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 United States Court of Appeals for the Seventh Circuit

BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTERESTS OF AMICUS CURIAE[1]

Amicus curiae Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the country's leading biopharmaceutical research companies. PhRMA's members develop innovative medicines that transform lives and create a healthier world. PhRMA advocates in support of public policies to ensure patients can access and afford medicines that prevent, treat, and cure disease. PhRMA member companies have invested more than $850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States. PhRMA members produce medicines that are distributed to pharmacies and hospitals throughout the United States.

PhRMA has a strong interest in the petition for certiorari, and believes that certiorari is warranted on both questions presented. However, PhRMA has a special interest in the second question. It is increasingly common for private citizen relators, incentivized by the possibility of significant financial payout under the qui tam provisions of the False Claims Act (FCA), to offer an idiosyncratic interpretation of a federal law or regulation—one that has never been endorsed or articulated by the governing agency. In such a case, like this one, the relator (rarely joined by the government) claims

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[1] No counsel for a party authored this brief in whole or in part. No party, counsel for a party, or any person other than amicus and its counsel made a monetary contribution intended to fund the preparation or submission of this brief. Counsel of record for the parties received timely notice of PhRMA's intent to file this brief pursuant to this Court's Rule 37.2.

entitlement to the False Claims Act's "essentially punitive" regime of treble damages based on the relator's bespoke interpretation. *Vermont Agency of Nat. Res.* v. *United States ex rel. Stevens*, 529 U.S. 765, 784-785 (2000). Unfortunately, the Seventh Circuit's decision encourages this type of abuse of the Act while creating significant uncertainty for PhRMA's members, even when they act in good faith to implement exceedingly complex regulatory regimes like the drug pricing calculation at the heart of this case.

INTRODUCTION AND SUMMARY OF ARGUMENT

Drug manufacturers that provide drugs to Medicaid patients face a complex web of statutory, regulatory, and contractual obligations. The Centers for Medicare and Medicaid Services ("CMS") has opted to approach the inherent indeterminacy in that regulatory regime by creating more uncertainty.

Under the terms of 42 U.S.C. § 1396r-8, a manufacturer of certain outpatient drugs must enter into a Rebate Agreement with the United States Department of Health and Human Services ("HHS") to qualify for Medicaid coverage. In that Rebate Agreement, the government instructs drug manufacturers, when they encounter an absence of specific guidance, to make and act upon "reasonable assumptions" in calculating reported prices.

Relator Ronald Streck has endeavored to profit from this system by seeking massive FCA liability against manufacturers that complied with available guidance, made reasonable assumptions in calculating the "average manufacturer price"

("AMP") of each drug they manufacture, and reported their AMP prices to the government consistent with their genuinely held, reasonable assumptions—all because he thinks a different reasonable assumption about one component of a service fee would have been preferable. On this theory, Streck obtained a $183 million judgment in this case.

Amicus curiae PhRMA urges this Court to grant certiorari and reverse. The Seventh Circuit's decision misunderstands—and undermines—the FCA's scienter requirement. But that requirement is the crucial element of a FCA violation: it is what differentiates *fraudulent* conduct actionable under the statute from non-fraudulent, even if mistaken, conduct that is not actionable. Under the FCA, a person is liable to the United States government if he "*knowingly* presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1) (emphasis added).

Instead of giving the term "knowingly" any substance, the Seventh Circuit treated the FCA as something akin to a strict-liability statute, finding that Lilly had *knowingly* defrauded the government even though there was *no evidence* that anyone at Lilly ignored available guidance, harbored doubt about whether the company was calculating AMP in a manner consistent with that guidance, or acted in anything other than good faith. To the contrary, the evidence showed that Lilly had been forthcoming with the agency about the way it calculated AMPs for its drugs.

As Lilly's petition explains, the company carefully made reasonable assumptions, including about

whether service fees paid *by Lilly* to drug wholesalers constituted the "price paid *to* the manufacturer" by the wholesaler—the key terminology in the relevant statutory definition. 42 U.S.C. §1396r-8(k)(1)(A) (emphasis added). Lilly explained its reasonable assumptions and AMP methodology to the government—in 2005, in 2011, in 2013, and in 2016—and the government did not raise any concerns about Lilly's approach. *See* Pet. 10-11; Pet. App. 7-15. The government even went so far as to describe the approach used by Lilly and other pharmaceutical companies as "generally * * * consistent with Federal requirements" after auditing their methodologies. CA7 App. 415.

