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

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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 and affirmance.[1]

PhRMA is a non-profit association that represents the nation's leading innovative biopharmaceutical research companies, which are laser-focused on developing innovative medicines that transform lives and create a healthier world. Over the last decade, PhRMA's members have invested more than $800 billion in the search for new treatments and cures. PhRMA's members closely monitor legal issues that affect the entire industry, and PhRMA often offers its perspective in cases raising such issues.

The Chamber is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and

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

from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus* briefs in cases, like this one, that raise issues of concern to the nation's business community, including cases involving the False Claims Act ("FCA").

Amici have a strong interest in this appeal because it concerns the scope of FCA liability. As explained in their brief in the first appeal, many of *amici*'s members are subject to complex and detailed regulatory schemes, and have successfully defended scores of FCA cases arising out of government contracts, grants, and participation in federal programs. With alarming frequency, private relators (rarely joined by the government itself) have asserted that *amici*'s members' reasonable interpretations of complex statutes, regulations, and contract provisions—with nothing more—can give rise to FCA liability and trigger the statute'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).[2] That is

[2] Unless otherwise noted, all alterations have been adopted, emphases added, and footnotes, citations, and quotation marks omitted.

not how the FCA was intended to work. Exposing companies to draconian penalties solely for adopting reasonable interpretations of legal requirements would unmoor the FCA from its fraud-prevention purpose and transform it into a weapon for pursuing regulatory violations. On this second appeal, Relator-Appellant invites the Court to distort the FCA further by forbidding motions to dismiss based on scienter and exposing *amici*'s members to substantial liability solely for acting reasonably in their efforts to comply with an ever-increasing number of complex and indeterminate rules. *Amici* urge the Court to reject that invitation and affirm the judgment below.

INTRODUCTION

This FCA case presents the question whether a regulated entity knowingly submits a false claim to the government when it *merely* makes a reasonable assumption about what a legal requirement means when the government has declined to provide clear guidance and the entity has no reason to be on notice that its *actual* interpretation is purportedly incorrect. The answer is plainly no.

In this case, that is straightforward because the defendant not only reasonably, but correctly, interpreted the legal requirement at issue, as *amici* have explained in prior briefing and comment letters. *See* Br. of *Amici*, *U.S. ex rel. Sheldon v. Allergan Sales, LLC*, No. 20-2330 (May 26, 2021), ECF No. 32-1. Regardless, even if the legal requirement could be viewed as ambiguous, the answer would still be no for the simple reason that an FCA relator cannot establish the rigorous elements of scienter and falsity when the complaint fails to plausibly allege a defendant's subjective beliefs and instead rests on the defendant's reasonable interpretation of a complex obligation. The Supreme Court's recent decision in *U.S. ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739 (2023), is not to the contrary—it addressed the situation in which a relator offered

some evidence that defendants' "claims were false and [defendants] actually thought that their claims were false," *id.* at 748-49. If anything, *Schutte* suggests that in circumstances such as those presented here, dismissal is required.

To conclude otherwise would mutate the FCA into a vehicle for punishing regulatory violations, subjecting companies to enormous liability solely for making reasonable assessments about the meaning of complex regulatory schemes. That result would be even more troubling here, when the government explicitly instructed drug manufacturers *to make reasonable assumptions* about Medicaid requirements. Yet relator seeks to recover damages *on the government's behalf* for a manufacturer following the government's instructions. That catch-22 is not what the FCA requires, and it cannot be squared with our legal system's dedication to fair notice and due process. This Court should again affirm the dismissal of this FCA complaint and keep the FCA within its statutory bounds.

BACKGROUND

In the intricate world of the Medicaid program, complex legal requirements are the norm. Recognizing this reality, the government has

instructed drug manufacturers facing unclear regulatory obligations to make "reasonable assumptions" about how relevant statutes and regulations operate. 72 Fed. Reg. 39,142, 39,164 (July 17, 2007). Appellant Sheldon, a *qui tam* relator, seeks to penalize Forest Laboratories, LLC and Forest Pharmaceuticals, Inc. (collectively, "Forest") on behalf of the United States for doing exactly what the government instructed.

