

**IN THE UNITED STATES COURT OF APPEALS  
FOR THE THIRD CIRCUIT**

---

UNITED STATES OF AMERICA, *ex rel.* VICTORIA DRUDING, et al.,  
*Plaintiffs-Appellants,*

v.

CARE ALTERNATIVES, INC.,  
*Defendant-Appellee.*

---

On Appeal from the United States District Court  
for the District of New Jersey  
No. 1:08-cv-02126 (Hon. Juan R. Sanchez)

---

**BRIEF *AMICI CURIAE* OF THE CHAMBER OF COMMERCE OF THE  
UNITED STATES OF AMERICA AND PHARMACEUTICAL RESEARCH  
AND MANUFACTURERS OF AMERICA (PHRMA) AND IN SUPPORT  
OF DEFENDANT-APPELLEE AND AFFIRMANCE**

---

Andrew R. Varcoe  
Jordan L. Von Bokern  
U.S. CHAMBER LITIGATION  
CENTER  
1615 H Street, NW  
Washington, DC 20062  
(202) 463-5337

James C. Stansel  
Melissa B. Kimmel  
PHARMACEUTICAL  
RESEARCH AND  
MANUFACTURERS OF  
AMERICA  
950 F Street, NW  
Washington, DC 20004  
(202) 835-3400

John P. Elwood  
Christian D. Sheehan  
Jayce L. Born  
ARNOLD & PORTER KAYE  
SCHOLER LLP  
601 Massachusetts Avenue, NW  
Washington, DC 20001  
(202) 942-5000  
fax: (202) 942-5999  
john.elwood@arnoldporter.com

*Counsel for Amici Curiae*

---

## **CORPORATE DISCLOSURE STATEMENT**

Pursuant to Federal Rule of Appellate Procedure 26.1, *amici* state as follows:

The Chamber of Commerce of the United States of America has no parent corporation and no publicly held company has a 10% or greater ownership interest in it.

The Pharmaceutical Research and Manufacturers of America has no parent corporation and no publicly held company has a 10% or greater ownership interest in it.

## TABLE OF CONTENTS

Corporate Disclosure Statement .....	1
Statement of Interest .....	9
Summary of Argument.....	11
Argument.....	12
I.    Materiality Can Be Decided as a Matter of Law Based on Evidence After the Submission of the Claim .....	12
II.   The Materiality Requirement Serves an Important Gatekeeping Function .....	18
A.   Meritless <i>Qui Tam</i> Actions Impose Needless Costs on American Businesses, The Government, and Taxpayers.....	19
B.   Materiality Plays an Essential Role in Cabining Expansive False Claims Act Liability.....	24
Conclusion .....	29
Certificate of Compliance .....	30
Certificate of Service .....	31

**TABLE OF AUTHORITIES**

	<b><u>Page(s)</u></b>
<b><u>Cases</u></b>	
<i>Abbott v. BP Expl. &amp; Prod., Inc.</i> , 851 F.3d 384 (5th Cir. 2017) .....	6
<i>Abraham Lincoln Mem. Hosp. v. Sebelius</i> , 698 F.3d 536 (7th Cir. 2012) .....	18
<i>AT&amp;T Mobility LLC v. Concepcion</i> , 563 U.S. 333 (2011).....	14
<i>D’Agostino v. EV3, Inc.</i> , 845 F.3d 1 (1st Cir. 2016).....	6
<i>Graham Cnty. Soil &amp; Water Conservation Dist. v. United States ex rel. Wilson</i> , 559 U.S. 280 (2010).....	12
<i>Grand Union Co. v. United States</i> , 696 F.2d 888 (11th Cir. 1983) .....	11
<i>H.B. Mac, Inc. v. United States</i> , 153 F.3d 1338 (Fed. Cir. 1998) .....	17
<i>H.B. Mac, Inc. v. United States</i> , 36 Fed. Cl. 793 (1996).....	17
<i>Mikes v. Straus</i> , 274 F.3d 687 (2d Cir. 2001) .....	11
<i>Rehabilitation Ass’n of Va., Inc. v. Kozlowski</i> , 42 F.3d 1444 (4th Cir. 1994) .....	18
<i>Schweiker v. Gray Panthers</i> , 453 U.S. 34 (1981).....	17

**Cases—Continued**

*United States ex rel. Anti-Discrimination Ctr. of Metro N.Y., Inc. v. Westchester Cnty.*,  
712 F.3d 761 (2d Cir. 2013) .....11

*United States ex rel. Bachert v. Triple Canopy, Inc.*,  
321 F. Supp. 3d 613 (E.D. Va. 2018) .....10

*United States ex rel. Berg v. Honeywell Int’l, Inc.*,  
740 F. App’x 535 (9th Cir. 2018) .....7

*United States ex rel. Bias v. Tangipahoa Parish Sch. Bd.*,  
86 F. Supp. 3d 535 (E.D. La. 2015).....11

*United States ex rel. Bilotta v. Novartis Pharm. Corp.*,  
50 F. Supp. 3d 497 (S.D.N.Y. 2014) .....11