To find a "knowing" violation under these circumstances would empty the term of all meaning. This Court and federal courts of appeals other than the Seventh Circuit have recognized that a party's subjective belief is what matters for scienter; where a party genuinely understands the law to require certain conduct—based on a diligent investigation, a regulatory directive to use discretion, and no definitive statement by the government that it holds a different interpretation from the party's—the party has not knowingly committed fraud. *See United States ex rel. Schutte* v. *SuperValu Inc.*, 598 U.S. 739, 753 (2023) (explaining that where a defendant acts consistently with how it "had honestly read the [ambiguous] phrase," that is "a forgivable mistake" even if a relator or court later prefer a different interpretation). That is especially so when a party conveys its interpretation to its regulator, and the regulator is silent or endorses the interpretation as consistent with federal law. *See id.*

(explaining that official guidance is relevant to scienter).

The Seventh Circuit's approach undermines the critical role that scienter serves in cabining the reach of this punitive statute. "[C]oncerns about fair notice and open-ended liability" are mitigated by "strict enforcement" of the statute's "rigorous" scienter requirement. *Universal Health Servs., Inc.* v. *United States ex rel. Escobar*, 579 U.S. 176, 192 (2016). Absent certiorari and reversal, the Seventh Circuit's analysis raises the prospect of costly litigation, crippling treble damages and statutory penalties, and grave reputational harm against businesses and other regulated parties based on genuinely held, reasonable interpretations of any of the countless regulations or contract provisions to which government contractors, grantees, and federal program participants are routinely bound. 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.

ARGUMENT

I. CERTIORARI IS WARRANTED TO RESTORE THE PROPER BOUNDARIES OF SCIENTER UNDER THE FCA.

Relying on a genuinely held and diligently investigated interpretation of an ambiguous statute cannot count as scienter. That is especially so when a party conveys its interpretation to its regulator, and the regulator is silent or endorses the interpretation as consistent with federal law. This Court should correct the Seventh Circuit's erroneous

holding that the FCA sweeps in what are (at most) innocent, good-faith mistakes about the meaning of an ambiguous or undefined statutory, regulatory, or contractual obligation.

A. The Knowledge Element Requires Evidence Of A Culpable State of Mind.

Under the FCA, a person is liable to the United States government if he "*knowingly* presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1) (emphasis added). "Knowingly" is defined in the FCA to include actual knowledge or acting in deliberate ignorance or reckless disregard of the truth. *Id.* § 3729(b)(1)(A).

The FCA's definition of knowledge "largely tracks the traditional common-law scienter requirement for claims of fraud." *Schutte*, 598 U.S. at 750; *see also, e.g.*, *Escobar*, 579 U.S. at 187 n.2 (courts "presume that Congress retained all * * * elements of common-law fraud that are consistent with the statutory text because there are no textual indicia to the contrary"); *Safeco Ins. Co. of Am.* v. *Burr*, 551 U.S. 47, 58 (2007) (noting "the general rule that a common law term in a statute comes with a common law meaning").

Relying on that common law gloss, this Court has explained that the FCA's reference to "[a]ctual knowledge" means a person was actually "aware" of the falsity of the claim. *Schutte*, 598 U.S. at 751. "Deliberate ignorance" means that a person is "aware of a substantial risk that [its] statements are false, but intentionally avoid[s] taking steps to confirm the statement's truth or falsity." *Id.* And "reckless disregard" means that a person was

subjectively "conscious of a substantial and unjustifiable risk that [its] claims [were] false" and opted to "submit the claims anyway." *Id.*

In each of these ways of proving knowledge, liability turns on a determination of whether someone acted with a "culpable state of mind." *Id.* at 752 (citation omitted). Congress's decision to make "knowledge" a predicate for FCA liability is therefore significant. "Congress could not have intended" "to treat a defendant who merely adopts one [of multiple reasonable] interpretation[s] as a knowing or reckless violator," "whatever [the defendant's] subjective intent may have been." *Safeco*, 551 U.S. at 70 n.20.

