

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

*ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES
COURT OF APPEALS FOR THE NINTH CIRCUIT*

**BRIEF FOR THE CHAMBER OF COMMERCE OF
THE UNITED STATES OF AMERICA, THE
NATIONAL DEFENSE INDUSTRIAL ASSOCIATION,
THE AMERICAN TORT REFORM ASSOCIATION,
THE AMERICAN HEALTH CARE ASSOCIATION,
AND THE NATIONAL CENTER FOR ASSISTED
LIVING AS *AMICI CURIAE* IN SUPPORT OF
PETITIONER**

STEVEN P. LEHOTSKY
WARREN POSTMAN
U.S. CHAMBER
LITIGATION CENTER
1615 H Street, NW
Washington, D.C. 20062
(202) 463-5337

*Counsel for the Chamber
of Commerce of the United
States of America*

JOHN P. ELWOOD
Counsel of Record
CRAIG D. MARGOLIS
RALPH C. MAYRELL
VINSON & ELKINS LLP
2200 Pennsylvania Ave.,
NW, Suite 500 West
Washington, D.C. 20037
(202) 639-6500
jelwood@velaw.com
Counsel for Amici Curiae

[Additional Counsel Listed on Inside Cover]

H. SHERMAN JOYCE
LAUREN S. JARRELL
AMERICAN TORT REFORM
ASSOCIATION
*1101 Connecticut Avenue,
N.W., Suite 400
Washington, D.C. 20036
(202) 682-1163*

*Counsel for the American
Tort Reform Association*

TABLE OF CONTENTS

	Page
Table Of Authorities	II
Interest Of <i>Amici Curiae</i>	1
Summary of Argument	4
Argument	5
I. The Ninth Circuit’s Decision Creates a Serious Risk That Immaterial Claims Will Be Allowed to Proceed to Discovery	5
II. Litigating Immaterial FCA Claims Past the Pleadings Stage Imposes High Costs on Nearly Every Sector of the Economy.....	9
III.The Ninth Circuit’s Watered Down Materiality Standard Will Be Costly and Disruptive to Agencies and Taxpayers	15
Conclusion.....	21

TABLE OF AUTHORITIES

Cases:	Page(s)
<i>A1 Procurement, LLC v. Thermcor, Inc.</i> , No. 15-cv-15, 2017 WL 2881350 (E.D. Va. July 5, 2017)	11
<i>Abbott v. BP Expl. & Prod., Inc.</i> , 851 F.3d 384 (5th Cir. 2017)	11
<i>Grand Union Co. v. United States</i> , 696 F.2d 888 (11th Cir. 1983)	10
<i>Heckler v. Chaney</i> , 470 U.S. 821 (1985)	9
<i>In re Kellogg Brown & Root, Inc.</i> , 756 F.3d 754 (D.C. Cir. 2014)	10
<i>Mikes v. Straus</i> , 274 F.3d 687 (2d Cir. 2001).....	9
Order <i>U.S. ex rel. Ruckh v. Salus Rehab. LLC</i> , No. 8:11-cv-1303 (M.D. Fla. Jan. 11, 2018) [Dkt. 468]	8, 9
<i>Smith v. Duffey</i> , 576 F.3d 336 (7th Cir. 2009)	15
<i>U.S. ex rel. Anti-Discrimination Ctr. of Metro N.Y., Inc. v. Westchester Cty.</i> , 712 F.3d 761 (2d Cir. 2013).....	10
<i>U.S. ex rel. Bias v. Tangipahoa Parish Sch. Bd.</i> , 86 F. Supp. 3d 535 (E.D. La. 2015).....	10
<i>U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.</i> , 543 F.3d 1211 (10th Cir. 2008).....	18
<i>U.S. ex rel. Howard v. Lockheed Martin Corp.</i> , 14 F. Supp. 3d 982 (S.D. Ohio 2014).....	18

III

Cases—Continued:	Page(s)
<i>U.S. ex rel. Koch v. Koch Indus., Inc.</i> , 57 F. Supp. 2d 1122 (N.D. Okla. 1999).....	10
<i>U.S. ex rel. Landis v. Tailwind Sports Corp.</i> , 51 F. Supp. 3d 9 (D.D.C. 2014)	10
<i>U.S. ex rel. Lemmon v. Envirocare of Utah, Inc.</i> , 614 F.3d 1163 (10th Cir. 2010)	10
<i>U.S. ex rel. McBride v. Halliburton Co.</i> , 848 F.3d 1027 (D.C. Cir. 2017)	7, 12, 14, 15
<i>U.S. ex rel. McLain v. Fluor Enters., Inc.</i> , 60 F. Supp. 3d 705 (E.D. La. 2014).....	10
<i>U.S. ex rel. McLain v. Fluor Enters., Inc.</i> , 681 Fed. Appx. 355 (5th Cir. 2017).....	12
<i>U.S. ex rel. Oliver v. Philip Morris USA, Inc.</i> , 101 F. Supp. 3d 111 (D.D.C. 2015)	10
<i>U.S. ex rel. Pritzker v. Sodexo, Inc.</i> , 364 Fed. Appx. 787 (3d Cir. 2010)	10
<i>U.S. ex rel. Purcell v. MWI Corp.</i> , 807 F.3d 281(D.C. Cir. 2015)	14
<i>U.S. ex rel. Rostholder v. California</i> , 745 F.3d 694 (4th Cir. 2014)	14
<i>U.S. ex rel. Shemesh v. CA, Inc.</i> , 89 F. Supp. 3d 36 (D.D.C. 2015)	10
<i>U.S. ex rel. Siewick v. Jamieson Sci. & Eng’g, Inc.</i> , 214 F.3d 1372 (D.C. Cir. 2000).....	18
<i>U.S. ex rel. Steury v. Cardinal Health, Inc.</i> , 735 F.3d 202 (5th Cir. 2013)	9
<i>United States v. Americus Mortg. Corp.</i> , No. 12-cv-02676, 2014 WL 4273884 (S.D. Tex. Aug. 29, 2014).....	10

