No. 22-593

IN THE

Supreme Court of the United States

UNITED STATES OF AMERICA
ex rel. DEBORAH SHELDON,

Petitioner,

v.

ALLERGAN SALES, LLC,

Respondent.

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

REPLY BRIEF OF PETITIONER

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TABLE OF CONTENTS

Table of Contents

TABLE OF CITED AUTHORITIES

Page

CASES

STATUTES AND REGULATIONS

OTHER AUTHORITIES

REPLY BRIEF OF PETITIONER

The issue raised in this case is whether an objective reasonableness test acts as a threshold barrier to FCA liability, regardless of the defendant's subjective intent. This issue is indistinguishable from the issue this Court will review in No. 21-1326, *United States ex rel. Schutte v. SuperValu Inc.,* and No. 22-111, *United States ex rel. Proctor v. Safeway, Inc.* The United States agreed in its *Schutte* Amicus brief when it relied on the Fourth Circuit's deadlock in this case as a justification for the grant of certiorari. United States *Schutte* Amicus Br. 22 (The Fourth Circuit's "inability to agree upon a governing standard highlights the need for this Court's review."). Even a cursory reading of the now-vacated Fourth Circuit panel decision in this case demonstrates that the issues in this case, *Schutte*, and *Proctor* are the same. *See* Pet. App. 3a-81a. And a cursory reading of the district court's now-controlling opinion demonstrates that this case was resolved upon the district court's application of a threshold objective reasonableness test. Pet.App. 82a-140a.

Allergan does not distinguish this case from *Schutte* and *Proctor*. Instead, Allergan tries to distract this Court with tangents by mistating the district court's holding and making a waiver argument that the appellate court deemed unworthy of any attention. Allergan also argues that it "clearly" complied with the Rebate Statute. Fifteen judges have heard that argument; the only judge to put pen to paper and resolve Allergan's purported compliance argument was Judge Wynn in his Fourth Circuit panel dissent. Pet.App 67a-74a. Judge Wynn unequivocally rejected Allergan's argument. Allergan's tangents are meritless and irrelevant; they should not have any effect

on this Court's decision to hold on this case for its decision in *Schutte* and *Proctor*.

There is no daylight between this case and *Schutte* and *Proctor*—to the contrary, this case further "highlights" the need for this Court's guidance. United States *Schutte* Amicus Br. 22. This Court should hold this Petition for the decision in *Schutte* and *Proctor* and then remand this case to the district court for application of that decision.

I. This Case is Materially Indistinguishable from *Schutte* and *Proctor*—This Case Should be Held Pending that Decision.

The question before this Court in this case and the question before this Court in *Schutte* and *Proctor* are the same—whether, and to what extent, the objective reasonableness test set forth in *Safeco Insurance Co. of America v. Burr*, 551 U.S. 47 (2007) applies in the FCA context. The Seventh Circuit held in *Schutte* and *Proctor* that objective reasonableness is a threshold test precluding analysis of the defendant's subjective intent. *See United States ex rel. Schutte v. SuperValu, Inc.*, 9 F.4th 455 (7th Cir. 2021); *United States ex rel. Proctor v. Safeway, Inc.*, 30 F.4th 649 (7th Cir. 2022). The Fourth Circuit panel that decided this case held the same; and when the equally divided Fourth Circuit sitting en banc vacated the panel decision, it left in place a district court judgment that held the same.

The similarities between this case and the *Schutte* and *Proctor* cases run deep. All three courts declined to dismiss based on the defendants' arguments that they complied with the applicable statutory mandates. *See* Pet. App. 12a; *Schutte*, 9 F.4th at 459; *Proctor*, 30 F.4th at 659. In all three cases, there was evidence that the defendant

knew its conduct was noncompliant but the defendant engaged in that conduct all the same. *See* Pet.App. 40a-41a; *Schutte*, 9 F.4th at 474 (Hamilton, J., dissenting); *Proctor*, 30 F.4th at 665 (Hamilton, J., dissenting). All three courts determined that the purported objective reasonableness of the defendant's statutory interpretation set forth in briefing precluded analysis of whether the defendant's interpretation was a *post hoc* legal argument or a good-faith contemporaneous belief. *See* Pet.App. 30a; *Schutte*, 9 F.4th at 470; *Proctor*, 30 F.4th at 658. In all three cases, the result would have been different had the court analyzed the defendant's actual knowledge, *i.e.*, subjective intent, as an independent standard. *See* Pet.App. 40a-41a; *Schutte*, 9 F.4th at 474 (Hamilton, J., dissenting); *Proctor v. Safeway, Inc.*, 30 F.4th at 665 (Hamilton, J., dissenting).

