No. 23-2134

IN THE

United States Court of Appeals for the Seventh Circuit

UNITED STATES OF AMERICA, et al., *ex rel.* RONALD J. STRECK,

Plaintiff-Appellee,

v.

ELI LILLY AND COMPANY,

Defendant-Appellant,

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

BRIEF OF *AMICI CURIAE* THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, NATIONAL ASSOCIATION OF MANUFACTURERS, AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF DEFENDANT-APPELLANT AND REVERSAL

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the Chamber of Commerce of the United States of America states that it is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the Chamber. Pharmaceutical Research and Manufacturers of America states that it has no parent corporation and no corporation or publicly held company has a 10% or greater ownership interest in it. The National Association of Manufacturers states it has no parent corporation and no publicly held company has a 10% or greater ownership interest in it.

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STATEMENT OF INTEREST[1]

Pursuant to Federal Rule of Appellate Procedure 29, the Chamber of Commerce of the United States of America (the "Chamber"), National Association of Manufacturers ("NAM"), and Pharmaceutical Research and Manufacturers of America ("PhRMA") submit this brief as *amici curiae* in support of defendant-appellant and reversal.

The Chamber is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than 3 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.

The NAM is the largest manufacturing association in the United States, representing small and large manufacturers in all 50 states and in every industrial sector. Manufacturing employs 13 million men and women, contributes $2.9 trillion

[1] No counsel for any party authored this brief in whole or in part and no entity or person, aside from *amici curiae*, their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief. Counsel for Appellant consents to the filing of this brief. Because counsel for Appellee does not consent, *amici* have filed a motion for leave to file the brief.

to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for over half of all private-sector research and development in the nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Over the last decade, PhRMA member companies have more than doubled their annual investment in the search for new treatments and cures, including nearly $101 billion in 2022 alone. PhRMA's mission is to advocate public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates in such cases as an *amicus curiae*.

Amici have a strong interest in the questions presented here, which are fundamental to the proper scope of the False Claims Act ("FCA"). *Amici*'s members must navigate complex and detailed regulatory schemes on a daily basis, often in the face of opaque direction and no explicit guidance from the agency involved. The District Court's decision deviates from established precedent on the falsity, materiality, and scienter elements of a claim under the Act and eviscerates crucial

guardrails that, by design, ensure that only defendants who knowingly defraud the government are subject to the FCA's "essentially punitive" regime of treble damages and statutory penalties. *Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 784 (2000). By failing to correctly apply these guardrails, decisions like the judgment below threaten *amici*'s members and other regulated parties with unavoidable punishment even when they act reasonably, in good faith, and without fair notice of supposed proscriptions on their conduct.

Imposing FCA liability where a defendant subjectively believes that it is in compliance, consistent with an objectively reasonable interpretation of an ambiguous statutory or regulatory provision, would convert the Act from a fraud prevention statute into something else entirely. That sort of radical expansion of liability under the Act is of particular concern to *amici* and their members, especially in a situation—like this one—where the regulated entity has expressly and repeatedly told its regulator *how* the entity understands its obligations and *what* the entity is doing to meet those obligations—and the regulator raised no concerns in response and even described the entity's methodology as "generally consistent with Federal requirements." DX-125 at 4.

Affirming the judgment here would have far reaching consequences for *amici*'s members, and for the myriad of industries, businesses, non-profit organizations, and even municipalities that receive funds through federal programs

or provide goods and services that are paid for by the government. Interpretations cannot be *false or fraudulent*, nor are they *knowingly* so, when an entity considers the relevant guidance; genuinely holds an objectively reasonable understanding of its obligations; and conveys that understanding to the government. The judgment here should be reversed.

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 in an unusual way. Under the terms of 42 U.S.C. § 1396r-8 (the "Rebate Statute"), 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 unclear regulatory obligations, to make and act upon "reasonable assumptions" about how those ambiguous statutes and regulations apply.

Relator Ronald Streck has endeavored to profit from this system by seeking massive FCA liability against manufacturers that studied available guidance, made reasonable assumptions in submitting their AMP calculations, and reported prices consistent with those 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, Relator obtained a $183 million judgment in this case.

