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 Writ of Certiorari to the U.S. Court of Appeals for the Seventh Circuit

BRIEF OF *AMICUS CURIAE* THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*[1]

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation. It represents approximately 300,000 members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

In recent years, profit-driven relators have abused the False Claims Act's ("FCA") *qui tam* mechanism. That abuse has exacted a substantial economic toll on businesses nationwide, and the Chamber has a significant interest in preventing such harm to its members. It thus submits this brief to explain how *qui tam* litigation violates Article II—and to show why the Court of Appeals' distortion of the FCA's scienter standard, which warrants this Court's review in its own right, magnifies those constitutional concerns.

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[1] No counsel for any party authored this brief in whole or in part and no entity or person, aside from *amicus curiae*, its members, or its counsel, made any monetary contribution intended to fund this brief's preparation or submission. Counsel for all parties received timely notice of the intention to file this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case is a prime candidate for review. Three Members of this Court have already recognized there are "substantial arguments that the *qui tam* device is inconsistent with Article II." *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 449 (2023) (Thomas, J., dissenting); *see id.* at 442 (Kavanaugh, J., joined by Barrett, J., concurring). And this profoundly important question has now percolated for nearly 40 years. Shortly after the 1986 FCA amendments "resuscitat[ed] the dormant qui tam device," the Department of Justice's Office of Legal Counsel concluded that this private enforcement scheme is "patently unconstitutional." *Constitutionality of the* Qui Tam *Provisions of the False Claims Act*, 13 Op. O.L.C. 207, 209, 238 (1989) (William Barr, Ass't A.G.) (hereafter, "Barr Memo"). Since then, lower court judges have exhaustively aired out the arguments on both sides.

This Court should settle the issue and hold *qui tam* litigation unconstitutional. Article II's text leaves no doubt on this score. It vests all "executive Power" in one elected President, who is singularly charged with "tak[ing] Care that the Laws be faithfully executed." U.S. Const. art. II, §§ 1, 3. The Framers adopted that unitary structure to promote accountability and ensure that "a President chosen by the entire Nation" would "oversee the execution of the laws." *Free Enter. Fund v. PCAOB*, 561 U.S. 477, 499 (2010). In addition, they "carefully husband[ed] the appointment power" to hold the President responsible for the "'Officers of the United States'" who wield executive Power in his

name. *Freytag v. Commissioner*, 501 U.S. 868, 881-84 (1991) (quoting U.S. Const. art. II, § 2, cl. 2).

The FCA runs roughshod over these safeguards. It vests unaccountable bounty hunters with substantial executive Power to litigate for the United States. And it enables these "relators" to bypass the Appointments Clause and "self-appoint[]" themselves into a "private attorney general" role. *United States ex rel. Milam v. Univ. of Tex. M.D. Anderson Cancer Ctr.*, 961 F.2d 46, 48-49 (4th Cir. 1992). Article II forbids such privatization of the President's Take Care charge.

The "primary counterargument" for upholding the FCA's *qui tam* provisions emphasizes *qui tam*'s "historical pedigree." *Polansky*, 599 U.S. at 450 (Thomas, J., dissenting). But the "adoption or acceptance of laws that are *inconsistent* with the original meaning of the constitutional text"—even laws passed near the Founding—"cannot overcome or alter that text." *N.Y. State Rifle & Pistol Ass'n v. Bruen*, 597 U.S. 1, 36 (2022) (citation omitted). And *qui tam*'s historical roots are limited at best. The practice "rapidly fell into disfavor" with the establishment of the Executive Branch. Barr Memo 235. Then, when the Civil War Congress revived *qui tam* decades later with the original FCA, the practice quickly fell into desuetude once again. Such scattered historical episodes cannot excuse the manifest conflict between the modern FCA's *qui tam* provisions and Article II's text.

Settling *qui tam*'s constitutionality is reason enough to grant certiorari. Yet this case illustrates just how badly relator-driven enforcement has jumped the tracks. The government told Petitioner Eli Lilly

and Company ("Lilly") to make "reasonable assumptions" about how to interpret a byzantine set of Medicaid regulations. Lilly followed those commands, repeatedly disclosed its assumptions, and the government never questioned them. But a serial relator, motivated by profit, took matters into his own hands. He sought to recover massive penalties on the government's behalf—for fraud no less—based on Lilly's following the government's instructions. And the Seventh Circuit watered down the FCA's "rigorous" scienter requirement to reward that effort. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 192 (2016). That ruling flouts our legal system's commitment to fair notice and due process, and allowing it to persist will only encourage further *qui tam* overreach.

