No. 17-936

In the Supreme Court of the United States

GILEAD SCIENCES, INC.,

Petitioner,

v.

UNITED STATES EX REL. JEFFREY CAMPIE AND SHERILYN CAMPIE,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF COALITION FOR GOVERNMENT PROCUREMENT AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*

Amicus curiae Coalition for Government Procurement (Coalition) is a nonprofit, nonpartisan organization comprising small, medium, and large commercial contractors that sell products and services to the federal government. The Coalition has over 200 member companies covering a wide variety of industries. Its members include many of the top federal contractors and collectively account for a significant percentage of the sales generated through General Services Administration (GSA) and Department of Veterans Affairs contracts, including those awarded through the Multiple Award Schedules (MAS) program. According to the GSA website, MAS contracts alone are responsible for $45 billion in annual spending, representing approximately 10 percent of overall federal spending. Coalition members are also responsible for many other commercial items purchased annually by the federal government through other contractual mechanisms. The Coalition has been active for more than 35 years in bringing together public- and private-sector procurement leaders to work toward the mutual goal of commonsense acquisition.[1]

The Coalition's members have been subject to a number of False Claims Act actions, brought both by relators and by the government. The Coalition there-

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[1]Pursuant to Rule 37.6, *amicus* affirms that no counsel for a party authored this brief in whole or in part and that no person other than *amicus*, its members, or its counsel made a monetary contribution to the brief's preparation or submission. Pursuant to Rule 37.2(a), counsel of record for all parties received timely notice of the intent to file this brief. All parties have consented to the filing of this brief.

fore has a strong interest in the strict enforcement of the False Claims Act's materiality and pleading requirements, as discussed and applied in *Universal Health Services, Inc.* v. *United States ex rel. Escobar*, 136 S. Ct. 1989 (2016).

INTRODUCTION AND SUMMARY OF ARGUMENT

The False Claims Act (FCA), 31 U.S.C. § 3729 *et seq*., imposes liability on anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). The penalties for defrauding the government are significant—in 2017, the range of penalties for FCA violations soared from $5,500-$11,000 to a new range of $10,781-$21,563 *per claim*.[2] For contractors that submit numerous requests for payment to the government in the normal course of contract performance, these penalties can be severe.

In *Escobar*, this Court clarified that recipients of federal funds can be liable under the FCA for submitting a facially accurate claim for payment if the claim contains "certain misleading omissions." 136 S. Ct. at 1999. Specifically, the Court held that "the implied false certification theory can, at least in some circumstances, provide a basis for liability" if (1) "the claim does not merely request payment, but also makes specific representations about the goods or services provided"; (2) "the defendant's failure to

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[2] The U.S. Department of Justice (DOJ) made this "catch up adjustment" pursuant to the Civil Penalty Inflation Adjustment Act, codified as Section 701 of the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, 129 Stat. 584. See Civil Monetary Penalties Inflation Adjustment for 2017, 82 Fed. Reg. 9131 (Jan. 3, 2017) (codified at 28 C.F.R. § 85.5).

disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths"; and (3) the representations are material to the government's decision to pay. *Id.* at 1999, 2001. At the same time, the Court sought to allay "concerns about fair notice and open-ended liability" by providing defendants with two resources for resisting meritless relator suits. *Id.* at 2002.

First, the Court emphasized the need for "strict enforcement" of the FCA's materiality and scienter elements. 136 S. Ct. at 2002. The Court stated that the materiality requirement, in particular, is "demanding" and that the FCA is "not an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Id.* at 2003 (internal quotation marks and citation omitted). Notably, the Court rejected as "extraordinarily expansive" the notion that noncompliance "is material so long as the defendant knows that the government would be entitled to refuse payment were it aware of the violation." *Id.* at 2004. Rather, courts must look to the "likely or actual behavior of the recipient of the alleged misrepresentation"—*i.e.*, whether the recipient probably would have refused payment or *actually has* refused payment. *Id.* at 2002. As especially relevant here, the Court explained that, "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is *very strong evidence* that those requirements are *not material*." *Id.* at 2003 (emphasis added).

Second, the Court reiterated that materiality is not "too fact intensive for courts to dismiss [FCA] cases on a motion to dismiss" and that plaintiffs must "plead

* * * facts to support allegations of materiality" with "plausibility and particularity." 136 S. Ct. at 2004 n.6.