Moreover, because the knowledge element polices the line between simple mistakes or errors and fraud, its enforcement must be "rigorous." *Escobar*, 579 U.S. at 192. "[E]stablishing 'even the loosest standard of knowledge, *i.e.*, acting 'in reckless disregard of the truth or falsity of the information,' is difficult when falsity turns on a disputed interpretive question." *United States ex rel. Purcell* v. *MWI Corp.*, 807 F.3d 287, 288 (D.C. Cir. 2015) (citation omitted).

B. No Knowing Fraud Exists Where A Party Acts On A Genuinely Held Interpretation Of An Impenetrable Federal Statutory Regime Directing Use Of Reasonable Assumptions.

A manufacturer cannot have the requisite scienter to violate the FCA when its allegedly false statement expresses a genuinely held understanding of a statutory or regulatory obligation, and the government has never interpreted the obligation to

require an alternative approach. That is because those circumstances negate the culpable state of mind that is key to the Act's scienter requirement.

This Court's recent decision in *Schutte* confirms this point. 598 U.S. 739. There, the Court held that a defendant may not rely on the mere fact that its actions represented an objectively reasonable interpretation of an ambiguous statute if the defendant nevertheless thought and believed that its claim was false. The Court reasoned that the scienter inquiry focuses "primarily on what [the defendants] thought and believed." *Id.* at 751. Where a defendant acts consistently with how it "had honestly read the phrase," that is "a forgivable mistake" even if a relator or court later prefer a different interpretation. *Id.* at 753.

The predicate described in *Schutte*—that the defendants submitted pricing information based on a statutory interpretation they believed to be, and had been informed was, incorrect—has no analogue in this case. The pharmacy-defendants there were obligated to report their "usual and customary" prices when submitting reimbursement claims to Medicare and Medicaid, which required deciding whether the price from membership discount programs or a non-discounted price was the usual and customary price. The Court acknowledged that the phrase "usual and customary" is one that "appears somewhat open to interpretation." *Id.* at 746. But given the procedural posture (summary judgment for the defendants on scienter), the Court assumed that the defendants in the case had been "informed that their lower, discounted prices were their 'usual and customary' prices" by state

Medicaid agencies; that the defendants "believed their discounted prices were their 'usual and customary' prices"; and that the defendants "tried to hide their discounted prices from regulators and contractors." *Id.*

This case, by contrast, is not about a *theoretically* available reasonable interpretation that a party does not genuinely hold. No knowing fraud has occurred where a pharmaceutical manufacturer subjectively believes that it has made reasonable assumptions in complying with ambiguous price reporting obligations, and its witnesses consistently testify that they consulted the relevant guidance and believed they were calculating reported prices consistent with that guidance. *See id.* at 753 (where a defendant acts consistently with how it "had honestly read the [ambiguous] phrase," that is "a forgivable mistake"); *see also, e.g.*, *United States ex rel. Ketroser* v. *Mayo Found.*, 729 F.3d 825, 831-832 (8th Cir. 2013) (a reasonable interpretation of ambiguous legal obligations "belies the scienter necessary to establish a claim of fraud under the FCA").

C. No Knowing Fraud Exists Where A Party Expressly Informs The Government About Its Interpretation And Hears No Objection.

The culpable state of mind covered by the FCA's scienter requirement is similarly lacking where a party has openly (and, as here, repeatedly) explained its interpretation of an ambiguous obligation to the government. The government's awareness of, and acquiescence in, a regulated

entity's interpretation precludes any finding of scienter. *See Schutte*, 598 U.S. at 754.

Lilly sought clarification from the government in 2005 about whether to include service fees in its AMP calculations, and memorialized its position in a follow-up letter to the agency. CA7 App. 228. Lilly received no objection. In 2011, Lilly again described in detail the approach it had taken over the years and asked CMS to inform Lilly if it disagreed. Lilly received no objection. CA7 App. 393-396. During a formal audit in 2013, Lilly again told the Inspector General how it treated the portion of service fees that Relator takes issue with. CA7 App. 400-404, 483. The audit report described Lilly's and other manufacturers' methodologies as "generally * * * consistent with Federal requirements." CA7 App. 415. For the fourth time, in 2016, Lilly came to CMS for clarification and explained its methodology, again without receiving any objection. CA7 App. 233, 489.

These facts are the antithesis of "knowingly" defrauding the government. Here, Lilly's communications with the government took place on multiple occasions for over a decade, and involved not just governmental *acquiescence* but governmental *approval*. That governmental approval should have made all the difference. Indeed, at oral argument in *Schutte*, the government conceded that where defendants "laid * * * out" their position to government regulators, "there wouldn't have been anything deceitful and there wouldn't have been any real danger that the [relevant agencies] would be deceived." Oral Argument Tr.