*United States ex rel. Conner v. Salina Reg’l Health Ctr., Inc.*,  
543 F.3d 1211 (10th Cir. 2008) .....19

*United States ex rel. Grenadyor v. Ukrainian Vill. Pharmacy, Inc.*,  
772 F.3d 1102 (7th Cir. 2014) .....13

*United States ex rel. Harman*,  
872 F.3d 645 (5th Cir. 2017) .....6

*United States ex rel. Howard v. Lockheed Martin Corp.*,  
14 F. Supp. 3d 982 (S.D. Ohio 2014) .....19

*United States ex rel. Kelly v. Serco, Inc.*,  
846 F.3d 325 (9th Cir. 2017) .....7

*United States ex rel. Koch v. Koch Indus., Inc.*,  
57 F. Supp. 2d 1122 (N.D. Okla. 1999).....11

*United States ex rel. Landis v. Tailwind Sports Corp.*,  
51 F. Supp. 3d 9 (D.D.C. 2014).....11

**Cases—Continued**

*United States ex rel. Lemmon v. Envirocare of Utah, Inc.*,  
614 F.3d 1163 (10th Cir. 2010) ..... 11

*United States ex rel. McBride v. Halliburton Co.*,  
848 F.3d 1027 (D.C. Cir. 2017).....5, 6, 9

*United States ex rel. McLain v. Fluor Enters., Inc.*,  
60 F. Supp. 3d 705 (E.D. La. 2014)..... 11

*United States ex rel. Newsham v. Lockheed Missiles & Space Co.*,  
722 F. Supp. 607 (N.D. Cal. 1989)..... 16

*United States ex rel. Petratos v. Genentech Inc.*,  
855 F.3d 481 (3d Cir. 2017) .....6, 16

*United States ex rel. Pritzker v. Sodexo, Inc.*,  
364 F. App'x 787 (3d Cir. 2010) ..... 11

*United States ex rel. Schweizer v. Canon, Inc.*,  
9 F.4th 269 (5th Cir. 2021) ..... 11

*United States ex rel. Sequoia Orange Co. v. Sunland Packing House  
Co.*, 912 F. Supp. 1325 (E.D. Cal. 1995)..... 17

*United States ex rel. Shemesh v. CA, Inc.*,  
No. 09-cv-1600, 2015 WL 1446547 (D.D.C. Mar. 31, 2015)..... 11

*United States ex rel. Siewick v. Jamieson Sci. & Eng'g, Inc.*,  
214 F.3d 1372 (D.C. Cir. 2000)..... 20

*United States ex rel. Steury v. Cardinal Health, Inc.*,  
735 F.3d 202 (5th Cir. 2013) ..... 11

*United States ex rel. Taylor v. Boyko*,  
No. 20-1661, 2022 WL 2336802 (4th Cir. June 29, 2022) ..... 7, 8

*United States ex rel. Tzac, Inc. v. Christian Aid*,  
No. 17-cv-4134, 2021 WL 2354985 (S.D.N.Y. June 9, 2021)..... 11

**Cases—Continued**

*United States ex rel. Vermont Nat’l Tel. Co. v. Northstar Wireless, LLC*, 34 F.4th 29 (D.C. Cir. 2022).....11

*United States ex rel. Vigil v. Nelnet, Inc.*, 639 F.3d 791 (8th Cir. 2011) .....17

*United States ex rel. Zissa v. Santa Barbara Cty. Alcohol, Drug, & Mental Health Servs.*, No. CV 14-6891, 2019 WL 3291579 (C.D. Cal. Mar. 12, 2019).....7, 10

*United States v. Americus Mortg. Corp.*, No. 12-cv-02676, 2014 WL 4273884 (S.D. Tex. Aug. 29, 2014).....11

*United States v. Data Translation, Inc.*, 984 F.2d 1256 (1st Cir. 1992) (Breyer, C.J.).....15

*United States v. McNinch*, 356 U.S. 595 (1958).....16

*United States v. Sanford-Brown, Ltd.*, 840 F.3d 445 (7th Cir. 2016) .....7, 11

*United States v. Sci. Applications Int’l Corp.*, 626 F.3d 1257 (D.C. Cir. 2010).....11

*United States v. Stanford-Brown, Ltd.*, 788 F.3d 696 (7th Cir. 2015) .....17

*United States v. Strock*, 982 F.3d 51 (2d Cir. 2020) .....5

*Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016)..... *passim*

*Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765 (2000).....12

**Statutes & Regulations**

31 U.S.C.  
    § 3729(a) ..... 13

42 U.S.C.  
    § 1320a-7(b) ..... 14  
    § 1437f(o)(8)(C) ..... 19  
    § 1437f(o)(8)(D) ..... 19  
    § 1437f(o)(8)(E) ..... 19

2 C.F.R.  
    § 180.800 ..... 13

28 C.F.R.  
    § 85.3(a)(9) ..... 13

87 Fed. Reg. 27,513, 27,515 (May 9, 2022) ..... 13

Federal Acquisition Regulation  
    31.205-47(a)(3) ..... 15  
    31.205-47(e) ..... 15