As the petition demonstrates, the Ninth Circuit disregarded both of these holdings by concluding that dismissal was not warranted here because the relators "allege *more than the mere possibility* that the government would be *entitled* to refuse payment if it were aware of the violations" and by insisting that the materiality of the representations is a "matter[] of proof" not amenable to disposition on a motion to dismiss. Pet. App. 32a (emphasis added).

In addition to deviating from *Escobar* and diluting the protections this Court affords to defendants, the decision below has consequences that particularly affect government contractors. Government contracting is heavily regulated, and procuring agencies have recourse to a number of enforcement provisions to deter and punish fraudulent activity. Unlike the FCA, these statutes and regulations are specific to government contracting and tailored to fit its unique demands. Additionally, federal law places primary responsibility for negotiating, managing, and enforcing contracts with the contracting officer (CO), who is charged with making a host of complex policy trade-offs in order to advance the mission delegated to the agency by Congress.

Failure to strictly enforce *Escobar*'s materiality standard enables opportunistic relators to second-guess agency policy decisions. It also undermines the ability of COs to discharge their statutory duties to manage the procurement process. Dismissal when the relator fails to plead any explanation for an agency's acquiescence to a defendant's purported misrepresentation (other than that it was immaterial) not only is required by *Escobar* but properly bal-

ances the interests of defendants, agencies, and the enforcement community.

ARGUMENT

A. Government Contracting Is A Regulated Business Relationship That Requires Agencies To Make Complex Policy Trade-Offs

Government contracting is different from commercial contracting in many fundamental respects. Since they are financed with funds from the public fisc, government contracts are highly regulated. In addition to the Federal Acquisition Regulation (FAR), 48 C.F.R. § 1.000 *et seq.*, and agency FAR supplements, contractors are subject to numerous enforcement statutes and regulations that are unique to the government. Aside from the FCA, these include the Truth in Negotiations Act, 10 U.S.C. § 2306a & 41 U.S.C. § 3501 *et seq.*[3]; various anti-kickback[4] and anti-bribery[5] statutes; domestic-pref-

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[3] The Truth in Negotiations Act requires certain contractors (in negotiated, or non-commercial, procurement actions exceeding $750,000) to disclose "cost or pricing data"; to certify that the data are accurate, complete, and current; and to lower their prices to reflect any price increase caused by a defective disclosure. 10 U.S.C. § 2306a. These requirements apply to all contracts that are priced or performed on the basis of cost.

[4] The Anti-Kickback Act of 1986, 41 U.S.C. § 8701 *et seq.*, prohibits government contractors from accepting or soliciting bribes or kickbacks from businesses seeking a subcontracting contract.

[5] For instance, federal law prohibits any person, including a contractor, from directly or indirectly giving, offering, or promising anything of value to agency officials for or because of any official act performed or to be performed by such official. 18 U.S.C. § 201(c)(1)(a).

erence statutes such as the Buy American Act, 41 U.S.C. § 8301 *et seq.*[6]; various regulations prohibiting the use of foreign counterfeit parts[7]; and more.

Because they spend taxpayer funds, agencies face a number of restrictions as buyers that do not affect buyers in the commercial sector. Of particular relevance here, it is a fundamental principle of government contracting that the government can be bound by a contract or contract modification only if it is approved by a CO with actual authority[8] to bind the government—"[c]ontracts may be entered into and signed on behalf of the Government only by contracting officers." FAR 1.601, 48 C.F.R. § 1.601. Federal law broadly confers on COs "authority to enter into, administer, or terminate contracts," and it charges COs with "ensur[ing] that all requirements

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[6] The Buy American Act requires the U.S. government to purchase only "unmanufactured articles, materials, and supplies" that "have been mined or produced in the United States" and only "manufactured articles, materials, and supplies" that have been manufactured in the United States "substantially all" from U.S. components, unless doing so is "inconsistent with the public interest" or would result in "unreasonable" cost. 41 U.S.C. §§ 8302(a)(1), 8303(a)-(b).

