No. 25-1126

IN THE

Supreme Court of the United States

ELI LILLY AND COMPANY,

Petitioner,

v.

UNITED STATES, ET AL., EX REL.
RONALD J. STRECK,

Respondent.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Seventh Circuit

BRIEF IN OPPOSITION

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BRIEF IN OPPOSITION

For over a decade, petitioner Eli Lilly and Company knowingly underpaid Medicaid drug rebates, depriving the federal and state governments of money that was intended to pay for the care of indigent beneficiaries. Lilly accomplished its scheme by misreporting the prices at which it sold drugs—which were the key input in determining the amount of rebates Lilly owed to Medicaid. Specifically, Lilly reported the amounts it initially charged to customers without including the subsequent charges it imposed on the same customers, thus avoiding its obligation to pay Medicaid rebates on that additional profit. In this way, Lilly unlawfully excluded over $600 million in revenues from its reported prices, and knowingly shorted the government over $61 million in violation of the federal and state False Claims Acts.

After an adverse jury verdict and a unanimous loss at the Seventh Circuit, Lilly presents two questions that are uniquely poor candidates for this Court's review.

First, Lilly seeks to invalidate the False Claims Act's 160-year-old *qui tam* mechanism based on a constitutional challenge it repeatedly failed to litigate below. For years, Lilly remained silent on this issue before the district court and the Seventh Circuit panel, finally raising it only in a petition for rehearing *en banc*. In denying that petition, the Seventh Circuit concluded Lilly "forfeited if not waived its constitutional argument." Pet.App.65. As a result of Lilly's failure to preserve this argument, it has not been briefed or decided by any court in this case. This Court is not a forum for rescuing sophisticated litigants from

their own procedural blunders, particularly absent a circuit split on the underlying issues, and given the existence of other substantial vehicle problems in this case.

Second, Lilly asks this Court to decide whether Lilly's interpretation of the price reporting requirements could "be deemed so 'objectively unreasonable' as to constitute 'highly probative' evidence of scienter under the False Claims Act." Pet. i. This asserted error does not implicate any important legal question, and instead is a garden-variety challenge to the sufficiency of the evidence at trial. Stripped of legal jargon, Lilly argues that the Seventh Circuit erred in how it weighed one among many pieces of evidence when it sustained the jury's scienter verdict, and asks this Court to reweigh the evidence. Even if Lilly were right on the merits, this fact-bound, backward-looking question is simply not important enough to warrant this Court's review.

Lilly's plea for error correction also fails because there was no error. The jury's verdict was supported by myriad evidence of scienter, all of which the Seventh Circuit was required to credit. As to the specific evidence Lilly seeks to undermine, Lilly presented its arguments to the jury, which rejected them—and was correct to do so. Indeed, Lilly's interpretation of the relevant legal requirements is objectively unreasonable. The key requirement provided that Lilly's reported prices "must be adjusted … if cumulative discounts or other arrangements ***subsequently adjust the prices actually realized***." CA7.App.436-437 (emphasis added). Notwithstanding this clear language, Lilly never adjusted its reported prices to include the

additional charges it imposed on wholesalers after the initial sale.

Despite Lilly's claim that its interpretation was "objectively reasonable," its petition remarkably fails to *even mention* the Price Actually Realized Requirement. This follows on the heels of Lilly's inability in the district court and before the Seventh Circuit to offer any sensible interpretation of the requirement that would justify its conduct. Alongside a trove of other inculpatory evidence, the jury was plainly permitted to conclude that the interpretation Lilly offered was circumstantial evidence of scienter. There is no reason for this Court to reweigh the evidence and thereby second-guess the jury's fact-bound conclusion.

Because neither question warrants this Court's intervention, the petition should be denied.

STATEMENT OF THE CASE

I. Legal and Regulatory Background

1. In response to skyrocketing Medicaid prescription drug expenditures, Congress established the Medicaid Drug Rebate Program ("MDRP") in 1990. *See* 104 Stat 1388. This "cost-saving measure" has "two basic parts": (1) to qualify for Medicaid reimbursement of their products, "drug companies must enter into agreements … to provide rebates on their Medicaid sales of outpatient prescription drugs;" and (2) in exchange, drug manufacturers receive nearly guaranteed Medicaid coverage for their drugs. *Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 649-652 (2003). In short, "if a drug manufacturer wanted Medicaid to cover a given drug, the manufacturer had to subsidize some of the cost." Pet.App.4.

Medicaid drug rebates are calculated based on confidential pricing information submitted by drug manufacturers to the Centers for Medicare & Medicaid Services ("CMS") each quarter. Manufacturers must report the "average manufacturer price," or "AMP" for each of their drugs, and AMP is "the central component for determining the amount of the rebate." CA7.Supp.A.436. "[A]n increase or decrease in a drug's AMP will have a corresponding effect on its rebate amount—the higher the AMP, the more the manufacturer will owe." Pet.App.4. Accordingly, manufacturers have a financial incentive to report a lower AMP.

2. The foundational document governing the MDRP is the Medicare Rebate Agreement, which "more clearly define[s] the structure of the calculations and other key requirements of the Rebate Program." CA7.Supp.A.353. To participate in the MDRP, manufacturers simply sign the Rebate Agreement and abide by its requirements. 42 U.S.C. § 1396r-8(a).

As relevant here, the Rebate Agreement provided Lilly with detailed requirements for calculating AMP, including that AMPs "must be adjusted by the manufacturer if cumulative discounts or other arrangements ***subsequently adjust the prices actually realized***." CA7.App.436-437 (emphasis added). This "Price Actually Realized Requirement" reflects "the fundamental principle that AMP" must "be determined based on the amounts manufacturers ***ultimately receive*** for the sale of their drugs." CA7.Supp.App.16 (emphasis added). It expressly prohibits manufacturers from artificially reducing AMP and AMP-based rebates owed to Medicaid by dissecting payments into multiple, ostensibly discrete, transactions and only including the *initial* payment in AMP. Lilly agreed to

abide by the Price Actually Realized Requirement when it signed the Rebate Agreement in 1991, and the requirement remained binding upon Lilly at all times relevant to this litigation. CA7.Supp.App.279.