**Other Authorities**

John T. Bentivoglio et al., *False Claims Act Investigations: Time for a New Approach?*, 3 Fin. Fraud L. Rep. 801 (2011) ..... 13

1 John T. Boese, *Civil False Claims and Qui Tam Actions*, at xxi (4th ed. 2011) ..... 12

Christina Orsini Broderick, Note, *Qui Tam Provisions and the Public Interest: An Empirical Analysis*, 107 Colum. L. Rev. 949, 975 (2007) ..... 12



**Other Authorities—Continued**

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 (2007).....13

Civ. Div. U.S. Dep’t of Justice, *Fraud Statistics—Overview* (Feb. 1, 2022) .....12

Cong. Globe, 37th Cong., 3d Sess. 348 (1863) .....16

*Constitutionality of the Qui Tam Provisions of the False Claims Act*, 13 Op. O.L.C. 207 (1989).....19

Sean Elameto, *Guarding the Guardians: Accountability in Qui Tam Litigation Under the Civil False Claims Act*, 41 Pub. Cont. L.J. 813 (2012).....14

David Freeman Engstrom, *Agencies as Litigation Gatekeepers*, 123 Yale L.J. 616, 672 n.180 (2013) .....18

Steven R. Koltai, *How the Healthcare.gov Mess Happened and How To Fix It*, Brookings Inst. (Nov. 25, 2013), <https://brook.gs/3oaOkdr> .....18

Ralph C. Mayrell, *Digging Into FCA Stats: In-House Litigation Budget Insights* (July 13, 2021), <https://bit.ly/3hUp89K> .....12

Memorandum from Michael D. Granston, Dir., Commercial Litig. Branch, Fraud Section, U.S. Dep’t of Just., to Attorneys, Commercial Litig. Branch, Fraud Section (Jan. 10, 2018) .....23

Ralph C. Nash & John Cibinic, *Suspension of Contractors: The Nuclear Sanction*, 3 Nash & Cibinic Rep. ¶ 24 (Mar. 1989).....14

1 F. Shannon, *The Organization and Administration of the Union Army, 1861–1865* (1965) .....16

S. Rep. 98-50 (1983).....15

## STATEMENT OF INTEREST<sup>1</sup>

Pursuant to Federal Rule of Appellate Procedure 29, the Chamber of Commerce of the United States of America (the “Chamber”) and Pharmaceutical Research and Manufacturers of America (“PhRMA”) submit this brief in support of defendant-appellee and affirmance.

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

PhRMA is a voluntary, non-profit association that represents the nation’s leading biopharmaceutical and biotechnology companies. PhRMA’s mission is to advocate for public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA’s members invest billions of dollars each year to

---

<sup>1</sup> No counsel for a party authored this brief in whole or 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. The parties have consented to this filing.

research and develop new drugs, more than 500 of which have been approved since 2000. The members of PhRMA closely monitor legal issues that affect the entire industry, and PhRMA often offers its perspective in cases raising such issues.

*Amici* have a strong interest in the questions presented in this case, which are fundamental to the scope of False Claims Act liability. *Amici*'s members, many of which are subject to complex regulatory schemes, have successfully defended scores of False Claims Act cases in courts nationwide, including the Third Circuit, arising out of government contracts, grants, and participation in federal programs. Private relators (only infrequently joined by the government) have routinely asserted that defendants have run afoul of the False Claims Act despite evidence that the government was aware of the alleged violation of a law, rule, or regulation applicable to the claim for payment and took no action to recover the funds it paid out for that claim.

If this Court were to relax the False Claims Act's materiality standard and allow such cases to proceed to trial, it would have far-reaching consequences for *Amici*'s members. Such a decision would harm not just hospice care providers like defendant-appellee in this case, but also the myriad other businesses, non-profit organizations, and even municipalities that perform work for (or financed by) the federal government, or which receive funds through a vast array of federal programs. Relators' position that claims should proceed to trial despite "very strong" evidence

that the government did not view the alleged violation as material, *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 195 (2016), would impermissibly broaden the Act’s intended scope and threaten the *in terrorem* effect of quasi-criminal liability based on claimed violations of the kind of complex statutory and regulatory regimes that *Amici*’s members must navigate every day.

### **SUMMARY OF ARGUMENT**

The Supreme Court in *Escobar* made clear that the False Claims Act’s “demanding” and “rigorous” materiality requirement should be strictly enforced at the summary judgment stage. 579 U.S. at 181, 192-94, 195 n.6. Doing so provides a critical check on meritless, but costly, False Claims Act actions raising allegations of which the government was aware but about which it declined to act. Like numerous circuit courts of appeals around the country, the district court here followed *Escobar*’s teaching and granted defendant-appellee summary judgment where the undisputed evidence showed that the government investigated Relators’ allegations but continued to pay defendant-appellee’s claims and failed to take any steps to recoup payments already made. Both Relators and the government, however, ask this Court to ignore *Escobar* and adopt a rule under which materiality could rarely (if ever) be decided without a trial.