This Court should grant certiorari to review both questions presented.

ARGUMENT

I. This Court Should Grant Certiorari to Settle the Constitutionality of the False Claims Act's *Qui Tam* Provisions.

The FCA's *qui tam* provisions violate Article II several times over. They empower self-appointed private persons to litigate on behalf of the United States, in violation of Article II's Vesting Clause and the Appointments Clause. And they usurp both the President's prosecutorial discretion and control over FCA actions, in violation of the Take Care Clause.

A. The *Qui Tam* Provisions Violate Article II's Vesting Clause.

Congress may not authorize private bounty hunters to litigate for the United States. Rather, the Framers understood that "[a] basic step in organizing a civilized society" was to take the "sword" of law-enforcement actions "out of private hands and turn it over to an organized government, acting on behalf of all the people." *Robertson v. United States ex rel. Watson*, 560 U.S. 272, 282-83 (2010) (Roberts, C.J., dissenting from dismissal of writ of certiorari as improvidently granted). To that end, the Constitution established a unitary and accountable Executive who alone was responsible for enforcing federal law.

This conception of centralized executive authority finds roots in the political theory of John Locke. As he explained, "in the state of Nature[,] every one has the executive power of the law of Nature." John Locke, *Two Treatises on Civil Government* 197 (George Routledge & Sons ed., 1884) ("Locke"). But "when they enter into society," individuals "give up" the "executive power they had in the state of Nature into the hands of the society." *Id.* at 258. That is, the people delegate their executive authority to public officials, whose power is "to be directed to no other end but the peace, safety, and public good of the people." *Id.* at 259.

Blackstone's Commentaries reflect a similar understanding. "In a state of society," he reasoned, the right "to put [the law] in execution" is "transferred from individuals to the sovereign power," who "alone" bears "the sword of justice by the consent of the whole community." 4 William Blackstone, *Commentaries on the Laws of England* 7-8 (1769) ("Blackstone"). And

when the public "delegate[s] all its power and rights, with regard to the execution of the laws, to one visible magistrate," that officer is "the proper person to prosecute for all public offences." 1 Blackstone 258-59.

Of course, the common law recognized that one who personally "suffered the damage" from a public infraction might have a *concomitant* right to demand redress "in his own name." Locke 196. But that would not permit him to pursue relief on behalf of the public writ large. "[N]o person" other than the official entrusted with the executive authority "can have an action for a public nuisance, or punish it," unless that "private person suffers some extraordinary damage." 3 Blackstone 219-20. Because individuals give up the executive power by entering society, "the law gives no *private* remedy for any thing but a *private* wrong." *Id.* at 219.

The Framers enshrined this basic understanding in Article II's text, vesting all "executive Power" in a single "President." U.S. Const. art. II, § 1, cl. 1; *see Seila Law LLC v. CFPB*, 591 U.S. 197, 213 (2020). It would therefore be "utterly inadmissible" for Congress to vest executive authority "in any other person." *Martin v. Hunter's Lessee*, 14 U.S. 304, 330 (1816).

That, however, is precisely what Congress did with the FCA's *qui tam* provisions. It "sought to disperse some quantum of executive authority amongst the general public." *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 750 (9th Cir. 1993). That dispersion cannot be justified as remedying private wrongs, for the alleged harm, by definition, was "suffered by the United States." *United States ex rel. Hunt v. Cochise*

Consultancy, Inc., 887 F.3d 1081, 1091 (11th Cir. 2018), *aff'd*, 587 U.S. 262 (2019). Such "public offences" may be prosecuted only by those acting on behalf of the President, in whom the people have vested all executive Power. 1 Blackstone 259.

This Court's precedent confirms the point. The executive Power includes the "exclusive authority and absolute discretion to decide whether to prosecute a case" on the United States' behalf. *United States v. Nixon*, 418 U.S. 683, 693 (1974). And the "[s]ettled rule" has long been that courts cannot entertain "any suit, civil or criminal, as regularly before them, if prosecuted in the name and for the benefit of the United States," unless the government is represented by the Executive. *Confiscation Cases*, 74 U.S. 454, 457 (1869). The FCA's *qui tam* provisions contravene Article II's Vesting Clause by outsourcing that responsibility to private parties.

