

No. 25-1126

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In the  
**Supreme Court of the United States**

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ELI LILLY AND COMPANY,  
*Petitioner,*

v.

UNITED STATES, *et al.*, EX REL., RONALD J. STRECK,  
*Respondents.*

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

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**REPLY BRIEF FOR PETITIONER**

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## REPLY BRIEF

The nearly \$200 million judgment in this False Claims Act case is the product of an unaccountable private bounty hunter's years-long crusade to exploit uncertainty in a byzantine statutory regime to secure a massive personal windfall. The Constitution cannot tolerate that result, and neither can the FCA.

Respondent has little to say in defense of the FCA's private-prosecution regime. Instead, he cries waiver and forfeiture. But Lilly noted its constitutional challenge in its panel briefing, which is all it had to do since the panel was bound by circuit precedent rejecting the arguments—circuit precedent that respondent conspicuously fails to mention. And Lilly unquestionably pressed those arguments in its *en banc* petition, which was the first real opportunity it had to do so. In all events, structural constitutional violations are the last place where such weak objections ought to carry the day—especially when lower courts largely perceive this Court as having sanctioned the FCA's *qui tam* regime. This Court's intervention is sorely needed to put the executive power back where it belongs: with the Executive.

It is also sorely needed to keep the FCA from being a trap for the unwary—and one wielded by unaccountable bounty-seekers. After two federal courts rebuffed respondent's efforts to fault manufacturers for failing to follow his preferred view of the law, the Seventh Circuit held that his interpretation of the Medicaid Act is the *only* reasonable reading, and that Lilly's bare act of following a contrary reading was itself "highly probative circumstantial evidence of a culpable state

of mind,” Pet.App.38—even though much of the industry followed the same reading, the agency never rejected it, and three Third Circuit judges and a district court before them had all found that reading reasonable. Unable to deny that the Seventh Circuit created a circuit split while flouting this Court’s instruction in *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739 (2023), that scienter is about subjective beliefs, not the objective reasonableness of legal positions, respondent tries to make this case appear factbound. But the decision below speaks for itself. And there is simply no denying that the Seventh Circuit held that Lilly acted with scienter by concluding that neither Lilly nor anyone else could sincerely share the Third Circuit’s view that Lilly’s reading of the law was reasonable. If that were enough to prove intent to commit *fraud*, then the FCA’s scienter requirement would be meaningless.

**I. This Court Should Grant Certiorari To Decide Whether The FCA’s *Qui Tam* Regime Violates The Separation of Powers.**

“The potential inconsistency of *qui tam* suits with Article II has been noticed for decades,” and three members of this Court have recently expressed their desire to “consider the competing arguments on the Article II issue in an appropriate case.” *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 442 (2023) (Kavanaugh, J., joined by Barrett, J., concurring); *see also id.* at 450 (Thomas, J., dissenting); *Wis. Bell, Inc. v. United States ex rel. Heath*, 604 U.S. 140, 167 (2025) (Kavanaugh, J., concurring). This is that appropriate case.

Of course, the ills wrought by private bounty hunters are present in every *qui tam* suit brought under the False Claims Act; each is an affront to the constitutional separation of powers and the individual liberty it serves to protect. Pet.18-23. But the abuse is particularly evident here. Lilly is being forced to pay a nearly \$200 million fraud judgment for failing to adopt an idiosyncratic interpretation of federal law pressed by a private prosecutor—even though Lilly not only did exactly what the Executive Branch asked it to do (namely, make “reasonable assumptions” about the byzantine statutory framework), but explicitly and repeatedly told the Executive Branch exactly what it was doing (and why it was reasonable). It is time to end the misbegotten *qui tam* experiment once and for all, and this is the case in which to do so.

Respondent’s argument to the contrary is curious. Respondent is in this case (brought in the name of the United States) only because of the *qui tam* device. Yet he offers no meaningful constitutional defense of the FCA’s *qui tam* regime. He says not one word in response to Lilly’s arguments that relators are not vested with their position in a manner that satisfies the Appointments Clause; that their power to enforce federal law lacks any legitimate source; and that Congress gave relators this extraconstitutional power for the avowed goal of usurping executive prerogatives. Pet.18-23. Indeed, the closest he comes to offering a defense of the FCA’s private prosecution regime is to note that some courts bound by their own circuit precedents have “rejected ... as unpersuasive” Judge Mizelle’s opinion holding the FCA’s *qui tam* regime unconstitutional in *United States ex rel. Zafirov v. Florida Medical Associates, LLC*, 751

F.Supp.3d 1293 (M.D. Fla. 2024). BIO.19. To the extent that is even an argument, the most that can be said about it is that it highlights the disagreement among the lower courts on an exceedingly important and frequently recurring issue of constitutional law.