36:21-37:8, *United States ex rel. Schutte* v. *SuperValu Inc.*, No. 21-1326 (U.S. Apr. 18, 2023).

And in the opinion that followed, this Court reasoned that a sign directing drivers to "Drive Only Reasonable Speeds" could be "knowingly" violated if a driver had been told "earlier in the day by a police officer that speeds over 50 mph are unreasonable and then noticed that all the other cars around him are going only 48 mph." *Schutte*, 598 U.S. at 753. It follows that a driver who tells an officer that he is driving 55 mph, upon which the officer says nothing to discourage him (and even concludes that the driver's speed is reasonable), cannot have knowingly violated the statute. As *Schutte*'s hypothetical sign makes clear, although facial ambiguity does not "by itself" permit a party to avoid FCA liability where other evidence shows the party "actually knew what the phrase meant," governmental guidance regarding the ambiguity should be dispositive. *Id.* at 754.

Yet absent this Court's review, a company that explicitly told the government what it was doing multiple times and received not only no objection but also actual affirmance now faces nearly $200 million dollars of liability for embracing a reading of the law that several federal judges on other courts found reasonable, just because a relator persuaded three Seventh Circuit judges to see it differently. *See United States ex rel. Streck* v. *Allergan, Inc.*, 894 F. Supp. 2d 584, 600 (E.D. Pa. 2012), *aff'd*, 746 F. App'x 101, 103 (3d Cir. 2018).

Other courts of appeals agree that scienter under the Act is negated where a defendant has accurately described its approach to compliance to the

government. *See, e.g.*, *United States ex rel. Spay* v. *CVS Caremark Corp.*, 875 F.3d 746, 755 (3d Cir. 2017) ("[W]e join with our sister circuits and hold that the government's knowledge of the facts underlying an allegedly false record or statement can negate the scienter required for an FCA violation.") (citation and internal quotation marks omitted); *United States ex rel. Burlbaw* v. *Orenduff*, 548 F.3d 931, 954 (10th Cir. 2008) (acknowledging that it becomes difficult to infer scienter as "the depth of the government's knowledge of the facts underlying the allegedly false claim" grows); *United States ex rel. Becker* v. *Westinghouse Savannah River Co.*, 305 F.3d 284, 289 (4th Cir. 2002) ("[P]rior government knowledge of an allegedly false claim can negate the scienter required for an FCA violation."); *United States* v. *Southland Mgmt. Corp.*, 288 F.3d 665, 686 (5th Cir. 2002) (rejecting government knowledge defense but noting that such a defense would be viable where "the government approved and paid the claim with full knowledge of the relevant facts").

This Court should grant certiorari to ensure that the FCA's scienter element can continue to play the role Congress assigned it—*i.e.*, the role of limiting FCA liability to situations where a party acts with a culpable state of mind to submit false claims.

II. CERTIORARI IS WARRANTED BECAUSE OF THE IMPORTANCE OF THE ISSUES IN THIS CASE.

The Seventh Circuit's outlier approach is a dangerous one, especially for drug manufacturers. Allowing FCA liability to stand in this case would inject untenable uncertainty and chaos into the

daily routines of *amicus*'s members and other regulated entities as they seek in good faith to navigate complex regulatory regimes. The importance of this issue provides an additional reason for a grant of certiorari.

A. The Seventh Circuit's Scienter Standard Will Impose Significant Costs On American Businesses.

Under the Seventh Circuit's approach, anytime a court disagrees that a regulated entity correctly interpreted a requirement in a complex regulatory scheme, that judicial interpretation amounts to "highly probative circumstantial evidence" of knowing misconduct by the regulated party, even if other judges, other regulated entities, and even the regulator may see things differently. Pet. App. 38. And even where, as here, that divergence in interpreting the scope of the legal obligation is the sum total of evidence, a party can face hundreds of millions of dollars in liability for knowingly defrauding the government. That cannot be right.

Absent certiorari, the Seventh Circuit's decision raises the prospect of costly litigation, crippling statutory penalties, and grave reputational harm for regulated parties based on reasonable interpretations of any of the countless regulations and contract provisions to which government contractors, grantees, and federal program participants are routinely bound. As this Court has made clear before, it is imperative to address "concerns about fair notice and open-ended liability" in FCA actions through "strict enforcement" of the statute's "rigorous" scienter requirement. *Escobar*, 579 U.S. at 192.

