NO. 23-2134, 23-2216, 23-2958, 23-3035, & 24-1352

IN THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

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

Plaintiff-Appellee, Cross-Appellant,

v.

ELI LILLY AND COMPANY,

Defendant-Appellant, Cross-Appellee.

On Appeal from the United States District Court
for the Northern District of Illinois
Case No. 1:14-cv-09412
(Hon. Harry D. Leinenweber)

BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE SUPPORTING DEFENDANT-APPELLANT'S PETITION FOR REHEARING EN BANC

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INTEREST OF AMICUS CURIAE

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as an amicus curiae in qui tam cases under the False Claims Act (FCA), to stress the need for fair notice and regulatory certainty. *See, e.g., SuperValu Inc. v. United States ex rel. Schutte*, 598 U.S. 739 (2023); *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016). WLF also participated as an amicus before the panel here.

INTRODUCTION AND SUMMARY OF ARGUMENT

The FCA punishes fraud, not good-faith compliance. Yet the panel's decision turns the FCA into a trap for the unwary, allowing hindsight-driven liability in the face of regulatory ambiguity. For more than a decade, from 2005 to 2017, Eli Lilly relied on a reasonable interpretation of ambiguous regulations governing the calculation of a drug's "average manufacturer price" (AMP)—a key input for determining Medicaid rebates under the Medicaid Drug Rebate Program (MDRP). *See* 42 U.S.C.

§ 1396r-8(k)(1) (defining AMP as the "average price paid to the manufacturer for the drug in the United States").

In Lilly's supply chain, wholesalers purchased drugs at an initial price but, if Lilly later increased the price before resale to pharmacies, wholesalers remitted additional value through "price appreciation credits" (PACs) or similar adjustments. Lilly excluded these post-sale increases from its AMP calculations, treating them as distinct from the initial "prices realized," akin to service fees or offsets. This practice was entirely consistent with the statute's text, the Centers for Medicare & Medicaid Services' (CMS's) implementing regulations (42 C.F.R. § 447.504), and the MDRP agreement's explicit allowance for "reasonable assumptions" absent specific guidance.

Lilly fully disclosed its methodology to CMS on multiple occasions—including a 2005 meeting, a 2011 letter, and a 2014 audit—none of which prompted agency objections at the time. Existing case law in other circuits further supported Lilly's view that such exclusions were permissible under CMS rules. Yet the panel here held that Lilly's AMP reports were false as a matter of law, Op. at 2–5, 10–15 and affirmed the

jury's findings of scienter and materiality, *id*. at 15–20, 20–25, imposing $184 million in damages.

That result raises grave due-process concerns. It penalizes Lilly for lacking prophetic insight into how courts might later interpret vague and nebulous regulations. But the Constitution demands that Lilly receive "fair notice" before punitive liability may be imposed. The Due Process Clause guarantees regulated entities the right to know in advance how to conform their conduct to the law without fear of arbitrary enforcement. Here Lilly lacked ascertainable certainty that its approach violated the law, given the regulatory silence on post-sale price adjustments like PACs until 2016 and the MDRP's flexibility clause.

The panel's contrary holding conflicts with this Court's precedents strictly enforcing fair-notice protections in regulatory contexts. *See Wis. Res. Prot. Council v. Flambeau Min. Co.*, 727 F.3d 700, 708 (7th Cir. 2013); *United States v. Cinergy Corp.*, 623 F.3d 455, 458 (7th Cir. 2010). And it contravenes Supreme Court case law barring retroactive liability without prior guidance. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156–59 (2012); *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012).

The panel opinion also creates a direct circuit split with the Third Circuit's holding in *United States v. Allergan, Inc.*, 746 F. App'x 101 (3d Cir. 2018). Both cases involve the same relator, Ronald Streck, advancing identical legal theories about the same course of conduct: whether drug manufacturers' exclusion of PACs from AMP calculations under the MDRP is objectively reasonable and thus precludes FCA liability. The Third Circuit deemed the exclusion reasonable, foreclosing liability; the panel here deems it objectively unreasonable, permitting liability. This square conflict on a question of exceptional importance demands en banc review to maintain uniformity in federal law and prevent forum-shopping in nationwide qui tam actions.