B. The *Qui Tam* Provisions Violate the Appointments Clause.

Qui tam suits also conflict with the Appointments Clause, which works in tandem with the Vesting Clause to ensure that "executive Power" is exercised only by appointed "Officers of the United States." U.S. Const. art. II, § 2, cl. 2.

The key test for an "Officer" is whether the person "exercis[es] significant authority pursuant to the laws of the United States." *Buckley v. Valeo*, 424 U.S. 1, 126 (1976). Such authority includes the power to "conduct[] civil litigation in the courts of the United States for vindicating public rights." *Id.* at 140. And that describes the power of an FCA relator to a tee: The relator may sue "for the United States" and "in

the name of the Government" for "penalt[ies]" and "damages which the Government [has] sustain[ed]." 31 U.S.C. §§ 3729(a)(1), 3730(b)(1).

Buckley forbids such a diffusion of executive Power. There, the Court struck down the FEC's original structure, which permitted congressional leaders to appoint commissioners. *See* 424 U.S. at 113. That violated the Appointments Clause, because the commissioners performed executive "functions" by wielding "enforcement power" to "seek judicial relief" for violations of law. *Id.* at 138-40. Such executive "functions may be discharged *only* by persons who are 'Officers of the United States' within the language" of the Appointments Clause. *Id.* at 140 (emphasis added).

In considering whether one exercises an executive "function," *Buckley* reflects the original public meaning of "Officer." "Etymologically, an 'office' is an *officium*, a duty; and an 'officer' was simply one whom the King had charged with a duty." Edward S. Corwin, *The President: Office and Powers 1787-1957*, at 70 (4th ed. 1957). In keeping with that understanding, the Crown argued prior to the Founding that "every Man is a publick officer who hath any duty concerning the publick." *King v. Burnell*, Carth. 478, 479 (K.B. 1700). Later dictionaries reflected the same understanding. *See* Officer, 2 Timothy Cunningham, *A New and Complete Law-dictionary* (1765) (recounting *Burnell* formulation); Officer, 2 Noah Webster, *American Dictionary of the English Language* (1828) ("A person commissioned or authorized to perform any public duty.").

The Framers likewise regarded an "Officer" as one "invested with some portion of the sovereign functions of the government." Floyd R. Mechem, *A Treatise on the Law of Public Offices and Officers* 2 (1890). In Hamilton's words, persons to whose "management" the "executive details" of government "are committed ought to be considered as the [President's] assistants or deputies" and "ought to derive their offices from his appointment." The Federalist No. 72, at 435-36 (Alexander Hamilton) (Clinton Rossiter ed., 2003). Those executive appointees alone are "the officers who may be [e]ntrusted with the execution of [the] laws." The Federalist No. 29, at 183 (Alexander Hamilton).

This understanding explains why the Appointments Clause was no mere matter of "etiquette or protocol." *Buckley*, 424 U.S. at 125. It was instead regarded among the "significant structural safeguards of the constitutional scheme." *Edmond v. United States*, 520 U.S. 651, 659 (1997). "The Appointments Clause prevents Congress from dispensing power too freely" to those who might wield it improperly. *Freytag*, 501 U.S. at 880. And it simultaneously "ensures that those who exercise the power of the United States are accountable to the President, who himself is accountable to the people." *Dep't of Transp. v. Ass'n of Am. R.R.*, 575 U.S. 43, 63 (2015) (Alito, J., concurring).

The FCA's *qui tam* provisions upend these safeguards. Indeed, Congress could hardly have dispensed executive Power more freely, "effectively permit[ting] all private persons in the entire world to appoint themselves special fraud prosecutors in the name of the United States." James T. Blanch, *The*

Constitutionality of the False Claims Act's Qui Tam *Provision*, 16 Harv. J.L. & Pub. Pol'y 701, 742 (1993). Congress also shielded relators from removal—and thus presidential supervision—by providing them a "right to continue as a party" even after duly appointed officials intervene. 31 U.S.C. § 3730(c)(1). The result is a relator "that is not accountable to the President, and a President who is not responsible for the [relator]." *Free Enter. Fund*, 561 U.S. at 495. That violates Article II.