IV

Cases—Continued:	Page(s)
<i>United States v. BAE Sys. Tactical Vehicle Sys., LP</i> , No. 15-cv-12225, 2017 WL 1457493 (E.D. Mich. Apr. 25, 2017).....	19
<i>United States v. Data Translation, Inc.</i> , 984 F.2d 1256 (1st Cir. 1992).....	16
<i>United States v. Sanford-Brown, Ltd.</i> , 788 F.3d 696 (7th Cir. 2015)	10
<i>United States v. Sci. Applications Int’l Corp.</i> , 626 F.3d 1257 (D.C. Cir. 2010)	10
<i>United States v. United Techs. Corp.</i> , 782 F.3d 718 (6th Cir. 2015)	14
<i>Universal Health Servs., Inc. v. U.S. ex rel. Escobar</i> , 136 S. Ct. 1989 (2016)	<i>passim</i>

Statutes:

28 U.S.C. § 2461	16
31 U.S.C. § 3730(c)(2)(A)	19
31 U.S.C. § 3729(a).....	16
31 U.S.C. § 3730(d)(1)-(2).....	16
42 U.S.C. § 1437f(o)(8)(C)-(E)	18

Regulations:

2 C.F.R. § 180.800	16
28 C.F.R. § 85.5	16
FAR 31.205-47(a)(3).....	16
FAR 31.205-47(e)	16

Other Authorities:	Page(s)
Anne K. Walsh, <i>Ninth Circuit Revives False Claims Act Case Applying Escobar Materiality Standard</i> , Hyman, Phelps & McNamara: FDA Law Blog (July 17, 2017), http://goo.gl/HmFxWH	5
Conor Duffy, <i>Ninth Circuit Relies on Escobar to Revive False Claims Act Suit Against Pharmaceutical Manufacturer</i> , Robinson & Cole LLP (July 21, 2017), http://goo.gl/HdcPgF	6
Constitutionality of the Qui Tam Provisions of the False Claims Act, 13 Op. O.L.C. 207 (1989)	18
David Freeman Engstrom, <i>Public Regulation of Private Enforcement: Empirical Analysis of DOJ Oversight of Qui Tam Litigation Under the False Claims Act</i> , 107 Nw. U. L. Rev. 1689 (2013)	19
David Hogberg, <i>The Next Exodus: Primary-Care Physicians and Medicare</i> , Nat'l Ctr. for Pub. Policy Res. (Aug. 2012), http://goo.gl/ZseD58	17
David O'Brien et al., <i>9th Circ. Decision Could Be a Bitter Pill for Pharma Cos.</i> , Law360 (Aug. 8, 2017), http://goo.gl/yFTdbw	5
DOJ FOIA Data Spreadsheet, http://goo.gl/iaOgeG	13
Eric J. Buescher, <i>Ninth Circuit Overturns Dismissal of False Claims Case Against Gilead, Clarifies Types of Falsity That Give Rise to Liability</i> , Cotchett Pitre & McCarthy Blog (July 17, 2017), https://goo.gl/NNDCmj	6

Other Authorities—Continued:	Page(s)
John T. Bentivoglio et al., <i>False Claims Act Investigations: Time for a New Approach?</i> , 3 Fin. Fraud L. Rep. 801 (2011).....	13
Laurence Freedman & Jordan Cohen, <i>2017 Health Care En-forcement Review: Materiality Under FCA</i> , Law360 (Jan. 18, 2018), http://goo.gl/vF84sz	5
Memo. from Michael Granston, Dir. Commercial Litig. to Commercial Litig. Br., Fraud Sec. (Jan. 10, 2018), http://goo.gl/rjeGk7	9, 17, 19, 20
Michael A. Baudinet & Jeremy S. Byrum, <i>Ninth Circuit Ruling Weakens Materiality Standard Under the FCA</i> , McGuireWoods Blog (July 28, 2017), http://goo.gl/xiE7rM	6
Michael Macagnone, <i>DOD Buying Group Pushes House Panel for Rules Reform</i> , Law360 (May 17, 2017), http://goo.gl/TaqwDO ..	17
Michael Rich, <i>Prosecutorial Indiscretion: Encouraging the Department of Justice to Rein in Out-of-Control Qui Tam Litigation Under the Civil False Claims Act</i> , 76 U. Cin. L. Rev. 1233 (2008)	19
Ralph C. Nash & John Cibinic, <i>Suspension of Contractors: The Nuclear Sanction</i> , Nash & Cibinic Rep. ¶ 24 (Mar. 1989).....	16
Reply Mem. in Supp. of Defs.’ Bill of Costs, <i>U.S. ex rel. McBride v. Halliburton Co.</i> , No. 05-cv-828 (D.D.C. Nov. 13, 2015) [Dkt. 228]	15