Relator's FCA claim boils down to whether Forest knowingly committed fraud when it calculated the "best price" for its drugs—one of the "thorniest issues" in Medicaid price calculations. *U.S. ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340, 352 (4th Cir.) (*Sheldon I*), *vacated on reh'g en banc,* 49 F.4th 873 (4th Cir. 2022), *cert. granted, judgment vacated,* 143 S. Ct. 2686 (2023). The Medicaid program reduces the prices that state and federal governments pay for prescription drugs by having participating drug manufacturers pay statutorily-set rebates on drugs dispensed to Medicaid beneficiaries. Under Medicaid's Rebate Statute, 42 U.S.C. §1396r-8, a manufacturer must enter into a Rebate Agreement with the United States Department of Health and Human Services ("HHS") to receive Medicaid reimbursement for drugs covered by the

program. To determine the rebate a manufacturer will owe, the Rebate Statute requires the manufacturer to regularly report its pricing to the Centers for Medicare and Medicaid Services ("CMS"), the agency that oversees the Medicaid program. The amount of the rebate is based off the average manufacturer price ("AMP"), and as relevant here, the "best price" for covered drugs. *Id.* §1396r-8(b)(3)(A).

To calculate "best price," drug manufacturers must run the gauntlet of interpreting a thicket of Medicaid 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 within the United States." *Id.* §1396r-8(c)(1)(C). Although it does not further define "best price," the statute does specify what should *not* be included in calculating best price and then provides "[s]pecial rules" that apply to the calculation. *Id.* The Rebate Agreement also 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.

Importantly, neither the Rebate Statute nor the Rebate Agreement speaks to whether and how every pricing-related mechanism commonly used in the industry should be considered in determining best price.

Recognizing this complexity, CMS encourages manufacturers to make "reasonable assumptions" about Medicaid requirements in the absence of clear guidance or a definitive interpretation. 72 Fed. Reg. at 39,164 (codified at 42 C.F.R. pt. 447); *see also* 81 Fed. Reg. 5,170 (Feb. 1, 2016) (also codified at 42 C.F.R. pt. 447). So does the Rebate Agreement. JA361. Following the government's instruction, manufacturers routinely rely on reasonable assumptions when navigating unclear Medicaid requirements. *See* HHS Office of Inspector General, *Reasonable Assumptions in Manufacturer Reporting of AMPs and Best Prices* (Sept. 2019), https://bit.ly/2Qohfzg ("OIG Report").

Relator's complaint takes fault with Forest's calculation of one aspect of best price: discount aggregation. Specifically, Relator asserts that, to calculate best price, Forest should have aggregated discounts it offered to different customers in the distribution chain, such as a pharmacy and an insurer. By failing to "stack" discounts offered to separate customers, Relator asserts that Forest inflated its best price,

and thereby reduced the rebates owed to the government. The problem for Relator's claim is that the Rebate Statute and Agreement plainly do not require this stacking of discounts—quite the opposite. At best for Relator, they are arguably ambiguous as to stacking, yet Forest reasonably assumed stacking is not required.[3]

Faced with a less-than-pellucid calculation, manufacturers have reasonably assumed that stacking is not required—and have told CMS so for years. Manufacturers unequivocally told CMS their view that the best price definition "has always been interpreted to mean the single lowest price *to a particular customer* unless the customer or transaction is exempt." JA401; *see* JA447 (letter from PhRMA stating "[b]est price is not calculated as a price derived by aggregating price concessions to different customers … [a]nd nothing in the … guidance issued by CMS would support such an interpretation"). Manufacturers explained that their position is based on the Rebate Statute's definition of best price as the lowest price "available" to "any" customer, which they assert does not

[3] *Amici* maintain that Relator's complaint fails based on the best reading of the statute, but *amici* explain why this complaint was deficient even taking the assumption in Relator's favor that the definition of "best price" could be viewed as ambiguous.

encompass the hypothetical price that would be available only by combining discounts offered to different entities. Manufacturers have thus shown that the best reading of the Rebate Statute is that stacking is not required.

Nonetheless, to avoid being whipsawed, manufacturers have repeatedly asked CMS to clarify that stacking of discounts is not required. *See* JA224 ("It is critical that the final rule clarify that only discounts and price concessions to the same entity to which a drug is sold should be included in the computation of best price to that entity."); JA413 ("CMS should clarify that [the language is] not intended to require a manufacturer to aggregate discounts offered to *different* entities.") (emphasis in original); JA427 ("We therefore request that CMS clarify that discounts to a single entity should be cumulated, but discounts to different purchasers should not be cumulated, when determining best price."). CMS is thus well aware of manufacturers' position on discount aggregation and their requests that CMS provide guidance.