Contrary to Lilly's characterization of a "byzantine and notoriously unclear regulatory regime," Pet. 16, the Price Actually Realized Requirement quite simply provides that if post-sale activity causes the manufacturer to receive more money for the drug, that money must be included in AMP. Beyond the clarity of the requirement itself, CMS has repeatedly "reinforced the fundamental principle" underlying the Price Actually Realized Requirement that AMP must "be determined based on the amounts manufacturers ultimately receive for the sale of their drugs." CA7.Supp.App.16. For instance, CMS repeatedly provided guidance reminding manufacturers of their obligation to "revise AMPs … to reflect the impact of cumulative discounts or other arrangements on the prices actually realized in any quarter." CA7.Supp.App.325. Likewise, CMS explained that it "consider[s] any price adjustment which ultimately affects the price actually realized by the manufacturer" to constitute "other arrangements" that must be "included in the calculations of AMP." CA7.Supp.App.329.

3. Based on manufacturers' self-reported AMPs, CMS calculates a "unit rebate amount" on each individual drug. CA7.Supp.A.437. CMS provides the unit rebate amounts to the 50 state Medicaid programs, which then invoice each manufacturer based on the utilization of each of the manufacturer's drugs by Medicaid beneficiaries in the respective states during that quarter. CA7.Supp.A.438. Because the federal

government partially funds Medicaid, the rebates are shared between the federal government and state governments. *Id.*

When manufacturers submit their AMPs to CMS, they "do not also submit narrative descriptions and quantifications of their various types of sales, agreements, and other transactions, or detailed descriptions of how they calculated their AMPs." CA7.Supp.A437. Instead, manufacturers simply submit the raw AMP numbers. *Id.* Consequently, CMS is wholly reliant on manufacturers to comply with the legal requirements governing their AMP calculations. To that end, CMS requires manufacturers to certify that the AMPs they submit are accurate and comply with the Rebate Agreement and other legal requirements. CA7.Supp.A.279-280, 438.

II. Factual Background

Lilly sells its products to drug wholesalers, who distribute the drugs to pharmacies and other customers. Pet.App.2. Lilly sets the prices charged to wholesalers and unilaterally implements price increases at its discretion. CA7.Supp.A.81-82. When it does so, the wholesalers pass the price increases through to downstream customers. Pet. App.27. Before 2005, "the wholesalers would reap the profit of the price increase." Pet.App.6.

In 2005, Lilly entered contracts with its wholesalers that created a new revenue stream for Lilly. Pet.App.7. Under the 2005 contracts (and throughout the relevant time period of 2005 to 2017), Lilly "charged the wholesalers at two stages." Pet.App.2. "First, the wholesalers paid the initial drug price Lilly set. Second, if Lilly raised the price after the

wholesalers took possession of the drugs, but before the wholesalers resold to a pharmacy, Lilly required the wholesalers to credit the subsequent price increase." *Id.* This second type of revenue was commonly known as "Price Increase Value" or "PIV." Pet.App.7. Lilly alternatively referred to this money as "price recapture," "retroactive price increase," and "clawbacks." CA7.Supp.A.195-196.

As Lilly's own monikers indicate, through PIV, Lilly "gained the value of the price increases." Pet.App.7. As a simplified example, if "Lilly sold a drug for $10 on Monday, and raised the price to $11 before the wholesaler sold it on Wednesday, the wholesaler needed to remit Lilly an additional dollar of value" in PIV. Pet.App.2. More concretely, in one instance, Lilly increased the price of a product from $2,277 to $2,502, and a wholesaler had 3,477 units of the drug in its inventory at the time of the price increase. CA7.Supp.A.423. Accordingly, the wholesaler owed Lilly $782,325 in PIV for that one product. *Id.*

Lilly recognized PIV for what it was: additional revenue. As an internal memo described: "At the time of a price increase, Lilly earns additional revenue as it receives a price recapture from the wholesalers." Supp.A402. Likewise, Lilly treated PIV as revenue for accounting and tax purposes. Pet.App.40. Given the magnitude of its price increases, Lilly "amass[ed] over $600 million in revenue" from PIV during the relevant time period. Pet.App.3.

Although Lilly internally recognized PIV as revenue, and although PIV plainly adjusted the price Lilly actually "realized," Lilly entirely excluded the $600 million in PIV from its AMP calculations. Pet.App.10. Because lower AMPs directly result in reduced rebate

liability, this led Lilly to pay $61.2 million less in Medicaid rebates. Pet.App.14. In short, "Lilly increased prices, took more profit, but did not increase the AMP," allowing Lilly to "pocket[] part of the rebate owed to the government." Pet.App.4.

III. Procedural Background

1. Alleging that Lilly underpaid its Medicaid rebates by excluding PIV from AMP, Relator (respondent here) filed claims under the federal FCA and corresponding state statutes on behalf of the United States and twenty-eight States. Pet.App.15. Lilly moved to dismiss, Relator opposed, and the United States filed a statement of interest in favor of Relator. CA7.Supp.App.6. The district court denied Lilly's motion to dismiss. D.Ct.Dkt.122.

After the conclusion of discovery, Relator moved for partial summary judgment. The district court granted summary judgment as to the falsity element of FCA liability. Applying the Price Actually Realized Requirement, the court held that Lilly's exclusion of Price Increase Value from AMP "is foreclosed by the AMP's definition, which explicitly states that the AMP 'must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.'" Pet.App.98. The court explained that "Lilly has not proffered, nor has the Court been able to imagine, a reasonable alternative interpretation to both the mechanics and the definition of 'price increase value' to be anything other than an adjustment of price and thus within the definition" of AMP. Pet.App.96.