In the words of the United States in its brief in support of certiorari in *Schutte*, the Fourth Circuit's "inability to agree upon a governing standard [in the *Sheldon* en banc decision] highlights the need for this Court's review." United States *Schutte* Amicus Br. 22. Both replies in support of certiorari in *Schutte* and *Proctor* also explained how the Fourth Circuit's inability to reach a consensus regarding the application of an objective reasonableness test to the FCA in this case demonstrates the need for this Court's guidance. *Schutte* Pet. 1; *Proctor* Pet. 3-4. And Senator Grassley, the principle sponsor of the relevant amendments to the FCA, also noted in a recent Amicus brief that this case and *Schutte* raise the same questions. *See* Grassley *Schutte* Amicus Br. 15 n.5 (The decision in *Schutte* and *Sheldon* "followed this same pattern"). Everyone to express an opinion on this case's similarities to *Schutte* and *Proctor* has agreed: the decision in this case "highlights" exactly why it was necessary for this Court to grant certiorari in *Schutte* and *Proctor*.

The logical conclusion is that this Court's decision in *Schutte* and *Proctor* will set out the applicable law controlling application of the objective reasonableness test in this case. For this reason, this Court should hold this case for the decision in *Schutte* and *Proctor*.

II. Allergan Presents No Reason to Deny Certiorari—its Opposition is a Mere Distraction Technique.

A. Sheldon Pointedly Asked this Court to Overturn the District Court's Not-False-Because-Objectively-Reasonable Finding.

In an effort to divert attention from the obvious similarities between this case and *Schutte* and *Proctor*, Allergan suggests the district court's dismissal rested on two independent determinations and that Sheldon has not challenged one of them. BIO 10-12. Allergan's assertion is incorrect. Allergan asks this Court to focus solely on the label the district court attached to its finding, but to ignore the substance and reasoning; Allergan's argument also relies on selectively quoting Sheldon's Petition. These arguments should not prevent the Court from holding this Petition pending the decision in *Schutte* and *Proctor*.

1. The District Court's Application of the Objective Reasonableness Test is Materially Indistinguishable from the Analysis that this Court is Reviewing in *Schutte* and *Proctor*.

Allergan argues the district court dismissed based on the FCA's falsity prong. That is inaccurate. The district court did not make a falsity determination but

instead conflated falsity and scienter. To rule on falsity, a court must decide whether the defendant complied with the relevant statute. *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364,383-84 (4th Cir. 2015). In direct conflict with that precedent, the district court stated it is "impossible to meaningfully" discuss falsity and scienter separately. Pet.App. 128a. And the district court stated it did *not* determine whether Allergan complied with the Rebate Statute. Pet.App. 130a; 134a (the Rebate Statute "may be susceptible to multiple interpretations, including Relator's construction" and Sheldon's reading of the Rebate Statute is plausible). The district court applied the objective reasonableness test to the interpretation of Best Price presented in Allergan's Motion to Dismiss. Pet.App. 137a. The objective reasonableness test is a scienter test.

An even more obvious signpost that the district court did not resolve falsity is that the district court identified "warned away" as an exception to the objective reasonableness test. Pet.App. 138a. It is well-settled that warned away is part of a scienter analysis, not a scienter-based exception to the FCA's falsity prong. *See, e.g.*, *United States v. Mallory*, 988 F.3d 730, 737 (4th Cir. 2021). And even though warned away is a fact issue that must be resolved in Sheldon's favor at the pleadings stage, the district court resolved that fact issue in Allergan's favor, further demonstrating the district court's confusion. *See United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 288 (D.C. Cir. 2015).

In sum, holding this case for resolution of *Schutte* and *Proctor* is warranted because the district court engaged in the same objective reasonableness analysis that this Court is reviewing in *Schutte* and *Proctor*.

2. The Petition Explicitly Asks this Court to Determine Whether *Safeco*'s Objective Reasonableness Test Applies to FCA Falsity Analyses.