Despite manufacturers' requests for clarity, CMS has declined to provide any definitive guidance as to whether stacking is required. Instead, CMS's guidance parrots statutory language, such as "price

available from the manufacturer," without any explanation of how that phrase intersects with stacking. *Compare* 42 C.F.R. §447.505(a), *with* JA377 (Medicaid Drug Rebate Program Release No. 14). In sum, CMS has never contradicted manufacturers' clear position that discounts need not (and should not) be aggregated across multiple customers in calculating best price. Instead, CMS allowed manufacturers to continue operating on their reasonable assumption—which manufacturers maintain is the correct interpretation—that stacking is not required.[4]

Unsurprisingly, the district court dismissed Relator's complaint for failing to allege the FCA's scienter and falsity elements. JA213-256. As the court explained, Forest did not knowingly submit a false claim by making a reasonable assumption about whether the best-price calculation required stacking, an obligation the court found ambiguous. JA253-254. After a panel of this Court affirmed, 24 F.4th 340, the en banc Court also affirmed by an equally divided court, 49 F.4th 873.

[4] In 2023, CMS proposed a rule that—for the first time—would have required stacking, 88 Fed. Reg. 34,238 (May 26, 2023), but it never finalized that rule, JA833. If anything, this abandoned proposal serves only to confirm that CMS understood its regulations did not unambiguously require stacking prior to its proposal. *See also* JA972; Appellee Br. 36-39.

The Supreme Court vacated the judgment and remanded for consideration in light of its recent decision addressing FCA scienter in *Schutte*. *See U.S. ex rel. Sheldon v. Allergan Sales, LLC*, 143 S. Ct. 2686 (2023). On remand, the district court again dismissed Relator's complaint, explaining that the complaint had still failed to plausibly plead scienter and falsity. JA913-976.

Relator's appeal challenges this dismissal. As *amici* explain, nothing about *Schutte* saves Relator's deficient complaint, and Relator's position would expand the FCA beyond its bounds. This Court should again affirm.

ARGUMENT

The FCA does not punish a regulated party for making a reasonable assumption about the meaning of what relator sees as an arguably ambiguous legal requirement when no other allegations suggest the party either subjectively believed its claim was false, or was subjectively aware of a substantial risk that its claim was false. To prevail on an FCA claim on behalf of the United States, a relator must show: (1) "there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the

government to pay out money or to forfeit moneys due." *U.S. ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 700 (4th Cir. 2014). As Forest aptly explains, the district court correctly dismissed Relator's complaint because it failed to plausibly plead the first two elements—falsity and scienter. Appellee Br. 16-51.

Amici focus on three reasons why this Court should again affirm the dismissal of Relator's complaint. First, there was nothing improper about disposing of this complaint in the motion-to-dismiss posture. After *Schutte*, dismissal is required where, as here, a relator fails to plausibly allege any subjective beliefs as to the defendant and instead rests solely on an arguably ambiguous legal requirement to prove scienter. Second, when applying the FCA's elements to a complaint, the context matters, and in this context, *the government required manufacturers to make reasonable assumptions* about the meaning of numerous Medicaid requirements. Third, the district court's approach vindicates the fundamental principles of fair notice and due process, whereas Relator's approach would raise serious constitutional questions. This Court should reject Relator's attempt to distort the FCA to punish regulated parties for good-faith interpretations of the legal requirements at issue.

I. FCA COMPLAINTS THAT DEFICIENTLY ALLEGE SCIENTER AS THIS ONE DOES MAY BE PROPERLY RESOLVED ON MOTIONS TO DISMISS.

A motion to dismiss is a key tool for courts to enforce the "rigorous" FCA requirement of scienter. *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 192 (2016). To sufficiently plead scienter, a relator must plausibly allege one of three mental states: (1) actual knowledge, (2) deliberate ignorance, or (3) reckless disregard. 31 U.S.C. §3729(b)(1)(A). All three mental states "focus primarily on what [a defendant] thought and believed." *Schutte*, 598 U.S. at 751. Actual knowledge "refers to whether a person is aware of information." *Id.* Deliberate ignorance "encompasses defendants who are aware of a substantial risk that their statements are false, but intentionally avoid taking steps to confirm the statement's truth or falsity." *Id.* And reckless disregard "captures defendants who are conscious of a substantial and unjustifiable risk that their claims are false, but submit the claims anyway." *Id.* The Supreme Court recently addressed one aspect of FCA scienter in *Schutte*.