2. The case proceeded to trial as to the remaining elements of FCA liability, including, as relevant here,

scienter. Lilly argued to the jury that it had operated in good faith based on a reasonable legal interpretation. Pet.App.40. Yet, Lilly could not offer any plausible interpretation of the Price Actually Realized Requirement that would justify its exclusion of PIV from AMP. Pet.App.38-39. Apart from Lilly's inability to offer a sensible interpretation of the Price Actually Realized Requirement, "[t]he jurors also heard ample evidence to allow them to infer that Lilly either was aware of, or disregarded, an unjustifiable risk of skirting the law and chose to obfuscate rather than conduct a reasonable inquiry." Pet.App.33. This evidence included:

- Lilly had an obvious financial motive in excluding PIV from AMP, since doing so reduced its rebate liability by scores of millions of dollars. Pet.App.40.
- Lilly was "explicitly required [to] memorialize how it calculated AMP" but "could not produce one shred of paper through 2011 that even discussed the clawback feature, let alone explain why it was reasonable to exclude it from AMP." Pet.App.41-42. Thus, a highly regulated and global pharmaceutical company "lacked any actual documentation justifying why it excluded the price increase values from AMP calculations between 2005 and 2011." Pet.App.11.
- Lilly claimed that it wholly delegated the decision whether to exclude PIV from AMP to "a middle-management employee" and gave her "unchecked and unreviewed discretion over a decision affecting substantial revenue." Pet.App.41. Even that employee "was unable to recall any specifics about her thought process." Pet.App.11. Nor,

although PIV was an entirely new revenue stream to Lilly in 2005, could she "recall conferring with any of her supervisors about how she decided to exclude clawbacks from AMP reporting." Pet.App.39.

- The employee's "supervisors, including one who certified the AMP submissions as true and accurate to the government, consistently disavowed any knowledge of how Lilly made the decision to exclude clawback increases." Pet.App.40. Moreover, "one of the executives who certified AMPs and supervised [the employee] in her government pricing work, did not recall ever reading the MDRP agreement, or discussing why Lilly first decided to exclude price increase values from AMP." Pet.App.11.
- In 2005—around the same time as it first began receiving PIV revenue—Lilly wrote a letter to a government agency generally describing its AMP calculation. However, the letter failed to mention the critical fact, namely, that Lilly was excluding clawback revenue from AMP, even though that revenue was directly tied to the amount of money Lilly actually realized from its sales, which is the entire purpose of the AMP requirement. Thus, the letter could be viewed by the jury as evidence of "misdirection." Pet.App.42.
- In 2009—in the middle of the time period Lilly claimed it was confused and needed guidance—Lilly retained an expert government pricing firm to, *inter alia*, review and audit Lilly's AMP reporting calculations. No one at Lilly—including Lilly's head of government pricing, who was interviewed multiple times in connection with the

audit—shared Lilly's exclusion of PIV from its AMP calculations. CA7.Supp.A.236-237, 271. The jury was entitled to infer that if Lilly was genuinely confused regarding whether PIV should be included in AMP, Lilly would have asked its retained experts for their views.

- In 2011, Lilly mailed a letter to CMS that, for the first time, described its exclusion of PIV from AMP. But CMS had specifically instructed manufacturers not to mail such letters, and instead to take advantage of the various other means of communicating with CMS. Indeed, "multiple Lilly employees testified that they were on first-name bases with CMS employees, had their telephone numbers, and could arrange meetings to communicate with them when needed." Pet.App.43-44. Yet, Lilly never did so, instead choosing to send a letter that it "had every reason to think would go unreviewed." Pet.App.12. Thus, Lilly "curiously chose to 'inform' the government of its methodology through a medium CMS flatly rejected, rather than utilize the email addresses or phone numbers it regularly used." Pet.App.44.
- In response to an audit of its AMP practices in 2013, Lilly described its methodology using only "an equivocal and partial explanation in a footnote" that a "reasonable factfinder could find … highly deceptive" because it "simply restated the law" and stated that "Lilly was following the law" without actually explaining what Lilly was doing about clawbacks. Pet.App.44. Indeed, "Lilly's stark turnabout in content and tone when it knew government officials were reading, versus when it knew they were not, is revelatory evidence" of

scienter. Pet.App.45. "After comparing the opaque and misleading explanation Lilly knew the government would read to the clear and thorough one it knew the government would never open, the jury was free to find Lilly acted with a culpable state of mind." Pet.App.36-37.

- Lilly admitted that under the Price Actually Realized Requirement, AMP was cumulative and thus had to take into account transactions after the initial sale that affected the price of a drug. But the only attempt Lilly made to square this admission with its exclusion of PIV from AMP was to suggest that AMP could only *decrease* after the initial sale, such that PIV – which *increased* AMP – did not have to be included. That interpretation lies "in irreconcilable tension with the text" of the Price Actually Realized Requirement, which is directionally neutral. Pet.App.22. It also "leads … to a nonsensical destination inconsistent with the statute's clear purpose." *Id.* Since decreased AMPs resulted in reduced rebate liability and vice versa, Lilly's atextual interpretation would allow it to both include post-sale transactions that reduced rebate liability and exclude post-sale transactions that increased rebate liability.

Based on this evidence, the jury found as a matter of fact that Lilly knowingly underpaid its Medicaid rebates by $61.2 million. The district court subsequently denied Lilly's post-verdict motion for judgment as a matter of law on scienter. Pet.App.16.

3. On appeal, the United States filed an amicus brief in support of Relator and participated in oral argument. CA7.Dkt.58. A unanimous panel of the

Seventh Circuit affirmed. As relevant here, the court concluded that a sufficient evidentiary basis supported the jury's scienter determination such that the district court properly denied Lilly's post-verdict motion. Pet.App.36-46.

Lilly sought rehearing *en banc*, primarily focusing on a constitutional challenge to the FCA's *qui tam* device that had not been litigated in the district court or before the panel. CA7.Dkt.119. The Seventh Circuit denied rehearing, concluding that Lilly "forfeited if not waived its constitutional argument." Pet.App.65.

4. Lilly's petition for a writ of certiorari followed.

5. One factual point bears emphasis. A core theme of Lilly's petition is that this case is the work of a lone bounty hunter pressing his own interpretation of the law without any support from the United States. Lilly cannot cite anything to support this skewed narrative because it is false. As the United States recently explained, "a qui tam action cannot proceed at all … until the government has had an opportunity to determine whether to 'intervene and proceed with the action,' intervene and move to dismiss it, or allow the relator 'to conduct the action' subject to ongoing government oversight. 31 U.S.C. § 3730(b)(2)-(4). This review ensures that qui tam actions only proceed when they are consistent with the government's priorities for enforcement of federal law." U.S. Br., *United States ex rel. Zafirov v. Fla. Med. Assocs., LLC*, No. 24-13581, Doc. 39, at 28 (11th Cir. 2025). The facts of this case confirm the government's characterization. In the district court, the government filed a statement of interest responding to Lilly's motion to dismiss, specifically arguing that "the government has neither approved of nor acquiesced in defendants' MDRP price

reporting practices," D.Ct.Dkt.97.15 (heading capitalization altered). In the Seventh Circuit, the United States filed an amicus brief supporting Relator, and then participated in oral argument. Throughout, the government cited multiple statements from CMS likewise showing that Lilly's conduct violated the law in the view of the United States.