1. A Rigorous Scienter Standard Disincentivizes Meritless Suits.

Many FCA claims lack merit. More than seventy percent of the 24,000 FCA actions filed since 1986 have been qui tam suits, U.S. Dep't of Justice, *Fraud Statistics - Overview: Oct. 1, 1986-Sept. 30, 2024*, at 3 (2025), https://www.justice.gov/archives/opa/media/1384546/dl, but the United States continues to decline to intervene in (or otherwise pursue) the majority of cases alleging fraud on HHS, *see id.* at 7. And the Department of Justice itself has admitted that it "declines to intervene in some cases due to the lack of legal or factual support." U.S. Dep't of Justice, *Acting Associate Attorney General Jesse Panuccio Delivers Remarks at the American Bar Association's 12th National Institute on the Civil False Claims Act and Qui Tam Enforcement* (June 14, 2018), https://www.justice.gov/opa/speech/acting-associate-attorney-general-jesse-pa nuccio-delivers-remarks-american-bar.

Yet the FCA's "essentially punitive" treble damages and statutory penalties loom large for any entity that receives federal funds. *Vermont Agency of Nat'l Res.*, 529 U.S. at 784. Businesses face the specter of treble damages and civil penalties that can exceed $28,000 per false claim, which quickly adds up in health-care matters involving thousands of claims. *See Civil Monetary Penalties Inflation Adjustment*, 89 Fed. Reg. 106,308, 106,310 (Dec. 30, 2024); 31 U.S.C. § 3729(a); 28 C.F.R. § 85.3(a)(9). And a finding of liability can result in suspension and debarment from government contracting, *see* 2 C.F.R. § 180.800, or exclusion from participation in federal healthcare programs, *see* 42 U.S.C. § 1320a-

7(b). Furthermore, mere allegations of having committed fraud on the government "can do great damage to a firm." *United States ex rel. Grenadyor* v. *Ukrainian Vill. Pharmacy, Inc.*, 772 F.3d 1102, 1105-08 (7th Cir. 2014).

And simply *defending* a FCA suit carries tremendous cost, as suits often take years to resolve. *See* Ralph C. Mayrell, *Digging Into FCA Stats: In-House Litigation Budget Insights*, Law360 (July 13, 2021), https://bit.ly/3hUp89K. And "extensive discovery and disruption in a lawsuit could allow plaintiffs with weak claims to extort settlements from innocent companies." *Stoneridge Inv. Partners* v. *Scientific-Atlanta*, 552 U.S. 148, 149 (2008); *see also Texas Dep't of Hous. & Cmty. Affairs* v. *Inclusive Cmtys. Project, Inc.*, 576 U.S. 519, 587 (2015) (Alito, J., dissenting) (Even where a defendant "believes it is likely to prevail if [a suit] is fully litigated, the costs of litigation, including the expense of discovery and experts, may push cost-conscious defendants to settle even anemic cases. Defendants may feel compelled to abandon substantial defenses and pay settlements in order to avoid the expense and risk of going to trial." (internal citations, quotation marks, and alteration omitted)).

For example, in one recent case involving a defense contract, the defendant "produced over two million pages of documents" before the relator's claims were dismissed on summary judgment nine years after the relator filed the suit. *United States ex rel. McBride* v. *Halliburton Co.*, 848 F.3d 1027, 1029-30 (D.C. Cir. 2017); *see also United States ex rel. Barko* v. *Halliburton Co.*, 954 F.3d 307, 309 (D.C. Cir. 2020) (describing qui tam discovery that included 64

document requests and more than 2.4 million pages of potentially responsive documents). In another, after the case dragged on for a decade, it was dismissed for relator misconduct after years of discovery. *United States ex rel. Nargol* v. *DePuy Orthopaedics, Inc.*, No. CV 1:12-10896, 2021 WL 5831626, at *12 (D. Mass. Dec. 8, 2021), *aff'd*, 69 F.4th 1 (1st Cir. 2023). In yet another, a declined qui tam action was filed in 2010, and even though the defendant vaccine manufacturer won at the summary judgment stage, litigation between the parties over the FCA and related antitrust claims only ended in 2025, when this Court denied certiorari. *See United States ex rel. Krahling* v. *Merck & Co.*, No. CV 10-4374, 2023 WL 8367939, at *1, *8 (E.D. Pa. July 27, 2023), *aff'd*, No. 23-2553, 2024 WL 3664648 (3d Cir. Aug. 6, 2024); *Chatom Primary Care, P.C.* v. *Merck & Co.*, 146 S. Ct. 325 (2025).