Dismissals of complaints that fail to plausibly plead scienter remain appropriate after *Schutte*. The district court's ruling here

illustrates why dismissals of such complaints are both appropriate and necessary.

A. *Schutte* Does Not Foreclose Dismissals of Complaints that Fail to Plausibly Plead Scienter.

As the Court held in *Schutte*, the mere fact that a defendant's acts comported with an objectively reasonable interpretation of an arguably ambiguous statute does not negate scienter by itself. *See id.* at 749. Instead, evidence of a defendant's subjective beliefs is relevant to the scienter inquiry. *Id.* at 753. So if a defendant subjectively believed his claim violated such a legal requirement, his scienter will not be expunged by the happenstance that his conduct also comported with an objectively reasonable, but incorrect, interpretation of that requirement. That is, a law's "facial ambiguity *alone* is not sufficient to preclude a finding that [defendants] knew their claims were false." *Id.* at 749. The Court did not, however, disturb the established principle that scienter is lacking when a defendant acts consistently with how he "had honestly read the [ambiguous] phrase" in a legal requirement. *Id.*; *see U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 287 (D.C. Cir. 2015) ("Consistent with the need for a knowing violation, the FCA does not reach an innocent, good-faith mistake about the meaning of an applicable rule or regulation.").

That principle did not apply in *Schutte* because the relators proffered evidence that the defendants subjectively believed their interpretation was wrong and regulators had warned them against it. *See* 598 U.S. at 746-47.

Nothing about *Schutte* forecloses a dismissal based on scienter—much less falsity.[5] To be sure, *Schutte* instructed courts not to ignore a relator's *evidence* of a defendant's subjective beliefs, even when the legal requirement at issue is unclear. But it did not upend Federal Rule of Civil Procedure 12(b)(6)'s requirement that a relator's complaint must state a claim to survive dismissal. Nor did it diminish the Court's guidance that a relator must raise *plausible* allegations to support his claim. *E.g.*, *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.").

[5] In this type of FCA claim, asserting fraud based on a failure to comply with a legal requirement, the falsity element requires a "statement or conduct" that "represent[s] an objective falsehood." *U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376-77 (4th Cir. 2008). But "differences in interpretation growing out of a disputed legal question are … not false under the FCA." *Id.* at 377.

Schutte thus stands for the simple proposition that when a relator provides sufficient evidence that a defendant subjectively believed it was submitting a false claim, his FCA claim can survive the statute's scienter requirement, regardless of the objective reasonableness of the defendant's actions. The logical corollary is that when a relator does not provide sufficient evidence of scienter, his FCA claim must fail. At the dismissal stage, this means that a relator must plausibly allege scienter to survive a motion to dismiss.

Indeed, this Court has already concluded that district courts may "decid[e] the issue of scienter at the Rule 12(b)(6) motion-to-dismiss stage." *See U.S. ex rel. Complin v. N.C. Baptist Hosp.*, 818 F. App'x 179, 183 n.5 (4th Cir. 2020) (citing *Omnicare*, 745 F.3d at 703). And after *Schutte*, district courts continue to dismiss FCA complaints that fail to allege scienter. *See U.S. ex rel. Henig v. Amazon.com, Inc.*, No. 19-CV-05673, 2025 WL 27736, at *7 (S.D.N.Y. Jan. 3, 2025) (appeal pending, No. 25-207 (2d Cir.)) (dismissing relator's complaint when he failed to sufficiently allege scienter); *U.S. ex rel. McSherry v. SLSCO, L.P.*, No. 18-CV-5981, 2024 WL 1934443, at *2 (E.D.N.Y. May 2, 2024) (appeal pending, No. 24-1460 (2d Cir.)) (dismissing relator's complaint with

prejudice because "Relators have again failed to allege anything about the City's scienter at the time it submitted its claim to the federal government"). Dismissing a complaint that fails to plausibly allege scienter not only conserves scarce judicial resources, but it also ensures the fairness to defendants that Rule 12(b)(6) preserves. *See Robbins v. Oklahoma*, 519 F.3d 1242, 1248 (10th Cir. 2008) (motions to dismiss serve "to weed out claims that do not … have a reasonable prospect of success"). Relator's position would remove Rule 12(b)(6) dismissals out of 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 position, and instead district courts should continue to be able to dismiss FCA complaints when appropriate based on the allegations.