* * *

Before moving on to the reasons to deny the writ, it is worth pausing to note just how different Lilly's description of the facts is from the foregoing summary. Indeed, one obvious tell that Lilly is asking this Court to wade into the facts of the case (at least for its second question) is that Lilly's statement of the factual and legal background almost never cites the facts as the Seventh Circuit described them. Instead, Lilly asserts its own version of the facts, which forms the essential premise of Lilly's legal argument. *See* Pet.5-11 (citing the petition appendix once). Similarly, although Lilly strains to characterize its conduct as "reasonable," the petition *does not even mention* the Price Actually Realized Requirement, which is the critical legal requirement Lilly violated. This alone is a red flag that what Lilly seeks is not review of a pure question of law, but instead a reweighing of facts in the light most favorable to Lilly, which is the opposite of the appellate standard for review of a jury verdict.

REASONS TO DENY THE WRIT

I. The First Question Presented Does Not Warrant Certiorari

1. The Seventh Circuit correctly concluded that Lilly "forfeited or waived its constitutional argument." Pet.App.65. This Court "has often said that we are a

Court of review, not of first view." *Rivers v. Guerrero*, 605 U.S. 443, 458 (2025) (quotations omitted). Indeed, "[n]o procedural principle is more familiar to this Court than that a constitutional right, or a right of any other sort, may be forfeited in criminal as well as civil cases by the failure to make timely assertion of the right before a tribunal having jurisdiction to determine it." *United States v. Olano*, 507 U.S. 725, 731 (1993) (quotations omitted).

Lilly twice waived or forfeited its constitutional challenge. First, despite multiple opportunities to do so across five years of litigation—including motions on the pleadings, summary judgment motions, and motions for judgment as a matter of law—Lilly never advanced a constitutional challenge before the district court. In the Seventh Circuit, Lilly's opening brief included a one-sentence footnote asserting that "[t]he judgment should also be vacated to the extent the False Claims Act's *qui tam* structure is unconstitutional." CA7.Dkt.37.66 n.11. Lilly did not develop any argument or offer any justification for its failure to litigate the issue in the district court. Consistent with customary waiver principles, *Singleton v. Wulff*, 428 U.S. 106, 120 (1976) ("It is the general rule, of course, that a federal appellate court does not consider an issue not passed upon below."), and the party presentation principle this Court has emphasized, *United States v. Sineneng-Smith*, 590 U.S. 371, 377 (2020), the Seventh Circuit panel did not address Lilly's conclusory footnote. *See, e.g.*, *Parker v. Franklin Cnty. Cmty. Sch. Corp.*, 667 F.3d 910, 924 (7th Cir. 2012) (arguments presented only in an underdeveloped footnote are waived).

After its loss before the panel, Lilly substantively raised a constitutional challenge for the first time in its rehearing petition. But Lilly's attempt to radically reshape this decade-old litigation came too late. Parties cannot present issues in a rehearing petition that were not presented to the panel. *See* 16AA Charles Alan Wright et al., Federal Practice and Procedure § 3986.1 (5th ed.).

Burying the lede, Lilly waits until the final paragraph of its petition to confront this threshold defect. Pet.36. Lilly does not dispute that it failed to litigate its constitutional challenge in the district court or before the Seventh Circuit panel. Instead, it offers two justifications. First, Lilly argues that "this Court has often 'exercised its discretion' to consider non-jurisdictional claims implicating the separation of powers." Pet.36 (quoting *Freytag v. Comm'r*, 501 U.S. 868, 878 (1991)). If by "often," Lilly means "rarely," that is correct. Indeed, *Freytag* itself described such review as "rare," and appropriately limited to certain objections relating "to judicial officers"—which this case does not involve. 501 U.S. at 878-79. As Justice Scalia's concurrence explained, "structural constitutional claims have no special entitlement to review," and when they are forfeited, they should be reviewed only "in truly exceptional circumstances." *Id.* at 893-94 (Scalia, J., concurring in part and concurring in the judgment). Lilly presents no such exceptional circumstance here. Moreover, in *Freytag*, the petitioner's constitutional challenge to the authority of the Tax Court judge was pressed and passed upon in the court of appeals. *See id.* at 872 (majority op.). Here, by contrast, Lilly waived its argument twice.

Second, Lilly asserts that its "argument [wa]s foreclosed by circuit precedent." Pet.36. This attempted justification falters at the gate since there is no "futility exception" to preservation even when a "uniform wall of precedent" forecloses an argument. *Greer v. United States*, 593 U.S. 503, 511, 514 (2021). What is more, there was no circuit precedent that foreclosed Lilly's constitutional challenge. Although Lilly conspicuously fails to cite the supposedly preclusive precedent in its petition, Lilly identified the precedent as *United States ex rel. Hall v. Tribal Development Corp.*, 49 F.3d 1208 (7th Cir. 1995) when seeking *en banc* review. CA7.Dkt.119.7. Lilly's reluctance to cite *Hall* to this Court is understandable. First, *Hall* concerned the Indian Traders Licensing Act, not the FCA. *Id.* at 1210. Further, *Hall* addressed a question of Article III standing, not the very different Article II arguments Lilly raises in its petition. Indeed, the Seventh Circuit in *Hall* expressly said that it was not addressing Article II. *Id.* at 1216 ("That question we leave for another day."). Accordingly, Lilly's assertion that circuit precedent somehow excuses it from advancing its constitutional argument fails. Indeed, the only way *Hall* is relevant here supports Relator. Specifically, the Seventh Circuit determined that because the Article II challenge before it was "non-jurisdictional" and had not been "raised by either party," below, it was not appropriate to decide. *Id.* at 1216. So too here.[1]