Apparently unable (or at least unwilling) to refute the separation-of-powers problems at the heart of this litigation, respondent pens a plea for patience. But the fact that “[t]here is no circuit split” on the question as of this filing, BIO.19, is no reason to delay review of a question that multiple members of this Court have suggested lower courts have long been getting wrong—particularly when many have done so under the (mis)impression that this Court has already blessed the *qui tam* regime. Moreover, to the extent this Court would prefer to wait for more lower courts to weigh in, it likely will not need to wait long, as the issue is currently pending before multiple courts of appeals. Pet.33. At the very least, the Court should call for the views of the Solicitor General in the meantime, or hold this petition until those decisions come down. That said, there is no reason for this Court to continue to sit on the sidelines. Respondent openly acknowledges “the importance of th[is] question.” BIO.21. The time to resolve it is now.

Instead of addressing the merits, respondent devotes his attention to accusing Lilly of having “forfeited or waived its constitutional argument.” BIO.14-15. Lilly did not. There can be no serious argument that Lilly affirmatively “waive[d] [its] constitutional challenge”; Lilly indisputably never “consent[ed] to” being sued by a private bounty hunter. *Jones Bros., Inc. v. Sec’y of Lab.*, 898 F.3d 669,

677 (6th Cir. 2018). Nor did Lilly forfeit this issue; Lilly explicitly preserved its constitutional objections to the *qui tam* regime in its Seventh Circuit panel briefing. Dkt.37.at.66.n.11.

To be sure, Lilly did not spill much ink on the separation-of-powers issue below until the *en banc* stage. But that is because it would have been futile. At the time of Lilly’s appeal (and still today), the constitutionality of *qui tam* litigation had been (and is) settled in the Seventh Circuit. Respondent insists that the Seventh Circuit did not resolve that question in *United States ex rel. Hall v. Tribal Development Corp.*, 49 F.3d 1208 (1995). BIO.17-18. That is wrong, but it is also beside the point, as the Seventh Circuit most certainly did resolve it in *United States v. UCB, Inc.*, 970 F.3d 835 (2020), holding in no uncertain terms that “the False Claims Act[’s]” *qui tam* regime does not “unconstitutionally usurp[] the executive power.” *Id.* at 847. The panel was of course bound by that precedent, which is why Lilly did not elaborate on its constitutional challenges until the *en banc* stage, where the court actually had the power to consider that challenge.

In all events, it is well within this Court’s power to consider even arguments that (unlike this one) were never fully developed below. Indeed, this Court has reviewed separation-of-powers issues even in cases where the petitioner “expressly consented” to the adjudicator whose appointment it later challenged. *Freytag v. Comm’r*, 501 U.S. 868, 900-01 (1991) (Scalia, J., concurring). Here as there, “[t]he alleged defect ... goes to the validity of the ... proceeding that is the basis for this litigation.” *Id.* at 879 (majority

opinion). And Lilly’s eminently reasonable decision to focus its lower-court briefing on issues that were not squarely foreclosed by circuit precedent “does not ... overcome ... ‘the strong interest of the federal judiciary in maintaining the constitutional plan of separation of powers.’” *Id.* at 878-79 (quoting *Glidden Co. v. Zdanok*, 370 U.S. 530, 536 (1962)).