It makes no difference that relators lack a "continuing and formalized relationship of employment with the United States." *Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749, 757-58 (5th Cir. 2001) (en banc). They still unquestionably wield "core executive power." *United States ex rel. Zafirov v. Fla. Med. Assocs., LLC*, 751 F. Supp. 3d 1293, 1300 (M.D. Fla. 2024). So, whether or not "public officers in a strict sense," relators may not be "charged with the exercise of executive functions" unless appointed through the method Article II commands. *Springer v. Gov. of Philippine Islands*, 277 U.S. 189, 203 (1928). Certainly, they cannot exercise the core executive function of prosecuting claims on the public's behalf for penalties that are "essentially punitive in nature." *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784 (2000). This "power to seek daunting monetary penalties against private parties" is a "quintessentially executive power." *Seila Law*, 591 U.S. at 219.

The employment argument also reads "Officer" too narrowly. While the word often "embraces the ideas of tenure, duration, emolument, and duties," *United*

States v. Germaine, 99 U.S. 508, 511 (1878), this Court has never held all such indicia to be necessary. To the contrary, *Morrison v. Olson* held that an independent counsel—a temporary prosecutor appointed for a single investigation—was "clear[ly]" an "'officer' of the United States." 487 U.S. 654, 671 & n.12 (1988).

As in *Morrison*, a *qui tam* relator functions as a single-case officer empowered to sue on the government's behalf. *See* 31 U.S.C. § 3730. While the "office is limited in tenure" and "'temporary' in the sense that [relators are] appointed essentially to accomplish a single task," those limits do not foreclose officer status "in the constitutional sense." *Morrison*, 487 U.S. at 671-72 & n.12. Rather, "the office of an FCA relator is continuous" by operation of law, "even if it is not continually filled." *Zafirov*, 751 F. Supp. 3d at 1314. The FCA empowers individuals to appoint themselves to that office—in which they represent the United States in complex, high-stakes litigation for years.

At bottom, "there is not even a fig leaf of constitutional justification" for empowering "private entities" to prosecute alleged FCA offenders on the government's behalf. *Ass'n of Am. R.R.*, 575 U.S. at 62 (Alito, J., concurring). As independent and self-appointed bounty hunters, *qui tam* relators operate well outside Article II's carefully crafted scheme.

C. The *Qui Tam* Provisions Violate the Take Care Clause.

Qui tam litigation violates the Take Care Clause too. The Framers knew that there "can be no liberty" if a single body "should enact tyrannical laws," to have them then "execute[d]" "in a tyrannical manner." The

Federalist No. 47, at 303 (James Madison) (emphasis and citation omitted). So they divided the Nation's lawmaking and law-enforcement powers. That "separation of legislative and executive functions helps prevent tyranny precisely because a discretionary decision by executive officers intervenes between the enactment of the prohibition and its application to any particular individual." Zachary S. Price, *Enforcement Discretion and Executive Duty*, 67 Vand. L. Rev. 671, 702 (2014).

At the same time, "[t]he Constitution does not leave to speculation who is to administer the laws enacted by Congress"—and exercise discretion in their execution. *Printz v. United States*, 521 U.S. 898, 922 (1997). "[T]he President, it says, 'shall take Care that the Laws be faithfully executed.'" *Id.* (citation omitted). Included within that charge "is the power to protect individual liberty by essentially under-enforcing federal statutes regulating private behavior." *In re Aiken County*, 725 F.3d 255, 264 (D.C. Cir. 2013) (opinion of Kavanaugh, J.). For that reason, "the choice of how to prioritize and how aggressively to pursue legal actions against defendants who violate the law falls within the discretion of the Executive Branch, not within the purview of private plaintiffs (and their attorneys)." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 429 (2021).

The FCA's *qui tam* provisions cannot be squared with these principles either. They permit unharmed private parties to commandeer the Executive's enforcement discretion and decide whether, where, when, and how to sue alleged violators. This "allows Congress to circumvent the Executive's check and to

have its laws enforced directly by its own private bounty hunters." Barr Memo 211. Such reallocation of power not only threatens individual liberty, but also undermines the Executive's power to set "overall policies." *Heckler v. Chaney*, 470 U.S. 821, 831 (1985).