B. The District Court Properly Dismissed Relator's Complaint.

Because Relator failed to plausibly allege scienter and falsity, the district court properly dismissed this complaint. A comparison with *Schutte* shows why this dismissal was obviously correct. In *Schutte*, the relators survived summary judgment because they mustered enough

evidence that the defendants "believed that their claims were not accurate[,]" even though there was some ambiguity as to calculating the "usual and customary" price for a Medicaid drug. 598 U.S. at 757. In particular, the relators proffered evidence that defendants did not include certain discounts in calculating their usual and customary prices, even though (1) state Medicaid agencies had informed them that the discounts should be counted and (2) defendants had "tried to hide their discounted prices from regulators and contractors." *Id.* at 746-47.

By contrast, Relator raised no plausible allegations that Forest *subjectively* believed the calculation of best price required it to stack discounts to separate customers, or that it *subjectively* believed there was a substantial risk that stacking was required.[6] Instead, Relator's assertion of scienter ultimately rests on the arguably ambiguous legal requirement of calculating best price, which Forest had reasonably assumed did not require stacking. Unlike *Schutte*, Relator raised no

[6] As the district court and Forest have explained, the allegations regarding Forest's audit failed to *plausibly* plead scienter because "[t]he Relator has not pleaded any specific facts that would substantiate the contention that the audit was undertaken with a culpable mental state." JA967; *see* Appellee Br. 49-52. The mere existence of an audit is not a plausible allegation of subjective beliefs.

plausible allegations of anything to warn Forest away from its reasonable interpretation. After all, CMS was aware that manufacturers had interpreted best price not to require stacking but declined to issue further guidance. *See Sheldon I*, 24 F.4th at 354 (Although "manufacturers asked CMS to 'clarify' or 'confirm' that" stacking is not required, "CMS nonetheless failed to clarify and thereby maintained strategic ambiguity."). Forest is therefore 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, the driver asked the officer to interpret the sign, but the officer refused to say anything. There is nothing reckless about the driver's actions in that context, which do not evince actual knowledge or deliberate ignorance either. The same is true here.

Without any plausible allegations regarding Forest's subjective beliefs, Relator could not show that Forest had actual knowledge or deliberate ignorance, both of which turn on what a defendant was "aware of" itself. *Id.* at 751. And the district court correctly concluded that Relator had not established scienter through reckless disregard. Reckless disregard occurs when a person acts "in the face of

an unjustifiably high risk of harm that is either known or so obvious that it should be known." *Farmer v. Brennan*, 511 U.S. 825, 836 (1994). Because Relator has not plausibly alleged that Forest had the requisite subjective intent, reckless disregard may be alleged, at best, by showing that the risk of an erroneous interpretation of the Medicaid statute was "so obvious that it should have been known" to Forest. *Id.*

A district court is of course well-equipped to decide this *objective* question at a motion to dismiss, and the district court here has now twice determined this question in Forest's favor. Without resolving any factual disputes, a court can determine based on the complaint's plausible allegations whether a risk was so obvious that it *should have been known* to the defendant. *See also* 5B Fed. Prac. & Proc. Civ. §1356 (4th ed. June 2024 update) (explaining that a motion to dismiss "tests whether the claim has been adequately stated in the complaint"). In another fraud context (private securities fraud), courts already assess whether a plaintiff has sufficiently pleaded recklessness at the dismissal stage. *E.g.*, *Yates v. Mun. Mortg. & Equity, LLC*, 744 F.3d 874, 884, 894 (4th Cir. 2014) (dismissing securities-fraud complaint because the plaintiff

"fail[ed] to adequately plead [a strong inference of] scienter" of "intentional or severely reckless conduct").