If this Court were to adopt Relators’ and the government’s position in this case, it would undermine defendants’ ability to resolve meritless *qui tam* actions at

summary judgment (let alone on the pleadings), including those the government itself has deemed unworthy to pursue. It presents the possibility of False Claims Act liability—with the risk of crippling treble damages, penalties, and grave reputational harm—for every government contractor, grantee, and program participant even if the defendant presents undisputed evidence that the government investigated the allegations at issue and then took no action to recoup any funds. It also threatens to stretch the False Claims Act beyond its intended limits. The decision below has implications far beyond the hospice care context, potentially affecting any entity, public or private, that receives federal funds under a host of programs. Congress intended for the Act to root out fraud, not to convert every breach of contract or deviation from regulations into a fraud claim subject to the False Claims Act’s quasi-criminal penal regime, regardless of whether the government finds the supposed discrepancy worthy of action.

This Court should affirm.

## **ARGUMENT**

### **I. Materiality Can Be Decided as a Matter of Law Based on Evidence After the Submission of the Claim**

Relators and the government argue that the materiality inquiry can involve consideration of a variety of factors and quote *Escobar* for the proposition that “no one factor is dispositive.” Relators’ Br. 6-7; Gov’t Br. 11. Relators and the government also incorrectly argue that a district court cannot resolve materiality at

summary judgment by finding one factor dispositive, Relators’ Br. 10; Gov’t Br. 22. But that is not what the Supreme Court said. Rather, it held that “the Government’s *decision to expressly identify a provision as a condition of payment is . . . not automatically dispositive.*” *Escobar*, 579 U.S. at 194 (emphasis added). And it expressly and pointedly rejected the argument that the “rigorous and demanding” materiality requirement is “too fact intensive” to be resolved on the pleadings. *Id.* at 195 n.6 (“We reject Universal Health’s assertion that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment.”).

The Court made clear that “if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence” of immateriality. *Id.* at 195. Where, as here, there is clear evidence of how the government “*actual[ly]*” responded after learning of alleged misconduct, and no contrary evidence presented by Relators, there is no need to look to the other factors discussed in *Escobar* designed for determining how the government “likely” would have reacted had it known. *See id.* at 193 (emphasis added; citation omitted). “[C]ourts need not opine in the abstract when the record offers insight into the Government’s actual payment decisions.” *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1032 (D.C. Cir. 2017); *see United States v. Strock*, 982 F.3d 51, 60 (2d Cir. 2020) (“*Escobar* eschews a materiality analysis that

prioritizes the government’s claims about how it would treat a requirement over how the government actually treats a requirement upon discovering a violation.”).

Courts therefore routinely hold that continued payment after discovery of a violation is dispositive of materiality as a matter of law. *See United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017) (in False Claims Act case based on drug manufacturer’s alleged suppression of data, finding absence of materiality where government had taken no adverse action against drug manufacturer with knowledge of allegations); *United States ex rel. Harman*, 872 F.3d 645, 665-68 (5th Cir. 2017) (directing entry of judgment for defendant because government’s continued payment for, and approval of, allegedly noncompliant highway guardrails with knowledge of alleged noncompliance was “very strong evidence” of lack of materiality); *McBride*, 848 F.3d at 1034 (holding government’s failure to “disallow any charged costs” after investigating alleged noncompliance demonstrated lack of materiality at summary judgment); *Abbott v. BP Expl. & Prod., Inc.*, 851 F.3d 384, 388 (5th Cir. 2017) (affirming summary judgment because the fact that agency “decided to allow [the well] to continue drilling after a substantial investigation into Plaintiffs’ allegations” “represent[ed] ‘strong evidence’ that the requirements in those regulations are not material”); *D’Agostino v. EV3, Inc.*, 845 F.3d 1, 7-8 (1st Cir. 2016) (in FCA case relating to alleged defective devices, affirming dismissal on materiality grounds because government “ha[d] not denied

reimbursement” for device with knowledge of allegations and had not withdrawn approval for device); *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447-48 (7th Cir. 2016) (affirming dismissal of FCA claim where government had examined alleged non-compliance by for-profit college with federal subsidy program but had neither imposed administrative penalties nor terminated college from program); *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 334-35 (9th Cir. 2017) (finding lack of materiality where government accepted and paid public vouchers for contractor’s services despite alleged non-compliance with regulatory accounting standard); *United States ex rel. Berg v. Honeywell Int’l, Inc.*, 740 F. App’x 535, 538 & n.5 (9th Cir. 2018) (treating continued payment with knowledge of fraud allegations as dispositive at summary judgment stage); *United States ex rel. Taylor v. Boyko*, No. 20-1661, 2022 WL 2336802, at \*9 (4th Cir. June 29, 2022) (dismissing complaint for failure to plead materiality despite allegation that “CMS decided, *on a single occasion*, to revoke a company’s Medicare billing privileges” for similar conduct because it “hardly shows ‘that the Government *consistently* refuses to pay claims in the mine run of cases based on’” such conduct (emphasis in original) (quoting *Escobar*, 579 U.S. at 195)); *see also United States ex rel. Zissa v. Santa Barbara Cty. Alcohol, Drug, & Mental Health Servs.*, No. CV 14-6891, 2019 WL 3291579, at \*6-7 (C.D. Cal. Mar. 12, 2019) (dismissing False Claims Act claim for lack of materiality because government’s continued payment despite knowledge of



violations outweighed fact that certain requirements purportedly were conditions of payment and that “noncompliance was more than ‘insubstantial’ in an absolute sense” because “the Government’s reaction . . . demonstrat[es] the noncompliance . . . was not of such great magnitude” to affect payment).