That is why the Framers entrusted these sorts of enforcement decisions to one, publicly accountable President. "[O]nly a unitary executive properly can balance the competing interests at stake, including law enforcement, foreign affairs, national security, and the overriding interest in just administration of the laws." Barr Memo 232. That is, only the President can "take Care that the Laws be faithfully executed," U.S. Const. art. II, § 3, so as to best serve the "public-welfare needs of the American people," *United States v. Texas*, 599 U.S. 670, 680 (2023).

D. History Cannot Salvage the *Qui Tam* Provisions' Affront to Article II.

History cannot wash away these constitutional shortcomings. After all, "[t]he Constitution, not history, is the supreme law." Barr Memo 233; *see Bruen*, 597 U.S. at 36. Historical practice thus cannot cure constitutional infirmities even when it "covers our entire national existence and indeed predates it." *Walz v. Tax Comm'n of City of New York*, 397 U.S. 664, 678 (1970).

At any rate, *qui tam* suffers from a checkered history. It did not become ubiquitous until Congress amended the FCA in 1986—two centuries after the Founding. Those modern amendments, of course, are the very provisions at issue.

1. Abuses in Early English *Qui Tam* Practice Led to its Decline.

Qui tam actions originated in medieval times, "when private individuals who had suffered injury began bringing actions in the royal courts on both their own and the Crown's behalf." *Stevens*, 529 U.S. at 774. This practice was originally aimed at getting "private claims into the respected royal courts, which generally entertained only matters involving the Crown's interests." *Id.* But as the "royal courts began to extend jurisdiction to suits involving wholly private wrongs" in the 14th century, "the common-law *qui tam* action gradually fell into disuse." *Id.* at 775.

Around that time, Parliament was "[f]aced with limited public enforcement resources and the difficulty of implementing national policies" over an expansive region. J. Randy Beck, *The False Claims Act and the English Eradication of* Qui Tam *Legislation*, 78 N.C. L. Rev. 539, 567 (2000). It therefore began experimenting with statutory *qui tam* litigation. *See id.* at 567-73.

Over the next two centuries, however, *qui tam* "proved a vexatious device that ultimately could not be reconciled with the institutions of free and responsible government." Barr Memo 235. Informers "occupied in this branch of executive jurisprudence" did not "give impartial efficiency to the laws," but acted instead as "instrument[s] of individual extortion, caprice, and tyranny." 8 Legal Observer No. 204, at 20 (1834) (citation omitted). They unearthed old and forgotten statutes "as means to gratify ill-will." 4 William S. Holdsworth, *A History of English Law* 356 (1924). They threatened enforcement suits

to "levy[] blackmail" against others. *Id.* And they stirred up litigation simply in the hopes of recovering money. *Id.*

These abuses led to considerable outrage—prompting Lord Coke to denounce the informers as "viperous vermin" who "vex and depauperize the subject" for "malice or private ends, and never for love of justice." 3 Sir Edward Coke, *Institutes of the Laws of England* 194 (4th ed. 1797). Parliament responded by curbing *qui tam* abuses. *See* Beck, *supra*, at 574-89. And, by the Jacobean era, "many of the old enactments were repealed" entirely. *Stevens*, 529 U.S. at 775.

Some English *qui tam* statutes did remain in effect up through the Founding. But even those lend little support to the constitutionality of *qui tam* litigation. After all, "the Constitution's creation of a separate Executive Branch coequal to the Legislature was a structural departure from the English system of parliamentary supremacy, from which many legal practices like *qui tam* were inherited." *Polansky*, 599 U.S. at 450 (Thomas, J., dissenting) (citation omitted). The English history only underscores the hazards posed by legislative transfers of executive power to private hands. Article II eliminated those hazards.

2. Early Congressional Laws Do Not Support *Qui Tam*'s Constitutionality.

Some courts counter that "the First Congress enacted a number of statutes authorizing *qui tam* actions." *Riley*, 252 F.3d at 752. But even "a longstanding history of related federal action does not demonstrate a statute's constitutionality." *United States v. Comstock*, 560 U.S. 126, 137 (2010). And

early congressional practice provides a weak precedent for the modern-day FCA.