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[1] Tellingly, district courts in the Seventh Circuit considering constitutional challenges do not cite any controlling Seventh Circuit case on point. *See United States ex rel. Heath v. Wisconsin Bell, Inc.,* 808 F.Supp.3d 917 (E.D. Wis. Oct. 29, 2025); *United States ex rel.*

Preservation requirements "prevent[] a litigant from sandbagging the court—remaining silent about his objection and belatedly raising the error only if the case does not conclude in his favor." *Puckett v. United States*, 556 U.S. 129, 134 (2009) (quotations omitted). The circumstances here vividly demonstrate this principle. Lilly is "one of the largest drug companies in the world" and was represented by sophisticated counsel throughout this litigation. Pet.App.1. Yet, despite now claiming that the FCA's *qui tam* mechanism is so obviously unconstitutional that it "offends two bedrock principles of our constitutional order," Pet.1, Lilly waited until it had lost before a jury, the district court, and the Seventh Circuit panel to press its constitutional arguments. Even now, Lilly can offer no explanation for why it failed to litigate the issue in the lower courts.

Lilly's waiver also disserves this Court's ability to fully and fairly evaluate the arguments for and against *qui tam* actions—as neither the parties nor the lower courts had the opportunity to explore the issue. This Court generally refuses to take up important questions "without the benefit of thorough lower court opinions to guide [its] analysis." *Zivotofsky ex rel. Zivotofsky v. Clinton*, 566 U.S. 189, 201 (2012). There is no reason to resolve novel constitutional questions without further development (and disagreement) in the lower courts. *Cf. Maslenjak v. United States*, 582 U.S. 335, 354 (2017) (Gorusch, J., concurring in part and concurring in judgment) ("[T]he experience of our

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McCullough v. Anthem Ins. Cos., 2025 WL 2782576 (S.D. Ind. Sept. 30, 2025); *Bantsolas ex rel. United States v. Superior Air & Ground Ambulance Transp., Inc.,* 2004 WL 609793, at *5 (N.D. Ill. Mar. 22, 2004).

thoughtful colleagues on the district and circuit benches … could yield insights (or reveal pitfalls) we cannot muster guided only by our own lights.").

2. Beyond Lilly's repeated waivers, other considerations weigh against review in this case. There is no circuit split, as every court of appeals to consider the issue has upheld the FCA's *qui tam* mechanism. *Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749, 753-758 (5th Cir. 2001) (en banc); *United States ex rel. Stone v. Rockwell Int'l Corp.*, 282 F.3d 787, 804-807 (10th Cir. 2002); *United States ex rel. Taxpayers Against Fraud v. General Elec. Co.*, 41 F.3d 1032, 1040-1042 (6th Cir. 1994); *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 749-759 (9th Cir. 1993). And the majority of circuits have not yet had a chance to weigh in.

The lone outlier is a single district judge. *United States ex rel. Zafirov v. Florida Med. Assocs., LLC*, 751 F. Supp. 3d 1293 (M.D. Fla. 2024); *see United States ex rel. Gose v. Native Am. Servs. Corp.*, 2025 WL 1531137 (M.D. Fla. May 29, 2025) (same judge). The *Zafirov* decision is currently on appeal, and every court to address *Zafirov* has rejected it as unpersuasive.[2]

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[2] *See United States v. JP Pharma, LLC*, 2025 WL 3640892, at *22 (W.D. Va. Dec. 16, 2025) ("*Zafirov* stands alone."); *United States ex rel. Phillips v. Pediatric Servs. of Am., Inc.*, 123 F. Supp. 2d 990, 994 (W.D.N.C. 2000); *United States ex rel. Wallace v. Exactech*, 703 F. Supp. 3d 1356 (N.D. Ala. 2023); *United States ex rel. Butler v. Shikara*, 748 F.Supp.3d 1277, 1295-97 (S.D. Fla. 2024); *United States ex rel. Heath v. Wisconsin Bell, Inc.*, 808 F.Supp.3d 917, 934-35 (E.D. Wis. 2025); *United States ex rel. Gonite v. UnitedHealthcare of Georgia*, 785 F.Supp.3d 1325, 1335-36 (M.D. Ga. 2025); *United States ex rel. Stenson v. Radiology Ltd., LLC*, 2025 WL 1785266 (D. Ariz. June 27, 2025); *Proctor v. Wound Care*

3. If the Court is inclined to consider the constitutionality of the FCA's *qui tam* device, it will have many better vehicle options. The Eleventh Circuit and Third Circuit recently held oral arguments in cases challenging the constitutionality of *qui tam* claims. *See United States ex rel. Zafirov v. Fla. Med. Assocs., LLC*, Nos. 24-13581 & 24-13583 (11th Cir., argued Dec. 12, 2025); *United States ex rel. Penelow v. Janssen Prods., L.P.*, No. 25-1818 (3rd Cir., argued Mar. 18, 2026). The same issues were also recently briefed in a Fifth Circuit case. *United States ex rel. Taylor v. Healthcare Associates of Texas LLC*, No. 25-10842 (5th Cir.). In those cases, the defendants presented their constitutional challenges to the district courts and on appeal. Thus, not only will the forthcoming decisions provide the Court with additional viewpoints,