Amici urge the Court to reverse and submit this brief to address two aspects of the District Court's decision, each of which threaten to radically expand the FCA to reach businesses that, like Eli Lilly and Company ("Lilly"), make good-faith efforts to comply with ambiguous regulatory requirements. *First*, in granting summary judgment to the Relator on falsity, the District Court ignored the well-established principle that the FCA is a fraud prevention statute that punishes only "'objective falsehood[s],'" *U.S. ex rel. Yannacopoulos v. Gen. Dynamics*, 652 F.3d 818, 836 (7th Cir. 2011), not reasonable assumptions with which a court later disagrees. Because the relevant requirements did not foreclose Lilly's interpretation about how to calculate AMP—as both the Eastern District of Pennsylvania and the Third Circuit concluded, *U.S. ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584, 600 (E.D. Pa. 2012), *aff'd*, 746 F. App'x 101 (3d Cir. 2018)—the District Court's view that the Relator had a better interpretation is not sufficient to open the door to FCA liability. And it is improper to evaluate a company's *prior* reasonable assumptions based on *later* promulgated regulations, which is what happened here.

Second, in denying Lilly's request for post-judgment relief on scienter, the District Court applied the FCA as something akin to a strict-liability statute. The

court found 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 brief explains, the company carefully made reasonable assumptions, including 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). 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. The HHS Office of Inspector General 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. DX-125.

The Supreme Court's decision last year in *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739 (2023), further confirms that there was no "knowing" violation here. The Supreme 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." *Id.* at 753 (emphasis added). 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.

Finding a "knowing" violation under these circumstances is not only contrary to FCA precedent, but it ignores the critical role that scienter serves in cabining the reach of this punitive statute. As the Supreme Court recognized in *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016) ("*Escobar*"), "concerns about fair notice and open-ended liability" are mitigated by "strict enforcement" of the statute's "rigorous" scienter requirement. *Id.* at 192. Under the statute, "knowingly" means a person actually knew the truth, or acted in deliberate ignorance or reckless disregard thereof. 31 U.S.C. § 3729(b)(1)(A)(i-iii). No court has ever held that this language reaches honest mistakes—which is at most what the facts could support here. And when a regulated entity has informed the regulator (and in this case, repeatedly) about the assumptions it is making in complying with an obligation, and the regulator has not objected to that approach, no reasonable finder of fact can conclude that the entity has *knowingly* defrauded the government.[2]

[2] For similar reasons, and as Lilly explains, the government's failure to act after Lilly disclosed its methodology and reasonable assumptions should have precluded

Absent reversal, the decision below 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 *amici*'s members and other regulated entities as they seek in good faith to navigate complex regulatory regimes.

ARGUMENT

I. A Finding Of Falsity For Purposes Of FCA Liability Requires An Objective Falsehood.

As this Court has long held, to be false or fraudulent, a claim must contain an "objective falsehood." *Yannacopoulos*, 652 F.3d at 836. Because the FCA is "a fraud prevention statute," the FCA targets "lies to the government." *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999). Where a party's legal obligations are "not exactly clear" due to ambiguity in the governing legal instrument, that is "precisely the sort of claim that courts have determined not to be

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a finding of materiality. Those facts show that the government did not "attach importance" to Lilly's failure to use the approach Relator says should have been used. *Escobar*, 579 U.S. at 193. *Amici* support Lilly's arguments that Relator's claims accordingly should have failed as a matter of law under the FCA's materiality prong as well. *See* Lilly Br. 55-66.

a false statement under the FCA." *U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 377 (4th Cir. 2008). The statute's falsity requirement is therefore not met merely because a relator or a court thinks one interpretation among reasonable ones is better than another. *U.S. ex rel. Hopper v. Anton*, 91 F.3d 1261, 1267 (9th Cir. 1996) ("For a certified statement to be 'false' under the Act, it must be an intentional, palpable lie. Innocent mistakes, mere negligent misrepresentations and differences in interpretations are not false certifications under the Act.") (internal citation omitted); *cf. United States v. Harra*, 985 F.3d 196, 215 (3d Cir. 2021) (in false statements prosecution, concluding that ambiguity of reporting obligation is relevant to both scienter and falsity; "ambiguity is relevant to falsity in its own right").