VII

Other Authorities—Continued:	Page(s)
Samuel M. Shapiro, <i>Ninth Circuit Holds That FDA Violations Can Lead to FCA Liability</i> , Arnall Golden Gregory LLP (Aug. 2017), http://goo.gl/G12ZR3	6
Sean J. Hartigan et al., <i>Ninth Circuit Issues Expansive Reading of Escobar</i> , Smith Pachter McWhorterPLC (July 14, 2017), http://goo.gl/f6VRwc	5
Todd J. Canni, <i>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</i> , 37 Pub. Cont. L.J. 1 (2007)...	13

INTEREST OF *AMICI CURIAE*¹

The Chamber of Commerce of the United States of America (the “Chamber”) is the world’s largest business federation. It represents 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry, 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. The Chamber regularly files *amicus curiae* briefs in cases raising issues of concern to the nation’s business community, including cases involving the False Claims Act (“FCA”).

The National Defense Industrial Association (“NDIA”), a non-profit, non-partisan organization, has a membership of more than 1,650 companies and nearly 90,000 individuals spanning the entire spectrum of the defense industry. NDIA’s corporate members include some of the Nation’s largest defense contractors, among them companies that provide the U.S. military and other federal departments and agencies with a multitude of professional, logistical, and technological services, both domestically and in overseas combat zones and other dangerous locations. Individuals who are NDIA members come from the government, the military services, small businesses,

¹ No counsel for a party authored this brief in whole or part, and no counsel or party made a monetary contribution to fund the preparation or submission of this brief. No person other than the *amici curiae*, their members, and their counsel made any monetary contribution to its preparation and submission. The parties were given timely notice and have consented to this filing.

corporations, prime contractors, academia, and the international community.

The American Tort Reform Association (“ATRA”) is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled their resources to promote reform of the civil justice system with the goal of ensuring fairness, balance, and predictability in civil litigation. For over two decades, ATRA has filed *amicus curiae* briefs in cases before state and federal courts that have addressed important liability issues.

The American Health Care Association and the National Center for Assisted Living (“AHCA/NCAL”) are the Nation’s leading long-term care organizations. They serve as the national representative of more than 13,000 non-profit and proprietary facilities dedicated to improving the delivery of professional and compassionate care to more than 1.5 million frail, elderly, and disabled Americans who live in skilled nursing facilities, assisted living residences, subacute centers, and homes for persons with mental retardation and developmental disabilities. One way in which AHCA/NCAL promote the interests of their members is by participating as *amici curiae* in cases with important and far-ranging consequences for their members—including cases before this Court raising important questions under the FCA.

Amici have a strong interest in ensuring that courts rigorously police the boundaries of FCA liability at the pleadings stage. FCA litigation affects businesses from all sectors of the American economy. *Amici*’s members, many of which are subject to complex regulatory schemes, have successfully defended scores of FCA cases in courts nationwide arising out

of government contracts, grants, and program participation, but often have succeeded only after years of costly litigation and discovery. The potential liabilities and litigation costs have only increased as relators invoke ever more esoteric and complex “implied false certification” theories that attempt to transform minor deviations from obscure contractual terms or regulations into potentially devastating treble damages claims. When courts allow such weak but complex cases to continue past the pleadings stage, as the Ninth Circuit did here, Pet. App. 27a-32a, they often collapse at summary judgment after years of costly discovery.

This Court in *Universal Health Services, Inc. v. United States ex rel. Escobar* recognized that the FCA’s materiality and scienter requirements should be “demanding” to provide a critical check on the potentially boundless implied certification theory (and on the FCA in general) to guard against “open-ended liability.” 136 S. Ct. 1989, 2002, 2003 (2016). As this Court recognized, “rigorous” enforcement of the materiality standard at the pleadings stage is essential to prevent the harms of disruptive, costly, and prolonged litigation, see *id.* at 2004 n.6. The principles at issue here affect countless businesses across a broad array of industries, as well as non-profit organizations and even municipalities and state-affiliated entities that directly or indirectly perform work for the federal government or administer funds under a vast range of federal programs. *Amici* and their members therefore have a substantial interest in this Court correcting the Ninth Circuit’s precedential decision below to bring it in line with this Court’s deci-

sion in *Escobar* and the rulings of six other courts of appeals.

SUMMARY OF ARGUMENT

The petition for a writ of certiorari should be granted because the Ninth Circuit's opinion and judgment undercuts the viability of challenging materiality on the pleadings based on the government's acquiescence to the alleged misconduct, inviting meritless FCA litigation that will impose great costs on industry and the taxpayer.