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Mgmt., LLC, 2025 WL 2444133, at **2-3 (E.D. La. Aug. 25, 2025); *United States ex rel. McCullough v. Anthem Ins. Cos., Inc.*, 2025 WL 2782576, at **15-16 (S.D. Ind. Sept. 30, 2025); *Mayer v. ADCS Clinics, LLC,* 2026 WL 369912 (E.D. Pa. Feb. 10, 2026); *United States ex rel. Shepherd v. Fluor Corp.*, 2026 WL 97279 (D.S.C. Jan. 14, 2026); *United States ex rel. Souza v. Embrace Home Loans, Inc.,* 808 F. Supp. 3d 314 (D.R.I. 2025); *Kenley Emergency Med. v. Schumacher Grp. of La. Inc.*, 2025 WL 1359065, at *5 (N.D. Cal. May 9, 2025); *United States ex rel. Adams v. Chattanooga Hamilton Cty. Hosp. Auth.*, 2024 WL 4784372, at *3 (E.D. Tenn. Nov. 7, 2024); *United States ex rel. Sullivan v. Murphy Med. Ctr., Inc.*, 2026 WL 657192, at *15 (E.D. Tenn. Mar. 9, 2026); *United States ex rel. Bryant v. Comfort Care Hospice, LLC*, 2026 WL 473999, at *6 (M.D. Ala. Feb. 19, 2026); *United States ex rel. Relator LLC v. Pape*, 2025 WL 3707557, at *4 (N.D. Cal. Dec. 22, 2025); *Josephs v. Amentum Servs. Inc.*, 2025 WL 3223772, at *12-14 (D. Md. Nov. 19, 2025); *United States ex rel. Publix Litig. P'ship, LLP v. Publix Super Mkts., Inc.,* 2025 WL 2468832, at *3 (M.D. Fla. Aug. 27, 2025); *Deligdish v. North Brevard Cty. Hosp. Dist.,* 2025 WL 2217710, at *12 (M.D. Fla. Aug. 5, 2025); *United States ex rel. Permenter v. eClinicalWorks, LLC*, 2025 WL 1762264, at *11 (M.D. Ga. June 25, 2025).

but those cases do not come with the waiver concerns present here.

Waiting for a better vehicle is plainly the prudent course. The FCA's *qui tam* provision sits at the heart of "the Government's primary litigative tool for combatting fraud." S. Rep. No. 99-345, at 2 (1986). Lilly would have this Court upend the status quo that has persisted for over 160 years. Precisely because the question is so significant, and the consequences of getting it wrong so severe, this Court should await a case in which the matter has been fully briefed by the parties, ensuring that all arguments have been preserved and fully considered by the lower courts. This will ensure that this Court has the benefit of the best reasoning if and when it takes up the question. Put slightly differently, the importance of the question presented is a reason to *deny review in this case*.

4. A final problem makes this litigation a particularly poor vehicle to address the constitutionality of the FCA's *qui tam* provision. Because Medicaid is jointly funded by the federal and state governments, Lilly's misconduct violated the federal FCA and the corresponding statutes of twenty-eight States. CA7.Dkt.37. Thus, Relator's claims are brought under both the federal FCA and dozens of state statutes. As Lilly acknowledges, the state law claims "rest on substantially the same legal theories and factual allegations as Relator's federal claims." CA7.Dkt.37.172-173. Indeed, given the similarity between the federal and state claims, the jury was not even asked to apportion damages between the federal and state governments. D.Ct.Dkt.486. Nor does the district court's judgment do so. CA7.Dkt.37.174.

Lilly does not challenge the constitutionality of the *qui tam* provisions in the state statutes under the federal Constitution, nor would there be any basis to do so. If this Court were to grant certiorari and agree with Lilly on the merits as to the federal claims, that would leave the lower courts and the parties to disentangle the interwoven state law claims. Had Lilly timely asserted its constitutional challenge before the district court, Relator would have sought to have the jury apportion damages between the federal and state governments.

In sum, the first question presented was repeatedly waived below and does not implicate a circuit split—and this case is the worst available vehicle to decide it.

II. The Second Question Presented Does Not Warrant Certiorari

The second question presented is whether "a legal interpretation can be deemed so 'objectively unreasonable' as to constitute 'highly probative' evidence of scienter under the False Claims Act when it was widely held throughout the industry, no government actor rejected it, and four federal judges expressly found it reasonable." Pet.i. For a variety of reasons, this question is not certworthy.

1. On its face, the question presented does not ask this court to resolve an important question of federal law. Instead, Lilly's argument boils down to an assertion that the Seventh Circuit gave improper weight to one of many pieces of evidence regarding scienter when affirming the jury's verdict. But the question of whether Lilly's interpretation of the Price Actually Realized Requirement (which Lilly never mentions in its

petition) from 2005 through 2017 was "so objectively unreasonable" that a jury could treat it as evidence of scienter is not important to anyone other than Lilly. This is a paradigmatic fact-bound dispute—and the many factual qualifiers Lilly includes in its question (*i.e.*, "widely held throughout the industry, no government actor rejected it, and four federal judges expressly found it reasonable") show just how fact-bound it is. Moreover, those factual qualifiers were disputed—and no lower court resolved those disputes in Lilly's favor. Accordingly, this Court would have to agree with Lilly about all of the contested factual predicates based on the Court's own review of the trial record to even decide the question on its own terms.

The unimportance of the question is confirmed by the strong possibility that even if the Court were to undertake the factual review, resolve the factual questions in Lilly's favor, and then also decide the question presented in Lilly's favor, the result below would likely stay the same. Lilly does not dispute that the Seventh Circuit, when reviewing Lilly's Rule 50 motion for judgment notwithstanding the verdict, was required to "draw all reasonable inferences in favor of" the verdict, "disregard all evidence favorable to [Lilly] that the jury is not required to believe," and "review the record as a whole." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000). Applying this deferential standard, the Seventh Circuit properly asked "whether a highly charitable assessment of the evidence supports the jury verdict or if, instead, the jury was irrational to reach its conclusion." Pet.App.31 (quotations omitted).

In concluding that the jury's verdict was well supported by the proof, the Seventh Circuit did not place

dispositive weight on any one piece of evidence. Correctly so. Scienter determinations are holistic, and consequently the inquiry "is not to scrutinize" each piece of evidence on its own. *Tellabs, Inc. v. Makor Issues & Rts., Ltd.,* 551 U.S. 308, 323 (2007). Instead, appellate courts must consider any and all evidence supporting the jury's scienter verdict, including Lilly's obvious profit motive to lie, its shifting and misleading communications to the government, its failure to ever document any justification for its approach despite a legal requirement to document its so-called "reasonable assumptions"), its delegation of a new multi-hundred-million dollar revenue stream to a mid-level employee, and other factors. *See* Pet.App.36-46; *see also supra* pp. 9-12 (detailing the evidence). Among that evidence, the objective unreasonableness of Lilly's interpretation of the rules was just one piece, and even without it, the verdict would have stood under the proper standard of review.

Put another way, to reverse the decision below, this Court would not only have to resolve the question presented—but would then have to go further and review the entire cold trial record and reweigh all of the evidence and testimony to determine whether it was sufficient to sustain the verdict, which is a garden-variety effort and an obvious waste of this Court's time and resources.