In short, Relator's complaint was a prime candidate for a motion to dismiss. The district court did what courts across the country routinely do under Rule 12(b)(6). It took Relator's plausible factual allegations as true and correctly concluded that the complaint had failed to allege scienter: Relator failed to plausibly allege Forest's subjective beliefs and also failed to plausibly allege that Forest acted objectively recklessly. Relator could not allege objective recklessness as a matter of law because Forest's interpretation of the Medicaid requirement was reasonable (and indeed, correct). *See infra* at 19-26. Dismissal of this deficient complaint was thus warranted. *Schutte* demands nothing more where, as here, a relator fails to plausibly allege any subjective beliefs as to the defendant and instead rests solely on an arguably ambiguous legal requirement to prove scienter, which the defendant had reasonably interpreted.

II. A REASONABLE-ASSUMPTIONS FRAMEWORK APPLIES IN ASSESSING SCIENTER AND FALSITY UNDER THESE MEDICAID REGULATIONS.

In applying the FCA elements to Relator's complaint, context is important, as Relator acknowledges. Appellant Br. 34 (acknowledging

that "context matters" and "[t]he Rebate Statute and Rebate Agreement should be interpreted and applied with this context in mind"). 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 has declined to delineate the meaning of many Medicaid requirements, instead specifically instructing manufacturers to make "reasonable assumptions" in the absence of clear guidance or a definitive interpretation. *E.g.*, 72 Fed. Reg. at 39,164 ("We remind manufacturers that in the absence of specific guidance, they may make reasonable assumptions."); *see also* 81 Fed. Reg. 5,170 (final rule mentioning manufacturers' reasonable assumptions more than 80 times). "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. And in the Rebate Agreement, CMS reiterated that Forest should "make reasonable assumptions in its calculations of … Best Price," so long as there was no "specific guidance"

in the Medicaid statute, regulations, or terms of the Rebate Agreement. JA361.

Thus, in assessing falsity and scienter in cases like this one, by definition the question is not whether a defendant's approach to its regulatory obligations was *correct* (though it was), but whether it was based on assumptions that were *reasonable*.

Indeed, the government's own watchdog—the Office of Inspector General ("OIG")—has recognized that drug manufacturers must routinely make reasonable assumptions about Medicaid requirements, given the "complexities" of the industry and "absence of explicit Federal guidance." OIG Report at 1 ("[T]he use of reasonable assumptions is common practice among responding manufacturers[.]"). According to the OIG Report, "[a]lmost *all* … manufacturers reported making reasonable assumptions that affected the [best prices] used to determine Medicaid rebates." *Id.* at 9.

This framework of reasonable assumptions forms the background against which Relator's complaint must be judged. After all, Relator does not bring the "paradigmatic FCA Action" of *factual* fraud, such as a doctor seeking reimbursement for a medical service he did not actually provide.

See Sheldon I, 24 F.4th at 349. Relator instead pursues a claim that Forest knowingly failed to comply with a legal requirement. *See id.* To assess *that* claim, a court must consider whether Forest made and followed *reasonable* assumptions in the midst of the "complex enterprise" of calculating the best price. *See Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 115 (2011).

In other words, given the reasonable-assumptions framework, when a relator fails to plausibly allege that a defendant subjectively believes it is not complying with regulatory obligations, the defendant's "reasonable interpretation of any ambiguity inherent in the [Medicaid] regulations belies the scienter necessary to establish a claim of fraud under the FCA." *U.S. ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 831-32 (8th Cir. 2013). In a similar vein, it belies falsity because falsity in this context turns on the framework of reasonable assumptions: the defendant's obligation is to be reasonable, not to be right.[7]

[7] After *Schutte*, courts have sensibly continued to consider the reasonableness of a defendant's interpretation of an ambiguous obligation. *See U.S. ex rel. Kraemer v. United Dairies, LLP*, 82 F.4th 595, 606 (8th Cir. 2023), *reh'g denied,* No. 22-3306, 2023 WL 7015733 (8th Cir. Oct. 25, 2023) (concluding that "Defendants' interpretation of the ambiguous insurance policy was objectively reasonable" when assessing FCA scienter).