The Fourth Circuit’s recent decision in *Taylor v. Boyko* is particularly instructive because, like this case, it involved alleged recordkeeping failures—specifically, “the [defendant’s] loss of its certificate of corporate authorization and attendant regulatory violations” stemming from “its failures to file an annual report and pay a \$25 fee.” 2022 WL 2336802, at \*10. The Court rejected the relator’s contention that it was “common sense” that such violations were material, reasoning that the relator did not allege “that these failures impacted or influenced the medical services provided . . . or the medical qualifications of the physicians employed by [the defendant] . . . —which is what the Government was paying for all along.” *Id.* Relators suffer from the same failure of proof here, as they have failed to present any evidence that the alleged documentation gaps “impacted or influenced the medical services provided.” *Id.* Moreover, just as in *Taylor*, where the court considered it important that “a dissolved corporate charter can be reinstated,” *id.*, recordkeeping deficiencies in the hospice care context may be cured based on evidence outside of the medical record. *See Care Alternatives Summary Judgment Br. 35-37* (Sept. 11, 2017) [ECF No. 134].

Contrary to Relators' argument, the fact that the government became aware of alleged misconduct only after defendant submitted its claims for payment does not warrant a different result here. There is no *genuine* dispute that (1) a physician had certified that each patient in defendant's care was terminally ill, and the only question is whether the physician's medical judgment about the terminal status of certain patients was sufficiently supported by documentation, Relators' Br. 7-9, 11-13; Gov't Br. 5-7; (2) the government had the ability to recoup funds paid to defendant-appellee, Defendant's Br. 16-19; and (3) after learning of and investigating the allegations, the government declined to take any steps to recoup the amounts it had paid, *id.*

Faced with this "very strong evidence" of immateriality, *Escobar*, 579 U.S. at 195, Relators and the government attempt to draw a distinction between paying a claim in the first instance and failing later to recoup costs paid, arguing that the former may be evidence of immateriality but the latter is not. Relators' Br. 21-22; Gov't Br. 19-22. Yet, there is no meaningful distinction between the two situations. In both instances, the government's actions reflect its belief that the alleged misconduct is not sufficiently important to deny the defendant payment for the goods or services it provided. Courts have held that the government's failure to demand repayment is every bit as significant as deciding to pay in the first instance. *See, e.g., McBride*, 848 F.3d at 1029 ("[N]either DCAA nor any other Government agency

disallowed or challenged any of the amounts *KBR had billed* for MWR services under Task Order 59.” (emphasis added)); *United States ex rel. Bachert v. Triple Canopy, Inc.*, 321 F. Supp. 3d 613, 620-21 (E.D. Va. 2018) (granting partial summary judgment for defendant under *Escobar* where government reviewed the alleged fraud and “never asked for any money back from defendant”); *Zissa*, 2019 WL 3291579, at \*6 (government did not attempt to “recoup funds”).

Adopting Relators’ urged distinction would allow any number of cases to proceed to trial at great expense to the parties—and potentially exert significant pressure on a defendant to settle a matter for substantial sums—despite “very strong evidence,” *Escobar*, 579 U.S. at 195, that the correct disposition would be judgment for the defendant. This Court should take *Escobar* at its word and affirm the district court’s finding that, as a matter of law, Relators have not proven materiality.

## **II. The Materiality Requirement Serves an Important Gatekeeping Function**

Relators’ position improperly exposes government contractors and others participating in government programs to the threat of treble damages and statutory penalties for noncompliance with any one of thousands of statutory provisions, rules, regulations, and contract clauses that govern relationships with the federal government—even where the government has taken steps to evaluate the submitted claims and decided to take no action to recoup any funds. The uncertainty of such potentially broad False Claims Act liability would profoundly increase litigation risk

to thousands of businesses and individuals, to the detriment of the business community, the government, and taxpayers.

**A. Meritless *Qui Tam* Actions Impose Needless Costs on American Businesses, The Government, and Taxpayers**

False Claims Act liability potentially affects any person or entity, public or private, that receives or handles federal funds in myriad forms. A broad cross-section of businesses and individuals would be exposed to protracted litigation and potential liability under the expansive materiality standard that Relators advocate in this case.<sup>2</sup>

---

<sup>2</sup> 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. 17-cv-4134, 2021 WL 2354985 (S.D.N.Y. June 9, 2021) (charitable aid organization); *Sanford-Brown, Ltd.*, 840 F.3d 445 (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 Cnty.*, 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. Sodexo, Inc.*, 364 F. App'x 787 (3d Cir. 2010) (public school lunches); *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001) (healthcare); *Grand Union Co. v. United States*, 696 F.2d 888 (11th Cir. 1983) (food stamps); *United States ex rel. Shemesh v. CA, Inc.*, No. 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. 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); *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).