Nor is that all. In *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, the Supreme Court held that the FCA's "partial assignment of the Government's damages claim" to the relator, alongside "the long tradition of qui tam actions in England and the American Colonies," showed that qui tam actions were "cases and controversies" under Article III. 529 U.S. 765, 774–77 (2000). The Court left open, however, whether the FCA's partial assignment of the government's right of action "violate[s] Article II, in particular the Appointments

Clause of § 2 and the 'Take Care' Clause of § 3." *Id.* at 778 n.8. Those purely legal questions are also ripe for resolution here.

In fact, the FCA's qui tam provisions are unconstitutional. They violate the Appointments Clause, which balances executive authority with legislative oversight. *United States ex rel. Zafirov v. Fla. Med. Assocs., LLC*, 751 F. Supp. 3d 1293, 1322 (M.D. Fla. 2024). And they violate the Take Care Clause, which embodies the Framers' vision of a unitary Executive. In short, the qui tam provisions hand private relators—self-styled bounty hunters—the reins of federal law enforcement, stripping the President of control over litigation brought in the government's name. That's a direct assault on the Constitution's text and structure.

En banc review is essential to ensure uniformity on the fair notice required to impose FCA liability, provide the pharmaceutical sector with certainty on FCA scienter and materiality, and resolve the pressing Article II question.

ARGUMENT

I. THE PANEL'S DECISION CONFLICTS WITH THIS COURT'S CASE LAW ON FAIR NOTICE AND FCA ELEMENTS.

The panel's ruling undermines this Court's longstanding commitment to fair notice in regulatory enforcement actions, where ambiguity shields parties from liability unless the law provides clear direction. In *Flambeau Mining*, this Court held that because due process bars penalties when a regulated entity cannot determine requirements with "ascertainable certainty," vague statutes cannot support enforcement without explicit guidance. 727 F.3d at 708. Similarly, in *Cinergy Corp.*, the Court rejected the EPA's attempt to impose liability based on novel interpretations not previously promulgated, noting that agencies must operate within reasonable bounds to avoid unfair surprises. 623 F.3d at 458. These cases reflect a consistent principle: regulated industries deserve protection from after-the-fact reinterpretations that turn compliance efforts into liability traps.

The regulatory regime governing Medicaid rebates is notoriously "impenetrable," *Rehab. Ass'n of Virginia, Inc. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994), and the 2007 Final Rule did not clarify whether post-sale adjustments like PACs must be included in AMP. *See* 72 Fed.

Reg. 39,142, 39,148 (2007). So Lilly's exclusion of PACs from AMP was reasonable under the cryptic guidance available at the time. It also aligned with the MDRP's allowance for assumptions absent "specific guidance" and CMS's own silence despite Lilly's repeated disclosures.

The panel's contrary holding—that Lilly's AMPs were knowingly false based on a "plain language" and "common sense" reading, Op. at 2–5, 10–15—contravenes circuit precedent. The panel erred in affirming liability despite overwhelming evidence of Lilly's good-faith reliance on its MDRP agreement and repeated disclosures to CMS, which elicited no corrections. Op. at 15–20, 20–25. This conflicts with precedents like *Kropp Forge Co. v. Secretary of Labor*, where this Court vacated penalties because of "ambiguity in the regulation," and the agency's prior practice had supported the employer's approach. 657 F.2d 119, 122 (7th Cir. 1981). *Kropp Forge* should have resolved this case.

Likewise, in *In re Metro-East Manufacturing Co.*, 655 F.2d 805, 810 (7th Cir. 1981), the Court emphasized that agencies must provide "adequate notice" of standards before enforcement. Where ambiguity leads to reasonable misinterpretation, no liability can attach. *Id.* at 808–10. Here CMS's inaction—despite detailed disclosures about its PAC

exclusions in 2005, 2011, and 2014—reinforced the reasonableness of Lilly's assumptions. By insisting on liability anyway, the panel's opinion injects great incoherence into this circuit's case law. En banc review is necessary to maintain uniformity and reaffirm that the FCA is not a vehicle for punishing regulatory uncertainty.