The District Court paid lip service to this Court's precedent requiring an objective falsehood, but did not enforce it. The court granted summary judgment *against Lilly* on falsity, even as it pointed to no evidence of facts or circumstances demonstrating that Lilly's reporting was objectively false or that Lilly did anything other than reach an interpretation different from the one the Relator and court found most persuasive. Nor did the District Court address the Third Circuit's decision finding that the same interpretation Lilly held was reasonable. Satisfying the objectively-false requirement requires more. The Relator had to prove—as a matter

of law—that Lilly's reasonable assumptions were in fact *un*reasonable based on the facts and circumstances at the time those assumptions were made.

Requiring an objective falsehood before imposing FCA liability is critically important to entities that do business with the government. That requirement avoids subjecting those entities to potentially crippling liability anytime—and every time—a company must make a judgment call, interpret a disputed legal question, or act in the absence of a clear obligation. *Lamers*, 168 F.3d at 1018. Businesses increasingly find themselves faced with those choices in today's regulatory environment, and in this case, the rebate regime makes those choices unavoidable. Indeed, the HHS Office of Inspector General itself has 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://oig.hhs.gov/oei/reports/oei-12-17-00130.pdf ("OIG Report"). In situations like these, imposing FCA liability would improperly extend the statute far from its *fraud* bearings.

This Court should therefore make clear that when a relator's position reflects one possible interpretation but not necessarily the *only* reasonable interpretation given available guidance, the falsity element of a FCA claim is not satisfied. The Eastern District of Pennsylvania and the Third Circuit have already held that Lilly's

interpretation is reasonable, in a case this same Relator filed against Lilly and other pharmaceutical companies, making the same arguments about the same AMP methodology shortcoming that he alleged again here. As the Third Circuit explained, "while the statute could be interpreted to include price-appreciation credits in the AMP calculation, the statute is—as the District Court observed—susceptible to multiple interpretations, one of which excludes the price-appreciation credits." *Streck*, 746 F. App'x at 108; *see also Streck*, 894 F. Supp. 2d at 600. And, on top of the statutory ambiguity, "the available scattershot guidance failed to articulate a coherent position on AMP and, specifically, price-appreciation credits." *Streck*, 746 F. App'x at 108. This case should have ended for the same reason.

Requiring an objective falsehood also encourages good government practices by requiring agencies to specify when there is, in fact, a particular approach that the agency concludes regulated entities must follow. It similarly protects the regulated public by ensuring that there are clear directions, announced in advance, providing guidance about where regulated entities do and do not have discretion about how to execute a statutory, regulatory, or contractual obligation. It is a matter of first principles and fair notice that an agency must clearly communicate its policies *before* a private party can be sanctioned with treble damages and statutory penalties for violating them. *See Harra*, 985 F.3d at 212 (explaining the "fundamental principle" of our legal system "that laws which regulate persons or entities must give fair notice

of conduct that is forbidden or required") (quoting *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012)); *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156 (2012) ("[A]gencies should provide regulated parties fair warning of the conduct a regulation prohibits or requires.") (cleaned up) (quoting *Gates & Fox Co. v. Occupational Safety and Health Review Comm'n*, 790 F.2d 154, 156 (D.C. Cir. 1986) (Scalia, J.)). 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."

If upheld, the approach that the court took below would open the doors to expansive FCA liability, as well as considerable financial and reputational costs, for an array of ambiguous and unsettled statutory, regulatory, or contractual requirements. The risk of crippling treble damages and statutory penalties may also force many businesses to settle even meritless cases out of concern a court, or a jury, might prefer a different choice from the available reasonable interpretations of ambiguous obligations. Given Lilly's genuinely held reasonable assumptions, reversal for lack of falsity is warranted here.