This potential expansion of liability coupled with the skyrocketing number of *qui tam* suits over the past decade underscores the importance of rigorously applying the False Claims Act’s materiality standard. Since 1986, an “army of whistleblowers, consultants, and, of course, lawyers” has been released onto this landscape. 1 John T. Boese, *Civil False Claims and Qui Tam Actions*, at xxi (4th ed. 2011). Over that period, more than 20,000 False Claims Act actions were filed, nearly 14,600 of which were *qui tam* suits. Civ. Div. U.S. Dep’t of Justice, *Fraud Statistics—Overview* (Feb. 1, 2022) (“DOJ Fraud Statistics”). But only a small fraction of those suits results in any monetary recovery for the government: “about 10 percent of non-intervened cases result in recovery.” Christina Orsini Broderick, Note, *Qui Tam Provisions and the Public Interest: An Empirical Analysis*, 107 Colum. L. Rev. 949, 975 (2007); Ralph C. Mayrell, *Digging Into FCA Stats: In-House Litigation Budget Insights*, Law360 (July 13, 2021), <https://bit.ly/3hUp89K> (DOJ declines to intervene in approximately 75 percent of cases, and 90 percent of declined cases ended in no recovery for the government).

Meritless *qui tam* actions are “downright harmful” to the business community. See *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 298 (2010). The Act’s treble damages and penalties provisions are “essentially punitive.” *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784-85 (2000). Businesses face the specter of treble damages as well as

civil penalties of over \$25,076 per false claim. Civil Monetary Penalties Inflation Adjustment, 87 Fed. Reg. 27,513, 27,515 (May 9, 2022); 31 U.S.C. § 3729(a); 28 C.F.R. § 85.3(a)(9). Wholly apart from the prospect of an eventual judgment, simply *defending* a False Claims Act case requires a “tremendous expenditure of time and energy.” 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 n.66 (2007). For example, “[p]harmaceutical, medical devices, and health care companies” alone “spend billions each year” dealing with False Claims Act investigations. John T. Bentivoglio et al., *False Claims Act Investigations: Time for a New Approach?*, 3 Fin. Fraud L. Rep. 801, 801 (2011).

Moreover, the mere existence of allegations (however tenuous) that a company “defraud[ed] our country sends a message,” and “[r]eputation[,] ... once tarnished, is extremely difficult to restore.” Canni, *supra*, at 13; *accord United States ex rel. Grenadyor v. Ukrainian Vill. Pharmacy, Inc.*, 772 F.3d 1102, 1105-08 (7th Cir. 2014) (“[A] public accusation of fraud can do great damage to a firm.”). For companies that do significant government work, “the mere presence of allegations of fraud may cause [federal] agencies to question the contractor’s business practices.” Canni, *supra*, at 13. And a finding of False Claims Act liability can result in suspension and debarment from government contracting, *see* 2 C.F.R.

§ 180.800—“equivalent to the death penalty” for many contractors, Ralph C. Nash & John Cibinic, *Suspension of Contractors: The Nuclear Sanction*, 3 Nash & Cibinic Rep. ¶ 24 (Mar. 1989)—as well as exclusion from participation in federal healthcare programs, *see* 42 U.S.C. § 1320a-7(b). False Claims Act allegations also can trigger satellite litigation, such as shareholder derivative suits. *E.g.*, Stipulation of Settlement at 1, *In re Oracle Corp. Derivative Litig.*, No. 10-cv-3392 (N.D. Cal. May 28, 2013), [ECF No. 95].

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). Punitive liability and the potential that lawsuits will drag on creates intense pressure to settle even “questionable claims.” *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 350 (2011). This pressure will only intensify if government contractors, grantees, and program participants face the specter of crippling liability based on claims that the government investigated but concluded did not warrant action to recoup purported losses.

The prospect of choosing between settling a meritless claim and paying millions of dollars to litigate a case and face the risk of an adverse judgment and treble damages has a real and predictable chilling effect on companies and individuals that are evaluating whether to do business with the federal government.

In turn, a reduction in qualified entities and individuals willing to deal with the government deprives the government of choice, and reduced competition means that the government very likely will pay higher prices, receive less valuable products or services, or both. *See, e.g., United States v. Data Translation, Inc.*, 984 F.2d 1256, 1262 (1st Cir. 1992) (Breyer, C.J.) (“[S]ignificantly increasing competitive firms’ cost of doing federal government business[] could result in the government’s being charged higher . . . prices.”); Memorandum from Michael D. Granston, Dir., Commercial Litig. Branch, Fraud Section, U.S. Dep’t of Just., to Attorneys, Commercial Litig. Branch, Fraud Section at 5 (Jan. 10, 2018) (“Granston Memo”) (“[T]here may be instances where an action is both lacking in merit and raises the risk of significant economic harm that could cause a critical supplier to exit the government program or industry.”); S. Rep. 98-50, at 3 (1983) (“[C]ompetition in contracting saves money.”).