[7] Department of Defense procurement regulations require government contractors to obtain electronic parts from the original manufacturer or an authorized aftermarket manufacturer, if possible. The rule requires contractors to vet contractor-approved suppliers and to "assume[] responsibility for the authenticity of the parts provided" by them. See Defense Federal Acquisition Regulation Supplement: Detection and Avoidance of Counterfeit Electronic Parts—Further Implementation, 81 Fed. Reg. 50,635 (Aug. 2, 2016).

[8] See, *e.g.*, *Federal Crop Ins. Corp.* v. *Merrill*, 332 U.S. 380, 384 (1947) (holding that doctrine of apparent authority does not apply to government).

of law, executive orders, regulations, and all other applicable procedures, including clearances and approvals, have been met." FAR 1.602–1, 48 C.F.R. § 1.602-1. Government contracting is a regulated business relationship that is actively managed by COs, who are "allowed wide latitude to exercise business judgment" in discharging their statutory responsibilities. FAR 1.602–2, 48 C.F.R. § 1.602–2.

To be sure, COs are charged with ensuring that contractors are in compliance with the law, and they do not have the power to disregard laws or waive regulatory requirements, absent statutory authority to do so. But, as discussed below, large swaths of public contract law are highly complex and subject to interpretation and negotiation. Within these gray areas of the law, COs have considerable discretion to decide whether to accept a contractor's performance and to determine whether a contractor is complying with applicable contractual and legal requirements.

Although DOJ has exclusive authority to litigate and settle claims on behalf of the U.S. government, its freedom of action to adopt a particular argument in litigation is bounded by the actions of COs. Likewise, the strict materiality and pleading requirements set forth in *Escobar* safeguard the ability of COs to discharge their statutory duties, free of interference from opportunistic *qui tam* relators.

B. Failure To Strictly Enforce *Escobar*'s Materiality Standard Enables Opportunistic Relators To Second-Guess Agency Policy Decisions And Interferes With The Ability Of Agencies To Manage Contracts

Particularly in the case of large acquisitions, the relationship between the procuring agency and the contractor is an ongoing, regularly evolving one. For example, all federal public contracts contain a Changes Clause, which allows the CO to make "unilateral changes * * * within the general scope of the contract." FAR 43.201, 48 C.F.R. § 43.201. Such alterations are routinely made and negotiated in response to changing needs and circumstances.

Likewise, contractors regularly request guidance from the procuring agency about compliance with legal or contractual requirements. For instance, cost-reimbursement contracts are subject to complicated cost-allowability rules set forth in FAR Part 31, 48 C.F.R. § 31.000 *et seq.*, which prohibit contractors from recovering costs unless they are able to establish that the costs are (a) allowable, (b) allocable to the contract, and (c) reasonable. Contractors with large cost-type contracts are also subject to government-specific cost accounting standards (CAS) that govern how contractors account for their costs.[9]

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[9] Awardees with large cost-type contracts must modify their accounting systems to ensure that "unallowable costs"—which may be chargeable to private-sector clients—are not charged to the government. The CAS apply in full only to contracts of $50 million or more (so-called "full" CAS coverage). See FAR 30.201-4(b), 48 C.F.R. § 30.201-4(b). For contracts "over $750,000 but less than $50 million," only 4 of the 19 CAS standards apply. *Id.* Since CAS are different from the generally accepted accounting

Whether a particular cost incurred by a contractor is "allowable" is frequently unclear. In fact, accounting disputes can take years to resolve. According to the Government Accountability Office, in FY 2016 the Defense Contract Audit Agency "averaged 885 days from when a contractor submitted an adequate incurred cost proposal to when the audit was completed."[10] In light of this complexity, good-faith disagreements are commonplace. Accordingly, and under the authority over contracts delegated to COs, they are properly resolved by negotiation, without interference from self-interested relators.

In order for relationships between contractors and procuring agencies to function smoothly, contractors need to be able to rely on the decisions and actions of COs. In particular, if a CO agrees to a contractor's approach to a complicated regulation, contract term, or performance requirement, and then pays the contractor in full, the contractor must be able to rely on such acceptance.