I. As commentators have already noted, the decision below diverges from other circuits in its treatment of materiality after *Escobar*. The lower court disregarded *Escobar*'s holding that government acquiescence is "very strong evidence" of immateriality and that materiality can be resolved on the pleadings, even in the face of government's plain lack of concern even years after learning about the alleged misconduct.

II. All sectors of the American economy are exposed to the high costs of litigating weak FCA cases that are allowed to proceed past the pleadings stage. Perversely, the weaker and the more attenuated the legal theory underlying the relator's claims, the more complex and costly the discovery is for defendants. Strictly enforcing materiality at the pleadings stage minimizes the deadweight loss to the economy of weak FCA cases.

III. Contractors will pass those litigation costs on to the government, billing them directly to the government or indirectly passing those costs on by increasing the prices they bid, if they bid at all. Immaterial FCA claims can also disrupt agencies' balance

between regulatory goals and sanctions. Stopping immaterial claims at the pleadings stage protects agencies from needless costs and disruption.

ARGUMENT

I. The Ninth Circuit’s Decision Creates a Serious Risk That Immaterial Claims Will Be Allowed to Proceed to Discovery

Amici agree with Gilead that the Ninth Circuit misapplied *Escobar*’s materiality standard (Pet. 20-22), improperly relieved relators’ burden in pleading materiality (see Pet. 12, 19, 22, 27), and exacerbated a circuit split about when government acquiescence can render an alleged FCA violation immaterial (Pet. 11-20). The opinion below represents a break from *Escobar* as well as the law adopted by other circuits, effectively gutting a materiality standard that this Court has emphasized is “demanding” and “rigorous.” *Escobar*, 136 S. Ct. at 1996, 2002, 2003, 2004 n.6.²

² See, e.g., David O’Brien et al., *9th Circ. Decision Could Be a Bitter Pill for Pharma Cos.*, Law360 (Aug. 8, 2017), <http://goo.gl/yFTdbw> (“a break from the Fourth Circuit[]”; “open[s] the door for more plaintiffs to attempt to transform FDA violations into FCA suits”; “stands in contrast to the law in other circuits”); Laurence Freedman & Jordan Cohen, *2017 Health Care Enforcement Review: Materiality Under FCA*, Law360 (Jan. 18, 2018), <http://goo.gl/vF84sz> (“found unconvincing” arguments that were successful in the Third Circuit; “lack of a prospective bright-line rule of materiality”); Sean J. Hartigan et al., *Ninth Circuit Issues Expansive Reading of Escobar*, Smith Pachter McWhorter PLC (July 14, 2017), <http://goo.gl/f6VRwc> (“establish[es] a low bar * * * to meet *Escobar*’s implied certification test”); Anne K. Walsh, *Ninth Circuit Revives False Claims Act Case Applying Escobar Materiality Standard*, Hyman, Phelps & McNamara: FDA Law Blog (July 17, 2017), <http://goo.gl/HmFxWH> (“reached the opposite conclu-

Unless this Court grants review and reverses, there is a substantial risk that the decision below will eliminate government acquiescence as a basis for challenging materiality on the pleadings in the Ninth Circuit. That result is contrary to *Escobar*'s plain expectation that such issues could be adjudicated at that stage. *Id.* at 2003-2004 & n.6.

The Ninth Circuit's materiality ruling arises out of circumstances that should have—and in six other circuits *would* have, Pet. 13-20—easily resulted in a dismissal on materiality grounds. This case involves precisely the circumstances that *Escobar* said would constitute strong evidence of immateriality: “[I]f 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.” 136 S. Ct. at 2003.

sion from the First Circuit”; “may be an outlier in the post-*Escobar* world”); Conor Duffy, *Ninth Circuit Relies on Escobar to Revive False Claims Act Suit Against Pharmaceutical Manufacturer*, Robinson & Cole LLP (July 21, 2017), <http://goo.gl/HdcPgF> (“particularly notable as compared to a recent Third Circuit holding”; “creates a potential split among circuits”); Michael A. Baudinet & Jeremy S. Byrum, *Ninth Circuit Ruling Weakens Materiality Standard Under the FCA*, McGuireWoods Blog (July 28, 2017), <http://goo.gl/xiE7rM> (“reduces the rigor of *Escobar*'s materiality analysis”); Samuel M. Shapiro, *Ninth Circuit Holds That FDA Violations Can Lead to FCA Liability* 4, Arnall Golden Gregory LLP (Aug. 2017), <http://goo.gl/G12ZR3> (“a significant expansion of the Supreme Court's ‘materiality’ standard”). The relators’ bar likewise suggests the case is an outlier. *E.g.*, Eric J. Buescher, *Ninth Circuit Overturns Dismissal of False Claims Case Against Gilead, Clarifies Types of Falsity That Give Rise to Liability*, Cotchett Pitre & McCarthy Blog (July 17, 2017), <https://goo.gl/NNDCmj> (“an important case in explaining the reach of the various theories of falsity under the statute”).

