IN THE
SUPREME COURT OF THE UNITED STATES

No. ___

ELI LILLY AND COMPANY,

Applicant,

v.

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

Respondents.

APPLICATION TO THE HON. AMY CONEY BARRETT FOR AN EXTENSION OF TIME WITHIN WHICH TO FILE A PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

Pursuant to Supreme Court Rule 13(5), Eli Lilly and Company, hereby moves for an extension of time of 30 days, to and including March 21, 2026, for the filing of a petition for a writ of certiorari. Unless an extension is granted, the deadline for filing the petition for certiorari will be February 19, 2026.

In support of this request, Applicant states as follows:

1. The United States Court of Appeals for the Seventh Circuit rendered its decision on September 11, 2025 (Exhibit A), and denied a timely petition for rehearing on November 21, 2025 (Exhibit B). This Court has jurisdiction under 28 U.S.C. §1254(1).

2. This case raises questions both prosaic (How should Medicaid rebates be calculated?) and profound (May private bounty hunters, accountable to no one but themselves, enforce federal law on behalf of and in the name of the United States?).

3. Under the Medicaid Drug Rebate Program, manufacturers execute a written agreement with the Department of Health and Human Services ("HHS"), under which they must regularly report to the Department's Centers for Medicare and Medicaid Services ("CMS") their Average Manufacturer Price ("AMP") for certain of their drugs. 42 U.S.C. §1396r-8(a)(1), (b)(3); *see also id.* §1396r-8(k)(1). CMS uses AMP to determine the rebate manufacturers owe. *See id.* §§1396r-8(c)(1), (c)(3)(A)-(B). Generally, the higher the AMP, the more the rebate a manufacturer owes—and the less the federal government has to pay to the states itself.

4. Determining AMP may seem straightforward enough, but it is far from an easy task; the statute is byzantine, pointing in different directions on some salient issues, and staying silent on a host of others. For that reason, manufacturers have long sought guidance on how to calculate AMP given the real-world complexity of the prescription-drug supply chain in this country. The most CMS would tell them, however, is to make "reasonable assumptions."

5. With no more clarity than that, Eli Lilly and Company concluded that certain adjustments to fees they owed to wholesalers, and vice versa, were not part of the "average price" received by the manufacturer, and thus should not be included in AMP. Several other manufacturers reached the same conclusion. These adjustments came to be known as "Price Increase Values," or PIV.

6. Lilly decided to exclude PIV from AMP out of an abundance of caution, as the opposite view would yield lower reported prices—and, consequently, lower rebates for states under Medicaid. Lilly also told the government about both its conclusion and its reasoning. Lilly informed the HHS Office of Inspector General that it "ha[d] decided to exclude the wholesaler service fees from its [AMP] calculation … since doing so results in the most favorable outcome for the Medicaid programs." CA7.App.228. Lilly told the same to CMS. CA7.App.314-18, 393-96. The government never told Lilly that its interpretation was wrong—let alone so wrong that Lilly could face punitive liability for (openly) adopting it.

7. But a serial *qui tam* relator named Ronald Streck has long disagreed, and has long tried to convince courts to hold that manufacturers defrauded the government by following it. In 2008, Streck brought a *qui tam* action in Pennsylvania against more than 30 pharmaceutical manufacturers, including Lilly. *United States ex rel. Streck v. Allergan, Inc.*, 894 F.Supp.2d 584 (E.D. Pa. 2012). Streck pressed the exact theory there that he later pressed here—namely, that manufacturers should include PIV (but not the rest of wholesalers' distribution fee) in their AMP calculations. *Id.* at 589. Streck eventually voluntarily dismissed Lilly from the Pennsylvania suit, which ultimately proved a boon for him, as the district court dismissed all of Streck's claims against the remaining defendants in 2012. According to the district court in that case, it was objectively reasonable for manufacturers to exclude PIV from their AMP calculations given the unclear text of the applicable statute and regulations and the complete "dearth of guidance." *Id.* at 600. The Third

Circuit unanimously affirmed in 2018. *United States v. Allergan, Inc.*, 746 F.App'x 101, 103 (3d Cir. 2018).

8. Undeterred, Streck tried again in a different forum. He filed the present suit against 15 manufacturers, including Lilly, in 2014. D.Ct.Dkt.1. As in the Pennsylvania case, he alleged that the defendants violated the False Claims Act by miscalculating and misreporting AMP, thereby understating the rebates owed to states and causing the federal government to pay more to make up the difference, by excluding PIV from AMP calculations (while also arguing that manufacturers properly excluded the rest of its distribution fee from AMP calculations). D.Ct.Dkt.77 ¶¶10-24, 78-80.