## **II. The Seventh Circuit’s Approach To Scienter And “Objective Reasonableness” Turns This Court’s Precedent Upside Down.**

This Court held in *Schutte* that “[t]he FCA’s scienter element refers to [the defendant’s] knowledge and subjective beliefs—not to what an objectively reasonable person may have known or believed.” 598 U.S. at 749. When it comes to scienter, the focus is not “on *post hoc* interpretations that might have rendered the[] claims accurate” or inaccurate, but “on what the defendant knew when presenting the claim.” *Id.* at 752; *see also United States ex rel. Sheldon v. Allergan Sales, LLC*, 170 F.4th 227, 241 (4th Cir. 2026) (noting that, *post-Schutte*, “the scienter standard is a subjective one”). Yet the Seventh Circuit nevertheless ascribed a culpable “state of mind” to Lilly on the theory that Lilly’s “interpretation of the relevant law” must have been “objectively unreasonable” because, in the court’s *post hoc* view, the law is unambiguous. Pet.App.38. That holding not only creates a split with the Third Circuit on the interpretative question, but turns *Schutte* on its head. Pet.24-33.

Rather than try to defend the Seventh Circuit’s holding, respondent changes the subject. But no matter how hard he tries to convert it into one, this is not a sufficiency-of-the-evidence challenge. The

Seventh Circuit did not mince words about why it upheld the jury's finding of scienter: "If we thought the regulations were 'ambiguous' or Lilly's interpretation of the guidance was 'reasonable' *we might look at the verdict differently.*" Pet.App.39 (emphasis added); *see also* Pet.App.46 (stressing that scienter was "a close call"). That is a demonstrably *legal* conclusion. And it is demonstrably wrong. *See* Pet.24-27; PhRMA.Br.5-12. So, contrary to respondent's assertion, this Court need not "review the entire cold trial record and reweigh all of the evidence" to grant relief. BIO.24. "When this Court identifies a legal error, it routinely remands the case so the court of appeals may resolve whether the error was harmless." *Hicks v. United States*, 137 S.Ct. 2000, 2000 (2017) (Gorsuch, J., concurring). In that way (but only that way), this is "a garden-variety effort" indeed. BIO.24.

Respondent obfuscates the clear division of labor between judge and jury by insisting that "the very arguments Lilly now makes ... were the core of its presentation to the jury," because "Lilly was permitted to present the Third Circuit's decision [in *Streck I*]" to the jury. BIO.24-25. But Lilly was not permitted to argue to the jury that the *Streck I* opinions confirmed that its view of the law was objectively reasonable or at the very least confirmed that Lilly did not act with a culpable state of mind just for thinking otherwise. *See* D.Ct.Dkt.517.at.1351. And whether Lilly acted *in reliance* on those opinions is not the question Lilly has asked this Court to answer. The question for this Court is whether Lilly's bare decision to embrace a legal position that four federal judges expressly found reasonable can be deemed "highly probative

circumstantial evidence of a culpable state of mind,” Pet.App.38, simply because three Seventh Circuit judges thought they had the better view of the law. That is a legal question, not an evidentiary question—and it is a legal question that the Seventh Circuit got wrong.

Respondent asserts that Lilly’s interpretation of the governing regime *was* objectively unreasonable. BIO.28-32. But far from helping his cause, that fallback gives away the game. *Schutte* made clear that the bare fact that a court deems a defendant’s view of the law objectively reasonable is not itself proof that the defendant must have subjectively believed that view to be correct. Pet.24. By the same token, the bare fact that a court deems a defendant’s view of the law objectively *unreasonable* cannot itself be “highly probative circumstantial evidence of a culpable state of mind,” Pet.App.38—especially when the court deems that view objectively unreasonable simply because it does not think the statute is ambiguous. Either way, the focus must be on the defendant’s “subjective beliefs,” not “on *post hoc* interpretations” selected by courts. *Schutte*, 598 U.S. at 749, 752.

Regardless, while the Court need not resolve the interpretative issue in order to reject what the Seventh Circuit said about how it bears on scienter, respondent’s efforts to portray Lilly’s—and, by extension, the Third Circuit’s—understanding as objectively unreasonable fail on their own terms. Respondent criticizes Lilly—and, again by extension, the Third Circuit—for failing to justify its interpretation under the “Price Actually Realized Requirement,” which he deems the “focal point of the

Seventh Circuit’s analysis.” BIO.31. But that is more concession than contention. While one might not know it from reading the BIO, the so-called “Price Actually Realized Requirement”—which is mentioned a grand total of twice in the Seventh Circuit’s opinion, *see* Pet.App.21-22—does not come from the statute. It came from a version of the agency’s form Medicaid Drug Rebate Program agreement that long predated the advent of wholesaler service fee arrangements. And to the extent that contractual language could be read to require either those fees or price increase values to be included in the AMP calculation, the statute refutes any such requirement.