II. Rigorous Enforcement Of The Scienter Requirement Is Critically Important To Cabin Expansive False Claims Act Liability And Ensure Fair Notice.

Relying on a genuinely held, objectively reasonable, and diligently investigated interpretation of an ambiguous statute cannot count as scienter. All the

more 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 not endorse the radical view 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.

Knowingly is defined in the FCA to include actual knowledge or acting in deliberate ignorance or reckless disregard of the truth. 31 U.S.C. § 3729(b)(1)(A). This definition "largely tracks the traditional common-law scienter requirement for claims of fraud." *U.S. ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 750 (2023). "Actual knowledge" means a person was actually "aware" of the falsity of the claim. *Id.* 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.* (emphasis added).

In *Escobar*, the Supreme Court reinforced that the scienter requirement is "rigorous" and demands "strict enforcement" precisely because this element protects against "concerns about fair notice and open-ended liability." 579 U.S. at 192. Following *Escobar*, this Court has hewed to the Supreme Court's admonition to strictly enforce scienter. It has recognized that scienter marks the dividing line

between regulatory error or negligence, on the one hand, and fraud, on the other. *U.S. ex rel. Berkowitz v. Automation Aids, Inc.*, 896 F.3d 834, 842 (7th Cir. 2018) (relator's allegations were insufficient as to scienter because "[a]t most," they "amount to claims that the defendants made mistakes or were negligent"). By so doing, this Court has ensured that regulated parties receive the minimal fair notice that constitutional due process requires before ambiguous obligations are enforced using severe, punitive fraud liability. Only where the evidence shows a defendant "had actual knowledge" that it was required to act in a particular way, "or otherwise ignored or disregarded" such an obligation, is the scienter element satisfied. *U.S. ex rel. Fowler v. Caremark RX, L.L.C.*, 496 F.3d 730, 743 (7th Cir. 2007), *overruled on other grounds by Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907 (7th Cir. 2009).

A. A Party's Genuinely Held And Objectively Reasonable Interpretation Of An Ambiguous Obligation Cuts Against A Finding Of Scienter.

A manufacturer cannot have the requisite scienter for an FCA claim when the manufacturer's allegedly false statement is based on a genuinely held and objectively reasonable interpretation of an ambiguous statutory or regulatory obligation. That is because those circumstances negate the "culpable state of mind" that is key to the Act's scienter requirement. *See U.S. ex rel. Kraemer v. United Dairies, L.L.P.*, 82 F.4th 595, 605-606 (8th Cir. 2023).

The Supreme Court's recent decision in *Schutte* confirms this point. There, the Supreme 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 in situations of ambiguity, the scienter inquiry focuses "primarily on what [the defendants] thought and believed." *Id.* at 751. But 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. *Id.* at 753; *accord Hindo v. Univ. of Health Scis./The Chicago Med. Sch.*, 65 F.3d 608, 613 (7th Cir. 1995) ("Innocent mistakes or negligence are not actionable under" the FCA.).

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 Supreme Court acknowledged that the phrase "usual and customary" is one that "appears somewhat open to interpretation." 598 U.S. 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—as a matter of law—where a pharmaceutical manufacturer has no actual knowledge that there was anything unreasonable about the assumptions it made 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 U.S. 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").

Since *Schutte*, the Fifth and Eighth Circuits have confirmed that reasonableness remains important to determining scienter. *See Kraemer*, 82 F.4th at 606 (no scienter where "[d]efendants' interpretation of the ambiguous" regulatory document "was objectively reasonable"); *United States v. Corp. Mgmt., Inc.*, 78 F.4th 727, 740 (5th Cir. 2023) (finding scienter where defendants' "interpretation of

[the regulations] was not reasonable"). As *Schutte*'s hypothetical about the "Drive Only Reasonable Speeds" sign makes clear, 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" or was "aware of an unjustifiably high risk" the phrase carried a particular meaning. *Schutte*, 598 U.S. at 754. But where there is no such evidence—leaving only facial ambiguity coupled with a manufacturer's reasonable and genuinely held belief that its assumptions were appropriate in light of the (scattershot) available guidance—there should be no scienter under the Act as a matter of law.

