No. 24-1793

United States Court of Appeals
for the Fourth Circuit

UNITED STATES OF AMERICA, EX REL. DEBORAH SHELDON,
EXECUTRIX OF THE ESTATE OF TROY SHELDON,

Plaintiff - Appellant

v.

ALLERGAN SALES, LLC,

Defendant - Appellee.

On Appeal from the United States District Court
for the District of Maryland,
No. 1:14-cv-02535-ELH
Judge Ellen Lipton Hollander

BRIEF OF *AMICI CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA IN SUPPORT OF DEFENDANT-APPELLEE AND IN SUPPORT OF REHEARING EN BANC

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the Pharmaceutical Research and Manufacturers of America states that it has no parent corporation and no corporation or publicly held company owns 10% or more of its stock. The Chamber of Commerce of the United States of America ("Chamber") states that it is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the Chamber.

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INTEREST OF *AMICI CURIAE*

Pursuant to Federal Rule of Appellate Procedure 29, *amici curiae* Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Chamber of Commerce of the United States of America ("Chamber") submit this brief in support of Defendant-Appellee.[1]

PhRMA is a non-profit association that represents the nation's leading innovative biopharmaceutical research companies. PhRMA's members closely monitor issues that affect the industry, and PhRMA often offers its perspective in cases raising such issues.

As the world's largest business federation, the Chamber represents approximately 300,000 members and indirectly represents the interests of more than three million companies. The Chamber regularly files *amicus* briefs in cases of concern to the nation's business community, including False Claims Act ("FCA") cases.

Amici have a strong interest in this appeal. Relators (rarely joined by the government) increasingly assert that *amici*'s members' reasonable

[1] No counsel for any party authored this brief in whole or in part and no entity or person, aside from *amici*, their members, or their counsel, made any monetary contribution intended to fund this brief's preparation or submission. The parties have consented to this filing.

interpretations trigger the FCA's "essentially punitive" regime of treble damages. *Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 784-85 (2000). Unfortunately, the panel decision will enable abuses of the FCA while creating significant uncertainty for countless Medicaid participants. *Amici* urge the Court to grant rehearing, vacate the panel decision, and affirm the district court.

INTRODUCTION

This case asks whether a regulated entity knowingly submits a false claim when it makes a reasonable—indeed, *correct*—assumption about a legal requirement when it has no reason to suspect that a government agency will reject that assumption. The answer is no: An FCA complaint must plausibly allege both that defendants' "claims were false *and* [defendants] actually thought that their claims were false." *U.S. ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 748-49 (2023) (emphasis added).

Here, the panel decision makes it unduly difficult to dismiss an FCA case for lack of scienter. At minimum, Forest Laboratories, LLC and Forest Pharmaceuticals, Inc. ("Forest") reasonably interpreted the Rebate Statute (42 U.S.C. §1396r-8). Indeed, "Forest's reading … is the best reading of that text." *U.S. ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340, 353 (4th Cir. 2022) (*Sheldon I*). Plus, the government affirmatively instructed manufacturers to make "reasonable assumptions" about Medicaid requirements. 72 Fed. Reg. 39,142, 39,164 (July 17, 2007). Nonetheless, the panel held that Relator satisfied the

FCA's scienter requirement. That holding cannot be squared with the FCA, let alone fair notice.

What's more, the Court could end this litigation—pending since 2014—simply by reading the Rebate Statute to mean what it says. As Judge Keenan's dissent explains, Relator's interpretation defies the statute's "unambiguous plain meaning." Op.36. But the panel punted and remanded for yet more litigation, to be followed no doubt by another appeal. This refusal to interpret the Rebate Statute exacerbates significant legal uncertainty to the detriment of almost every pharmaceutical manufacturer in America. The Court should grant rehearing to correct these errors and end this long-running case.

BACKGROUND

Relator's FCA claim boils down to whether Forest knowingly committed fraud when it calculated the "best price" for its drugs. Manufacturers pay rebates on covered outpatient drugs dispensed to Medicaid beneficiaries. That rebate is based off the average manufacturer price ("AMP"), and as relevant here, the "best price" for covered drugs. 42 U.S.C. §1396r-8(b)(3)(A).