This Court's decision in *Escobar* requires "strict enforcement" of the materiality requirement. 136 S. Ct. at 2002. By obligating courts to consider the conduct of the government—for example, whether an agency with knowledge of the alleged violation has refused payment—*Escobar* forces relators to allege actual fraud and prevents them from using the FCA

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principles that are commonly used in the commercial marketplace, government contractors that also conduct business in the private sector face the burden of applying multiple accounting systems.

[10] GAO, *Federal Contracting: Additional Management Attention and Action Needed to Close Contracts and Reduce Audit Backlog* (Sept. 2017) (GAO-17-738), www.gao.gov/assets/690/687497.pdf.

as "a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Id.* at 2003. Failing to strictly enforce the materiality requirement places relators—and ultimately jurors—in a position to second-guess agency decisions.

For instance, in 2015 a federal district court in Texas awarded more than $660 million in damages to a relator based on the defendant's purportedly inadequate disclosures about its guardrail design to the Federal Highway Administration (FHWA). *U.S. ex rel. Harman* v. *Trinity Indus. Inc.*, 872 F.3d 645, 652 (5th Cir. 2017). The relator claimed that the defendant was required to disclose even minor changes in technical specifications to the agency but failed to do so. *Id.* at 649–650. FHWA—the government agency with the most knowledge about the underlying issue—consistently supported the defendant. In fact, shortly before trial FHWA issued a memorandum stating that it "validated" the safety of the defendant's guardrails; that "an unbroken chain of eligibility for Federal-aid reimbursement has existed since September 2, 2005"; and that the defendant's product "continues to be eligible today." *Id.* at 650 (internal quotation marks omitted). While the appeal was pending, DOJ announced that it had closed its investigation and would be taking no enforcement action.

The Fifth Circuit ultimately reversed and put an end to this abusive FCA litigation. Citing *Escobar*, the court of appeals recognized that the federal agency's repeated, "authoritative" findings that the design and product at issue were compliant with federal safety standards and eligible for federal reimbursement were fundamentally at odds with the notion that the disclosures at issue were material to the government's decision to pay the claim. 872 F.3d

at 650–51. As the court put it: "In turning back [the relator's] views and proofs, [the government] balances the federal fisc, motorist safety, and other factors across the spectrum of myriad presentations to disclaim victim status. Such decision making is policy making, not the task of a seven-person jury." *Id.* at 669.

As the *Trinity Industries* case demonstrates, failure to strictly enforce the FCA's materiality requirement by ignoring the policy determinations of the relevant agencies subverts federal procurement law, which gives policymakers and contracting officials at the procuring agency—not self-interested relators—primacy in managing contracting relationships and ensuring compliance with legal and contractual requirements. Permitting relators to second-guess the considered decisions of subject-matter experts at the FDA or FHWA, or at other agencies like the Department of Defense, the GSA, or the Department of Health and Human Services, undermines their ability to fulfill their missions.

C. Dismissal When The Government Acquiesces To The Purported Misconduct Without Any Contemporaneous Reservation Balances The Interests Of Defendants, Agencies, And The Enforcement Community

Although the defendant in *Trinity Industries* eventually prevailed, it did so only after years of litigation, which caused it to incur millions of dollars in attorney fees and business losses.[11] Throughout the

[11] Although the legal costs incurred by Trinity Industries have not been publicized, the district court in 2015 awarded the relator nearly $19 million in attorney fees. Litigation continued

process, moreover, FHWA's ability to reach its own conclusions about the safety of the products under its purview was called into question. Indeed, following the jury verdict, a number of states removed Trinity's guardrails from their qualified-products list, notwithstanding FHWA's determination that the guardrails were safe.[12] Absent some reassurance that defendants can obtain dismissal of meritless FCA suits on the pleadings, contractors will be more reluctant to do business with the government or will respond by increasing their prices to cover the litigation risks.

In *Escobar*, this Court addressed that threat by emphasizing that, if an agency acquiesces to the defendant's conduct by paying "despite its actual knowledge" of the purported noncompliance, its acquiescence is "strong evidence that the requirements were not material." 136 S. Ct. at 2003. The United States-as-litigant, however, has sought to downplay the significance of payment in numerous cases (though notably not in this one, see Pet. 7). For example, in one statement of interest DOJ argued that,

> [e]ven in the case where the Government has actual knowledge of the defendant's conduct, its inaction *may* not undermine a materiality

through September 2017, and Trinity Industries had a larger legal team than the relator, so the legal fees it incurred were likely considerably higher. See Mark Curriden, *Fight or settle? Dallas' Trinity Industries taking big chance in court to save face and massive fine*, DALLAS MORNING NEWS, Oct. 2016, https://www.dallasnews.com/business/business/2016/10/28/trinity-industries-goes-win.