B. No Knowing Fraud Exists Where A Party Expressly Informs The Government About Its Interpretation And Approach To Compliance And Receives No Objection Or A Positive Assurance Of Its Legality.

The "culpable state of mind" covered by the FCA's scienter requirement is similarly lacking as a matter of law 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. The District Court should have granted Lilly judgment as a matter of law on this basis.

Lilly sought clarification from the agency Inspector General in 2005 about whether to include service fees in its AMP calculations, and memorialized its position in a follow-up letter to the agency. Lilly Br. 25-26. 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. Lilly Br. 26. 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. Lilly Br. 27. The audit report described Lilly's and other manufacturers' methodologies as "generally consistent with Federal Requirements." DX-125 at 4. For the fourth time, in 2016, Lilly came to CMS for clarification and explained its methodology, again without receiving any objection. Lilly Br. 27-28.

These facts are the antithesis of "knowingly" defrauding the government. This Court has long recognized that "[i]f the government knows and approves of the particulars of a claim . . ., the presenter cannot be said to have knowingly presented a fraudulent or false claim." *U.S. ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542, 545 (7th Cir. 1999). Other appeals courts likewise agree that scienter under the Act is negated where a defendant has described its approach to compliance to the government accurately and directly. *See, e.g.*, *U.S. ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 954 (10th Cir. 2008) (inference of no scienter becomes stronger as "the depth of the government's knowledge of the facts underlying the allegedly false claim" grows); *U.S. ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d

284, 289 (4th Cir. 2002) (collecting cases).[3] Here, Lilly's communications with the government took place multiple times for *over a decade*, and involved not just governmental acquiescence but approval.

Finding a party liable under the FCA for knowing fraud in these circumstances raises serious due process concerns. 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). As a result, companies that do business with the government are regularly required to make difficult interpretive choices. And when they openly seek to engage with the regulator to share in detail their interpretive choice, a later judgment of $183 million is in no way consistent with fair notice and avoiding open-ended liability. As *Escobar* said, the scienter element must be rigorously enforced to mitigate concerns about those issues. 579 U.S. at 192.

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, *U.S. ex rel. Schutte v.*

[3] These cases involve "false claims," as opposed to "reverse false claims." But the rationale applies equally in both contexts: Companies cannot be found to have committed "fraud" on the government when they have explicitly told the government what they are doing and received no objection.

SuperValu, Inc., No. 21-1326 (U.S. Apr. 18, 2023). Yet in this case, the government now stands to collect over a hundred million dollars in a judgment from a company that explicitly told the government what it was doing *multiple times* and received no objection and actual affirmance.

A decision from this Court embracing the logic of the District Court's judgment would place companies in an impossible position, with no realistic way to avoid FCA liability. 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 FCA liability spreads as far as the government's work does. And here, the regulator knew that it would or could not provide specific guidance on all matters, and therefore required parties to make "reasonable assumptions" where ambiguity existed. Where a business made such a good-faith, reasonable assumption, and repeatedly conferred with the government about whether its interpretation was correct, the FCA requires more before liability can be imposed on the business. To hold otherwise would be to leave companies at the whim of arbitrary governmental decision-making.

III. Expanding False Claims Act Liability To Situations Involving No Objective Falsehood And No Evidence Of A Culpable State Of Mind Will Impose Needless Costs on American Businesses.

