Price" Was Clearly Correct

Finally, there is no need for this Court to hold this petition for *Schutte* and *Proctor* because Allergan's interpretation of the governing legal obligation was clearly correct. In *Schutte* and *Proctor*, there is no dispute that the defendant's legal construction has been held to be incorrect, and the question is whether the reasonableness of their position prevents them from having the necessary knowledge of falsity. See Pet. App. at 9a, *Schutte* (noting 7th Circuit had earlier rejected defendant's legal argument, and "[t]he district court, relying on [that decision] granted summary judgment to the Relators on the falsity

prong"); Pet. App. at 12a, 16a, *Proctor* ("all agree that after [the relevant 7th Circuit decision]," the defendant's position "would satisfy the FCA's falsity prong").

By contrast, there is no credible claim that Allergan submitted false claims. Both opinions below agreed with Allergan's interpretation of the governing legal standard, which the district court called the "plain and natural reading" of the relevant provisions, Pet. App. 131a, and the panel majority said is "in fact the best interpretation," *id.* at 33a. Petitioner does not even quote the "Best Price" definition, see Pet. 7-8, or even deem its text "relevant" to the disposition of this case, see Pet. App. 141a-143a. Petitioner provides no credible argument to reject the construction favored by both courts below. There is no reason to revisit their determination. Cf. *Glossip* v. *Gross*, 576 U.S. 863, 882 (2015) ("[T]his Court will not lightly overturn the concurrent findings of the two lower courts.") (citation omitted).

The Medicaid Rebate Statute is clear: Best Price is "the lowest price *available from the manufacturer* * * * *to any* wholesaler, retailer, provider, health maintenance organization, nonprofit entity, *or* governmental entity." 42 U.S.C. § 1396r-8(c)(1)(C)(i) (emphasis added). Every element of the statutory definition supports Allergan's interpretation. To begin with, the ordinary meaning of "price" is "consideration given in exchange" for goods, consistent with a sale to a particular customer. *Price*, Black's Law Dictionary (11th ed. 2019). The statute refers to a single "lowest price" available to "any" one of various entities identified using singular nouns joined by the disjunctive word "or," confirming that the definition is referring to the lowest single price to a single entity in an actual transaction. "Any" ordinarily means a single item if "used in [the] context of [a] singular noun." *United States* v. *Dunford*, 148 F.3d 385, 389 (4th Cir. 1998); accord *Any*, Oxford English Dictionary (3d ed. 2021). Moreover, the

statutory definition is absolutely unequivocal that it means a bilateral transaction, by specifying it means a price "*available from* the manufacturer * * * *to any*" specified party. Thus, as Judge Wilkinson explained, Allergan's reading was "in fact the best interpretation" of the statute. Pet. App. 33a.

Petitioner offers no explanation how this definition can be stretched to encompass its interpretation, under which "Best Price" means not an actual price obtained by any actual party in a bilateral transaction, but rather a "purely hypothetical" composite net revenue figure compiled using discounts to a number of unrelated entities, and that is literally "*not 'available' to an[y] entity*." Pet. App. 23a (emphasis added). "[T]he statute cannot be stretched" to include petitioner's reading. *Ibid.*

Allergan's interpretation is confirmed by the implementing regulations issued by the implementing agency, the Centers for Medicare and Medicaid Services (CMS). CMS regulations define Best Price as "the lowest price available from the manufacturer * * * to any entity in the United States." 42 C.F.R. § 447.505(a). Likewise, the Rebate Agreement (also promulgated by CMS regulation) defines Best Price as "the lowest price at which the manufacturer sells the [covered drug] to any purchaser in the United States." C.A.J.A. 213; 56 Fed. Reg. at 7050. Again, each term is singular, most naturally referring to the lowest price given to a single entity in a bilateral transaction. Cf. *Gibbons* v. *Malone*, 703 F.3d 595, 600 (2d Cir. 2013) ("Congress's use of the singular term 'any equity security' [under the Securities Exchange Act] supports an inference that transactions involving *different* equity securities cannot be paired" under the terms of a statutory prohibition).