Here, the government continued to pay for the allegedly adulterated drug, left regulatory approvals in place, and did not seek refunds for past sales, long after the relators notified the government of their allegations and after the government itself issued reports describing the alleged adulteration. Pet. 7-10. If government acquiescence does not provide a defense to materiality under such circumstances, the defense may be a practical nullity at the pleadings stage.

The court of appeals' reasoning is deeply flawed in several other respects that place it in conflict with other courts and could have costly effects on defendants in the Ninth Circuit. First, the decision below mistakenly concluded that government acquiescence could be shown only by establishing government knowledge contemporaneous with payment. It emphasized Gilead's alleged "false claims [to] procure[] certain approvals *in the first instance*," and that "the parties dispute exactly what the government knew *and when*, calling into question [the government's] 'actual knowledge.'" Pet. App. 29a, 32a (emphasis added). *Escobar* imposed no such contemporaneity requirement. Other courts have also rejected such a requirement, noting instead that the government's failure to take action to rescind approvals or recover payment *after* learning of the allegations is evidence of immateriality. See *Escobar*, 136 S. Ct. at 2001, 2003; accord *U.S. ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1034 (D.C. Cir. 2017) ("[That] DCAA investigated [relator]'s allegations and did not disallow any charged costs * * * is 'very strong evidence' that the requirements * * * are not material." (quoting *Escobar*, 136 S. Ct. at 2003)); Order 12-13, *U.S. ex*

rel. Ruckh v. Salus Rehab. LLC, No. 8:11-cv-1303 (M.D. Fla. Jan. 11, 2018) [Dkt. 468] (overturning \$348 million judgment in part because relators failed “to exclude the governments’ choosing to resort to a more moderate, more proportional, more efficacious remedy” or “some mediated solution” as the government’s likely response to learning of the alleged violations).

Second, the showing that the Ninth Circuit held was sufficient to defeat a motion to dismiss—“*more than the mere possibility* that the government would be *entitled* to refuse payment if it were aware of the violations”—squarely conflicts with *Escobar*’s materiality standard. Pet. App. 32a (emphasis added). Rather than looking to probabilities and legal entitlement, *Escobar* “look[ed] to the *effect* on the [government’s] *likely or actual* behavior,” a far higher standard than the court of appeals’ language suggests. 136 S. Ct. at 2002 (emphasis added and citation omitted).

Third, in support of its conclusion that the government’s failure to rescind payment or continued payment was not evidence of immateriality, the Ninth Circuit emphasized “there are many reasons the FDA may choose not to withdraw a drug approval,” Pet. App. 31a, that are “unrelated to the concern that the government paid out billions of dollars for nonconforming and adulterated drugs,” *ibid.* But *Escobar* made nothing of the fact that there might be *other* reasons the government would continue to pay (or not rescind payment). Rather, *Escobar* directed courts to look to facts that are outwardly and readily determinable: Did the government in fact rescind past payments or refuse to make future payments after learning of the violation, or has it done so in com-

parable cases where it knew of the violations? 136 S. Ct. at 2003-2004; accord Order 10, *Ruckh, supra* (“[A] disinterested observer, fully informed and fairly guided by *Escobar*, would confidently expect * * * evidence of how the government has behaved in comparable circumstances.”). Rightly so. *Every* decision—particularly every *government* decision—is a product of resource constraints and competing policy considerations. *Heckler v. Chaney*, 470 U.S. 821, 831 (1985) (listing considerations); cf. Memo. from Michael Granston, Dir. Commercial Litig. to Commercial Litig. Br., Fraud Sec. 4-5 (Jan. 10, 2018) (“Granston Memo.”), <http://goo.gl/rjeGk7> (collecting examples where agencies valued competing policy considerations more than recovering for alleged false claims). Government acquiescence would mean nothing at the pleadings stage if courts were tasked with disentangling the “many reasons” for government payment decisions, or if any imagined reason (beside immateriality) for continued government payment (or for failure to rescind payment) would suffice to defeat a motion to dismiss.

II. Litigating Immaterial FCA Claims Past the Pleadings Stage Imposes High Costs on Nearly Every Sector of the Economy

Cases brought under the FCA touch nearly every sector of the economy, including health care, defense, education, banking, construction, consulting, software, energy, mortgage lending, local government—even athletic sponsorship.³ FCA cases also can arise

³ See, e.g., *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001) (healthcare services); *U.S. ex rel. Steury v. Cardinal Health, Inc.*, 735 F.3d 202 (5th Cir. 2013) (per curiam) (medical manu-

out of any and every minor violation of any rule or contractual provision. Because this Court recognized in *Escobar* that “the implied false certification theory can,” “at least in some circumstances,” “be a basis for liability,” 136 S. Ct. at 1995, review here is necessary to ensure that consistent, “strict enforcement of the [FCA’s] materiality * * * requirement[],” *id.* at 2002, at the pleadings stage continues to protect industry from incurring crippling expenses to defend against insubstantial claims—no matter where the case is filed.