For starters, many early *qui tam* enactments are not "relevantly similar." *Bruen*, 597 U.S. at 29. They operated differently from the current FCA, which places unharmed plaintiffs in the government's shoes to litigate on its behalf. Many of the early statutes instead offered only a reward to informers for bringing a matter to the government, without providing a cause of action; others sought to redress private injuries, with the government receiving only incidental recoveries. *See Zafirov*, 751 F. Supp. 3d at 1319-20. These two categories differ in kind from the modern FCA and thus have little bearing on the inquiry. *See Bruen*, 597 U.S. at 29-30, 46-50.

As to the few enactments that allowed informers to pursue the sovereign's claims, these "were essentially stop-gap measures, confined to narrow circumstances" to assist the fledging Executive. Barr Memo 213. And the "transitory and aberrational" *qui tam* device "never gained a secure foothold within our constitutional structure." *Id.* It produced "little actual litigation" and was curtailed by Congress in short order. Ann Woolhandler & Caleb Nelson, *Does History Defeat Standing Doctrine?*, 102 Mich. L. Rev. 689, 728 (2004); *see* Barr Memo 235-36.

Moreover, there is "no evidence" that Congress ever "considered the constitutional status of qui tam." Barr Memo 214. The early *qui tam* statutes instead have all the hallmarks of action "taken thoughtlessly, by force of long tradition" from an archaic English device, "and without regard to the problems" presented to the new constitutional order. *Marsh v. Chambers*, 463

U.S. 783, 791 (1983). The Framers themselves recognized that early congressional practice should receive little weight where, as here, "the question of Constitutionality was but slightly, if at all, examined." Letter from James Madison to President Monroe (Dec. 27, 1817), in 3 *Letters and Other Writings of James Madison* 54, 55-56 (J.B. Lippincott & Co. 1867).

Reliance on congressional practice also proves too much. For many "qui tam provisions authoriz[ed] individuals to sue under *criminal* statutes to help enforce the law." Harold J. Krent, *Executive Control over Criminal Law Enforcement: Some Lessons from History*, 38 Am. U. L. Rev. 275, 296-97 & n.104 (1989) (emphasis added). An early larceny statute, for example, gave half the fine "to the informer and prosecutor," and provided that, "on conviction," the offender would "be publicly whipped." Act of Apr. 30, 1790, ch. 9, §§ 16-17, 1 Stat. 112, 116. There can be no doubt that outsourcing such "core executive power" to the plaintiffs' bar would violate Article II. *Seila Law*, 591 U.S. at 219.

3. The False Claims Act Revived an Unconstitutional Practice.

The early *qui tam* provisions fell into disuse before the antebellum period. During the Civil War, however, the country's resources were stretched to the breaking point, and Congress revived the concept by enacting the original FCA. *See United States v. McNinch*, 356 U.S. 595, 599 (1958).

Congress viewed aggressive enforcement as critical to funding the wartime emergency. So, it turned to the "unusual" practice of "authorizing private parties" to sue "on the Government's behalf." *Polansky*, 599 U.S.

at 423. In the legislature's view, allowing "any person" to sue "for the United States" and share in the proceeds, *see* Act of Mar. 2, 1863, ch. 67, § 4, 12 Stat. 696, 698, was the "most expeditious way" of enforcing the law, Cong. Globe, 37th Cong., 3d Sess. 956 (1863) (Sen. Howard). Congress therefore "let loose a posse of *ad hoc* deputies to uncover and prosecute frauds against the government." *Milam*, 961 F.2d at 49.

After the Civil War crisis receded, *qui tam* once again "fell into relative desuetude." Barr Memo 209. By 1986, though, Congress became "dissatisfied with the way the executive branch was enforcing government procurement laws." *Id.* And it sought to "check" the Executive's enforcement discretion with amendments designed to "encourage more private enforcement suits." S. Rep. No. 99-345, at 23-24, 26 (1986). This ushered in a new era of litigation, with *qui tam* actions surging more than a hundredfold. *Compare* U.S. Dep't of Justice, *Fraud Statistics—Overview* (Jan. 16, 2026), bit.ly/3LNm8yE, *with Zafirov*, 751 F. Supp. 3d at 1302 (citing pre-1986 statistics). Indeed, in every year since 1995, private relators have surpassed the Executive Branch as the primary executors of the statute. *See* Fraud Statistics, *supra*. The imbalance is now stark; relators brought over 75% of FCA cases this past year. *See id.*

This Court should grant certiorari to bury that unlawful and abusive practice for good. The sooner it does so the better. But if the Court concludes that a better vehicle for resolving this issue waits in the wings, *see* BIO.20-21, then it should at least hold this case for that resolution.