Considering this context, Relator failed to allege that Forest made an unreasonable assumption about the best-price calculation, thereby negating both scienter and falsity. As Forest explains, the best reading of the statutory definition of "best price" is that it does not require stacking. Appellee Br. 17-39. But even if one assumes, as the district court found, the statute is ambiguous as to whether a manufacturer must aggregate discounts to different customers, there is no plausible allegation that Forest's assumptions were unreasonable. *See* JA957. CMS has provided no definitive guidance as to the answer, despite manufacturers' repeated requests for confirmation—instead proposing and then tabling an interpretation. *E.g.*, JA239; JA413; JA427; 88 Fed. Reg. 34,238; *see Sheldon I*, 24 F.4th at 354. The absence of authoritative guidance is the very reason why CMS instructed manufacturers to make their own reasonable assumptions. Forest did as CMS instructed and reasonably assumed that the best price does not require aggregating discounts. *See Sheldon I*, 24 F.4th 355-56; *see also* Appellee Br. 39-45. That reasonable assumption dooms Relator's assertions of scienter and falsity.

The reasonable-assumptions framework also illustrates why Relator is wrong to assert that the district court had to definitively interpret the Rebate Statute after determining that it was ambiguous. This Court has already explained why no bottom-line conclusion as to an ambiguous legal requirement's meaning is required in this analysis. *See U.S. ex rel. Gugenheim v. Meridian Senior Living, LLC*, 36 F.4th 173, 181 (4th Cir. 2022). In *Gugenheim*, the Court explained that it "need not determine whether Defendants' interpretation of [a policy] [wa]s correct." *Id.* Because the "policy and related guidance from NC Medicaid [were] sufficiently ambiguous," that ambiguity "foreclose[d] the possibility of proving [FCA] scienter based solely on the clarity of the regulation." *Id.* Moreover, because the requirement at issue was "ambiguous and *Defendants' interpretation of the policy and agency guidance [was] reasonable*," the relator could not "prove, based on the policy alone, that Defendants knowingly submitted false claims." *Id.* So too here.

Particularly given the reasonable-assumptions framework, there is no need to determine the platonically correct interpretation of the obligation at issue to decide falsity (let alone scienter); all that is

necessary is to determine whether a defendant made reasonable assumptions about an arguably ambiguous Medicaid requirement. Put another way, Forest could not have knowingly made a false claim if it made a reasonable assumption as to whether calculating the best price required stacking, regardless of whether the statute could possibly be interpreted to require stacking. The district court's statutory analysis was meant, as it should have been, to determine only that "considering the statutory definition [of best price] alone, Forest could not have acquired any of the three mental states required for liability under the FCA." JA957; *accord Gugenheim*, 36 F.4th at 181. Rather than reach out and render an unnecessary statutory interpretation, the district court correctly concluded that Relator could not overcome Forest's reasonable assumptions.

Relator cannot erase the context in which his claim arose, and that includes the established framework that manufacturers must make reasonable assumptions when faced with myriad Medicaid requirements that have not been interpreted by the agency, let alone a court. Judges are well equipped to decide these legal questions, including at the dismissal stage. The "reasonableness of a defendant's asserted

understanding of applicable law" is a question that "the judge, and not the jury, must resolve." *United States v. Prigmore*, 243 F.3d 1, 18 (1st Cir. 2001) (considering claim for conspiracy to defraud, which also requires a false statement).

III. THE DISTRICT COURT'S APPROACH VINDICATES FUNDAMENTAL PRINCIPLES OF FAIR NOTICE AND DUE PROCESS, AVOIDING THE SERIOUS CONSTITUTIONAL QUESTIONS RAISED BY RELATOR'S APPROACH.

The tangle of complicated statutes and byzantine regulations created by federal regulatory schemes is ubiquitous, providing regulated parties with limited notice. The government rarely provides all the answers, and regulated parties are therefore forced to make reasonable assumptions about what the law requires—indeed, they are expressly required to make such assumptions in this context. In this case, the government even refused to provide an answer when the defendant asked for guidance on the very question at hand. *Sheldon I*, 24 F.4th at 354. Relator, however, seeks to put a regulated party on the hook for the FCA's severe penalties and treble damages whenever it makes an honest guess as to what the law requires. The Court need not adopt Relator's mangled understanding of the FCA. Instead, the district court's approach

interprets the FCA faithfully and comports with our legal system's demand of fair notice and due process.

Relator's alternative approach would raise palpable constitutional concerns: "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, Inc.*, 567 U.S. 239, 253 (2012). Under Relator's position, a company could be liable for the FCA's treble damages whenever it is forced to make an honest guess about an unclear legal requirement that a relator later asserts is wrong. But 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. The FCA does not impose those "heads I win, tails you lose" consequences on regulated parties.