Importantly, the very arguments Lilly now makes—*i.e.*, that its interpretation was reasonable, and that it subjectively believed it was doing the right thing—were the core of its presentation to the jury, which rejected those same arguments on the evidence. For example, Lilly relies heavily on *United States v. Allergan, Inc.*, 746 F. App'x 101, 106 (3d Cir. 2018)

("*Streck I*") as "evidence" of its reasonableness. We explain *infra* why that reliance was misplaced. But for present purposes, the key point is that, over Relator's objection, Lilly was permitted to present the Third Circuit's decision to the jury as evidence with respect to "the effect it had on the defendant's view of what the law was." D.Ct.Dkt.517.1315-1331, 1352. The jury thus considered the entire record—including the points Lilly now makes about *Streck I*—and nevertheless determined that Lilly acted knowingly. Since courts must "disregard all evidence favorable to the moving party that the jury is not required to believe," a reviewing court should not even consider *Streck I,* let alone accept the notion that it foreclosed a jury finding of scienter. *Reeves*, 530 U.S. at 150. But that is exactly what Lilly asks this Court to do.

2. Trying to make this issue sound like a broad legal dispute instead of a fact-bound quibble, Lilly argues that the decision below deviated from this Court's recent decision in *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739 (2023), which explained how the False Claims Act's scienter requirement works. In fact, the Seventh Circuit cited the case (which it called *SuperValu*) repeatedly in discussing the scienter requirement, Pet.App.30, 35-37, and specifically explained why "the logic of *SuperValu* essentially foreclosed the argument Lilly now forwards," Pet.App.35.

The Seventh Circuit got this exactly right. In *SuperValu*, this Court held that the False Claims Act's scienter standard looks to what the defendant subjectively believed, and "tracks the common law" of fraud. 598 U.S. at 750. That common-law standard embodies exactly the rule the Seventh Circuit adopted here.

Specifically, this Court cited the Restatement (Second) of Torts § 526, which explains that "[t]he fact that the misrepresentation is one that a man of ordinary care and intelligence in the maker's situation would have recognized as false … is evidence from which his lack of honest belief may be inferred," and "is a matter to be taken into account in determining the credibility of the defendant if he testifies that he believed his representation to be true." *Id.* § 526 cmt. d. Thus, under the common-law fraud scienter rule expressly endorsed by this Court in *SuperValu*, the Seventh Circuit was absolutely correct to hold that the objective unreasonableness of Lilly's view was evidence of Lilly's scienter.

In other cases, too, this Court has confirmed that "[c]ircumstantial evidence, including the significance of the legal error, the complexity of the relevant rule, the applicant's experience with … law, and other such matters, may also lead a court to find that an applicant was actually aware of, or willfully blind to, legally inaccurate information." *Unicolors, Inc. v. H&M Hennes & Mauritz, L.P.,* 595 U.S. 178, 187-88 (2022). And such circumstantial evidence is often essential to proving scienter in fraud cases. *See, e.g., Wood v. United States*, 41 U.S. 342, 360-61 (1842) ("[F]raud, being essentially a matter of motive and intention, is often deducible only from a great variety of circumstances, no one of which is absolutely decisive.").

Indeed, as the Seventh Circuit recognized, it is Lilly that seeks to resurrect the rule that this Court rejected in *SuperValu*. Specifically, before *SuperValu*, the rule in the Seventh Circuit was that if the defendant's conduct fell within an "objectively reasonable" interpretation of a legal requirement, the defendant could not have acted with scienter unless

"authoritative guidance cautioned defendants against it." *United States ex rel. Schutte v. SuperValu, Inc.*, 9 F.4th 455, 464 (7th Cir. 2021), *rev'd* 598 U.S. 739 (2023); *see also SuperValu*, 598 U.S. at 748 (describing the Seventh Circuit rule as asking "whether a defendant's acts were consistent with any objectively reasonable interpretation of the relevant law that had not been ruled out by definitive legal authority or guidance"). This Court rejected that rule, holding instead that "[t]he FCA's scienter element refers to [defendants'] knowledge and subjective beliefs," and that "facial ambiguity alone is not sufficient to preclude a finding that [defendants] knew their claims were false." 598 U.S. at 749.

Lilly's argument echoes that now-rejected standard. Specifically, Lilly argues it was unfair for the Seventh Circuit to deem Lilly's interpretation "objectively unreasonable" without showing that the interpretation had "been rejected by the agency tasked with interpreting a statute, or by the government in litigation, or by courts that have confronted it." Pet.25. Later, Lilly laments that "[t]he Seventh Circuit … did not and could not point to any authoritative source that would have put Lilly on notice" that its interpretation "was in fact so objectively unreasonable that the bare act of embracing it would be deemed 'highly probative' evidence of a culpable mind." Pet.32. That is indistinguishable, at its core, from the notion this Court rejected in *SuperValu* that "authoritative guidance" is a *sine qua non* of scienter. More broadly, Lilly's entire argument in this section of the petition is that the jury's finding that Lilly acted knowingly *must be set aside as a matter of law* because the underlying law was ambiguous, and had not been

sufficiently clarified by administrative agencies. That is exactly what this Court rejected in *SuperValu*, and what the Seventh Circuit recognized below when it rejected Lilly's argument. Pet.App.35.

Equally wrong is Lilly's suggestion that other courts of appeals applying *SuperValu* have applied the scienter standard differently from the Seventh Circuit here. For example, Lilly cites *United States ex rel. Sheldon v. Allergan Sales, LLC*, 170 F.4th 227 (4th Cir. 2026), which allowed an FCA claim to proceed past the pleading stage against a drug company that misreported its prices. Lilly argues that in *Sheldon*, CMS interpreted the relevant regulation the same way as the plaintiff. *See* Pet.28-29. But the Fourth Circuit, like the court below, focused on the defendant's subjective beliefs. Indeed, the Fourth Circuit cited the decision below approvingly, and never suggested any disagreement with its reasoning. *See* 170 F.4th at 245 (citing the decision below for the proposition that "[e]ven reasonable interpretations of a regulation can be false as a matter of law for purposes of the FCA."). Any factual differences between the cases do not demonstrate any legal divergence.