The FCA's "essentially punitive" treble damages and statutory penalties loom large for any person or entity, public or private, that receives or handles federal funds. *Vt. Agency of Nat. Res.*, 529 U.S. at 784. Since 1986, an "army of whistleblowers, consultants, and, of course, lawyers" has been released onto this landscape. John T. Boese & Douglas W. Baruch, *Civil False Claims and* Qui Tam *Actions*, at xxv (5th ed. 2023). More than seventy percent of the 21,000 FCA actions filed since 1986 have been *qui tam* suits, U.S. Dep't of Justice, *Fraud Statistics—Overview: Oct. 1, 1986-Sept. 30, 2022*, at 3 (2023), https://bit.ly/3IXOVLg, but only "about 10 percent of non-intervened cases result in recovery" for the government. *U.S. ex rel. Hunt* v. *Cochise Consultancy, Inc.*, 887 F.3d 1081, 1087 (11th Cir. 2018), *aff'd*, 139 S. Ct. 1507 (2019); Ralph C. Mayrell, *Digging Into FCA Stats: In-House Litigation Budget Insights,* Law360 (July 13, 2021), https://bit.ly/3hUp89K.

Businesses face the specter of treble damages and civil penalties of over $27,018 per false claim, which quickly mushrooms, for example, in health-care matters involving thousands of patient claims. Civil Monetary Penalties Inflation Adjustment, 88 Fed. Reg. 5776 (Jan. 30, 2023); 31 U.S.C. § 3729(a); 28 C.F.R. § 85.3(a)(9). Simply *defending* a FCA suit requires a tremendous expenditure of time and energy—as the suits often take years of investigation, litigation, trial, and appeal

to resolve. *See* John T. Bentivoglio et al., *False Claims Act Investigations: Time for a New Approach?*, 3 Fin. Fraud L. Rep. 801, 801 (2011) (pharmaceutical, medical devices, and health care companies "spend billions each year" dealing with FCA investigations).[4] The mere existence of allegations "can do great damage to a firm," *U.S. ex rel. Grenadyor v. Ukrainian Vill. Pharmacy, Inc.*, 772 F.3d 1102, 1105-08 (7th Cir. 2014), or "cause [federal] agencies to question the contractor's business practices." Todd J. Canni, *Who's Making False Claims, The* Qui Tam *Plaintiff or the Government Contractor? A Proposal to Amend the FCA to Require that All* Qui Tam *Plaintiffs Possess Direct Knowledge*, 37 Pub. Cont. L.J. 1, 11 (2007). A finding of liability can result in suspension and debarment from government contracting, *see* 2 C.F.R. § 180.800—a "death penalty" punishment for many contractors, Ralph C.

[4] 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. *U.S. ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1029–30 (D.C. Cir. 2017); *see also U.S. ex rel. Barko v. Halliburton Co.*, 954 F.3d 307, 309 (D.C. Cir. 2020). In another, after the case dragged on for a decade, it was dismissed for relator misconduct after years of discovery. *U.S. ex rel. Nargol v. Depuy Orthopaedics, Inc.*, No. CV 14 12-10896-MPK, 2021 WL 5831626, at *12 (D. Mass. Dec. 8, 2021), *aff'd*, 69 F.4th 1 (1st Cir. 2023). And in *Trinity Industries*, a dispute about highway guardrails, a declined *qui tam* action was filed in 2012 and only ended in 2019 when the Supreme Court denied certiorari. Along the way, the case generated 746 docket entries and a jury verdict of $682 million—before the court of appeals reversed because the government agency that supposedly was defrauded had made clear that it disagreed with the relator's allegations. *U.S. ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 670 (5th Cir. 2017).

Nash & John Cibinic, *Suspension of Contractors: The Nuclear Sanction*, 3 Nash & Cibinic Rep. ¶ 24 (Mar. 1989)—or exclusion from participation in federal healthcare programs, *see* 42 U.S.C. § 1320a-7(b).

As a result, FCA litigation brings with it the very real possibility of forcing defendants to settle even spurious claims to avoid burdensome discovery and the risk of disastrous treble damages and penalties. Would-be relators are thus keenly aware that 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. Cont. L.J. 813, 824 (2012).

The objective-falsity standard and rigorous application of the scienter element help ensure that the FCA actually protects the government against fraud, instead of incentivizing meritless nuisance lawsuits against private and nonfederal governmental entities that interact with the federal government in complicated regulatory areas. If this Court were to hold that falsity requires no proof of objective falsity, or that scienter requires no proof of a culpable state of mind, the consequences would be stark: a broad cross-section of businesses, non-profits, government entities, and individuals would face protracted litigation and potential liability any time a relator coins a theory that there was some interpretation out there other than the reasonable alternative the defendant chose—and that the relator's

approach is better.[5] Good faith compliance efforts, like Lilly's here, could still trigger massive liabilities.