Because the statute is clear, the Court need not resort to legislative history. *BedRoc Ltd., LLC* v. *United States*,

541 U.S. 176, 186 (2004). But the Rebate Statute's legislative history confirms Congress intended "Best Price" to mean the lowest price the manufacturer makes available to an actual customer. Congress explained that Medicaid "should have the benefit of the same discounts * * * that other large public and private consumers enjoy." H.R. Rep. No. 101-881, reprinted in 1990 U.S.C.C.A.N. 2017, 2108. The statute's purpose was to "give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug *to any public or private purchaser*." *Ibid.* (emphasis added). Congress wanted to ensure that Medicaid was given the lowest price received by one of the specified customers. Bill sponsor Senator David Pryor stated that the Best Price provisions were intended to ensure that Medicaid receives the "'lowest price' that the manufacturer makes available to other purchasers." 136 Cong. Rec. S12,961 (1990). That reading is also borne out by the implementing agency's statements. A 1991 Program Release explained that Best Price "represents *the single best price* * * * at which any package size of the product was sold." C.A.J.A. 245 (emphasis added).

Petitioner's argument turns largely on the fact that the Rebate Agreement (and various regulations) state that "[t]he best price * * * shall be adjusted by the manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized." C.A.J.A. 213. But in context, "prices actually realized" refers to the prices the manufacturer obtains on sales to an individual customer, after accounting for all price concessions *to that single customer*, whether realized at the time of sale or later, because some discounts are realized at different times. As both courts below concluded, "Best Price means the lowest made available, including all price concessions, to any one of the listed entities." Pet. App. 131a; accord *id.* at 25a ("the Rebate Agreement's 'prices actually realized' simply means

prices the manufacturer receives on sales to each individual customer").

Petitioner also makes much of Allergan's supposed "admi[ssion]" in a comment letter that proposed language "suggests that CMS views best price as the net amount realized by the manufacturer on a sale rather than the lowest price to a particular customer." Pet. 9. But that comment letter referenced only isolated "language in the *preamble*" of a proposed regulation. C.A.J.A. 239. The letter also noted that "[t]he statutory definition of Best Price has always been interpreted to mean the single lowest price to a particular customer," and clearly stated that the preamble language "must be interpreted to mean the associated discounts and price concessions are provided to the same entity" rather than aggregating between different transactions. *Ibid.* Allergan and numerous other manufacturers informed CMS that they would interpret both the preamble and the proposed regulation "to mean that Best Price is the lowest price realized by the manufacturer net of all price concessions to a specific * * * customer." C.A.J.A. 305. And although, as the district court noted, petitioner attempted to distort the regulatory history by "cherry-pick[ing]" isolated bits of language to try to support its reading, Pet. App. 135a, as both the district court and the panel majority concluded, there is not even "a single example where CMS explicitly state[d] that manufacturers must aggregate discounts to different customers along the supply chain." Pet. App. 6a (quoting *id.* at 136a).[4] Thus, Allergan reasonably relied on the

[4] For example, petitioner claimed that the agency "explicitly rejected [Allergan's] interpretation" in its responses to comments. Pet. C.A. Br. 11 (citing Medicaid Program; Prescription Drugs, 72 Fed. Reg. 39,142, 39,150-39,151, 39,197-39,199, 39,201 (July 17, 2007). However, the agency comments to which petitioner refers were fully consistent with Allergan's interpretation, and suggested that aggregation of discounts was appropriate only when they were

agency's direction that "in the absence of specific guidance, manufacturers should 'make reasonable assumptions in their calculations of … Best Price,'" *id.* at 30a (quoting Rebate Agreement), which the agency had reaffirmed "*nine* times" in Best Price rulemaking, *ibid.*

In short, there is no basis for petitioner's claim that Allergan submitted false claims. There is no basis for disturbing the judgment of the district court affirmed by the en banc Fourth Circuit.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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realized by the *same party*, rather than different parties in the distribution chain. See, *e.g.*, Medicaid Program; Prescription Drugs, 72 Fed. Reg. at 39,198-39,199. As the panel majority explained, the agency comments did not suggest "manufacturers were required to aggregate discounts given to separate entities on the supply chain." Pet. App. 28a.