3. Finally, Lilly's plea for error correction fails because there was no error. Lilly's interpretation of the law was, in fact, completely unreasonable. And to reach that conclusion, the Seventh Circuit did not do anything exotic; it simply engaged in straightforward "statutory and contract interpretation." Pet.App.20. Applying those standard judicial tools, the court recognized that the word "price" does not connote a one-time payment, as many prices are paid over a period of time. Pet.App.21. It also interpreted the Price Actually Realized Requirement, which required that Lilly's

AMPs "must be adjusted …. if cumulative discounts or other arrangements subsequently adjust the prices actually realized." Pet.App.21. As the Seventh Circuit explained, Lilly's textual response—that this requirement only "contemplated mechanisms leading to lower, not higher AMPs," was in "irreconcilable tension with the text," which is facially bidirectional, *i.e.,* facially neutral. Pet.App.22. Moreover, Lilly's interpretation would allow the AMP to become untethered from the amounts manufacturers actually receive—a result that would thwart the very purpose of the requirement, which is to capture the entire value the manufacturer receives for its drug, so that rebates to Medicaid reflect the actual price, not just the initial price received. Pet.App.22-24.

The Seventh Circuit illustrated the unreasonableness of Lilly's interpretation with a devastating hypothetical: "Imagine Lilly sold Drug A to the wholesaler for only $1 and then raised the price to $11 the next day. The wholesaler then sells Drug A for $11 and sends $10 back to Lilly. To say the average price Lilly received for Drug A was $1, rather than $11 ($1 + $10 increase) defies sense. Yet that was precisely Lilly's position." Pet.App.20. Thus, Lilly asked the jury to accept an interpretation that "would condone an egregious exploitation of the relevant law, allowing it to sell drugs at artificially low prices, obtain the full value in subsequent clawbacks, yet report the initial depressed prices for AMP." Pet.App.39.

Remarkably, in addition to not even *mentioning* the Price Actually Realized Requirement, Lilly's petition fails to offer an interpretation—*post-hoc* or otherwise—that would justify Lilly's exclusion of PIV from AMP. This goes far beyond the approach this Court

rejected in *SuperValu*, which at least required defendants to come up with some reasonable interpretation of its legal obligations.

Attempting to sidestep this glaring omission, Lilly faults the Seventh Circuit for not "explain[ing] what makes a legal interpretation 'objectively unreasonable.'" Pet.14. These assertions ignore the Seventh Circuit's lengthy explanation of the many reasons why Lilly's interpretation was patently unreasonable. Pet.App.22 ("Even putting aside that interpretation's irreconcilable tension with the text, it leads us to a nonsensical destination inconsistent with the statute's clear purpose."); Pet.App.33 ("Lilly's exclusion of clawbacks from AMPs was not objectively reasonable since it contradicted the plain text of the law, regulations, and MDRP agreement, ran against the MDRP's obvious purpose, and resulted in absurd consequences."); Pet.App.39 ("Lilly's interpretation would condone an egregious exploitation of the relevant law, allowing it to sell drugs at artificially low prices, obtain the full value in subsequent clawbacks, yet report the initial depressed prices for AMP."). In any event, Lilly cannot seriously be arguing that this Court must grant certiorari to explain to lower courts what the phrase "objectively unreasonable" means, as the term is simultaneously ubiquitous and inherently context-dependent.

Lilly's reliance on the Third Circuit's unpublished decision in *Streck I* as "evidence" of its reasonableness is similarly unpersuasive—especially given that the jury considered and rejected that very evidence. Even if the decisions were completely irreconcilable, this would not rise to the level of a circuit split because *Streck I* was not precedential. But that is only the beginning of Lilly's problems.

In *Streck I*, the Third Circuit applied the objective reasonableness framework that this Court subsequently rejected in *SuperValu*. 746 F. App'x at 106. Under this framework, the Third Circuit did not ask whether any drug manufacturer had a *subjective, good-faith* belief that it could exclude certain clawbacks from AMP; instead, it only asked whether it would have been reasonable for a hypothetical reasonable manufacturer to have done so. Applying that discredited scienter rule, the Third Circuit then considered solely whether the *statutory* definition of AMP was ambiguous—***without reference to the Rebate Agreement***, which sets forth the Price Actually Realized Requirement, and was the focal point of the Seventh Circuit's analysis in this case. *See id.* at 107. Thus, the Third Circuit applied a defunct legal standard to a different set of underlying legal requirements.

Independently, the clawback scheme the Third Circuit considered in *Streck I* was materially different from Lilly's PIV scheme. Thus, the Third Circuit hypothesized that a manufacturer might use "price-appreciation credits" to offset the fees it would pay to wholesalers in future transactions. *See* 746 F. App'x at 104. But for most of the time period here, Lilly did something quite different: It did not pay wholesalers less; it required the wholesalers to pay extra money to Lilly to account for price increases. Whatever the Third Circuit might have believed in *Streck I*, it never suggested that a manufacturer's receipt of extra payments from wholesalers was anything other than a price increase that had to be reported.

Further distinctions abound. For example, *Streck I* was decided at the pleading stage, while this case involves deferential review of a jury verdict that

included factual evidence of scienter. And the Third Circuit's decision came in 2018 *after* the relevant time period (2005-2017) for Relator's claims, Pet.App.2, and so it is not helpful retroactive evidence of the reasonableness of Lilly's interpretation. Instead, as *Super-Valu* made clear, the scienter inquiry looks to Lilly's acts and omissions at the time of the conduct. 598 U.S. at 750.

Finally, the evidence at trial showed that Lilly itself did not follow the *Streck I* holding. Specifically, the Third Circuit – again, looking only at the statutory definition of AMP, and not addressing (even in passing) the Price Actually Realized Requirement – held that the statutory language could be read to mean that AMP is only the initial price paid. But, as noted above, *supra* p. 12, Lilly's witnesses testified that the company commonly adjusted AMP after the initial sale (albeit only if it *lowered* Lilly's rebate payments to the government).

In sum, the second question presented is unimportant, fact-bound, based on numerous erroneous factual and legal premises, does not implicate any circuit split, and attacks a decision that is manifestly correct.

CONCLUSION

Certiorari should be denied.

Respectfully submitted,

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