To calculate "best price," manufacturers must navigate a minefield of statutes and regulations. The Rebate Statute defines "best price" as "the lowest price available from the manufacturer during the rebate period" to an eligible customer, which consists of "any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity." *Id.* §1396r-8(c)(1)(C). The associated Rebate Agreement with manufacturers further provides that "'Best Price' means … the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser in the United States in any pricing structure … in the same quarter for which the AMP is computed." JA357.

Neither the Rebate Statute nor Agreement, however, addresses many common pricing mechanisms. The Centers for Medicare and Medicaid Services ("CMS") thus instructs manufacturers to make "reasonable assumptions" about Medicaid requirements absent clear guidance or a definitive interpretation. 72 Fed. Reg. 39,164. So does the Rebate Agreement. JA361.

Relator asserts that Forest should have aggregated discounts to customers across its distribution chain for best-price purposes. By failing to "stack" discounts, Relator says Forest inflated its best price. Yet the

Rebate Statute and Agreement do *not* require stacking—and certainly do not do so unambiguously. To avoid doubt, moreover, manufacturers have repeatedly *told* CMS that they do not stack discounts, *e.g.*, JA401; JA447, and asked CMS to clarify that stacking is not required, *e.g.*, JA224; JA413; JA427. CMS has allowed manufacturers to continue operating on that reasonable view.

Unsurprisingly, the district court dismissed Relator's complaint for failing to meet the FCA's scienter and falsity elements. JA213-256. A panel affirmed, 24 F.4th 340, and the en banc Court affirmed by an equally divided court, 49 F.4th 873. After the Supreme Court vacated and remanded in light of *Schutte*, the district court again dismissed Relator's complaint.

Relator appealed and a divided panel reversed, reasoning that Forest knew CMS *might* interpret the Rebate Statute to require stacking. Although "[c]ompanies should not be held liable for making honest mistakes," the panel concluded Relator sufficiently alleged scienter as Forest was "subjectively aware of the risk" that CMS may disagree with Forest. Op.23. The panel focused on two key allegations: Forest (i) urged CMS to clarify that stacking is not required and (ii) afterwards conducted

an internal audit. Op.26-27. Instead of addressing the FCA's falsity element by resolving what the Rebate Statute means, the panel remanded. Op.30. Dissenting, Judge Keenan explained why the Rebate Statute does not require stacking, so there is no reason to "send[] the district court back to the very beginning of the inquiry." Op.38.

ARGUMENT

The Court should rehear this case en banc because the panel decision effectively makes it unduly difficult to dismiss FCA claims for lack of scienter. Nothing in *Schutte* precludes dismissal of FCA cases on scienter grounds, especially where, as here, the government itself instructs regulated parties to make "reasonable assumptions" about their regulatory duties. 72 Fed. Reg. 39,164.

The panel compounded its error by not interpreting the Rebate Statute. As *amici* have previously explained, the Court can resolve this case on scienter alone. If the Court does not do that, however, it should interpret the statute and end this litigation. "It is emphatically the province and duty of the judicial department to say what the law is." *Marbury v. Madison*, 1 Cranch 137, 177 (1803). The panel's refusal to perform that duty exacerbates significant uncertainty for the

pharmaceutical industry. Either error by itself warrants en banc rehearing. Combined, there can be no doubt.

I. THE PANEL'S SCIENTER ANALYSIS IS WRONG.

A. The Panel Misunderstood *Schutte*.

Before *Schutte*, this Court held that Relator's complaint should be dismissed. The question, therefore, is whether *Schutte* changes the outcome here. As the district court recognized, it does not. The panel, however, erroneously treated *Schutte* as a gamechanger. Op.25.

Schutte does not disturb the rule that scienter is lacking if a defendant acts consistently with how he "honestly read the [ambiguous] phrase." 598 U.S. at 749. Nor did *Schutte* upend Rule 12(b)(6)'s requirement that a complaint must raise "plausible" allegations. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Thus, even after *Schutte*, courts can and do dismiss FCA complaints that flunk scienter. *E.g.*, *U.S. ex rel. Henig v. Amazon.com, Inc.*, 2025 WL 27736, at *7 (S.D.N.Y. Jan. 3, 2025) (appeal pending); *U.S. ex rel. McSherry v. SLSCO, L.P.*, 2024 WL 1934443, at *2 (E.D.N.Y. May 5, 2024).