By contrast, enforcing the objective-falsity requirement and a culpable-state-of-mind scienter inquiry to backstop expansive FCA liability will encourage good agency practice. After all, the United States wears two hats in FCA cases: it is the very entity telling manufacturers to make reasonable assumptions *and also* the real party in interest who stands to benefit from huge damages awards if a relator succeeds in asserting that a company's reliance on reasonable assumptions make it

[5] *See, e.g., U.S. ex rel. Vermont Nat'l Tel. Co. v. Northstar Wireless, LLC*, 34 F.4th 29 (D.C. Cir. 2022) (telecommunications services); *U.S. ex rel. Schweizer v. Canon, Inc.*, 9 F.4th 269 (5th Cir. 2021) (photocopiers and office printers); *U.S. ex rel. Tzac, Inc. v. Christian Aid*, No. 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); *U.S. ex rel. Steury v. Cardinal Health, Inc.*, 735 F.3d 202 (5th Cir. 2013) (medical manufacturing); *U.S. ex rel. Anti-Discrimination Ctr. of Metro N.Y., Inc. v. Westchester Cnty.*, 712 F.3d 761 (2d Cir. 2013) (housing); *U.S. 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); *U.S. 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); *U.S. ex rel. Shemesh v. CA, Inc.*, No. 09-cv-1600, 2015 WL 1446547 (D.D.C. Mar. 31, 2015) (software development); *U.S. ex rel. Bias v. Tangipahoa Parish Sch. Bd.*, 86 F. Supp. 3d 535 (E.D. La. 2015) (public school ROTC programs); *U.S. ex rel. Bilotta v. Novartis Pharm. Corp.*, 50 F. Supp. 3d 497 (S.D.N.Y. 2014) (pharmaceutical manufacturing); *United States v. Americus Mortg. Corp.*, No. 12- cv-02676, 2014 WL 4273884 (S.D. Tex. Aug. 29, 2014) (mortgage lending); *U.S. ex rel. McLain v. Fluor Enters., Inc.*, 60 F. Supp. 3d 705 (E.D. La. 2014) (disaster relief construction); *U.S. ex rel. Landis v. Tailwind Sports Corp.*, 51 F. Supp. 3d 9 (D.D.C. 2014) (athletic sponsorship); *U.S. ex rel. Koch v. Koch Indus., Inc.*, 57 F. Supp. 2d 1122 (N.D. Okla. 1999) (crude oil purchasing).

a fraudster. *See* 31 U.S.C. § 3730(d). That means the government can both refuse to clarify the meaning of a statute at the request of regulated parties and then benefit to the tune of *millions and millions of dollars in treble damages and penalties* when manufacturers do their best to comply with unclear obligations and incomplete agency directions. *See Niz-Chavez v. Garland*, 141 S. Ct. 1474, 1486 (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.").

Between 600 and 750 *qui tam* suits have been filed every year for the past decade. *See* Department of Justice, *Fraud Statistics—Overview, October 1, 1986-September 30, 2022*, available at https://www.justice.gov/opa/press-release/file/1567691/download. More than half of those suits assert fraud on the Department of Health and Human Services, *id.* at 5, where government-directed use of reasonable assumptions to address gaps in authoritative guidance is a pervasive part of the Medicaid reimbursement scheme. In price reporting specifically, the 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." OIG Report, *supra*, at 10.

For all of these reasons, strict enforcement of the falsity and scienter requirements is particularly important. Businesses routinely face complex

contractual and regulatory schemes when they interact with the government, and good faith compliance efforts like those documented in this case should not be rewarded with any judgments at all, much less 9-figure judgments.

CONCLUSION

For these reasons, and those set forth in Appellant's brief, the judgment below should be reversed.

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Respectfully submitted,

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