As a result, FCA litigation often forces defendants to settle even spurious claims, to avoid burdensome discovery and the risk of disastrous treble damages and penalties. Would-be relators are keenly aware that allegations alone can "compel settlements on unjust terms." *United States ex rel. Jehl* v. *GGNSC Southaven, LLC*, No. 3:19-cv-00091, 2021 WL 2815974, at *4 (N.D. Miss. July 6, 2021); *see also, e.g.*, *United States* v. *Magnolia Reg'l Health Servs., Inc.*, No. 1:20CV025-MPM-DAS, 2024 WL 3626716, at *12 (N.D. Miss. Aug. 1, 2024) (noting "that qui tam actions have a serious potential to be abused by profit-seeking plaintiffs").

Proper application of the scienter requirement helps ensure that the FCA actually protects the

government against fraud, instead of incentivizing meritless lawsuits. Absent certiorari, the Seventh Circuit's decision will have severe consequences: regulated parties will face protracted litigation and potential liability anytime a relator articulates an alternative to a defendant's interpretation, even where the relator had neither evidence that the defendant adopted its interpretation with a culpable mind nor any indication from the government that its interpretation was incorrect.

2. A Rigorous Scienter Standard Ensures FCA Liability Meets Constitutional Requirements.

"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 Television Stations*, 567 U.S. 239, 253 (2012).

Under this fair notice principle, if the government expects regulated entities to adhere to a particular interpretation of a regulation, then it must first make that interpretation clear. As then-Judge Scalia explained, "[i]f a violation of a regulation subjects private parties to * * * civil sanctions, a regulation cannot be construed to mean what an agency intended but did not adequately express." *Gates & Fox Co.* v. *OSHRC*, 790 F.2d 154, 156 (D.C. Cir. 1986); *see also, e.g.*, *Purcell*, 807 F.3d at 287 (Fundamental notions of due process prohibit "penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule.") (quoting *Satellite Broad. Co.* v. *FCC*, 824 F.2d 1, 3 (D.C. Cir. 1987)).

That principle is especially important where, as here, defendants are faced with "damages that are essentially punitive in nature." *Vermont Agency of Nat'l Res.*, 529 U.S. at 784. If a defendant is found liable, they face "treble damages plus civil penalties of up to $[28,619] per false claim," not to mention the possibility of attorneys' fees and costs. *Escobar*, 579 U.S. at 182; *see* 31 U.S.C. §§ 3729(a), 3730(d)(4), (g); 89 Fed. Reg. at 106,310 (setting current per-claim penalty amount).[2] Worse, "private relators may not represent the interests of the United States in litigation," creating the risk that this punishment could be imposed even where it does not align with "the United States' interests." *United States ex rel. Polansky* v. *Exec. Health Res., Inc.*, 599 U.S. 419, 449-450 (2023) (Thomas, J., dissenting); *see also Hughes Aircraft Co.* v. *United States ex rel. Schumer*, 520 U.S. 939, 949 (1997) (noting that "*qui tam* relators" differ from government actors in that "[t]hey are motivated primarily by prospects of monetary reward rather than the public good").

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[2] The FCA's steep civil penalties and essentially punitive nature mirror its companion criminal statute. *Compare* 31 U.S.C. § 3729(a)(1)(A) (imposing liability for "knowingly present[ing]" a false claim (emphasis added)), *with* 18 U.S.C. § 287 (prohibiting the making of a false claim while "knowing such claim to be false" (emphasis added)); *see also United States ex rel. Marcus* v. *Hess*, 317 U.S. 537, 542 (1943) (FCA civil and criminal provisions are construed together). These provisions were originally enacted as part of the same statute, with the same standard for liability, *see* Act of March 2, 1863, ch. 67, 12 Stat. 696, 696-698, though they were later separated through codification, *see Rainwater* v. *United States*, 356 U.S. 590, 592 n.8 (1958).