This imposition of liability without fair notice violates due process, a requirement the Supreme Court has vigilantly protected in regulatory contexts. The Supreme Court has long held that regulated parties must be able to identify legal requirements with "ascertainable certainty," lest enforcement become arbitrary. *Johnson v. United States*, 576 U.S. 591, 595 (2015). In the administrative context, this demands that agencies provide clear guidance before penalizing conduct. Lilly lacked such certainty here, as CMS regulations were silent on whether PACs qualified as part of the "price paid to the manufacturer," and Lilly's interpretation aligned with the statute's text permitting "reasonable assumptions" in the MDRP agreement.

The panel's resort to a "common sense" reading—that Lilly "realized" the higher price, Op. at 2–5—imposes retroactive liability and contravenes *Christopher*, which refused to defer to an agency

interpretation that would "impose potentially massive liability" without warning. 567 U.S. at 156–59. Due process demands that agencies provide clear guidance before penalizing conduct—parties "should know what is required of them so they may act accordingly." *Fox*, 567 U.S. at 253. The panel's approach flouts these binding authorities by punishing Lilly for not anticipating a novel judicial gloss on silent rules, as no guidance addressed PACs until the 2016 Final Rule.

II. THE PANEL'S DECISION BREAKS WITH THE THIRD CIRCUIT ON WHETHER LILLY'S VERY INTERPRETATION OF THE STATUTE WAS REASONABLE.

The panel's decision also opens a circuit split by rejecting the Third Circuit's conclusion that the MDRP's AMP definition is ambiguous as to whether "price" encompasses initial or cumulative payments, including PACs. *See Allergan*, 746 F. App'x at 104–05. There, the court held that the statute's lack of temporal qualifiers renders a manufacturer's exclusion of such credits a reasonable interpretation, not reckless disregard under the FCA. *Id.* at 106–07 (citing 42 U.S.C. § 1396r-8(k)(1)(A); 42 C.F.R. § 447.504(h)(19)). Here, however, the panel declared the same interpretation "unambiguously" unreasonable, insisting that post-sale adjustments must be included in AMP if they affect the "price

actually realized." Op. at 20. This effectively brands the Third Circuit's reasoned analysis as "objectively unreasonable," Op. at 35, injecting disparity in the application of a uniform federal statute.

En banc review is needed for uniformity, as the split implicates the nationwide MDRP program, which demands consistent interpretation across circuits. In *Allergan*, the Third Circuit emphasized that administrative guidance, including CMS releases, supported excluding PACs as bona fide service fees, aligning with the statute's purpose. 746 F. App'x at 107 (citing 42 C.F.R. § 447.504(h)(19)). The panel here dismissed such guidance as non-binding and contrary to the MDRP's "obvious purpose," Op. at 30, yet offered no persuasive justification for overriding the Third Circuit's view. Absent en banc correction, manufacturers face conflicting obligations: reasonable conduct in one circuit becomes culpable in another, undermining the FCA's scienter requirement and inviting arbitrary enforcement.

The question is of exceptional importance, affecting not only the parties—Eli Lilly was initially a defendant in the Third Circuit action, *Allergan*, 746 F. App'x at 103 n.1—but the entire pharmaceutical industry's liability FCA exposure under Medicaid. The MDRP rebates

hinge on AMP calculations, so the split involves billions in inconsistent liabilities. *Cf.* Op. at 14 (noting $61 million in underpayments from 2005 to 2017). The Third Circuit rightly cautioned against FCA liability for reasonable interpretations of ambiguous statutes to ensure regulatory predictability. *Allergan*, 746 F. App'x at 106. By contrast, the panel's approach here perpetuates uncertainty in a vital area where damages are trebled and clarity is paramount.

III. THE FCA'S QUI TAM PROVISION VIOLATES ARTICLE II BY IMPROPERLY ENCROACHING ON THE EXECUTIVE BRANCH.

No one disputes that the False Claims Act's aim to ferret out fraud against the public fisc is a worthy goal. But good intentions cannot override constitutional limits. These structural protections are not picayune formalities; they are a crucial bulwark of our liberties.