Here, however, the panel's decision effectively removes Rule 12(b)(6) dismissals from the judicial toolbelt whenever a relator

alleges an FCA claim based on an arguably ambiguous legal requirement, no matter how paltry his allegations of the defendant's scienter. Neither Rule 12(b)(6) nor *Schutte* countenances that outcome.

Unlike *Schutte*, Relator raised no plausible allegations of anything to warn Forest away from its reasonable interpretation. CMS knew manufacturers had interpreted best price *not* to require stacking but declined to issue further guidance. *See Sheldon I*, 24 F.4th at 354. Forest therefore is like the "hypothetical driver who sees a road sign that says 'Drive Only Reasonable Speeds,'" but no "police officer [had told him] that speeds over 50 mph are unreasonable." *Schutte*, 598 U.S. at 753. In fact, here, the driver asked the officer to interpret the sign, but the officer declined. There is nothing reckless about the driver's actions in that context. So too here. Rather than counseling against dismissal, *Schutte* requires it.

B. The Panel Misunderstood Medicaid Rebate Calculations.

The panel did not apply that straightforward analysis but instead focused on two allegations: that Forest asked CMS for clarification and conducted an internal audit. Neither remotely supports scienter, especially given the context of Medicaid rebate calculations.

Relator admits that "context matters" when interpreting the Rebate Statute and Agreement. Appellant.Br.34. Yet the context here is "the veritable thicket of Medicaid [statutes and] regulations," which this Court has described as "among the most completely impenetrable texts within human experience." *Sheldon I*, 24 F.4th at 344, 352. The government thus told "manufacturers that in the absence of specific guidance, they may make reasonable assumptions." 72 Fed. Reg. 39,164. "In the very rulemaking that [Relator] highlights, CMS reaffirmed the need to make reasonable assumptions—not once, not twice, but *nine* times." *Sheldon I*, 24 F.4th at 355 (emphasis added). In the Rebate Agreement, CMS reiterated that Forest should "make reasonable assumptions in its calculations of … Best Price." JA361. Indeed, manufacturers *must* make reasonable assumptions given the "complexities" of the industry and "absence of explicit Federal guidance." HHS Office of Inspector General, *Reasonable Assumptions in Manufacturer Reporting of AMPs and Best Prices* at 1 (Sept. 2019), https://bit.ly/2Qohfzg ("OIG Report").

Simply put, Medicaid oftentimes requires manufacturers to make countless judgment calls. If merely knowing that ambiguity may exist is

enough to trigger treble damages under the FCA, companies will be punished for engaging in the very good-faith interpretation that Medicaid requires. It defies credulity that Congress intended to punish companies for transparently and reasonably doing their best to follow the law.

Even if the Rebate Statute were ambiguous (which it is not, regarding stacking), there is no plausible allegation that Forest's assumptions were so unreasonable that they exceeded the government's instruction to "make reasonable assumptions." Indeed, PhRMA and other manufacturers openly announced to CMS their understanding of the statute. It turns scienter on its head to say that someone who shares its interpretation with an agency and is not told to stop has engaged in *fraud*, let alone after the government refused to issue guidance and said to "make reasonable assumptions."

The panel decision thus punishes regulated parties for trying to obtain clarity. Yet "it would be perverse to attribute deliberate ignorance or reckless disregard to Forest on the basis of a statement it made to CMS in an effort to clarify its obligations regarding the reporting of 'Best Price.'" JA965. The full Court should reject such perversity.

Nor does any audit change that bottom-line. As the district court explained, Forest's audit failed to *plausibly* allege scienter because "Relator has not pleaded any specific facts that would substantiate the contention that the audit was undertaken with a culpable mental state." JA967. Regardless, because Forest's reading is (at least) reasonable, the instruction to "make reasonable assumptions" precludes liability. Essentially every business conducts audits; if that were enough alone to override undisputed context, it is hard to imagine *any* FCA case that could be dismissed under Rule 12(b)(6).