What is more, because the costs of False Claims Act litigation are passed on to the government, either directly or indirectly, those costs ultimately will be borne by the taxpayer. Already, taxpayers bear a significant part of the direct cost of False Claims Act suits. For instance, cost-based contractors are allowed to pass on to the government up to 80% of their legal expenses from litigating non-intervened qui tam cases when they prevail. FAR 31.205-47(a)(3), (e). And contractors undoubtedly pass those costs to taxpayers indirectly as well, by increasing the prices they charge



for their services to account for the risk that their service to the public will expose them to costly and protracted litigation.

**B. Materiality Plays an Essential Role in Cabining Expansive False Claims Act Liability**

The False Claims Act was enacted in 1863 and signed into law by President Lincoln “to prevent and punish frauds upon the Government of the United States.” Cong. Globe, 37th Cong., 3d Sess. 348 (1863) (statement of Sen. Wilson).<sup>3</sup> “The [False Claims Act] is a fraud prevention statute,” and materiality plays an important role in limiting the Act’s reach: a violation of a statute, rule, or regulation is not fraud unless it goes “to the very essence of the bargain” between the government and the defendant. *Petratos*, 855 F.3d at 489 (quoting *Escobar*, 579 U.S. at 194 n.5); *see also Escobar*, 579 U.S. at 192 (“[C]oncerns about fair notice and open-ended liability” in False Claims Act cases should be “addressed through strict enforcement of the Act’s” “rigorous” scienter and materiality requirements. (citation omitted)).

---

<sup>3</sup> The False Claims Act was enacted in response to allegations of rampant war profiteering during the Civil War. *United States v. McNinch*, 356 U.S. 595, 599 (1958). Private contractors supporting the Union Army were accused of defrauding the federal treasury through flagrantly wrongful acts: “For sugar, [the government] often got sand; for coffee, rye; for leather, something no better than brown paper; for sound horses and mules, spavined beasts and dying donkeys; and for serviceable muskets and pistols, the experimental failures of sanguine inventors, or the refuse of shops and foreign armories.” *United States ex rel. Newsham v. Lockheed Missiles & Space Co.*, 722 F. Supp. 607, 609 (N.D. Cal. 1989) (quoting 1 F. Shannon, *The Organization and Administration of the Union Army, 1861–1865*, at 54-56 (1965)).

The need for strict enforcement of the materiality requirement is particularly critical because of the complex contractual and regulatory schemes that businesses routinely face when they assist the government in implementing programs—as contractors, grantees, or simply as program participants. It is common, even typical, for those assisting the government in implementing its programs to be subject to detailed statutory, regulatory, and contractual obligations. Those legal regimes are at minimum “complex” (Federal Family Education Loan Program),<sup>4</sup> if not “complex [and] poorly-worded” (Small Disadvantaged Business regulations).<sup>5</sup> Government contracts regularly incorporate “thousands of pages of other federal laws and regulations” of comparable complexity.<sup>6</sup> Many federal regulatory regimes are so reticulated and challenging that courts and scholars routinely describe them as “byzantine[] and all-encompassing” (Agricultural Marketing Agreement Act of 1937),<sup>7</sup> “intricate” and “almost unintelligible” (the Social Security Act),<sup>8</sup> “onerous and impenetrable” and “byzantine to the point of incomprehensibility” (government

---

<sup>4</sup> *United States ex rel. Vigil v. Nelnet, Inc.*, 639 F.3d 791, 799 (8th Cir. 2011).

<sup>5</sup> *H.B. Mac, Inc. v. United States*, 36 Fed. Cl. 793, 816 (1996), *rev'd on other grounds*, 153 F.3d 1338 (Fed. Cir. 1998).

<sup>6</sup> *United States v. Stanford-Brown, Ltd.*, 788 F.3d 696, 707 (7th Cir. 2015).

<sup>7</sup> *United States ex rel. Sequoia Orange Co. v. Sunland Packing House Co.*, 912 F. Supp. 1325, 1329 (E.D. Cal. 1995).

<sup>8</sup> *Schweiker v. Gray Panthers*, 453 U.S. 34, 43 (1981).

procurement rules).<sup>9</sup> That brings us to the Medicare and Medicaid programs at issue here, which courts have described as “among the most completely impenetrable texts within human experience.”<sup>10</sup> Virtually every interaction that businesses undertake with the government is thus likely to involve a complex web of laws, rules, and regulations.

If the decision below is reversed, a statute enacted to address flagrant acts of fraud such as the provision of patently worthless goods, *see supra* note 4, would instead be used to pursue treble damages based on violations of frequently abstruse laws, rules, regulations based on nothing more than a relator’s argument that one of the countless requirements thereby imposed is a material condition of payment—regardless of whether the government’s actions reflect any belief that the condition was material.