Indeed, "concerns about fair notice and open-ended liability" prompted the Supreme Court to demand the "strict enforcement" of the FCA's "rigorous" scienter requirement. *Escobar*, 579 U.S. at 192. Absent such "strict enforcement," courts will transform the FCA into "a vehicle for punishing * * * regulatory violations" and negligence. *Id.* at 194; *see also, e.g.*, *United States ex rel. Sheldon* v. *Allergan Sales, LLC*, 24 F.4th 340, 350 (4th Cir. 2022) (Wilkinson, J.), *vacated on reh'g en banc and aff'd by an equally divided court,* 49 F.4th 873 (4th Cir. 2022) (en banc) (suggesting it is "profoundly troubling to impose such massive liability on individuals or companies without any proper notice as to what is required"). That is not the statute Congress enacted, and courts should interpret the FCA to avoid rather than invite a constitutional challenge.

Yet under the Seventh Circuit's decision, a company could be liable for treble damages whenever it is forced to make an honest assessment about an unclear legal requirement, even though the government told the company to "make reasonable assumptions" when faced with ambiguity. It is hard to imagine a starker example of unfair notice.

3. A Rigorous Scienter Standard Encourages Good Government Practices.

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* v. *Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 499 (2010). And ambiguities exist in regulations for a variety of reasons—from imprecise language to new

applications of an existing law to unexpected consequences. *See Kisor* v. *Wilkie*, 139 S. Ct. 2400, 2410 (2019).

Forgiving agency ambiguity "creates a risk that agencies will promulgate vague and open-ended regulations that they can later interpret as they see fit." *Christopher* v. *SmithKline Beecham Corp.*, 567 U.S. 142, 158 (2012). "It is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance or else be held liable when the agency announces its interpretations for the first time." *Id.* at 158-159. In other words, agencies cannot say one thing up front—"use your judgment"—only to have a relator later argue that a different judgment call would have been somehow "better." A rigorous understanding of the FCA's scienter standard encourages good government practices by requiring agencies to specify when there is a particular approach that regulated entities must follow.

A basic problem with the Seventh Circuit's decision is that it fails to acknowledge that the United States wears two hats in FCA cases: On the one hand, the government is the entity telling companies to make reasonable assumptions *and* on the other hand, the government stands to benefit from damages awards if a relator succeeds in asserting that a company's reasonable assumptions make it a fraudster. *See* 31 U.S.C. § 3730(d). That means the government can refuse to clarify the meaning of a statute, and then benefit to the tune of *hundreds of millions of dollars* when manufacturers

do their best to comply with unclear obligations and incomplete agency directions. *See Niz-Chavez* v. *Garland*, 593 U.S. 155, 171 (2021) ("If men must turn square corners when they deal with the government, it cannot be too much to expect the government to turn square corners when it deals with them."). That fact pattern is not fraud on the government.

B. Drug Manufacturers Are Particularly Vulnerable To Expanded FCA Liability If The Scienter Standard Is Toothless.

The FCA applies to a broad cross-section of businesses, non-profits, government entities, and individuals.[3] And because of the size and scope of the

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[3] *See, e.g.*, *United States ex rel. Vermont Nat'l Tel. Co.* v. *Northstar Wireless, LLC*, 34 F.4th 29 (D.C. Cir. 2022) (telecommunications services); *United States ex rel. Schweizer* v. *Canon, Inc.*, 9 F.4th 269 (5th Cir. 2021) (photocopiers and office printers); *United States ex rel. Tzac, Inc.* v. *Christian Aid*, No. 1:17-cv-4134, 2021 WL 2354985 (S.D.N.Y. June 9, 2021) (charitable aid organization); *United States* v. *Sanford-Brown, Ltd.*, 840 F.3d 445 (7th Cir. 2016) (higher education); *United States ex rel. Steury* v. *Cardinal Health, Inc.*, 735 F.3d 202 (5th Cir. 2013) (medical manufacturing); *United States ex rel. Anti-Discrimination Ctr. of Metro N.Y., Inc.* v. *Westchester County*, 712 F.3d 761 (2d Cir. 2013) (housing); *United States ex rel. Lemmon* v. *Envirocare of Utah, Inc.*, 614 F.3d 1163 (10th Cir. 2010) (waste disposal); *United States* v. *Sci. Applications Int'l Corp.*, 626 F.3d 1257 (D.C. Cir. 2010) (consulting); *United States ex rel. Pritzker* v. *Sodexho, Inc.*, 364 F. App'x 787 (3d Cir. 2010) (public school lunches); *Mikes* v. *Straus*, 274 F.3d 687 (2d Cir. 2001) (healthcare); *United States ex rel. Shemesh* v. *CA, Inc.*, No. 1:09-cv-1600, 2015 WL 1446547 (D.D.C. Mar. 31, 2015) (software development); *United States ex rel. Bias* v. *Tangipahoa Parish Sch. Bd.*, 86 F. Supp. 3d 535 (E.D. La. 2015) (public school ROTC programs); *United States ex rel.*