Before 2010, the Medicaid Act said not one word about wholesaler distribution fees, much less price increase values. *See* Pet.29-30. And when Congress amended the statutory definition of Average Manufacturer Price in 2010 to exclude bona fide service fees, *see* 42 U.S.C. §1396r-8(k)(1)(B)(i)(II)—a change that seemed to confirm Lilly’s approach of excluding wholesaler fees in full—Congress notably did not include anything like the “Price Actually Realized Requirement” that respondent claims is the linchpin. To hold that Lilly was unreasonable because it did not follow that ephemeral-at-best “requirement” is to deprive the word “unreasonable” of any meaning. And to use that holding as the basis for concluding that Lilly “knowingly” violated the FCA, as the Seventh Circuit did here, is to put the FCA on a collision-course with bedrock principles of due process. The FCA is supposed to be an anti-fraud statute, not a trap for the unwary to be wielded as a cudgel by bounty hunters. *See* U.S.Chamber.Br.19-24; Regeneron.Br.13-18.

At bottom, the bare fact that a court thinks a statute is unambiguous cannot itself be “highly probative circumstantial evidence of a culpable state of mind.” Pet.App.38. That is true in every case, but doubly true here, given that the Third Circuit squarely held that the reading Lilly adopted *is* reasonable, that reading was shared by many in the industry, and the agency never took any of the many opportunities it had to reject it if it truly thought it was unreasonable. *Cf. Henry Schein, Inc. v. Archer & White Sales, Inc.*, 586 U.S. 63, 70 (2019) (“It is not unheard-of for one fair-minded adjudicator to think a decision is obvious in one direction but for another fair-minded adjudicator to decide the matter the other way.”). The Seventh Circuit turned *Schutte* upside down and in doing so created a circuit split. That readily warrants this Court’s review.

### **III. The Questions Presented Are Exceptionally Important.**

This petition provides a much-needed opportunity for this Court to step in and remedy flagrant abuses of precedent and the Constitution. It presents purely legal questions that are ripe for plenary review. On the first issue, multiple Justices have explicitly called for a reappraisal of the constitutionality of the FCA’s *qui tam* regime. Pet.17-18. Even respondent acknowledges “the importance of th[at] question.” BIO.21. This Court should grant review to decide once and for all whether the separation of powers tolerates private bounty hunters accountable to no one but themselves enforcing federal law in the name of the United States.

There are thousands of *qui tam* actions pending. See Pet.34; see WLF.Br.13. Every single one of them is an affront to our constitutional order. Delay would serve only to further entrench flagrant violations of the Constitution. See U.S.Chamber.Br.18. And while separation-of-powers “harm[s] may sound a bit abstract,” *Axon Enter., Inc. v. FTC*, 598 U.S. 175, 191 (2023), there is nothing abstract about being forced to pay \$200 million (and being labeled a fraudster) solely because an unappointed and unaccountable bounty hunter was able to take the control rein of the executive power. Indeed, if “‘being subjected’ to ... a ‘proceeding by an unaccountable ALJ’ ... is ‘a here-and-now injury,’” *id.* (quoting *Seila L. LLC v. CFPB*, 591 U.S. 197, 212 (2020)), then this injury is *a fortiori*.

The scienter issue is equally worthy of this Court’s intervention, and the need for course-correction is equally pressing. Of course, on the interpretative question about the reasonableness of Lilly’s (and the Third Circuit’s) reading of the law on this particular issue, the decision below creates a clear circuit split that alone justifies this Court’s attention. But that is just the tip of the iceberg. “Allowing FCA liability to stand in this case would inject untenable uncertainty and chaos into the daily routines of all regulated entities that seek in good faith to navigate complex regulatory regimes.” PhRMA.Br.5. That is not a small universe. Nor is it hyperbole. If merely getting the law “unreasonably” wrong is enough to sanction the imposition of punitive liability and nine-figure judgments—and if private bounty hunters accountable to no one but themselves have free rein to initiate *qui tam* actions that leverage the ambiguity of

federal legislation—then the FCA will become the very worst sort of trap for the unwary.

**CONCLUSION**

For the foregoing reasons, this Court should grant the petition.

Respectfully submitted,

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