[12] See Margaret Fisk & Chris Dolmetsch, *Trinity Wins Reversal of $663 Million Guardrail Judgment*, BLOOMBERG, Sept. 29, 2017, https://www.bloomberg.com/news/articles/2017-09-29/trinity-wins-reversal-of-663-mln-fraud-ruling-in-guardrail-case.

> finding because other important considerations, such as public health or safety, *may* dictate that the Government continue to accept and pay for the items or services even with actual knowledge of the violations of a law, regulation, or contract.[13]

In another statement of interest, the government likewise took the position that "the fact that the government *may* continue to pay even after discovering wrongdoing does not establish a lack of materiality" and that "[t]he government *may* wish to avoid further cost or simply wish to afford an accused party the opportunity to be heard in court."[14]

The Ninth Circuit adopted this view below. The court of appeals declined "to read too much into the FDA's continued approval" and noted that "there are many reasons the FDA *may* choose not to withdraw a drug approval." Pet. App. 31a (emphasis added). But speculation about the hypothetical reasons an agency *may* have to continue paying despite knowledge of an alleged impropriety is inconsistent with *Escobar*'s holding that payment in such circumstances is "strong evidence" that the requirement in question is not a material condition for payment—and with its holding that the relator, not the defendant, bears the burden of establishing materiality with "plausibility and particularity." 136 S. Ct. at 2003–2004 & n.6.

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[13] U.S. Statement of Interest at 5, *United States* v. *Astrazeneca Biopharmaceuticals*, *Inc.*, No. 14-cv-1718 (E.D.N.Y. Aug. 8, 2016), ECF No. 103 (emphasis added).

[14] U.S. Statement of Interest at 15, *United States* v. *Celgene Corp.*, No. CV 10-3165 (C.D. Cal. Aug. 29, 2016), ECF No. 328 (emphasis added).

Accordingly, if an agency is aware of the alleged noncompliance but continues to pay in full, the appropriate question is not whether the agency "*may*" have had some reason to continue paying (apart from the immateriality of the representation) but whether the relator *has* sufficiently alleged that *evidence* of such a *contemporaneous* reason exists. Moreover, if the complaint establishes that the agency not only was aware of the alleged illegality, but conducted an investigation and concluded that the defendant was in compliance, dismissal is appropriate under *Escobar*. See*, e.g., D'Agostino* v. *ev3, Inc.*, 845 F.3d 1, 8 (1st Cir. 2016) ("FDA's failure actually to withdraw its approval * * * in the face of [relator's] allegations precludes [relator] from resting his claims on a contention that FDA's approval was fraudulently obtained"); *U.S. ex rel. Petratos* v. *Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017) (affirming district court's dismissal based on FDA's "continued * * * approval" of drug in question despite its knowledge of facts set forth in relator's complaint).

Contractors, agencies, and the enforcement community have differing interests. Contractors have an interest in minimizing their exposure to FCA liability. Purchasing agencies have an interest in conducting their procurements and managing their business affairs in a manner consistent with procurement statutes and regulations. And relators have an interest in identifying any violation, regardless of its significance, that can yield a settlement or judgment.

Dismissal in the event of government acquiescence appropriately balances these interests. Dismissal not only is required by *Escobar* but also—not coincidentally—is consonant with federal procurement

law. The purpose of the FCA is to punish "those who defraud the government," *Escobar*, 136 S. Ct. at 1995, not to provide an avenue for enterprising relators to encroach upon the domain of the subject-matter experts at procuring agencies. Although relators have a role to play in exposing actual fraud, self-interest can prompt them to pursue theories predicated on judgments that have been rejected by the agencies in question. In such cases, dismissal is necessary to preserve the balance of interests among defendants, relators, and the enforcement community.

CONCLUSION

The petition for a writ of certiorari should be granted and the case set for plenary review. In the alternative, the Court should summarily reverse.

Respectfully submitted.

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