administrative state, regulated entities are routinely faced with the need to make difficult judgment calls about legal requirements. The contractual and regulatory schemes that regulated entities routinely face when they assist the government in implementing programs—as contractors, grantees, or simply as program participants—can be a tangle of opaque provisions that interact in unpredictable ways. Those legal regimes are at a minimum "complex," *United States ex rel. Vigil* v. *Nelnet, Inc.*, 639 F.3d 791, 799 (8th Cir. 2011), if not "almost unintelligible," *Schweiker* v. *Gray Panthers*, 453 U.S. 34, 43 (1981).

But the Seventh Circuit's approach is particularly problematic for drug manufacturers given how pervasive reasonable assumptions are in the Medicaid reimbursement scheme. HHS itself noted that "the use of reasonable assumptions is common practice" among pharmaceutical manufacturers and that "nearly two-thirds reported wanting additional guidance from CMS on assumptions-related issues." HHS Office of Inspector General, *Reasonable Assumptions in Manufacturer Reporting of AMPs and Best Prices* (2019), https://perma.cc/C3ES-MXM2. In price reporting specifically, the

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Bilotta v. *Novartis Pharm. Corp.*, 50 F. Supp. 3d 497 (S.D.N.Y. 2014) (pharmaceutical manufacturing); *United States* v. *Americus Mortg. Corp.*, No. 4:12-cv-02676, 2014 WL 4273884 (S.D. Tex. Aug. 29, 2014) (mortgage lending); *United States ex rel. McLain* v. *Fluor Enters., Inc.*, 60 F. Supp. 3d 705 (E.D. La. 2014) (disaster relief construction); *United States ex rel. Landis* v. *Tailwind Sports Corp.*, 51 F. Supp. 3d 9 (D.D.C. 2014) (athletic sponsorship); *United States ex rel. Koch* v. *Koch Indus., Inc.*, 57 F. Supp. 2d 1122 (N.D. Okla. 1999) (crude oil purchasing).

government recognizes that "manufacturers may find it difficult to determine how to treat certain sales practices when calculating prices," given the limited guidance and "the complexities of sales practices in the pharmaceutical industry." *Id.* at 3-4.

And yet, FCA suits disproportionately target healthcare entities. Of the 1,402 new FCA matters filed in 2024, for example, 455 alleged fraud against HHS. *See* U.S. Dep't of Justice, *Fraud Statistics*, *supra*, at 2, 6. And more than half of the settlements and judgments in qui tam suits in 2024 involved the health care industry. *See id.* at 2, 6; *see also* U.S. Dep't of Justice, *Press Release: False Claims Act Settlements and Judgments Exceed $2.9B in Fiscal Year 2024* (Jan. 15, 2025), https://www.justice.gov/archives/opa/pr/false-claims-act-settlements-and-judgments-exceed-29b-fiscal-year-2024 (noting that "[i]n fiscal year 2024, health care fraud remained a leading source of False Claims Act settlements and judgments," and "[a]s in years past, the act was used to pursue matters involving a wide array of health care providers, goods, and services").

This Court should grant review to cabin application of FCA liability to the ordinary meaning of "fraud." CMS is hardly deceived by the fact that manufacturers rely on reasonable assumptions to navigate the best price statute; doing so is CMS's directive in the first place. And there is no reason to permit the United States to recover money through FCA litigation (whether prosecuted by a qui tam relator or the Department of Justice) based on conduct the government actively encouraged.

Certiorari is necessary to make this clear to all regulated parties—and the government itself.

CONCLUSION

For the foregoing reasons and those in the petition, this Court should grant certiorari and reverse the judgment of the United States Court of Appeals for the Seventh Circuit.

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