An overbroad materiality standard also can disrupt agency objectives. *See* Granston Memo 4 (noting instances where “a qui tam action threatens to interfere with an agency’s policies or the administration of its programs”). Agencies have

---

<sup>9</sup> Steven R. Koltai, *How the Healthcare.gov Mess Happened and How To Fix It*, Brookings Inst. (Nov. 25, 2013), <https://brook.gs/3oaOkdr> (referencing “onerous and impenetrable procurement rules”); David Freeman Engstrom, *Agencies as Litigation Gatekeepers*, 123 Yale L.J. 616, 672 n.180 (2013) (referencing the “byzantine” two-thousand-page Federal Acquisition Regulations governing federal government contracting and procurement).

<sup>10</sup> *Abraham Lincoln Mem. Hosp. v. Sebelius*, 698 F.3d 536, 541 (7th Cir. 2012) (quoting *Rehabilitation Ass’n of Va., Inc. v. Kozłowski*, 42 F.3d 1444, 1450 (4th Cir. 1994)).

numerous tools to address contractor non-compliance. They can demand information, require a certification of compliance, exercise audit or inspection rights, issue notices of corrective action, or even initiate a formal investigation, as was done in this case, all of which can address an issue without resorting to extreme measures like False Claims Act litigation that could negatively affect continued performance. *See, e.g.*, 42 U.S.C. § 1437f(o)(8)(C)-(E) (providing for regular inspections of public housing to ensure continued eligibility for subsidy); *United States ex rel. Howard v. Lockheed Martin Corp.*, 14 F. Supp. 3d 982, 1014 (S.D. Ohio 2014) (government issued Corrective Action Requests upon discovering contractual noncompliance). As the Justice Department itself explained, “it is frequently in the Government’s interest, as it would be in the interest of any contracting party, to avoid excessive concern over minor failings that might threaten a useful course of dealing with the other party,” particularly if “the contractor’s performance otherwise has been adequate.” *Constitutionality of the Qui Tam Provisions of the False Claims Act*, 13 Op. O.L.C. 207, 220 (1989).

A qui tam suit can undermine agencies’ efforts as contracting parties and as regulators, nullifying their decisions to correct (rather than penalize) discrepancies, and imposing the type of drastic sanctions that the agencies deliberately avoided. *See, e.g.*, *United States ex rel. Conner v. Salina Reg’l Health Ctr., Inc.*, 543 F.3d 1211, 1220 (10th Cir. 2008) (improper use of qui tam suits can “undermine the

government’s own administrative scheme for ensuring that hospitals remain in compliance and for bringing them back into compliance when they fall short of what the Medicare regulations and statutes require”); *United States ex rel. Siewick v. Jamieson Sci. & Eng’g, Inc.*, 214 F.3d 1372, 1378 (D.C. Cir. 2000) (permitting FCA claim based on violation of a statute could “unilaterally divest[] the government of the opportunity to exercise . . . the discretion to accept or disaffirm the contract on the basis of the complex variables reflecting the officials’ views of the government’s long-term interests”); Granston Memo at 4-5 (collecting examples where agencies valued competing considerations more than recovery for alleged false claims). Rigorous enforcement of the materiality requirement, particularly in cases like this one where the government has already investigated and made no attempts to recoup funds, will mitigate these disruptions.

## CONCLUSION

For these reasons, and those set forth in defendant-appellee's brief, the district court's decision should be affirmed.

Dated: July 7, 2022

Respectfully submitted,

Andrew R. Varcoe  
Jordan L. Von Bokern  
U.S. CHAMBER LITIGATION  
CENTER  
1615 H Street, NW  
Washington, DC 20062  
(202) 463-5337

James C. Stansel  
Melissa B. Kimmel  
PHARMACEUTICAL  
RESEARCH AND  
MANUFACTURERS OF  
AMERICA  
950 F Street, NW  
Washington, DC 20004  
(202) 835-3400

/s/ John P. Elwood  
John P. Elwood  
Christian D. Sheehan  
Jayce L. Born  
ARNOLD & PORTER KAYE  
SCHOLER LLP  
601 Massachusetts Avenue, NW  
Washington, DC 20001  
(202) 942-5000  
fax: (202) 942-5999  
john.elwood@arnoldporter.com

## CERTIFICATE OF COMPLIANCE

1. The foregoing Brief of Amici Curiae complies with the type-volume limitations of Fed. R. App. 29(a)(5) and 32(a)(7) and because the brief contains 4,920 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

2. The brief also complies with Third Circuit Rule 31.1(c) because the text of the electronic brief is identical to the text of the hard copies that will be provided. In addition, this document was scanned for viruses using Windows Security, and no virus was detected.

3. The brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14-point font.

Dated: July 7, 2022

/s/ John P. Elwood  
John P. Elwood

## **CERTIFICATE OF BAR MEMBERSHIP**

In accordance with Third Circuit Rule 28.3(d), the undersigned counsel hereby certifies that he is a member of the bar of the United States Court of Appeals for the Third Circuit.

Dated: July 7, 2022

/s/ John P. Elwood  
John P. Elwood



## CERTIFICATE OF SERVICE

I hereby certify that on July 7, 2022, I electronically filed the foregoing document with the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: July 7, 2022

/s/ John P. Elwood  
John P. Elwood