Allergan suggests that Sheldon "criticizes the district court's falsity ruling in passing" but "pointedly did not include the falsity issue among the issues presented for review." BIO 11. Allergan's assertion is again inaccurate. As outlined in the introduction in the Petition, Sheldon explicitly asked this Court to resolve three facets of the split related to application of *Safeco*'s "objective reasonableness" test in FCA cases:

> First, this Court should address whether *Safeco* applies to the FCA. **Second, this Court should address whether *Safeco* applies to the falsity or scienter prongs of the FCA.** And, third, this Court should address whether *Safeco* applies as a threshold test precluding liability. . . .

Pet. 5 (emphasis added).

Sheldon repeatedly identified that the district court's decision was grounded in conflating falsity and scienter. *See, e.g.*, Pet. 3 ("A Fourth Circuit panel reviewed the district court's determination that objective reasonableness is part of both falsity and scienter."); *id.* at 11 ("With regard to falsity, the district court conflated the falsity and scienter standards.").

As set forth in the Petition, and just like the question raised in *Schutte* and *Proctor* that the United States asked this Court to address, Sheldon asked this Court to

resolve a split related to the proper application of *Safeco*'s objective reasonableness test in the FCA context—Sheldon identified that part of that split is whether the objective reasonableness test is relevant when determining falsity.

Allergan's attempt to muddy these clear waters is to no avail. Sheldon's Petition explained in certain terms that, just like *Schutte* and *Proctor*, the issue for review in this case is a split regarding application of the objective reasonableness test in FCA cases.

B. Sheldon did Not Waive the Argument that Actual Knowledge and Deliberate Ignorance are Independent Standards.

Allergan also attempts to distract this Court from the merits of the Petition, and its obvious parallels with *Schutte* and *Proctor*, by raising a waiver argument. Allergan asserts that Sheldon "lulled the district court into believing" that objective reasonableness was the sole issue that the district court needed to address by citing *Purcell.* BIO 12-14. The Fourth Circuit found this argument so toothless that neither the three-judge panel nor the en banc panel thought it warranted any discussion.

Sheldon cited *Purcell* in the Opposition to the Motion to Dismiss in a paragraph addressing Allergan's good-faith defense. Pet. Opp. to Mot. to Dismiss 24-25, Dkt. 79. Sheldon added that Allergan could not sustain that good-faith defense at the pleadings stage because good faith is a factual issue and not a legal issue. *Id.* Despite Allergan's counterargument, no reasonable reader could conclude that Sheldon advised the district court that objective reasonableness is an all-encompassing threshold test that supersedes everything else.

Moreover, in *Purcell*, the D.C. Circuit analyzed reckless disregard through ignoring warnings—the opinion mentioned actual knowledge and deliberate ignorance only in its preliminary citation to the FCA standards—there was no in-depth analysis. *Purcell*, 807 F.3d at 287. As Sheldon explained at length in the Petition, *Purcell* is ambiguous as to whether the objective reasonableness test applies regardless of belief at the time of conduct. Pet. 20-21. In other words, even advocating for wholesale adoption of *Purcell* does not constitute embracing a threshold "objective reasonableness" test that precludes analysis of subjective intent, actual knowledge, and deliberative ignorance.

Finally, Sheldon asked the district court to assess Allergan's subjective intent and all three independent scienter standards. For example, Sheldon cited to facts alleged in the Complaint that show Allergan had "actual knowledge" it was not complying with the Rebate Statute. Pet. Opp. to Mot. to Dismiss 24, Dkt. 79. Sheldon also discussed the "ostrich" defense that is the foundation of the deliberate ignorance scienter standard. *Id.* at 25. If Sheldon was advocating that the district court adopt an all-encompassing objective reasonableness test, these arguments would have served no purpose.

Sheldon preserved the argument this Court will address in *Schutte* and *Proctor*—the FCA scienter analysis is not subject to an extra-statutory threshold "objective reasonableness" test. Allergan's argument is inaccurate.

C. Allergan Failed to Comply with the Rebate Statute and No Court has Held Otherwise.

Allergan's final roll of the dice is to argue that this Court should not grant certiorari because, despite the district court, the Fourth Circuit panel, and the Fourth Circuit en banc panel declining to hold that Allergan complied, Allergan claims it "clearly" complied with the Rebate Statute. BIO 14. Allergan is wrong.