facturing); *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 services); *United States v. Sanford-Brown, Ltd.*, 788 F.3d 696 (7th Cir. 2015) (higher education), *vacated*, 136 S. Ct. 2506 (2016), reinstated in part, superseded in part, 840 F.3d 445 (7th Cir. 2016); *U.S. ex rel. Shemesh v. CA, Inc.*, 89 F. Supp. 3d 36 (D.D.C. 2015) (software development); *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 services); *U.S. ex rel. Oliver v. Philip Morris USA, Inc.*, 101 F. Supp. 3d 111 (D.D.C. 2015) (cigarette manufacturing), *aff’d*, 826 F.3d 466 (D.C. Cir. 2016); *In re Kellogg Brown & Root, Inc.*, 756 F.3d 754 (D.C. Cir. 2014) (defense support services), *cert. denied*, 135 S. Ct. 1163 (2015); *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); *U.S. ex rel. Anti-Discrimination Ctr. of Metro N.Y., Inc. v. Westchester Cty.*, 712 F.3d 761 (2d Cir. 2013) (provision of low-income housing); *U.S. ex rel. Bias v. Tangipahoa Parish Sch. Bd.*, 86 F. Supp. 3d 535 (E.D. La. 2015) (public school Junior ROTC program); *U.S. ex rel. Pritzker v. Sodexo, Inc.*, 364 Fed. Appx. 787 (3d Cir.) (public school lunch services), *cert. denied*, 562 U.S. 838 (2010); *Grand Union Co. v. United States*, 696 F.2d 888 (11th Cir. 1983) (food stamp program).

1. Relators have sought to transform almost every manner of contractual or regulatory violation into a high-stakes FCA case, and will continue to do so if not checked at the pleadings stage by a rigorous materiality test. Among countless other attenuated theories that have been advanced in recent years, relators have claimed that:

- an oil well operating on a federal lease used equipment for which the design specifications were missing an engineer's stamp to document engineer approval required by applicable regulations, *Abbott v. BP Expl. & Prod., Inc.*, 851 F.3d 384, 388 (5th Cir. 2017) (affirming summary judgment after defendant's motion to dismiss was denied and discovery was completed in a case unsealed in 2010, because 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");
- a ship-repair business allegedly violated regulations requiring consideration of annual receipts and employees of affiliated companies in determining eligibility for small-business set-aside contracts, *A1 Procurement, LLC v. Thermcor, Inc.*, No. 15-cv-15, 2017 WL 2881350, at *5-7 (E.D. Va. July 5, 2017) (adopting magistrate judge's order granting summary judgment after some discovery for a case unsealed in 2013, because fact that Small Business Administration knew of eligibility problems but "did not * * * terminate [contractor] from the [set-aside] program" indicated alleged misrepresentations were not material);

- a defense contractor violated record-keeping regulations by recording inaccurate figures for how many individuals used recreation facilities, *McBride*, 848 F.3d at 1034 (affirming grant of summary judgment after defendant’s motion to dismiss was denied in part and three years of discovery was completed for case unsealed in 2006; holding that fact that auditor took no action after investigating allegations “is very strong evidence” requirements not material); and
- a construction company providing temporary shelter after Hurricane Katrina had subcontractors connect temporary housing units to power appliances and water pumps, but the subcontractors lacked state permits, violating subcontract requirement that “[a]ll work performed shall be in accordance with all applicable federal, state and local codes and regulations,” *U.S. ex rel. McLain v. Fluor Enters., Inc.*, 681 Fed. Appx. 355, 357, 360-362 (5th Cir. 2017) (per curiam) (affirming summary judgment after some discovery and multiple motions to dismiss had been litigated in a case unsealed in 2013).

These cases all reached discovery before *Escobar* was decided. Had the district courts in these cases had this Court’s guidance that materiality can and should be addressed on a motion to dismiss, the parties might have avoided significant discovery costs.

2. The cost to businesses of courts’ reluctance to dismiss weak FCA cases at the pleadings stage is significant. Defending FCA cases 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). “Pharmaceutical, medical devices, and health care companies” alone “spend billions each year” dealing with FCA litigation. John T. Bentivoglio et al., *False Claims Act Investigations: Time for a New Approach?*, 3 Fin. Fraud L. Rep. 801, 801 (2011). But FCA discovery imposes heavy burdens on every industry—defendants can spend hundreds of thousands of dollars (millions, even) just fielding discovery demands in a case.

FCA litigation is costly in part simply because cases take a long time. Even meritless no-recovery cases frequently drag on for years. Data obtained from DOJ under the Freedom of Information Act (“FOIA”) show that of the 2,086 cases in which DOJ declined to intervene between 2004 and 2013 and that ended with zero recovery, 278 dragged on for more than three years after the government declined to intervene. See DOJ FOIA Data Spreadsheet (hosted by Vinson & Elkins LLP), <http://goo.gl/iaOgeG>. Of those, 110 extended for more than *five years* after declination, and one case for more than ten years.