9. The case eventually was winnowed down to just Lilly. Lilly filed a motion to dismiss, which the district court denied. D.Ct.Dkt.122. Following discovery, Streck and Lilly each moved for summary judgment. D.Ct.Dkts.311, 314. In February 2022, the district court denied Lilly's motion. D.Ct.Dkt.374.at.2. But it granted Streck's motion in part as to the falsity of Lilly's AMP representations. According to the court, the "alternative readings of the statute as proposed by Lilly"—which all four judges in the Pennsylvania litigation unanimously blessed—"are objectively unreasonable." D.Ct.Dkt.374.at.39.

10. The case then proceeded to trial on the remaining elements of an FCA claim. The court instructed the jury that Lilly's statements were false as a matter of law. CA7.App.577. The jury returned a verdict in Streck's favor for over $61 million,

which was automatically trebled, before statutory penalties were further imposed. D.Ct.Dkt.486.

11. The Seventh Circuit affirmed in relevant part. Splitting with the Third Circuit, the Seventh Circuit held that Lilly's interpretation of the Medicaid Act was objectively unreasonable. Ex. A at 17-33. The court also upheld the jury's findings on materiality and scienter. Ex. A at 38, 48. Nevertheless, the court went out of its way to "express [its] dismay at the government's lethargy, or perhaps regulatory capture." Ex. A at 41. The court observed that "[t]he government allowed companies to make reasonable assumptions," yet refused to "so much as review a letter" (let alone weigh in). Ex. A at 41-42. Such a policy "runs the risk of rule-making by regulatory prosecution" and creates "clear" "incentives to abuse … discretion," and "the lack of industry-wide oversight likely cost taxpayers dearly." Ex. A at 41-42.

12. Lilly sought rehearing en banc. In its petition, Lilly renewed its argument, which it had preserved below but was foreclosed by circuit precedent, that the FCA's *qui tam* provisions violate the Constitution. The full court denied rehearing, declining to disturb the panel opinion or its *qui tam* precedent. Ex. B. So, as things stand now, Lilly faces a $200-million judgment grounded on the view that an interpretation of federal law that no one in the government has ever endorsed—is so clearly correct as to make the position blessed by four federal judges (including all three on the Third Circuit panel in Streck's first foray) objectively unreasonable.

13. That result would be troubling enough if it had been procured by the Executive, given the agency's refusal to provide manufacturers with the guidance

they repeatedly sought on a regulatory regime that is hardly the model of clarity and the Third Circuit's contrary conclusion about the same law and essentially the same facts. But it is untenable coming at the hands of a private bounty hunter who is not appointed by, removable by, or accountable to the President in any way, and who is—by Congress's design—motivated far more by personal profit than by any desire for regulatory clarity. The decision below thus creates not just a circuit split on the propriety of excluding adjustments to fees owed to wholesalers from AMP—and a split where the same private relator is on both sides, at that—but also a powerful incentive for the government to shirk pleas to clarify ambiguous regulations, in hopes of reaping massive windfall judgments from bounty-hunter actions pressing theories that the government is unwilling to use its own resources to advance. That trap-for-the-unwary formula cannot be reconciled with the Constitution's structural protections of liberty or bedrock principles of due process.

14. Applicant's counsel, Erin E. Murphy, requires additional time to prepare a petition that fully addresses the important issues raised by the decision below in a manner that will be most helpful to the Court. Ms. Murphy has substantial briefing and argument obligations between now and February 19, 2026. Those obligations include, among others: oral argument in *NetChoice v. Yost*, No. 25-3371 (6th Cir.), on February 4, 2026; oral argument in *NetChoice v. Skrmetti*, No. 25-5660 (6th Cir.), also on February 4, 2026; a reply brief in *National Shooting Sports Foundation v. Attorney General of New Jersey*, No. 25-2546 (3d Cir.), due February 6, 2026; a reply in support of a motion for preliminary injunction and response to a motion to dismiss in

Pharmaceutical Research and Manufacturers of America v. Torrez, No. 1:25-cv-1225 (D.N.M.), due February 9, 2026; an opening brief in *National Shooting Sports Foundation v. Brown*, No. 25-2404 (4th Cir.), due February 11, 2026; oral argument before the en banc court in *Koons v. Attorney General of New Jersey*, Nos. 23-1900 & 23-2043 (3d Cir.), on February 11, 2026; a reply in support of a motion for summary judgment in *Pharmaceutical Research and Manufacturers of America v. Rayfield*, No. 3:25-cv-1754 (D. Or.), due February 13, 2026; and an opposition to a motion to dismiss in *Pharmaceutical Research and Manufacturers of America v. Jackley*, No. 3:25-cv-3021 (D.S.D.), due February 13, 2026. Ms. Murphy will also be presenting oral argument in this Court on March 2, 2026, in *United States v. Hemani*, No. 24-1234 (U.S.), on behalf of the respondent.

WHEREFORE, for the foregoing reasons, Applicant requests that an extension of time to and including March 21, 2026, be granted within which Applicant may file a petition for a writ of certiorari.

Respectfully submitted,

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