C. The Panel Invites a Constitutional Challenge.

"A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *F.C.C. v. Fox Television Stations*, 567 U.S. 239, 253 (2012). Yet under the panel decision, a company could be liable for treble damages whenever it is forced to make an honest guess about an unclear legal requirement, even though the government told the company to "make reasonable assumptions" when faced with ambiguity. It is hard to imagine a starker example of *un*fair notice.

It would be "profoundly troubling to impose such massive liability on individuals or companies without any proper notice as to what is required." *Sheldon I*, 24 F.4th at 350. Indeed, "concerns about fair notice and open-ended liability" prompted the Supreme Court to demand the "strict enforcement" of the FCA's "rigorous" scienter requirement. *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 192 (2016). Absent such "strict enforcement," courts will transform the FCA into "a vehicle for punishing … regulatory violations" and negligence. *Id.* at 194. That is not the statute Congress enacted, and the Court should interpret the FCA to avoid rather than invite a constitutional challenge.

II. THE COURT SHOULD INTERPRET THE REBATE STATUTE.

The panel's misunderstanding of scienter is bad enough, but its refusal to interpret the Rebate Statute harms the pharmaceutical industry. The Court can resolve this case on scienter alone—there is no basis to fault Forest for making reasonable assumptions when the government told Forest to do just that. But if the Court does not resolve the case based on lack of scienter, it should interpret the statute and affirm dismissal, given the context here and of FCA litigation more generally. The United States spends almost a trillion dollars annually

on Medicaid, and "[a]lmost *all* … manufacturers reported making reasonable assumptions that affected the [best prices] used to determine Medicaid rebates." OIG Report at 9 (emphasis added). The stakes are hard to overstate.

Courts have a "duty" to answer legal questions. *Marbury*, 1 Cranch at 177. Yet the panel's decision not to answer the falsity question means this FCA case will proceed even though Judge Keenan has explained—correctly—why the challenged conduct is *lawful*. Failure to interpret the statute guarantees more litigation, no doubt followed by yet another appeal, even though Forest's reading is (and has always been) the best reading of the Rebate Act's plain terms.

If the Court will not rigorously enforce the FCA's scienter requirement, it should not also delay resolution of the falsity requirement—especially given just how prevalent FCA litigation has become. In 2025 alone, relators initiated an astounding 1,297 *qui tam* actions—the "highest in a single year in the history of the False Claims Act." DOJ, *False Claims Act Settlements and Judgments Exceed $6.8B in Fiscal Year 2025* (Jan. 16, 2026), https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-68b-fiscal-year-2025. And

the government acknowledges the problem of "meritless," "parasitic," and "opportunistic *qui tam actions*." DOJ Memorandum at 3-4 (Jan. 10, 2018), https://bit.ly/3oHszDq (capitalization altered).

Prolonging uncertainty increases the already considerable financial and reputational costs of defending these suits—costs that force many companies to settle meritless cases. This litigation proves the point. It has been dragging on since *2014*. Even Relator agrees "[t]he District Court should have … determined what the Rebate Statute and Rebate Agreement require[.]" Appellant.Br.21. But this Court can resolve that legal question as well as the district court, and there is no reason to delay doing so. As Judge Keenan explained, because "the unambiguous meaning of the statutory term 'best price' does not require such stacking," the Court should not effectively start the whole case over. Op.32. Otherwise, this litigation will become a roadmap for future abuses of the FCA.

CONCLUSION

The Court should grant rehearing en banc and affirm.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(b)(4) and Fourth Circuit Rule 32(b) because it contains 2,594 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

This brief also complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 32(a)(5) and 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Century font.

/s/ John C. O'Quinn
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CERTIFICATE OF SERVICE

I hereby certify that the foregoing brief has been served via the Court's CM/ECF filing system in compliance with Federal Rules of Appellate Procedure 25(b) and (c), on April 3, 2026, on all registered counsel of record, and has been transmitted to the Clerk of the Court.

/s/ John C. O'Quinn
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