FCA cases are also costly because highly complex and attenuated implied false certification theories require extensive discovery for relators to establish required elements. Failure to strictly enforce materiality at the pleadings stage results in an enormous deadweight loss to the economy, as even meritless cases that end without recovery require years of discovery. For instance, to show knowledge, an additional requirement under the FCA, relators have to show the rule the defendant allegedly failed to follow

is unambiguous, or that the defendants did not hold an objectively reasonable reading of the rule, or that the government warned the contractor away from its interpretation. *U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 287-291 (D.C. Cir. 2015), cert. denied, 137 S. Ct. 625 (2017). Also, under the Ninth Circuit’s rule, demonstrating or challenging materiality will require detailed discovery from the defendant and the government to determine *when* the government learned of the alleged misconduct in relation to opportunities the government had to deny or rescind payments or approvals.

Damages are also costly to establish. Although it is relatively straightforward to price an inoperable gun as having almost no value, it is far less simple to determine the value of (for instance) recreational services allegedly provided with inaccurate usage records, *McBride*, 848 F.3d at 1028-1029; jet engines that perform as specified but allegedly had their prices negotiated based on inaccurate data, *United States v. United Techs. Corp.*, 782 F.3d 718, 721-723 (6th Cir. 2015); or, similar to this case, pharmaceuticals manufactured in a factory that allegedly does not meet the latest industry standards, *U.S. ex rel. Rothholder v. California*, 745 F.3d 694, 698, 701 (4th Cir.), cert. denied, 135 S. Ct. 85 (2014). Valuing the impact of these “deficiencies,” if any, requires extensive discovery from the defendant and the government about market price to perform a “comparable sales’ analysis” to “establish[] ‘fair market value.’” *United Techs.*, 782 F.3d at 731 (citation omitted).

The *McBride* case involving allegations of faulty recordkeeping exemplifies the practical costs of a lax materiality standard: The litigation required the

production of “over two million pages of documents” from the defendant, *McBride*, 848 F.3d at 1029, and required defendant to manually scan thousands of pages of records from fifty military bases in the middle of a war zone. See Reply Mem. in Supp. of Defs.’ Bill of Costs at 3-5, *U.S. ex rel. McBride v. Halliburton Co.*, No. 05-cv-828 (D.D.C. Nov. 13, 2015) [Dkt. 228]. Relator’s claims eventually were dismissed on summary judgment *eight years* after the claims were unsealed. *McBride*, 848 F.3d at 1029-1030. For many defendants, the costs of years of discovery to win summary judgment are enough by themselves to drive them to settle. See *Smith v. Duffey*, 576 F.3d 336, 340 (7th Cir. 2009) (discovery in “complex litigation can be so steep as to coerce a settlement on terms favorable to the plaintiff even when his claim is very weak”). In cases where contractors prevail after years of litigation, they may pass a portion of those litigation costs on to the government. See pp. 15-17, *supra*.

III. The Ninth Circuit’s Watered Down Materiality Standard Will Be Costly and Disruptive to Agencies and Taxpayers

Litigation costs for weak FCA cases are passed on to the government directly and indirectly, and can be disruptive to agency policy and business objectives. Strict enforcement of materiality at the pleadings stage can mitigate those costs and disruptions. The decision below undermines the utility of materiality as a tool to weed out meritless cases early, and will make the Ninth Circuit a favored forum for relators to bring weak (but still costly and disruptive) FCA claims that would not survive in other circuits.

1. Defendants face huge risks from FCA litigation if it is allowed to proceed past the pleadings stage. In addition to litigation costs, see pp. 12-15, *supra*, if a defendant loses, it faces treble damages, 31 U.S.C. § 3729(a). Defendants also face penalties of between \$11,181 and \$22,363 per false claim for violations after November 1, 2015, 31 U.S.C. § 3729(a); 28 C.F.R. § 85.5, an amount that ratchets up annually even for pending cases, 28 U.S.C. § 2461 note. The FCA also authorizes relators to recover attorneys' fees and "reasonable expenses." 31 U.S.C. § 3730(d)(1)-(2). A finding of FCA liability also can result in suspension and debarment from government contracting, See 2 C.F.R. § 180.800—"equivalent to the death penalty" for government contractors. Ralph C. Nash & John Cibinic, *Suspension of Contractors: The Nuclear Sanction*, Nash & Cibinic Rep. ¶ 24 (Mar. 1989).

2. The risks and costs of litigating immaterial claims force companies to charge the government higher prices to compensate for far-reaching and potentially catastrophic FCA liability and litigation costs. Cf. *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."). Already, taxpayers bear a significant part of the direct cost of such 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).

Some firms may decline even to bid on contracts to avoid unpredictable but potentially catastrophic FCA

risk. As DOJ has recognized, “there 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.” Granston Memo. 5. Also, a former head of federal acquisition policy noted that potential contractors are wary of “the reputational risk and the very onerous application of [a] remedy for something that is certainly unintentional” when engaging in business with the government. Michael Macagnone, *DOD Buying Group Pushes House Panel for Rules Reform*, Law360 (May 17, 2017), <http://goo.gl/TaqwDO>. It is not just a theoretical possibility that people will decline to perform needed services for the government: For example, doctors have exited Medicare in droves, due partly to concerns about “fraud” liability based on auditors’ subjective assessment of deviations from program requirements. See David Hogberg, *The Next Exodus: Primary-Care Physicians and Medicare*, Nat’l Ctr. for Pub. Policy Res. (Aug. 2012), <http://goo.gl/ZseD58>. The reduction in qualified entities willing to do business with the government deprives the government of choice, and reduced competition likely means the government will pay higher prices. See, e.g., S. Rep. 98-50, at 3 (1983) (“[C]ompetition in contracting saves money.”).