II. The Seventh Circuit's Distorted Scienter Standard Also Warrants Review.

The Court of Appeals also watered down the FCA's scienter standard in a way that will fuel further *qui tam* overreach. That statutory distortion separately warrants review. And it underscores the need for this Court's immediate intervention.

A. A Rigorous Scienter Standard is Critical for Cabining Punitive Liability.

Profit-driven relators naturally push the bounds of the FCA's "essentially punitive" regime. *Stevens*, 529 U.S. at 784. In recent years, they have increasingly brought claims challenging good-faith interpretations of complex regulations as fraud. The Seventh Circuit indulged that effort here. And allowing its decision to stand will arm *qui tam* relators with a new weapon for punishing all sorts of honest regulatory mistakes with crippling penalties.

The FCA forbids that expansive authority. Congress imposed liability only for "knowingly" submitting false claims to the government. 31 U.S.C. § 3729(a)(1)(A). And it carefully defined "knowingly," in turn, to mean that the defendant "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." *Id.* § 3729(b)(1)(A). "That three-part test largely tracks the traditional common-law scienter requirement for claims of fraud." *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 750 (2023).

This test requires a "culpable state of mind." *Id.* at 752 (citation omitted). That is, the FCA focuses on what the defendant "thought and believed." *Id.* at 751. And that subjective focus applies across all three parts of Congress's definition. "Actual knowledge" requires "aware[ness]" of a claim's falsity. *Id.* (citation omitted). "Deliberate ignorance" means that a person is "aware of a substantial risk that [his] statements are false, but intentionally avoid[s] taking steps to confirm" his suspicions. *Id.* And "reckless disregard" similarly "captures defendants who are conscious of a substantial and unjustifiable risk that their claims are false, but submit the claims anyway." *Id.*

Those requirements are rightly "rigorous." *Escobar*, 579 U.S. at 192. Congress demanded "strict enforcement" of the FCA's scienter element to avoid "open-ended liability" for regulatory infractions. *Id.* (quotation marks omitted). After all, "billing parties are often subject to thousands of complex statutory and regulatory provisions." *Id.* And the provisions for Medicare and Medicaid, in particular, are "among the most completely impenetrable texts within human experience." *Rehab. Ass'n of Va., Inc. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994). Congress thus knew that perfect compliance would be impossible. So it "made plain 'its intention that the [FCA] not punish honest mistakes or incorrect claims submitted through mere negligence.'" *United States ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co.*, 612 F.3d 724, 728 (4th Cir. 2010) (citation omitted). Not even "gross negligence" will suffice. *United States ex rel. Farmer v. City of Houston*, 523 F.3d 333, 338 (5th Cir. 2008). Congress sought only to punish *fraud* with treble damages and civil penalties.

The Court of Appeals lost sight of Congress's charge. Its scienter analysis was driven, not by Lilly's state of mind, but by the court's own interpretation of the "legal framework." Pet.App.20. And its interpretive endeavor was anything but straightforward. Over nearly a dozen pages, the court sifted through the text of "interlac[ed]" statutory, regulatory, and contractual provisions, imposed its view of what "makes sense," rejected Lilly's contrary interpretation based on "the statute's clear purpose," and noted the court's interpretive "divergence" from a unanimous Third Circuit panel. Pet.App.20-30. Then, the court held that "Lilly's objectively unreasonable interpretation" was "highly probative" of scienter—and that the *jury* could weigh the *legal* "unreasonableness of that view in finding scienter." Pet.App.38-39.

That was mistaken. The "objective reasonableness of [a] defendant's view of the law is a legal question" that is "not [for] the jury" to decide. *United States v. Prigmore*, 243 F.3d 1, 18 (1st Cir. 2001) (citing *Cheek v. United States*, 498 U.S. 192, 203 (1991)). Nor does anything in the FCA task juries with divining how a court might later construe the law. *Post hoc* judicial pronouncements of what the law objectively required thus cannot substitute for a defendant's "subjective beliefs" and "thought[s] when submitting the false claim." *Schutte*, 598 U.S. at 749, 752. To hold otherwise—as the Seventh Circuit did—would allow relators to punish businesses absent the "culpable state of mind" that Congress demanded. *Id.* at 752 (citation omitted).