"[C]oncerns about fair notice and open-ended liability" are exactly what prompted the Supreme Court to demand the "strict enforcement" of the FCA's "rigorous" scienter requirement. *Escobar*, 579 U.S. at 192. Scienter is the critical dividing line between the fraud the FCA penalizes and innocent or negligent mistakes, which it does not. *See* Restatement (Third) of Torts: Liab. for Econ. Harm §10 (2020). If scienter is watered

down as Relator asks, the FCA will cease to be a fraud statute, and instead transform into "a vehicle for punishing … regulatory violations" and negligence. *Escobar*, 579 U.S. at 194; *see U.S. ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co.*, 612 F.3d 724, 728 (4th Cir. 2010) ("[T]he FCA is a fraud prevention statute.").

Relator's alternative approach would also perversely incentivize the government to "maintain[] strategic ambiguity" in the law. *Sheldon I*, 24 F.4th at 354. The government could refuse a regulated party's request to clarify a legal requirement, only to turn around and subject the party to "potentially ruinous liability" for making a reasonable assumption as to what is required. *Id.* at 356. "Retaining ambiguity in order to expand potential liability for regulated entities cannot pass muster." *Id.*

The facts of this case demonstrate that inherent unfairness. Faced with some uncertainty regarding stacking discounts for the best-price calculation, manufacturers asked the government for clarification. Rather than provide an answer, the government told the manufacturers to make reasonable assumptions, which they did. Relator now seeks to recover damages *on the government's behalf* for a manufacturer's doing

exactly what the government instructed. "To reward the state with treble damages for this treatment of parties in the private sector is something no court should do." *Id.* at 344.

Worse still, Relator unabashedly seeks to punish a regulated party for its efforts to obtain clarity from the government as to its legal obligations. Appellant Br. 51-52 (arguing that manufacturers' comments in the rulemaking process asking for clarification are evidence of scienter). As the district court explained, "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 alternative universe that Relator wants to create cannot be squared with our cornerstones of fair notice and due process.

Broader concerns with *qui tam* litigation are the final straw against Relator's desired expansion of FCA liability. As the Supreme Court has instructed, courts must be vigilant in keeping the FCA within its statutory bounds. *See Escobar*, 579 U.S. at 194 ("The False Claims Act is not an all-purpose antifraud statute, or a vehicle for punishing … regulatory violations."). Yet there has been an explosion in FCA

qui tams. *See* DOJ, Memorandum from Michael D. Granston to Attorneys, Commercial Litigation Branch, Fraud Section (Jan. 10, 2018) ("Granston Memo"), https://bit.ly/3oHszDq (highlighting "record increases" in *qui tams*). In 2024 alone, relators initiated an astounding 979 *qui tam* actions—the "highest number of qui tam actions filed in history." *See* DOJ, *False Claims Act Settlements and Judgments Exceed $2.9B in Fiscal Year 2024* (Jan. 15, 2025), https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-29b-fiscal-year-2024 (capitalization altered). The government openly acknowledges the problem of "meritless," "parasitic," and "opportunistic *qui tam actions*." Granston Memo at 3-4.

In light of this explosion in *qui tams*, subjecting regulated entities to FCA liability for their reasonable attempts to comply with uncertain legal requirements would increase the already considerable financial and reputational costs of defending these suits. These costs already force many companies to settle even meritless cases. Relator would not only expand that liability, but would also require courts to let meritless cases proceed past the pleading stage. *Cf. AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 350 (2011) (recognizing that procedural vehicles that

pressure parties to settle "questionable claims" should be avoided). This Court should avoid such a far-reaching result.

The correct and commonsense approach is exactly what the district court did here—an FCA complaint must be dismissed when a defendant made reasonable assumptions about a complex legal requirement and the relator fails to plausibly allege any subjective belief of wrongdoing. The FCA exists to remedy fraudulent claims, not to permit *qui tam* relators to collect damages purely over reasonable interpretive disputes.

CONCLUSION

The judgment should be affirmed.

Dated: February 7, 2025

Respectfully submitted,

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This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) and Fourth Circuit Rule 32(b) because it contains 6,405 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.

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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 February 7, 2025, on all registered counsel of record, and has been transmitted to the Clerk of the Court.

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