3. The risk and cost of litigating immaterial claims likewise create the danger of altering agencies’ careful policy and enforcement choices. Granston Memo 4 (noting instances where “a *qui tam* action threatens to interfere with an agency’s policies or the administration of its programs”). If an agency has concerns about compliance with contractual or regulatory requirements, for instance, it can demand in-

formation, require a certification of compliance, or exercise inspection rights. *E.g.*, 42 U.S.C. § 1437f(o)(8)(C)-(E) (providing for regular inspections of public housing to ensure continued eligibility for subsidy). The government can also issue notices of corrective action, addressing the issue without resorting to extreme measures that could negatively affect continued performance. See, *e.g.*, *U.S. 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 affirmatively undermine regulators’ efforts, nullifying their decisions to *correct* (rather than penalize) errors, and imposing the type of drastic sanctions that regulators deliberately avoided. See, *e.g.*, *U.S. 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”); *U.S. 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 longterm interests”).

With respect, the government cannot always be counted upon to protect agencies’ policy choices by dismissing immaterial FCA claims. DOJ itself recognizes that it “has utilized * * * sparingly” its authority under 31 U.S.C. § 3730(c)(2)(A) to dismiss *qui tam* actions. Granston Memo. 1. Instead, the government routinely lets relators “proceed with[] thousands of non-meritorious *qui tam* suits.” Michael Rich, *Prosecutorial Indiscretion: Encouraging the Department of Justice to Rein in Out-of-Control Qui Tam Litigation Under the Civil False Claims Act*, 76 U. Cin. L. Rev. 1233, 1264-1265 (2008); accord David Freeman Engstrom, *Public Regulation of Private Enforcement: Empirical Analysis of DOJ Oversight of Qui Tam Litigation Under the False Claims Act*, 107 Nw. U. L. Rev. 1689, 1717 (2013) (noting that 460-case subsample of *qui tam* actions “revealed exactly *none* in which DOJ exercised its termination authority”) (emphasis added); cf. generally Granston Memo. (collecting instances where DOJ has dismissed *qui tam* actions). In fact, in some cases, DOJ itself pursues cases where the contracting agency does not believe the case has merit. See, e.g., *United States v. BAE Sys. Tactical Vehicle Sys., LP*, No. 15-cv-12225, 2017 WL 1457493, at *2 (E.D. Mich. Apr. 25, 2017) (noting the Army withdrew underlying contract claim while DOJ persisted in the FCA action). And “the government expends significant resources in monitoring” “non-

intervened cases” and in “produc[ing] discovery.” Granston Memo. 1.

Just weeks ago, the government issued a memorandum setting forth “a general framework for evaluating when to seek dismissal under section 3730(c)(2)(A).” Granston Memo. 2. That memo encourages DOJ attorneys to consider dismissing non-intervened cases that “lack substantial merit” or that might “threaten[] to interfere with an agency’s policies.” Granston Memo. 1, 4. But it remains to be seen in practice whether DOJ will rein in relators (or itself) when there may be money on the table, and the memo itself makes clear that it is no panacea. The memo proposes such modest steps as simply “*consider[ing]* moving to dismiss where a *qui tam* complaint is facially lacking in merit,” “*consider[ing]* moving to dismiss a *qui tam* action that duplicates a pre-existing government investigation and adds no useful information,” and “*consider[ing]* dismissal where “an agency has determined that a *qui tam* action threatens to interfere with an agency’s policies.” Granston Memo. 3, 4 (emphasis added). The memo also emphasizes that dismissal of cases after investigation on the grounds that they are meritless “may be rare” for a variety of factors, including that the government “typically will investigate a *qui tam* action only to the point where it concludes that a declination is warranted,” not until it determines the action is *completely* meritless. Granston Memo. 4. Unless and until DOJ demonstrates that it will in fact dismiss weak FCA cases, defendants have to rely on courts’ strictly enforcing the materiality standard.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

STEVEN P. LEHOTSKY
WARREN POSTMAN
U.S. CHAMBER
LITIGATION CENTER
*1615 H Street, NW
Washington, D.C. 20062
(202) 463-5337*
*Counsel for the Chamber
of Commerce of the Uni-
ted States of America*

JOHN P. ELWOOD
Counsel of Record
CRAIG D. MARGOLIS
RALPH C. MAYRELL
VINSON & ELKINS LLP
*2200 Pennsylvania Ave.,
NW, Suite 500W
Washington, DC 20037
(202) 639-6500
jelwood@velaw.com*
Counsel for Amici Curiae

H. SHERMAN JOYCE
LAUREN S. JARRELL
AMERICAN TORT REFORM
ASSOCIATION
*1101 Connecticut Avenue,
N.W., Suite 400
Washington, D.C. 20036
(202) 682-1163*
*Counsel for the American
Tort Reform Association*

FEBRUARY 2018