The consequences of this position are dire. Relators are keenly aware that their mere allegations, regardless of merit, can "be used to extract settlements," Sean Elameto, *Guarding the Guardians: Accountability in Qui Tam Litigation Under the Civil False Claims Act*, 41 Pub. Contract L.J. 813, 824 (2012), because simply defending an FCA case requires a "tremendous expenditure of time and energy" and money, Todd J. Canni, *Who's Making False Claims, the* Qui Tam *Plaintiff or the Government Contractor?*, 37 Pub. Cont. L.J. 1, 11 & n.66 (2007). Indeed, companies in the "[p]harmaceutical, medical devices, and health care" industries alone "spend billions each year" dealing with FCA investigations. John T. Bentivoglio et al., *False Claims Act Investigations: Time for a New Approach?*, 3 Fin. Fraud L. Rep. 801, 801 (2011). And the Seventh Circuit's contortion of the FCA's scienter standard will only fan the flames in today's overbearing regulatory environment. Thousands of businesses, non-profits, and individuals now face protracted litigation—and potentially ruinous liability—any time a relator coins a theory that their interpretation of a complicated regulation or statute is better than the one the defendant embraced. That is not what Congress endorsed when it crafted the FCA.

B. A Rigorous Scienter Standard is Critical for Ensuring Fair Notice.

The problems with the Seventh Circuit's position go further still. "A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *FCC v. Fox TV Stations, Inc.*, 567 U.S. 239,

253 (2012). To that end, "[s]trict enforcement" of the FCA's scienter element "helps to ensure that innocent mistakes made in the absence of binding interpretive guidance are not converted into FCA liability, thereby avoiding the potential due process problems posed by 'penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule.'" *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 287 (D.C. Cir. 2015) (citation omitted).

This case places those problems in stark relief. Lilly carefully made reasonable assumptions about the law, including whether service fees paid *by* Lilly *to* drug wholesalers altered the "price paid to the manufacturer" by the wholesaler. 42 U.S.C. § 1396r-8(k)(1)(A); *see* Pet.9. The statute is "susceptible to multiple interpretations" in this regard. *United States ex rel. Streck v. Allergan, Inc.*, 746 F. App'x 101, 108 (3d Cir. 2018). And Lilly was always above board with its interpretation. The company repeatedly explained to the government its reasonable assumptions—in 2005, 2008, 2011, and 2013—and the government never raised any concerns. *See* Pet.10-11. On the contrary, the government described the approach used by Lilly and other pharmaceutical companies as "generally consistent with Federal requirements" after auditing those methodologies. Pet.App.43.

Imposing penalties in these circumstances raises serious due process concerns. Ambiguities abound in the law for any number of reasons. *See Kisor v. Wilkie*, 588 U.S. 558, 566 (2019). As a result, companies that do business with the government must regularly make interpretive choices. Those choices can be difficult. But when a company openly seeks to engage with

regulators and shares its interpretive choice, a later nine-figure judgment for fraud is in no way consistent with the Constitution's commitment to fair notice.

The government appears to recognize this too. In *Schutte*, it conceded that when defendants have "laid . . . out" their position to regulators, "there wouldn't [be] anything deceitful." Oral Arg. Tr. 36-37, No. 21-1326 (U.S. Apr. 18, 2023). Yet in this case, the government and relator collectively stand to extract nearly $200 million from a company that pled for clarity from the government, explicitly told the government what it was doing, and received no objection.

In short, the decision below creates an impossible bind. Companies cannot avoid complex and unclear regulatory schemes. The administrative state "wields vast power and touches almost every aspect of daily life," *Free Enter. Fund*, 561 U.S. at 499, and FCA liability spreads as far as the government's work. Here, the regulator refused to provide guidance and directed parties to make "reasonable assumptions" when faced with ambiguity. That is what Lilly did. But an unaccountable relator wielded the FCA's *qui tam* provisions to punish Lilly—on behalf of the government—for doing exactly what the government had instructed Lilly to do. That cannot be the law.

CONCLUSION

The Court should grant certiorari.

Respectfully submitted,

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