As a threshhold matter, Allergan's argument has no bearing on this Court's decision to hold this case pending a decision in *Schutte* and *Proctor*. Allergan's argument is a red herring designed to distract this Court. Fifteen judges have heard Allergen's argument, not one has ruled that Allergan complied with the Rebate Statute. Allergan's interpretation is simply wrong. This Court should not deny certoriari based on Allergan's meritless argument.

1. No Judge has Ruled that Allergan Complied with the Rebate Statute.

Allergan argued to the district court that it complied with the Rebate Statute's requirements. Def. Mot. to Dismiss 9-17, Dkt. 72-1. The district court declined to adopt Allergan's position. Pet.App. 130a. Instead, the district court held that the Rebate Statute was susceptible to multiple interpretations, including Sheldon's construction that aggregation is required. Pet.App. 130a. Similarly, the Fourth Circuit panel majority explicitly stated it was not deciding statutory compliance but instead ruling only on scienter. Pet.App. 12a. And the en banc decision was a one-sentence opinion with no interpretation of the Rebate

Statute. Pet.App. 2a. The district court, the Fourth Circuit panel, and the Fourth Circuit en banc panel all had the opportunity to hold that Allergan had complied with the Rebate Statute, all declined to reach that conclusion.

On the other hand, Judge Wynn gave a definitive opinion on Allergan's statutory compliance argument. Pet. App. 67a-74a. Judge Wynn completed a comprehensive analysis of the Rebate Statute's text and applied canons of construction; Judge Wynn concluded that Allergan's interpretation of the Rebate Statute was not only incorrect, it was unreasonable. Pet.App. 74a. Thus, despite Allergan's protestation that it "clearly" complied with the Rebate Statute, the only judge to fully address that argument rejected it.

Allergan's request that this Court lose focus on the key issue changes nothing—this case should be held for the decision in *Schutte* and *Proctor*. After this Court settles the circuit split, Allergan can raise its compliance arguments on remand.

2. Allergan did Not Comply with the Rebate Statute's Reporting Requirements.

Though it is not appropriate for Allergan to seek denial of Sheldon's Petition by arguing the propriety of its Best Price reporting, Sheldon would be remiss not to briefly address why Allergan falsely reported is Best Price and received $680 million in Medicaid funds to which it had no entitlement.

Allergan's compliance argument fails because it relies on isolated words in the Rebate Statute that are not

placed in context, and ignores that the force of the Rebate Agreement is the same as the force of the Rebate Statute. *See Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 114 (2011) (the Rebate Statute and Rebate Agreement are "one and the same"). Judge Wynn's Fourth Circuit panel dissent plainly demonstrates that Allergan's compliance arguments are meritless and no further analysis is necessary or warranted.

Best Price ensures manufacturers receive no more money from government sales of a single drug unit than private sales. 136 Cong. Rec. S. 12954 (1990). Any purported ambiguity must be read to best effectuate that goal. 56 Fed. Reg. 7049, 7053 (Feb. 21, 1991). Allergan fraudulently reported Best Price after it failed to report aggregated multi-level discounts. Pet. Am. Compl. 33-39, Dkt. 16. Allergan has not denied failing to report aggregated discounts, instead, at the pleadings stage, Allergan asked the district court to bypass the cannons of statutory construction, ignore the Rebate Statute's language and purpose, and ignore CMS's guidance. Def. Mot. to Dismiss 9-17, Dkt. 72-1. Despite CMS's guidance and the Rebate Agreement explaining that Best Price must reflect aggregated discounts, and that Allergan responded by initiating an audit to identify some multi-level discounts, Allergan asked the district court to ignore those factual allegations. Def. Rep. Mot. to Dismiss 15-16, Dkt. 88. As Judge Wynn explained, Allergan "acted under an objectively *unreasonable* reading of the Rebate Statute." Pet.App. 74a (emphasis added).

* * *

The three arguments raised in Allergan's opposition brief are meritless and irrelevant to the question before the Court. The issue raised in this Petition is the same as the issue raised in *Schutte* and *Proctor*. Accordingly, this Court should hold this case for that decision.

CONCLUSION

This Court has already granted certiorari in the companion cases *Schutte* and *Proctor*. This Court should hold this case for the *Schutte* and *Proctor* decision and then remand this case to the district court for application of that decision.

Respectfully submitted,

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