Start with the Appointments Clause. Article II, Section 2, Clause 2 requires that those exercising "significant authority" as officers of the United States be appointed by the President, often with Senate confirmation. U.S. Const. art. II, § 2, cl. 2; *Buckley v. Valeo*, 424 U.S. 1, 126 (1976). Qui tam relators, suing to recover penalties for the United States, wield such authority, yet they do so without such appointment.

Relators may argue that their temporary status or lack of formal employment exempts them, but this view clashes with precedent recognizing even limited prosecutorial roles as requiring proper appointment. *See Morrison v. Olson*, 487 U.S. 654, 671 (1988). The FCA's structure, offering bounties akin to early officers' fees, confirms that relators occupy a continuous and formal enough role to demand Article II's safeguards. *See Lucia v. SEC*, 585 U.S. 237, 245 (2018). This conflict—between statutory innovation and constitutional rigor—demands this Court's scrutiny to ensure that those wielding executive power remain accountable to the people.

Even if the Appointments Clauses des not wholly dispatch the FCA's qui tam provision, the Take Care Clause finishes the job. The Constitution obliges the President to "take Care that the Laws be faithfully executed." U.S. Const. art. II, § 3. This duty requires the President to weigh competing priorities, balancing enforcement with the public good, as Washington did in directing prosecutions and granting pardons during and after the Whiskey Rebellion.

The FCA, however, grants relators broad discretion to initiate suits, often driven by private gain rather than the broader public interest. Even

when the government intervenes, relators retain significant control, constraining the President's ability to align enforcement with the Executive's broader policy goals. *See* 31 U.S.C. § 3730(c)(1). Because this delegation impermissibly fragments the Executive's undivided authority, the FCA erodes the careful separation of powers that safeguards individual liberty.

Historical pedigree offers no reprieve. Yes, early Congresses enacted such statutes, but their actions do not override the Constitution's text. *See N.Y. State Rifle & Pistol Ass'n v. Bruen*, 597 U.S. 1, 36 (2022) ("the text controls"). Those early laws, unlike the FCA, imposed fewer barriers to presidential oversight and reflected a nascent government's practical needs, not a considered constitutional endorsement. *See Constitutionality of the Qui Tam Provisions of the False Claims Act*, 13 Op. O.L.C. 207, 235 (Jul. 18, 1989).

Early Congresses weren't infallible—their first statute, prescribing state officials' oaths, was blatantly unconstitutional. *See* Gary Lawson, *The Constitution's Congress*, 89 B.U. L. Rev. 399, 404–06 (2009). Or take the Sedition Act, which criminalized "false, scandalous, and malicious" statements against the government. An Act for the Punishment of

Certain Crimes Against the United States, 1 Stat. 596 (1798). Although the Sedition Act was never tested in court, "the attack upon its validity has carried the day in the court of history." *N.Y. Times v. Sullivan*, 376 U.S. 254, 276 (1964).

Nor is early presidential acquiescence to qui tam suits dispositive. Although one or more Presidents might accept a novel practice that violates Article II, "the separation of powers does not depend on the views of individual Presidents, nor on whether the encroached-upon branch approves the encroachment." *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 497 (2010) (internal quotation marks and citation omitted). A President cannot "choose to bind his successors by diminishing their powers." *Id.*

The FCA's modern framework, revived in 1986, goes much further, insulating relators from executive control in ways its predecessors did not. But the Constitution demands a unitary Executive, answerable to the people, to wield the sword of federal enforcement. The FCA's qui tam provisions, however well-intended, do violence to that principle. This Court must ensure that innovation does not outstrip constitutional bounds.

CONCLUSION

This Court should grant the petition.

Respectfully submitted,

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November 3, 2025

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limits of Seventh Circuit Rule 29 because it contains 2,600 words, excluding the parts exempted by Federal Rule of Appellate Procedure 32(f).

I also certify that this brief complies with the typeface and type-style requirements of Seventh Circuit Rule 32(b) and Federal Rule of Appellate Procedure 32(a)(6) because it uses 14-point Century Schoolbook font.

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